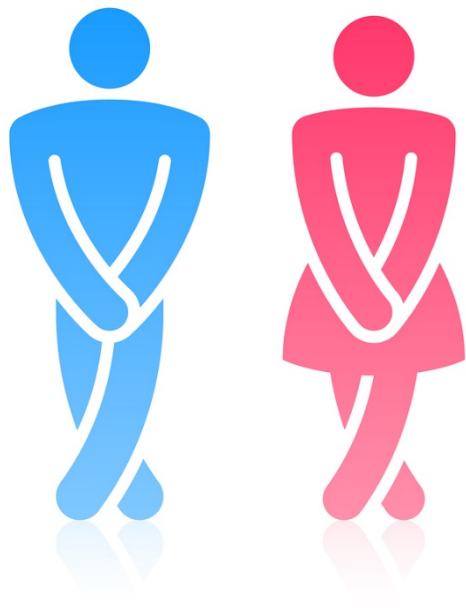


# OPTIMISATION OF RIZIV – INAMI LUMP SUMS FOR INCONTINENCE





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CAROLINE OBYN, VICKY JESPERS, CÉCILE CAMBERLIN



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- **Finally, this report has been approved by common assent by the Executive Board.**
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## LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
95% CI	95% confidence interval
AI	Anal incontinence
ACT	Adjustable compression therapy
AFS	Autologous fascial sling
APR-DRG	All Patient Refined Diagnosis Group
ATC	Anatomical therapeutic chemical (classification)
AUS	Artificial urinary sphincter
BAMS	Bone anchored male sling
BCFI-CBIP	Belgisch Centrum voor Farmacotherapeutische Informatie – Le Centre Belge d'Information Pharmacothérapeutique
BT	Bladder training
DDD	Defined daily dosis
EAS	External anal sphincter muscle
EPS	Echantillon Permanent – Permanente Steekproef
ER	Extended release
EStim	Electrical stimulation
FI	Faecal incontinence
FPS Public Health	Federal Public Service for Health, Food Chain Safety and Environment
FVC	Frequency volume chart
GR	Grade of recommendation
IAS	Internal anal sphincter muscle
ICD-9-CM	International Classification of Diseases-9th Revision-Clinical Modification
ICD-10-BE	International Classification of Diseases-10th Revision-Belgium



<b>ICS</b>	International Continence Society
<b>IMA – AIM</b>	InterMutualist Agenstchap – Agence InterMutualiste
<b>IR</b>	Immediate release
<b>LE</b>	Level of evidence
<b>LUTS</b>	Lower urinary tract symptoms
<b>MAX</b>	Maximum
<b>MDC</b>	Major Diagnostic Category
<b>MIN</b>	Minimum
<b>MNE</b>	Monosymptomatic nocturnal enuresis
<b>MMK</b>	Marshall-Marchetti
<b>MUS</b>	Mid-urethral sling
<b>MS</b>	Multiple sclerosis
<b>MUI</b>	Mixed urinary incontinence
<b>MZG – RHM</b>	Minimale Ziekenhuis Gegevens – Résumé Hospitalier Minimum
<b>NE</b>	Nocturnal Enuresis
<b>NMNE</b>	Non-monosymptomatic nocturnal enuresis
<b>OAB</b>	Overactive bladder
<b>P25</b>	25th percentile
<b>P75</b>	75th percentile
<b>PFM</b>	Pelvic floor muscle
<b>PFMT</b>	Pelvic floor muscle training
<b>POP</b>	Pelvic organ prolapse
<b>P-PTNS</b>	Percutaneous posterior tibial nerve stimulation
<b>PTNS</b>	Posterior tibial nerve stimulation



<b>PVR</b>	Post voiding residual volume
<b>RIZIV – INAMI</b>	Rijksinstituut voor ziekte- en invaliditeitsverzekering – Institut national d'assurance maladie-invalidité
<b>RP MUS</b>	Retropubic mid-urethral sling
<b>SD</b>	Standard deviation
<b>SIMS</b>	Single incision minisling
<b>SNS</b>	Sacral neurostimulation
<b>SOI</b>	Severity of illness
<b>SUI</b>	Stress urinary incontinence
<b>TCT</b>	Technical Cell – Cellule Technique
<b>TO</b>	Transobturator
<b>TO MUS</b>	Transobturator mid-urethral sling
<b>TOT</b>	Trans-obturator tape
<b>T-PTNS</b>	Transcutaneous posterior tibial nerve stimulation
<b>TURP</b>	Transurethral resection of the prostate
<b>TVT</b>	Tension-free vaginal tape
<b>TVT-O</b>	Tension-free vaginal tape obturator
<b>UTI</b>	Urine tract infection
<b>UUI</b>	Urgency urinary incontinence
<b>UI</b>	Urinary Incontinence
<b>VC</b>	Vaginal cones
<b>WHO</b>	World Health Organisation



## ■ SCIENTIFIC REPORT

### 1 GENERAL INTRODUCTION

#### 1.1 Aim of the study

Under specific conditions, persons suffering from incontinence can benefit from a grant for incontinence awarded by national health insurance. Two grants currently exist: a grant for dependent persons on one hand (the so-called large lump sum of 505.59 € in 2018 - yearly indexation) and a grant for untreatable urinary incontinence on the other hand (the so-called small lump sum of about 165.03 € in 2018 – yearly indexation).<sup>[1]</sup> The large lump sum for dependent persons was introduced in 1998. As still many patients with incontinence were not eligible for this large lump sum, another lump sum, the small one, was introduced later on in the year 2011. The large and the small lump sum were thus conceived separately from one another. Currently they are being criticised for lacking coherency and require rethinking. KCE has been requested by RIZIV – INAMI to explore options for a more coherent compensation for incontinence, at the same time taking into account the involvement of different policy levels, i.e. both the federal and federated level, and considering existing reimbursement interventions for other incontinence material.

The primary aim of this study is to examine the adequacy of the current payment model as to how it contributes to the triple aim of (1) improving quality of care, (2) improving health, whilst (3) limiting the cost per capita. More specifically, the main questions posed are:

- Does the current payment model ensure fair access to the payments, as well as to treatments and the use of materials?
- Is the current payment model an effective way to financially compensate patients with incontinence? In other words, do the grants fit to the real expenditures of patients?
- Is the current payment model an efficient model for compensating patients? Or can efficiency gains be realized by streamlining the payment or care delivery process?



- Is the current payment model internally coherent? Is the payment model in itself logical and comprehensible, both to healthcare professionals and patients?
- Finally, is the payment model externally coherent? Is the payment model aligned with the wider goals of care as defined in the most recent standards of care for incontinence? Does the payment model support evidence-based management of incontinence?

## 1.2 Scope

This study deals with both urinary and faecal incontinence. The focus is on patients living at home, which is a condition for being eligible for the RIZIV – INAMI incontinence lump sums. Incontinence material for hospitalised patients and patients in homes for the elderly are financed through other channels. Adults and children are included but babies are excluded. Ostomy products are not part of this study. For an analysis of the reimbursement of ostomy appliances, we refer to KCE report 21. <sup>[2]</sup>

## 1.3 Report outline

We start the report with a summary of the clinical scientific literature on incontinence, discussing prevalence, guidelines on diagnosis and treatments as well as care pathways in Chapter 2.

Consequently, Chapter 3 provides a description of the current reimbursement situation in Belgium, covering the reimbursement provided by RIZIV – INAMI but also by federated instances.

Chapter 4 gives an overview of the available data on incontinence in Belgium. We examine both reimbursement and treatment data.

In Chapter 5 we look at other countries to identify best practices in terms of reimbursement and care delivery models.

In Chapter 6 we bring together existing data on real costs from the patient's perspective in a Belgian and Dutch context.

In Chapter 7 we assess the possible use of BELRAI for the incontinence lump sums.

Finally, we bring the elements from the preceding chapters together in Chapter 8. Based on the stakeholder interviews and expert meetings, we make a critical appraisal of the current situation and propose possible options for improvement.



## 2 INCONTINENCE: PATIENTS, DIAGNOSIS AND TREATMENTS

### 2.1 Introduction

Incontinence is a common complaint that causes a great deal of distress. Urinary incontinence as well as faecal incontinence is a symptom that can be caused by a multitude of underlying causes which make the diagnosis and management complex. As a result, the care of the incontinent patient will mostly originate in primary care and advance to more specialised care when conservative treatment and first line pharmacological treatment is not sufficient. Several health professionals e.g. generalist, urologist, internist, nephrologist, paediatrician, surgeon, acute medicine, physiotherapist, nurse, incontinence nurse, are involved in the diagnosis and care of the patient and in more complex incontinence cases they will form a multidisciplinary team i.e. perineology clinic or pelvic floor clinic. Whilst, some conditions causing incontinence afflict either men or women, many affect both sexes and their management strategies are similar for both women and men.

#### 2.1.1 Chapter outline

In this chapter we will review the evidence to describe who the patients are, what types of incontinence are recognised, what the existing evidence of 'gold standard' incontinence diagnosis and treatment(s) are, and the related care pathways and algorithm(s).

#### 2.1.2 Methods

A data search was performed by the information specialist (NIF) for recent (2017-2018) high-quality reviews on urinary and faecal incontinence through a systematic search of Medline, the Cochrane library, and Embase, performed on February 22<sup>th</sup> 2018. The search terms, strategies and retrieved number of documents are summarised below. A further grey search for guidelines and reviews through the incontinence societies was performed by one researcher (VIJ) on February 26<sup>th</sup> 2018. The most recent guideline was the 6th Edition of 'Incontinence' [3]. This guideline was used as the basis for this chapter.

#### 2.1.3 PICO

**Table 1 – PICO**

PICO -Common search strategy	
P (Patient)	Patient with urinary incontinence OR faecal incontinence
I (Intervention)	Diagnosis, management and care of incontinence
C (Comparison)	No comparator
O (Outcome)	Description of diagnosis and treatment, and care pathways for incontinence
S (Study design/Settings)	Systematic review





### 2.1.4 Medline search

**Table 2 – Medline search strategy**

Table 2  
Medline Search Strategy

Medline		
Date	2018-02-22	
Database	Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R) <1946 to February 21, 2018>	
Segments	Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R) <1946 to February 21, 2018>	
Search Strategy		
Row	Query	Hits
#1	Exp Urinary Incontinence	30080
#2	(urinary adj2 incontinence?).ab,ti,kw.	21996
#4	fecal incontinence	9052
#5	(fecal adj2 incontinence).ab,ti,kw.	4072
#6	#1 or #2	36789
#7	#3 or #4	10489
#8	#5 or #6	44784
#8	Limit #7 to systematic reviews	1664
#8	Limit #8 to yr="2017-2018"	147
#8	Remove duplicates from #9	145

### 2.1.5 Cochrane search

**Table 3 – Cochrane search strategy**

Medline		
Date	2018-02-22	
Database	Cochrane @ Wiley	
Segments	Databases: DARE, CENTRAL, NHS eed, HTA db	
Search Strategy		
Row	Query	Hits
#1	[mh "Urinary Incontinence"]	1940
#2	(urinary near/2 incontinence?):ab,ti,kw	3
#3	#1 or #2	1942
#4	[mh "fecal incontinence"]	510
#5	(fecal near/2 incontinence):ab,ti,kw	798
#6	#4 or #5	798
#7	#3 or #6	2651
#8	#7 Publication Year from 2017 to 2018	81
#9	Restrict to Cochrane database of systematic reviews	10



### 2.1.6 Embase search

**Table 4 – Embase search strategy**

Medline		
Date	2018-02-22	
Database	Embase	
Segments	Embase	
Search Strategy		
Row	Query	Hits
#7	#6 NOT [medline]/lim	183
#6	#5 NOT ([conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim)	246
#5	#4 AND [2017-2018]/py	324
#4	#3 AND ('meta-analysis'/exp OR 'meta-analysis' OR 'systematic review'/exp OR 'systematic review')	2555
#3	#1 OR #2	94917
#2	(incontinence NEAR/2 (fecal OR urinary)):ab,ti,kw	42192
#1	'incontinence'/exp	90377

### 2.1.7 Grey literature search and websites incontinence societies

Websites searched by one researcher (VIJ) on 26<sup>th</sup> of February 2018:

- <https://www.ics.org/>
- <http://uroweb.org/guidelines/>
- NICE website: <https://www.nice.org.uk/news/blog/new-site>

### 2.1.8 Results from search: retrieved reviews and guidelines

The database search for systematic reviews and meta-analysis retrieved 145 results in Medline, 10 in the Cochrane database, and 183 in Embase. A further grey search for guidelines and reviews through the incontinence societies resulted in 36 references. After full reading 52 references were retained.

The most recent guideline was the 6<sup>th</sup> Edition of 'Incontinence' [3]. This is an extensive guideline from the International Continence Society, published in 2017. Belgian urologists and perineologists advised that this guideline is the bible for incontinence care internationally and in Belgium. Several Belgian specialists contributed to the literature review and chapters of the guideline. This guideline was appraised by VIJ with the 8 items of the third domain on rigour of development from the AGREE II checklist ([www.agreetrust.org](http://www.agreetrust.org)). This appraisal showed a high score of 8.7/10 showing a high quality (Appendix 2). We therefore based our summary of this chapter on this book and added information from the other reviews and guidelines to the summary. Therefore, we only placed references for the other reviews as the main text is fully based on the ICS guideline [3].



## 2.2 Definition incontinence

Incontinence is the unwanted and involuntary leakage of urine or stool (International Continence Society (ICS)). The disorder causes embarrassment and discomfort, as well as significant costs, to the affected individual and the wider society. Exact estimates of prevalence are not known and vary according to the population studied and the definition used for grading severity as there is no universally accepted threshold for clinically or biologically significant incontinence, and no objective tests that can be applied in the community. Incontinence is widely recognised as an important public health problem due to the immense human suffering and the economic cost. Despite a vast literature, there remain many uncertainties about the aetiology of incontinence.

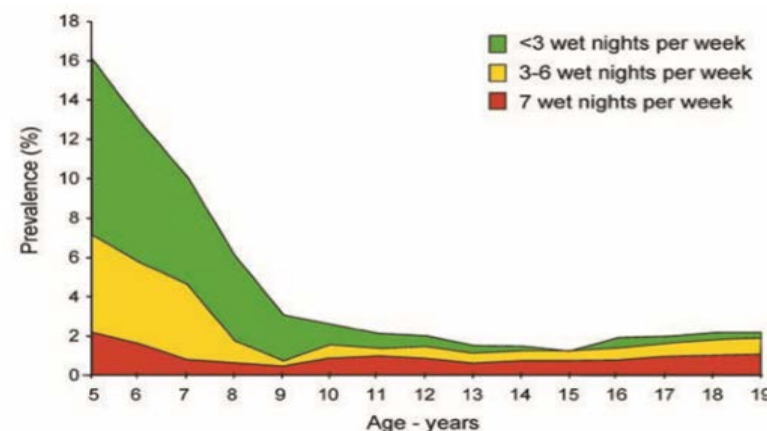
An estimated 18-45% of adults suffer from urinary incontinence (UI) and 11-15% from faecal incontinence (FI). UI, above the age of 60, is three times more common than FI and six times more present than combined incontinence. The prevalence of incontinence increases with age, with more than half of suffering individuals aged above 50 years. The highest prevalence is seen in nursing homes; with 70% of the population suffering from urinary or faecal incontinence or both. Of note, the spectrum severity of incontinence complaints of patients seen in hospital settings do not necessarily reflect the disease spectrum in the community.

The Belgian Health Interview Survey data from 2013 showed that for women aged 18 to 64, 5.4% had problems with UI and also had consulted their doctor, while for the above 65 year old women this increased to 15.7% [4]. In the Netherlands, 29% of women above 60 years from a general practice population study showed urinary incontinence (more than twice a month) [5]. A health Survey in women 18-40 years demonstrated a 36.1% prevalence of complaints of UI increasing with older age [6]. For faecal incontinence, a prevalence of 6% (FI minimum twice a month) was shown in the study by Teunissen [5]. In another survey, responders stated to be incontinent in the past 6 months for solid stool in 3.5%, for loose stools in 12.3%, and loss of flatus for 39% [7].

### 2.2.1 Urinary incontinence in children and adolescents

The prevalence of nocturnal enuresis (NE) with one episode a month or more in children aged 7 years, is estimated at 11%. It decreases to 3.5% at the age of 11-12 years, and further reduces to 1.3% at age 16-17 (Figure 1; [8]. NE constitutes of discrete episodes of UI during sleep, regardless of the presence of day-time UI. Monosymptomatic (MNE) and non-monosymptomatic nocturnal enuresis (NMNE) denote the absence or presence of concomitant day-time symptoms.

**Figure 1 – Nocturnal enuresis prevalence in children and adolescents**





Functional lower urinary tract dysfunction defined as any other leakage than NE, and often seen with symptoms as frequency, urgency and infections, is present in 3.2 to 9% of children; with a decreasing frequency of UI more than once a week with age: 7 years 2.6%, 11-13 years 1.1% and 15-17 0.3%. NE has been identified as an independent risk factor for day-UI. Diurnal UI in children has been linked to bowel problems (constipation and functional FI), family history and socio-cultural factors, minor neurological dysfunction, developmental delay, organic anomalies such as infra-vesical obstruction in boys and sexual abuse. Urinary and faecal incontinence often coexist with approximately one-third of children with UI suffering from constipation or functional FI.

### 2.2.2 Urinary incontinence in women and men

An estimated 30% to 60% of middle-aged and older women in the general population suffer with UI. Daily UI estimated prevalence is 5% to 15%, rising over 15% for women above 70 years who are in residential care. The UI prevalence in men (11-34%) is less than half as common compared to women but prevalence increases more steadily with age.

Among young and middle-aged women, only age, body mass index, parity and mode of delivery are unambiguously associated with incontinence, and for all of these, the association with stress UI is greater than with urgency UI (UUI). For women, pregnancy, delivery and parturition factors e.g. instrumental delivery and birth weight, are risk factors for UI in the post-partum period. Further, body mass has been established as an important risk factor for UI while other modifiable factors include smoking, diet, depression, constipation, urine tract infections, and strenuous exercise (e.g. jumping). Although associated with UI, they are not considered established independent risk factors. In older women, physical function and moderate and severe dementia are individual risk factors for UI. Overflow of urine commonly presents when the bladder is continuously full, with or without weakening of the bladder muscles, and when there is no urge to urinate or bladder contractions.

Predisposition factors for UI in men are less well documented in the literature and include presence of lower urinary tract symptoms (LUTS), urinary tract infections, functional and cognitive impairment, diabetes, neurological

disorders, and surgery e.g. cystoprostatectomy, prostatectomy. In men, UI is often part of a multifactorial problem and accompanied by LUTS such as weak stream, hesitancy, dribbling, and erectile dysfunction. Overflow of urine commonly presents when the bladder is continuously full, as a result of outflow obstruction with prostate hypertrophy, with or without weakening of the bladder muscles, and when there is no urge to urinate or bladder contractions. UI, a common complication of prostatectomy, has become more prevalent with the increase of prostatectomy operations. Radical prostatectomy induces more UI than transurethral resection of the prostate (TURP) and rates vary from 2% to 57%. Rates are high after surgery and decline up to 2 years after surgery and recovery is influenced by age, obesity, and type of surgery (no difference for open, laparoscopic, and robotic surgery). Other risk factors in men have been described as follows: increasing age, LUTS, urinary tract infections, functional and cognitive impairment, diabetes, alcohol intake, and neurological disorders.

### 2.2.3 Faecal incontinence

Faecal incontinence (FI) is the involuntary loss of faeces (solid or liquid). Anal Incontinence (AI) is FI including the involuntary loss of flatus. A third cause of soiling that is distinguished from FI is anal mucoid seepage. In this condition the anal sphincter functions normally and the soiling is not treatable by standard incontinence treatment. AI is as common in men as in women (level of evidence (LE) 2) and present in all age groups; increasing with age from 1.5% in children towards 50% in nursing home residents (LE 1). Risk factors for AI are not well defined in general. In the elderly at home and in nursing homes often FI is accompanied by UI (LE1) and commonly so in the cognitively impaired [9]. Patients and carers perceive the cause of the FI due to childbirth, menopause, old age, paralysis, haemorrhoids, rectal or anal surgery, neurological disorders [10]. The risk of post-partum FI is reduced by intrapartum pelvic floor education (LE 1) whereas mode of delivery has no influence on development of FI. With age, concomitant illnesses e.g. surgery, neurological disease, stroke and cognitive impairment become risks for FI.



## 2.3 Causes of incontinence

A subdivision of incontinence is made in neurological and non-neurological related incontinence. This is in line with how care is organised <sup>[11]</sup>.

### 2.3.1 Neurological causes

Neurological causes of incontinence include patients with a variety of neurological conditions such as different forms of paralysis, spina bifida, stroke, multiple sclerosis, motor neurone disease, but also diabetes. Patients can have UUI or dysfunction of sphincter(s) with or without FI.

Neurological disorders affecting the brain, spinal cord, or the peripheral nervous system have FI due to impaired anal sphincter control, reduced or absent anorectal sensibility, or abnormal anorectal reflexes. Diabetic patients can have neuropathy of the anal canal or chronic diarrhoea.

**Table 5 – Neurological causes of incontinence**

Cause of faecal and urinary incontinence	Underlying pathology
Neurological disorders	<ul style="list-style-type: none"><li>• Spinal cord injuries</li><li>• Stroke</li><li>• Multiple sclerosis</li><li>• Spina bifida</li><li>• Diabetic neuropathy</li><li>• Obstetric <i>N. pudendus</i> damage</li></ul>

### 2.3.2 Non-Neurological causes

The non-neurological incontinence group can be divided into three main categories: a large group with stress urinary incontinence (SUI), UUI and mixed UI (MUI). A second patient group with FI, and lastly, incontinence in the frail elderly and cognitive impaired.

#### 2.3.2.1 Subtypes of incontinence: stress, urgency, mixed and other

The SUI clinical subtype or the loss of urine on effort, exertion, sneezing or coughing (increasing intra-abdominal pressure) typically includes the younger and middle-aged female patient presenting during pregnancy or after childbirth. Urgency and mixed UI often presents in middle-aged women affected by bladder and or pelvic floor problems and middle-aged and older men. Urgency is defined as the leakage of urine with or immediately preceded by urgency (a sudden compelling desire to urinate that is difficult to delay) whereas MUI is the leakage of urine associated with both urgency and exertion, effort, sneezing or coughing often accompanied by an overactive bladder (OAB), frequency and nocturia. The urgency and mixed types tend to suffer from higher volume leakage episodes. In men UUI is mostly represented (40-80%), followed by mixed forms of UI (10-30%), and SUI in less than 10%. On the contrary, in women SUI is the most common subtype, followed by MUI, and then UUI. Other types of urinary incontinence are:

- Postural (urinary) incontinence: Complaint of involuntary loss of urine associated with change of body position, for example, rising from a seated or lying position;
- Incontinence associated with chronic retention of urine;
- Nocturnal enuresis: Complaint of involuntary loss of urine which occurs during sleep;
- Continuous (urinary) incontinence: Complaint of continuous involuntary loss of urine;
- Insensible (urinary) incontinence: Complaint of urinary incontinence where the individual is unaware of how it occurred;
- Coital incontinence (for women only): Complaint of involuntary loss of urine with coitus;
- Functional incontinence: Complaint of involuntary loss of urine that results from an inability to reach the toilet due to cognitive, functional or mobility impairments in the presence of an intact lower urinary tract system.



- Multifactorial incontinence: Complaint of involuntary loss of urine related to multiple interacting risk factors, including factors both within and outside the lower urinary tract such as comorbidity, medication, age-related physiological changes and environmental factors.

Two types of continence problems that in the first place give cause to retention of urine (bladder is full and can't be emptied) and in a second instance can cause incontinence are:

- Urinary retention results from a blockage of the bladder outlet (benign prostatic hyperplasia, prostate cancer, or narrowing of the urethra), with or without a weakening of the bladder muscle, or as side effect of certain medications. Acute retention is treated with catheterisation and removal of the cause. With chronic retention repeat self-catheterisation or catheterisation by a third person may be indicated.
- Overflow incontinence is the involuntary release of urine from an overfull urinary bladder often related to chronic retention.

### 2.3.2.2 Faecal incontinence

Faecal continence is a complex interaction of the internal anal sphincter muscle (IAS), the external anal sphincter muscle (EAS), the rectal smooth muscle, the puborectalis muscle, sensory nerve cells of the anal canal, and the anal sampling reflex. Any disturbance of the factors above can make a subject incontinent. FI is considered secondary when an underlying pathology can be demonstrated whereas primary FI is functional or idiopathic and without a pathology. Conditions and pathologies that can cause FI are summarised below <sup>[12]</sup>. Congenital, traumatic e.g. post-vaginal delivery, iatrogenic defects of the anal sphincter are well known. Non-neurological disorders exclude disorders affecting the brain, spinal cord or the peripheral nervous system.

**Table 6 – Non-neurological causes of faecal incontinence**

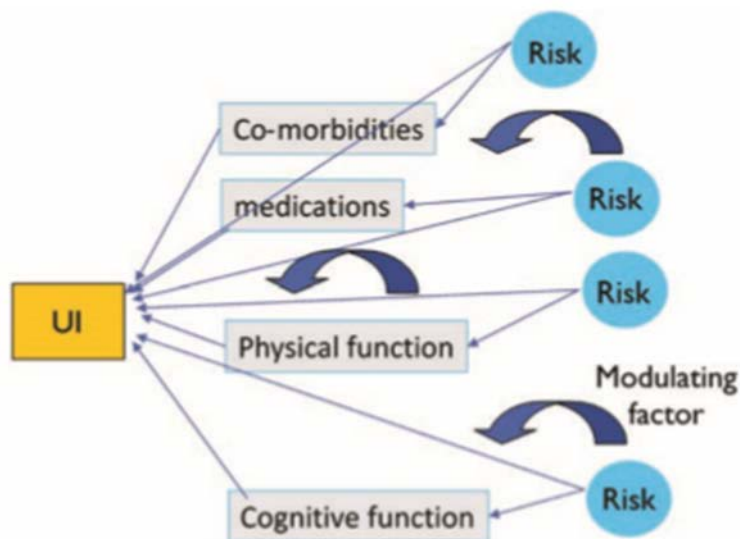
Cause of faecal incontinence	Underlying pathology
Anal sphincter dysfunction	<ul style="list-style-type: none"><li>• Congenital anorectal abnormalities</li><li>• Radiation therapy</li><li>• Obstetric anal sphincter injury</li><li>• Anal surgery</li><li>• Perianal fistulas</li><li>• Hirschprung disease</li><li>• Sexual abuse</li></ul>
Cause of faecal incontinence	Underlying pathology
Rectal disorders	<ul style="list-style-type: none"><li>• Inflammatory bowel disease</li><li>• Radiation therapy</li><li>• Rectocele</li><li>• Rectal intersusception</li><li>• Rectal prolapse</li><li>• Faecal impaction</li><li>• Rectal surgery</li></ul>
Myopathy	<ul style="list-style-type: none"><li>• Systemic scleroderma</li></ul>
Fast colorectal transit time	<ul style="list-style-type: none"><li>• Chronic diarrhoea</li><li>• Irritable bowel syndrome</li></ul>
Psychological	<ul style="list-style-type: none"><li>• Encopresis</li><li>• Dementia</li></ul>



### 2.3.2.3 Frail elderly and the cognitively impaired

A frail older person is aged over 65 with a combination of impaired physical activity, mobility, balance, muscle strength, motor processing, cognition, nutrition, and endurance (including feelings of fatigue and exhaustion). Frail people usually have multiple chronic medical conditions, take multiple medications, require care from others and assistance to perform some or all of the personal daily activities (bathing, dressing, toileting, mobility) and are often homebound or institutionalised. They have high risk of concurrent disease, increased disability, hospitalisation, and death. Single or combined incontinence in this group is often the result of multiple risk factors, including age-related changes, polypharmacy, and multi-morbidity e.g. dementia, diabetes, and Parkinson's disease and pathways between them (Figure 2). The relationship between UI, FI and frailty is not unidirectional.

**Figure 2 – Incontinence as a geriatric symptom**



## 2.4 Management of urinary incontinence in healthy adults

The management of UI is often a combination of options, including conservative, pharmacological and surgical management <sup>[13]</sup>. The care pathways are described further below. After an initial assessment (history, physical examination, laboratory tests) establishing a presumptive diagnosis, and excluding underlying organ-specific conditions requiring specialist intervention, as well as assessing the level of bother and desire for intervention from information obtained from the patient or caregivers, the management and treatment can be planned and started. Concurrent conditions and medication should be assessed for a relation with UI. When conservative management and pharmacological treatment have not adequately treated the symptoms, surgery or other invasive treatment may be considered <sup>[13]</sup>. The level of improvement should be assessed after the intervention. A summary of comparison of treatment for UI is presented in Table 7. The details of the treatments are discussed further below in this section.





Table 7 – ICS Recommendations for the treatment of UI

	Pelvic floor muscle training	Vaginal cones	Electrical Stimulation	Bladder Training	Pessary	Posterior tibial nerve stimulation	Acu-puncture	Drug therapy	Surgery	Grade of recommendation *	Explanation
<b>Women</b>											
Stress UI	X	X								B	Both effective as conservative therapy, although PFMT is better because inability of use and side effects are experienced with VC in some women.
	X		X							B	PFMT is better than ESTim as first line conservative therapy.
	X			X						B	PFMT is better than BIT as first line conservative therapy.
	X				X					B	Both effective in first line conservative therapy.
	X							X		B	Both effective as first line therapy, although PFMT is better because of side effects experienced with drug therapy.
	X								X	B	Surgery is more effective than PFMT, but potential benefit should be weighed against potential adverse events. PFMT should be offered as first line therapy due to its being less invasive.
<b>Women</b>											
Stress UI or Mixed UI	X	X								B	VC do not appear to be better than PFMT in the treatment of UI. PFMT should be





		X		X							D	recommended as first-line conservative therapy. Both seem equally effective. Side effects and discomfort appear to limit their utility in clinical practice.
Urgency UI or Mixed UI	X			X							B	Both are effective first-line conservative therapy.
	X							X			B	PFMT is better than oxybutynin as first line therapy.
							X	X			B	When choosing between acupuncture and anticholinergic drug for women with OAB, UUI and MUI, either may be effective.
Urgency UI	X			X							B	Both are effective first line conservative therapy.
				X				X			B	Both may be effective. BIT may be preferred by women and clinicians because it is not associated with the drug related side effects (GR D).
	Pelvic floor muscle training	Vaginal cones	Electrical Stimulation	Bladder Training	Pessary	Posterior tibial nerve stimulation	Acupunct ure	Drug therapy	Surgery	Grade of recommendation *	Explanation	
Women												
UI			X					X		B	Based on current limited evidence, EStim could be considered as an alternative to medical treatment. Drugs appear to be no more effective than EStim.	
						X		X		B	PTNS may be considered for women as it is associated with fewer and less bothersome adverse effects than those from drug treatment.	



Men											Explanation
	Pelvic floor muscle training	Vaginal cones	Electrical Stimulation	Bladder Training	Pessary	Posterior tibial nerve stimulation	Acupuncture	Drug therapy	Surgery	Grade of recommendation *	
UI	X									B	Some pre-operative instruction or immediate post-operative instruction in PFMT for men undergoing resection of prostate may be helpful in earlier recovery of continence.
	X									C	Offer men with post micturition dribble instruction to do a strong PFM contraction immediately after voiding, or urethral massage to empty the urethra.
	X				X					B	Use of biofeedback to assist PFMT should remain a therapist/patient decision based on economics and preference.
Men and women											Explanation
	Pelvic floor muscle training	Vaginal cones	Electrical Stimulation	Bladder Training	Pessary	Posterior tibial nerve stimulation	Acupuncture	Drug therapy	Surgery	Grade of recommendation *	
Urgency UI						X		X		B	Percutaneous PTNS can be offered as an alternative to tolterodine for OAB/UUI in adult men and women.
UI						X		X		B	Oxybutynin may be considered in addition to percutaneous PTNS in adults with detrusor overactivity

PFMT: Pelvic floor muscle training; VC: Vaginal cones; EStim: Electrical stimulation; BIT: Bladder training; PTNS: Posterior tibial nerve stimulation; \*Grade of recommendation from the ICS 2017.



### 2.4.1 Conservative treatment

Conservative options include: lifestyle interventions, pelvic floor muscle training (PFMT), vaginal cone (VC) therapy, electrical stimulation, and containment products such as pads and catheters (intermittent (self-catheterisation or by carer) or indwelling urethral or suprapubic) to collect and contain leakage.

**Lifestyle interventions** include fluid intake regulation and restriction (Grade of recommendation (GR) B), and modifications of the patient's diet e.g. reducing caffeine (GR B), alcohol, and carbonated drinks or increasing fibre for constipation. An elimination diet (bladder diet) will eliminate specific foods in the evaluation of urinary urgency (GR B)<sup>[14]</sup>. The evidence for cure of UI is limited with only weight reduction known to improve UI (women GR A; men GR B) whereas other interventions e.g. smoking cessation (GR C), caffeine reduction (GR C), fluid intake modification, may improve urgency and frequency but not UI.

**Pelvic floor muscle re-education and training** encompasses patient education to improve the function, the strength, endurance and relaxation of the pelvic floor and deeper abdominal muscles, improving urethral stability. The pelvic floor muscles are the base of the group of 'core' muscles that include the abdominal muscles, the diaphragm, and the muscles of the vertebrae and back. These 'core' muscles ideally should work and adapt jointly to regulate the pressure within the abdomen. In the assessment of the pelvic floor muscles the total of core muscles should be considered and evaluated.

PFMT involves a repeated PFM exercise programme and depends highly on patient adherence. When biofeedback is added to the PFM training it can help the patient to be more aware of muscle function, and enhance the motivation during training. The types of biofeedback include: perineal, vaginal, and anal surface electromyography, urethral, vaginal or anal manometry, vaginal dynamometry, and real-time ultrasound.

- The most intensive locally available exercises should be offered to each patient with UI (GR A). PFMT is a key aspect of the treatment of UI, SUI as well as UUI.
- Often PFMT is augmented with biofeedback (using visual, tactile or auditory stimuli) surface electrical stimulation or vaginal cones although no clear benefit has been shown (GR A) for adding any 'extra' therapy to PFMT.
- In men undergoing radical prostatectomy PFMT should be offered pre-operatively and post-operatively to speed recovery of UI (GR B).
- In men immediately post-prostatectomy, use of biofeedback to assist PFMT should remain a therapist/patient decision based on economics and preference (GR B).
- Intense supervised training should be offered as first-line therapy to women (including older women) with SUI or MUI (Level of evidence (LE) 1; GR A), or UUI (GR B), and to post-natal women (LE 1; GR A).
- PFMT can be performed in groups, individually, and at home. PFMT with supervision (e.g. weekly) is better than PFMT without or with little supervision (LE 1).
- Antenatal PFMT can be organised as a population based intervention comprising of a daily home PFMT and weekly physiotherapist-led exercise classes for 12 weeks, starting at 16-24 weeks' gestation for pregnant women (GR C).
- Pregnant continent women should be offered intensive strengthening PFMT to prevent antepartum and postpartum UI (LE 1; GR A).
- Evidence for prevention of UI in healthy elderly women (LE 2; GR C) is lacking.



**Vaginal cone therapy** consists of applying weighted devices that are inserted into the vagina to perform exercises to strengthen the pelvic floor. The exercises should be performed daily. Potential side effects reported are pain, vaginitis, bleeding and a sense of unpleasantness or inconvenience.

- For women with SUI, vaginal cones with supervised training sessions by a trained health professional may be offered as a first-line conservative therapy to those who can and are prepared to use them (GR B).

**Neuromuscular Electrical stimulation (EStim)** applies electrical transcutaneous shocks with pads to the lower back or sacral area stimulating the sacral nervus plexus delivering electrical stimuli to the pelvic floor. There is no clear biological rationale nevertheless, the mechanisms of action for SUI is to improve the muscle function of an atrophied or weak PFM, while for UII the objective seems to be to inhibit detrusor overactivity. EStim is provided by clinic-based mains powered machines or portable battery powered stimulators delivering a variety of current waveforms, intensity etc. Confusion is created by the relatively rapid developments in the area of EStim, and a wide variety of stimulation devices and protocols that have been developed even for the same condition.

- EStim is often used to assist women who cannot initiate contractions to identify their pelvic floor muscles as part of PFMT.
- Adverse effects of pain and discomfort are not uncommon and therapy should be offered together with PFMT.
- The clinic intense treatment is performed in cycles of weekly sessions each whereas home low-intensity treatment is applied daily.
- For women with SUI maximal clinic-based EStim might be better than daily low-intensity home-based EStim in improving symptoms (GR B).
- EStim could be considered as an alternative to medical treatment (limited evidence).
- Drugs appear to be no more effective than EStim (GR B)

**Posterior tibial nerve stimulation (PTNS)** is a form of peripheral nerve stimulation and is either performed by inserting a fine needle i.e. percutaneous stimulation (P-PTNS) above the ankle or applying transcutaneous electrical shocks (T-PTNS) with pads. The peripheral neurostimulation of the tibial nerve will reach the sacral plexus and the method of action is the same as with Estim. PTNS is targeted towards symptom relief of OAB and UII.

- Percutaneous PTNS is performed as an outpatient procedure and should be delivered at least once weekly and the protocol determined by patient preference (GR B).
- Transcutaneous PTNS may be delivered either in clinic or self-administered at home.
- For women with UII or OAB, PTNS may be more effective than no active treatment in symptom control (GR C).
- PTNS may be considered for UII and OAB in women as it is associated with fewer and less bothersome adverse effects than those from drug treatment (GR B).
- Percutaneous PTNS can be offered to men and women (adults) with UII/OAB who do not achieve satisfactory results from first line lifestyle and behavioural intervention and pharmacological therapy (GR B)
- Percutaneous PTNS can be offered as an alternative to tolterodine (not available in Belgium) for OAB/UII in adult men and women (GR B)
- Percutaneous PTNS is a treatment option in some children with therapy- refractory nocturnal enuresis <sup>[15]</sup>.



**Scheduled voiding regimens** can be applied actively to cognitively intact patients at home, the cognitively impaired (passive assistance toileting programme), and UI secondary to central nervous system or spinal cord disease. The types of scheduled voiding regimens can be categorised as: bladder training, timed voiding, habit training, and prompted voiding. Aspects that will influence the application of a scheduled regimen are:

- the active or passive involvement of the patient,
- the nature of patient education including the teaching of strategies to control urgency and prevent stress leakage,
- the use of reinforcement techniques,
- the nature of the interactions between clinicians and patients.

**Bladder training (BIT)** (drill, discipline, re-education, retraining) means patient education with a scheduled voiding regime with gradually adjusted voiding intervals to improve bladder control. It is advised as first-line therapy for UUI and MUI. It is often combined with a fluid intake consumption and restriction lifestyle intervention.

- BIT should be recommended as first line conservative therapy for UI in women (GR A).
- When considering BIT and anticholinergic drug for women with DO or UUI, either may be effective (GR B).
- BIT may be preferred by women and clinicians because it is not associated with the drug related side effects (GR D).

**Timed voiding** is a fixed voiding schedule that remains unchanged over the course of treatment. The goal is to prevent UI by providing regular opportunities for bladder emptying prior to exceeding bladder capacity. Evidence is limited. For women with mild UI (or infrequent voiding patterns) a two-hour voiding schedule may be beneficial as a single intervention or as adjunct (GR C).

**Habit training** is a toileting schedule matched to the individual's voiding pattern based on their voiding diary. The toileting schedule is assigned to fit a time interval that is shorter than the person's normal voiding.

**Prompted voiding** aims to teach people to initiate their own toileting through requests for help and positive reinforcement from caregivers, often done in combination with a scheduled voiding regime every 2 h.

**Acupuncture** may include body acupuncture, hand acupuncture, electroacupuncture and acupressure, amongst others. When choosing between acupuncture and anticholinergic drug for women with OAB, UUI and MUI, either may be effective (GR B).

**Pessaries** are devices inserted into the vagina to provide structural support to one or more of descending vaginal compartments. They offer a non-surgical option for the treatment of urinary incontinence. Major complications have been seen only with neglected pessaries. Minor complications such as vaginal discharge, odour, and erosions can usually be successfully treated<sup>[16]</sup>.

**Toileting aids** are important to consider as they can help overcome UI due to problems of e.g. mobility, access, and toilet proximity. Examples are handheld urinals, and body worn urinals.

**Containment** is important when active treatment does not cure the problem, is not available or not possible or when it's the individual's preference. Nevertheless, adults with incontinence and their carers should be informed regarding available treatment options before deciding on containment alone. Detailed description of material is available further in the report.

- Light incontinence: disposable insert pads for women and men
- Moderate/severe incontinence: pads, external devices and catheters, balancing benefits and harms, patient's circumstances and preference, in collaboration with a healthcare professional with expertise in UI



## 2.4.2 Pharmacological treatment

### 2.4.2.1 Pharmacological treatment for urgency incontinence

Anticholinergics are commonly used for the treatment of UUI. In Belgium the following are available: oxybutynin, immediate release (IR) and extended release (ER) transdermal, darifenacin ER, fesoterodine ER, propiverine IR and ER, tolterodine ER and solifenacin ER (BCFI <sup>[17]</sup> accessed July 10<sup>th</sup> 2018).

Mirabegron, a  $\beta_3$ -adrenoceptor agonist, is the only of this class so far approved for treatment of UUI in humans (ER formulation). It has been shown to increase bladder capacity with no change in micturition pressure and residual volume.

From a third drug class, desmopressin can be considered for nocturia but should be used with caution in the above 65 years with cardiovascular disease. Finally, botulinum neurotoxin is applied by injection into the bladder wall. Botulinum neurotoxin (BoNT) is a potent neurotoxin produced from the bacterium *Clostridium botulinum*. *C. botulinum* strains produce seven immunologically different neurotoxins (serotypes A to G)<sup>[18]</sup>. Only serotype A toxins BoNT/A serotype Botox® is FDA approved for OAB treatment. It acts by blocking the presynaptic release of acetylcholine from efferent nerve vessels and reduces the sensory receptors of the afferent nerve system.

The action of all treatments is the same and aims to reduce the overactive detrusor bladder muscle activity, to suppress involuntary bladder contractions, and to maintain low bladder pressures. Increased bladder pressure may also lead to upper tract complications due to stasis and poor drainage of the upper tracts.

The drugs that are **highly recommended** (grade A; level 1 evidence) based on ICS assessment of efficacy, tolerability and safety are presented in Table 8 with their contra indications and side effects. Care should be taken in patients with co-morbidities, children and the elderly <sup>[17]</sup>.

Side effects for *anticholinergic drugs*, summarised below, are common and responsible for the low compliance and high discontinuation rates. The side

effects are less pronounced for extended release (ER) and transdermal products as compared to immediate release (IR).

- dry mouth in 50% and taste disturbances
- constipation in 15% and flatulence
- blurred vision in 5%
- drowsiness in 12%, fatigue, dizziness, cognitive dysfunction
- skin reactions

For a full discussion of the adverse events and safety profile of each molecule, we refer you to the ICS guideline where RCTs results are summarised. The advantage of the newer formulations (of which 5 are available in Belgium) is their improved dosing schedule and side-effect profile implicating better compliance in the long term. At present more studies are needed to decide which drug should be first-, second-, or third-line treatment. None of the available drugs is ideal for first-line for all patients and treatment should be individualised (depending on co-morbidities and poly-medication).

*Mirabegron* is reported to have an acceptable side effect profile with mostly reports of nausea, headache, hypertension (predominantly in patients with baseline hypertension), diarrhoea, constipation, dizziness, and tachycardia <sup>[19]</sup>. The cardiovascular safety appears to be acceptable at therapeutic doses <sup>[20]</sup>. Dry mouth and constipation are not commonly reported as with the anticholinergic drugs. The most recent review on Mirabegron is from 2017 with search up till June 2015 (see Table 11) <sup>[21]</sup>. The latest update of the folia pharmaceutica on UI is from 2016 and states that mirabegron is not superior to the anticholinergics with patients experiencing a similar burden of side-effects (cardiac arrhythmia, hypertension, urine tract infection, lithiasis, skin reactions).

The injection of *botulinum toxin A* in the bladder wall (Onabotulinum toxin A) impairs afferent and efferent bladder nerve ends. The toxin (100 U of onabotA; BOTOX®) is dissolved in 10 mL saline and 0.5 mL is injected in 20 points of the bladder wall above the trigone. Licensing in Europe is for the specified dose and for the indication of OAB with persistent and



refractory UUI in adults, only. Continued efficacy is seen with continued injections but patient discontinuation has been high. Adverse events are urine tract infection and increased post PVR that may require intermittent catheterisation. The efficacy and safety of intradetrusor injection of onabotulinumtoxin A for the treatment of overactive bladder are sensitive to injection volume and depth, and this issue has motivated researchers to study injection-free modes of drug delivery into the bladder [22].

In summary, guidance for pharmacological treatment:

- Higher doses are more effective but result in higher risk of side effects.
- Patients should be evaluated four weeks after initiating therapy.
- Adherence is lowest
  - In young male population
  - With IR formulations

- When high expectations at start [23]

- Offer ER or transdermal products if side effects are intolerable with IR formulations
- Cycling between anticholinergic is not effective; 1 drug should be trialled and the dosage increased if the lower dose has an acceptable adverse event profile
- Offer mirabegron (alone or in combination with anticholinergics) or alternative therapies if side effects are intolerable with anticholinergics

The evidence of cure or improvement of UI with any of the drugs is limited due to lack of standards, and the overall treatment effect is usually small (30 to 40%) but larger than placebo. Highest cure rates at 12 months are demonstrated with the newer anticholinergics and mirabegron. A summary of the cure rates is presented in Table 11.

**Table 8 – Drugs for urgency incontinence with ICS grade A recommendation**

Drug	GR	Immediate release	Extended release	Transdermal	ICS assessment: tolerability and safety acceptable	Available in Belgium	Contra-indications	Risk patients and co-morbidities	Side effects
<b>Anticholinergic</b>									
Trospium	A	X		X	YES	No	Glaucoma, reflux oesophagitis, pyloric stenosis, intestinal atony, paralytic ileus, colitis ulcerosa, myasthenia gravis	Children, elderly, prostate hypertrophy, diarrhoea, hyperthermia, tachycardia, hypertension, myocardial infarction, alcohol, sedating medication	Dry mouth and eyes, blurred vision, nausea, constipation, fatigue, bladder retention, tachycardia, cognitive dysfunction (of note particularly for oxybutynin in elderly and children), dizziness. Skin reaction for transdermal oxybutynin
Tolterodine	A	X	X		YES	No			
Darifenacin	A		X		YES	ER 7.5 mg & 15 mg			
Fesoterodine	A		X		YES	ER 4 mg & 8 mg			
Imidafenacin	A	X			YES	No			
Solifenacin	A		X		YES	ER 5 mg & 10 mg			
Oxybutynin	A	X	X	X	YES	IR 5 mg ER transdermal 36 mg/patch 2/week			
Propiverine	A	X	X		YES	IR 5 mg & 15 mg ER 30 mg			





<b>β<sub>3</sub>-adrenoceptor agonist</b>					Hypertension	Kidney and liver insufficiency	Severe hypertension
Mirabegron	A	X	YES	ER 25 mg& 50 mg			
<b>Toxins</b>							
Botulinum toxin	A						
<b>Other drugs (Nocturia)</b>							Hyponatremia
Desmopressin	A	Orally, nasally, injection					

#### 2.4.2.2 Pharmacological treatment of stress incontinence

The serotonin reuptake inhibitor duloxetine can be considered in SUI in women when other treatment options including surgery are not an option or have failed. No options are available for men, unfortunately.

**Table 9 – Drugs for stress incontinence**

Drug	GR	Side effects	Type of drug
Duloxetine	B	Nausea and vomiting very common (40%) in first weeks mostly	Antidepressant: Serotonine reuptake inhibitor

#### 2.4.3 Surgical management

**Women** with uncomplicated (no previous surgery, no severe prolapse, not considering future pregnancy) SUI can benefit from a surgical intervention. Today, the mid-urethral sling (MUS) is the most frequently used surgical intervention in Europe for women with SUI [23]. UI related to genitourinary prolapse can improve with open and laparoscopic colposuspension. Other surgical procedures are intramural bulking agents, artificial urinary sphincter, and the injection of botulinum toxin A in the bladder wall.

Incontinence in **men** is a complication of prostate surgery in 0.5% to 8% of patients. Surgical treatment of the incontinence is indicated when postoperative conservative treatment of incontinence fails (5-25%). Slings and artificial urinary sphincter (AUS) are the preferred strategies. The AUS has provided a satisfactory result in most cases, regardless of the degree of urinary incontinence, with a positive impact on quality of life. Sling procedures have emerged as an efficacious treatment in many men with mild to moderate stress urinary incontinence, however, they have not proven predictably successful in men with higher degrees of incontinence. Injectable agents have not shown durable long-term results. Volume adjustable balloons have been limited in their utility due to a high complication rate. Newer techniques involving adjustable urethral slings have demonstrated efficacy similar to that of non-adjustable slings, with the potential advantage of postoperative alterations in sling tensioning (tightening) but a higher complication rate.

Men with milder degrees of incontinence and normal bladder function are candidates for either artificial urinary sphincter placement or sling surgery, each with similar success rates. Sling surgery appears to have a lower risk of surgical complications in this population and patient preference may be for a sling vs a mechanical device in this group of patients. On the other hand, with more severe incontinence, AUS surgery has a more predictable success profile than does sling surgery.



**Table 10 – Indications for surgery in men**

Conditions that can be surgically corrected	
Sphincter Related	<ul style="list-style-type: none"><li>• Postoperative</li><li>• Post-prostatectomy for prostate cancer</li><li>• Post-prostatectomy for benign disease</li><li>• TURP and radiation for prostate cancer</li><li>• Post-cystectomy and neobladder for bladder cancer</li><li>• Post-traumatic</li><li>• After prostatic-membranous urethral reconstruction</li><li>• Pelvic floor trauma</li><li>• Unresolved pediatric urologic incontinence</li><li>• Exstrophy and epispadias</li></ul>
Bladder Related	<ul style="list-style-type: none"><li>• Refractory urgency incontinence</li><li>• Small fibrotic bladder</li></ul>

#### 2.4.3.1 Traditional bladder neck pubovaginal sling

The 'traditional' sling procedures involve a combined abdominovaginal approach with the sling placed at the bladder neck. Sling materials vary widely and while not affecting the efficacy, they do influence the long-term outcomes and the associated morbidity. Materials may be synthetic or biological. The latter include autografts (rectus fascia, fascia lata, round ligament, dermis, vaginal skin, and gracilis, levator, and rectus muscles), cadaveric allografts (fascia, dermis, and dura mater) and xenografts (porcine dermis and small intestinal submucosa, bovine dermis and pericardium). The autologous fascial sling (AFS) is the most widely evaluated biological sling and is an effective and durable treatment for SUI (LE 1). There is little short term difference in efficacy between biological slings using autograft or allograft (LE 2/3) and synthetic slings and biological slings placed at the bladder neck. However, those studies that find a difference between biological materials for sling all favour autologous materials (LE 2). As compared to AFS, adverse events may be more common following the use

of synthetic materials as 'traditional' sling procedures (exposure, erosion, etc.) (LE 3).

- AFS is recommended as an effective treatment for female SUI, which has longevity for both primary and redo surgery (GR A)

#### 2.4.3.2 Mid-urethral sling for women

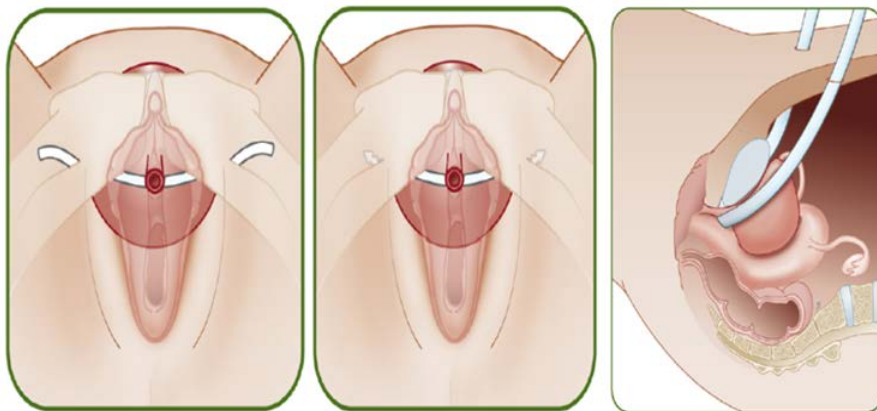
The retropubic mid-urethral sling (RP MUS) is the tension-free vaginal tape (TVT) procedure that was first developed in 1996. It applies a mesh through an incision in the vagina.

The transobturator (TO) MUS is applied from inside the thighs through the obturator foramina bilaterally. The procedure was modified to be an inside-out procedure, now called the tension-free vaginal tape-obturator (TVT-O) or trans-obturator tape (TOT). The materials used for TO MUS have continued to be modified to decrease risk of erosion, extrusion and infection. Today, nearly all of the commercially-available synthetic TO MUS products are made of polypropylene mesh and have an extrusion and erosion rate well below 5%. The TO technique has since gained immense popularity, owing to its reproducible results and low rates of complications. It is currently the procedure with the highest use in Belgium.

The single incision mini-slings (SIMS) is performed as an outpatient procedure. Several SIMSs were launched with different anchoring mechanisms in the obturator foramen. All are made of polypropylene mesh however the length and anchoring mechanisms are variable. The method of insertion is either U shaped, inserted in the same manner as the TVT or the H "hammock" insertion of the TO MUS.

- RP MUS is recommended as an effective and durable treatment for SUI (GR A).
- TO MUS may be offered as an effective treatment for SUI with appropriate counselling (adverse events, limited long term RCT data regarding durability) (GR B).
- SIMS is an option for some individuals with SUI after appropriate counselling including the lack of long term RCT data (GR B)

**Figure 3 – Sling operations for stress incontinence in women**



\*Figure from VVOG 2016 *Incontinentie informatie voor patiënten*.  
<https://www.vvog.be/brochure/incontinentie>

Side effects of the MUS surgery include visceral trauma i.e. urethra or bladder perforation during operation, difficulty in urinating immediately following the operation, groin and thigh pain, erosion of the vaginal wall, discomfort and pain on intercourse, and tape exposure and extrusion [24]. The experts consulted by KCE note that adverse events as a result of operating e.g. pain and neuralgia, are probably underreported and can lead to chronic pain and disability affecting quality of life and inability to keep work. The adverse events of chronic pain are difficult to treat and treatments are not covered by health insurance.

#### 2.4.3.3 Mid-urethral sling for men

The sling procedures in men compresses the ventral side of the urethra rather than the circular compression caused by a natural or artificial sphincter. Sling surgeries rely on a device that is placed under tension, occluding the urethra at rest, and during stress manoeuvres. Adjustable and fixed pressure slings exist. The transobturator (TO) male sling technique was introduced in 2004 and has become the most common approach for

male sling placement. The bone anchored male sling (BAMS) goes without the suprapubic incision for suture passage and fixation. In the intermediate term, the male sling appears to be a reasonable option and are currently the most common surgical treatment for post-prostatectomy incontinence. Guidelines recommend the following:

International Continence Society (LE 3; GR C):

- Men with lower and moderate (pad weight 100 to 400 gm/24 hours) degrees of incontinence, who have neither had previous radiation nor AUS placement.
- Lower risk of urethral erosion and atrophy than the AUS in the intermediate term.
- Patients have been reported to overwhelmingly choose the male sling over an artificial urinary sphincter (mild to severe incontinence).
- BAMS and transobturator male sling are durable treatments.
- Short-term outcomes of the quadratic sling are also favourable.

The European Association of Urology Guidelines [23]:

- Limited short term evidence that fixed slings cure or improve postprostatectomy incontinence in patients with mild to moderate incontinence (LE 3) and that men with severe incontinence, previous radiotherapy or urethral stricture surgery may have poorer outcomes (LE 3).
- There is no evidence that one type of male sling is better than another (LE 3)
- There is no evidence that adjustability of the male sling offers additional benefit over other types of sling (LE 3).

UK, the National Clinical Guidelines Centre [25]:

- Implanted compression devices and slings can be offered to men with SUI within the context of a randomized clinical trial



#### 2.4.3.4 *Open and laparoscopic colposuspension*

Open pubovaginal sling colposuspension is a surgical treatment which involves lifting the tissues near the bladder neck and proximal urethra in the area behind the anterior pubic bones to correct deficient urethral closure. Since its introduction in 1910, various alternative techniques have been described. The Marshall-Marchetti (MMK) and the Burch procedures are two traditional approaches that have had long-term success rates in restoring continence.

- The MMK Procedure is NOT recommended for the treatment of SUI in women (GR A).
- Open Burch colposuspension can be recommended as an effective treatment for primary and recurrent stress urinary incontinence, which has longevity. (GR A).

Open Burch colposuspension can be considered for those women in whom an open abdominal procedure is required concurrently with surgery for SUI (GR D)

Laparoscopic minimally invasive approaches was introduced in 1991, as an alternative technique of open colposuspension that features the advantages of reduced pain, a shorter length of hospitalisation, and a more expedient return to activity while avoiding the morbidity associated with the open colposuspension.

- Laparoscopic colposuspension can only be recommended for the surgical treatment of SUI in women by surgeons with appropriate training and expertise (GR C).
- Women should be advised about the limited evidence available about the long term durability of laparoscopic colposuspension (GR C).

#### 2.4.3.5 *Injecting bulking agents*

Injectable therapy consists of injecting a composition of fat, collagens, or synthetic material e.g. silicone particles in the urethral wall by periurethral and transurethral injection to increase the urethral resistance to urinary flow.

Several agents for injection have been developed to overcome limitations of durability (due to leakage, migration, resorption), antigenicity and placement issues. The procedure is indicated for SUI by artificially inflating the submucosal tissues of the bladder neck and urethra and aims to improve the intrinsic sphincter deficiency. Bulking agents are not reimbursed by the Belgian insurances.

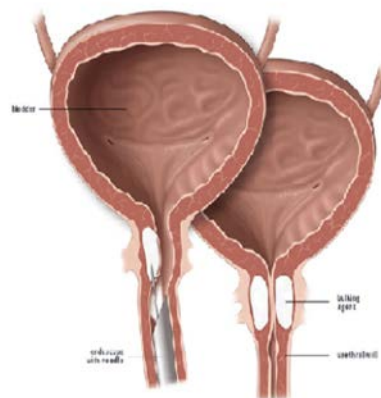
For women:

- Not be offered as first-line therapy for those women desiring a “one-time” durable solution for primary or recurrent SUI (GR B).
- Option for selected individuals with SUI (e.g. poor candidates for anti-incontinence surgery or those desiring an office-based, minimally invasive procedure) after appropriate counselling regarding lack of long term durability (GR B)
- First-line therapy for recurrent or persistent SUI following anti-incontinence surgery, although these outcomes are likely inferior to repeat anti-incontinence surgery in the long term (GR C).

For men:

- Should only be utilized when other more effective treatments are contraindicated (GR C).

**Figure 4 – Injection of bulking agents**



\*Figure from VVOG 2016 *Incontinentie informatie voor patiënten*.  
<https://www.vvog.be/brochure/incontinentie>

#### 2.4.3.6 Artificial urinary sphincter

The artificial urinary sphincter device **for women** consists of two inflatable spherical balloons placed on either side of the bladder neck. The volume can be adjusted through a subcutaneous port positioned within the labia majora. Several devices with different design are on the market. For example, a recently introduced adjustable AUC can respond to changing intra-abdominal pressure.

- AUS for female SUI should be limited only to highly selected individuals usually with recurrent SUI and only with appropriate counselling regarding the likely need for revision over time and the lack of long term RCT data (GR C). For men a non-circumferential compression device and a circumferential AUS is used. The last one is mostly used and the port is implanted in the scrotum. Importantly, men should have the ability, cognitive as well as dexterity, to operate the pump. Candidates

for treatment with the AUS are patients with incontinence due to intrinsic sphincter deficiency that have normal bladder compliance.

- The AUS is a successful surgical treatment option for post-prostatectomy incontinence in men with benign hypertrophy (GR A).
- The AUS remains the most predictably successful surgery for the treatment incontinence after radical prostatectomy for cancer in patients with severe incontinence (GR A). It has high patient satisfaction and this outweighs the need for periodic revisions in some patients.
  - in those who have had external beam radiation treatment
  - in those who have had prior sling or AUS implantation

#### 2.4.3.7 Sacral neurostimulation

Sacral neurostimulation (SNS) delivers continuous stimulation of the sacral root S3 with an electrode connected to an implanted pulse generator and modulates detrusor and sphincter activity.

- SNS is an effective therapy for selected individuals with urgency/frequency and UUI refractory to behavioural therapy and oral medications (GR B).
- Patients should be counselled regarding the potential for adverse events, need for long term monitoring and intervention/adjustment of the implant, and additional surgeries to maintain favourable therapeutic effects (GR B)

#### 2.4.4 Cure rates

A review of cure rates of treatment for UI was published in 2017 by Riemsma et al. [21]. The aim of the review was to describe how many patients remained dependent on containment strategies. Cure was defined as no leakage; and the median cure rate was the percentage of the total population treated with the intervention that was cured. Studies of any design were included with patients above 18 years of age with UI; evaluating an intervention in line with the ICS; enrolling at least 50 patients with a minimum follow-up time of 3



months; and published between January 2005-June 2015. The following paragraphs summarise the results for SUI, UUI and MUI.

#### 2.4.4.1 Stress urinary incontinence

**Conservative treatment with PFMT** for SUI in **women** has a cure rate of 59% at 12 months, and for **men** it was shown to be 78% at 6 months. One study by Marciori *et al.* in men post-prostatectomy showed a 100% cure rate (cure in this study defined as self report of recovery of continence: no use of pads or a mild leakage needing 2 mini-pads a day) at 12 months with a combined intense intervention of supervised PFMT, biofeedback, and pelvic floor electrical stimulation.

The median cure rate for the **surgical treatment** of SUI in **women** at 12 months is 84% [21] and similar cure rates are found for recurrent SUI cases, and MUI. The evaluation of cure is slightly higher for the clinician 84% as compared to the patient's view 77% [23]. After five years, approximately 70% of women are still expected to be dry with surgery [26].

**Surgical treatment** of SUI in **men post-prostatectomy** has a cure rate of 53% [21]. Patients evaluated the success at 58% at a mean follow-up of 15 months. The only preoperative predictive factor was 24-hour pad weight. If pad weight was less than 423 gm, there was a 6-fold greater success rate compared to those with a preoperative pad weight of greater than 423 gm. The use of organic (resorbable) material is less efficacious than synthetic (permanent) sling material due to maintained tension. In addition, poor suture fixation of the TO sling and failure to adequately tunnel the sling arms are also related to poor efficacy. Similarly, the quadratic sling without proper fixation has a substantially lower success rate than does the sling with properly fixated prepubic and transobturator sling components.

Very limited evidence exists for treatment with **injecting bulking agents** in **men**. Bulking therapy fails in up to 75% of men. All agents for which there is peer-reviewed data available, show only modest success rates with very low cure rates. Effects tend to deteriorate over time.

#### 2.4.4.2 Urgency urinary incontinence

Conservative treatment of UUI with PFMT in combination with PTNS has good cure rates at 3 and 6 months. UUI, mostly treated by pharmacological means in addition to conservative treatment, has a median cure rate of 46% [21]. Limited evidence from long term follow up is available for cure rates. An extensive number of RCTs do not report cure but describe the effect of the drugs in terms of reduction in the number of incontinence periods with or without change of clothing or pads, frequency and severity of urgency, warning time, health related quality of life, etc.

The IR form of oxybutynin is recognised for its efficacy and more recent anticholinergic drugs have been compared to it once efficacy has been demonstrated over placebo. Roughly spoken, the efficacy of oxybutynin-IR and other anticholinergic drugs is equivalent. The advantage of the newer formulations is their improved dosing schedule and side-effect profile implicating better compliance in the long term.

Darifenacin, Oxybutinin has a low cure rate of 20% to 25% at three month follow up and no data for longer follow up. The highest cure rate at 12 months is shown for solifenacin with more than 50% of patients being cured.



**Table 11 – Cure rates for urgency urinary incontinence from individual studies**

Treatment	3 months follow-up (number of studies if more than 1)	6 months follow-up	12 months follow-up (number of studies if more than 1)
<b>Women:</b>			
Sacral neurostimulation		39%	
Percutaneous PTNS + PFMT	93%	39%	
Darifenacin	38%	41%	42%
Fesoterodine	49% - 64% (5)		
Mirabegron	47%		43% - 46% (2)
Oxybutinin	20% - 25% (2)		
Propiverine			
Solifenacin	56% - 60% (4)	11%	58%
Tolterodine	13% - 57% (4)	70%	45%
<b>Men:</b>			
PFMT			24% - 35% (2)*
Lifestyle advice unsupervised			23% - 38% (2)*

PTNS: posterior tibial nerve stimulation. Data from <sup>[21]</sup> search data from 2005 till June 2015; \* both studies after resection of prostate

#### 2.4.4.3 Mixed urinary incontinence

MUI has variable cure rates depending on the nature of the underlying condition and the intervention used. A summary from Riemsma is presented below <sup>[21]</sup>. The conservative treatment with PFMT in combination with PTNS has good cure rates at 3 but no longer follow-up data is available.

**Table 12 – Cure rates for mixed urinary incontinence from individual studies**

Treatment	3 months follow-up	6 months follow-up	12 months follow-up
<b>Women:</b>			
PFMT - supervised	5%		
PFMT + percutaneous PTNS	93%		
PFMT + lifestyle advice	25%	28%	
Vaginal cone therapy	9%		
Solifenacin			52%
<b>Men:</b>			
PFMT supervised	44% - 46% (2)	47% - 67% (2)	24% - 83% (4)
PFMT unsupervised	40%	50%	64%
Lifestyle advice unsupervised			23% - 38% (2)
Solifenacin	27%		

#### 2.4.5 Initial evaluation and management

An initial evaluation by the primary care physician should include a **history** and **physical examination** to characterise the type of incontinence, the severity, the degree of bother, the timing (day versus night or both), the presence or absence of urgency, stress, or mixed symptoms. This allows for the UI to be categorised as stress urinary incontinence (SUI), urgency urinary incontinence (UUI) or mixed urinary incontinence (MUI). The physical examination includes general status (mobility, obesity, and mental





status), an abdominal, rectal examination and pelvic examination including prostate assessment in men and oestrogenic status and pelvic organ prolapse (POP) in women. The pelvic floor muscles strength is assessed digitally and a cough test with full bladder can demonstrate SUI.

A **Questionnaire**, validated in the applied language, can be used when a standardised measurement of symptoms and health related quality of life is required. Typically, the questionnaires are repeated to evaluate outcome of a care and treatment pathway. It is outside the scope of this project to present all the available questionnaires. The ICS discusses this topic fully and presents the incontinence modular questionnaire that covers all aspects of incontinence with modules for specific evaluation topics <sup>[3]</sup>(pag 557). The modules are to be translated and validated in the language that it will be used in before use. An example of a validated 7 question incontinence impact questionnaire and the long version is presented in 0. A **frequency-volume chart** (FVC) recording the time of each micturition and volume) and **bladder diary** reporting fluid intake, pad usage, number of incontinence episodes, and degree if incontinence, of ideally should be completed by the patient. A **urine analysis** with reagent strips should be performed to exclude urine tract infection (UTI). **Ultrasound measurement of the post-void residual** (PVR) volume is advised in patients presenting with bladder voiding difficulties. The **pad test**, ideally standardised when used for diagnosis of SUI, measures the leakage over a certain period of time or during an exercise protocol by quantifying the increase in weight of the perineal pad used pre- and post-testing. Urodynamic tests should not be offered for uncomplicated UI. Similarly, imaging e.g. X-ray, magnetic resonance imaging, ultrasound, should not be used routinely in the assessment of UI. The initial evaluation and management by gender is described in the next part.

#### 2.4.6 Care pathway for the management of urine incontinence in men

An initial assessment (history, physical examination, laboratory tests) will establish a presumptive diagnosis, and exclude underlying conditions requiring intervention and specialist referral (see red box in Figure 5).

Poor bladder emptying may be suspected from symptoms, physical examination or if imaging has been performed by X-ray or ultrasound after voiding.

Four other main groups of men should be identified by initial assessment as being suitable for initial management.

- Those with post-micturition dribble alone,
- Those with OAB symptoms: urgency with or without urgency incontinence, together with frequency and nocturia
- Those with stress urinary incontinence (most often post-prostatectomy),
- Those with mixed urinary urgency and stress incontinence (most often post- prostatectomy)

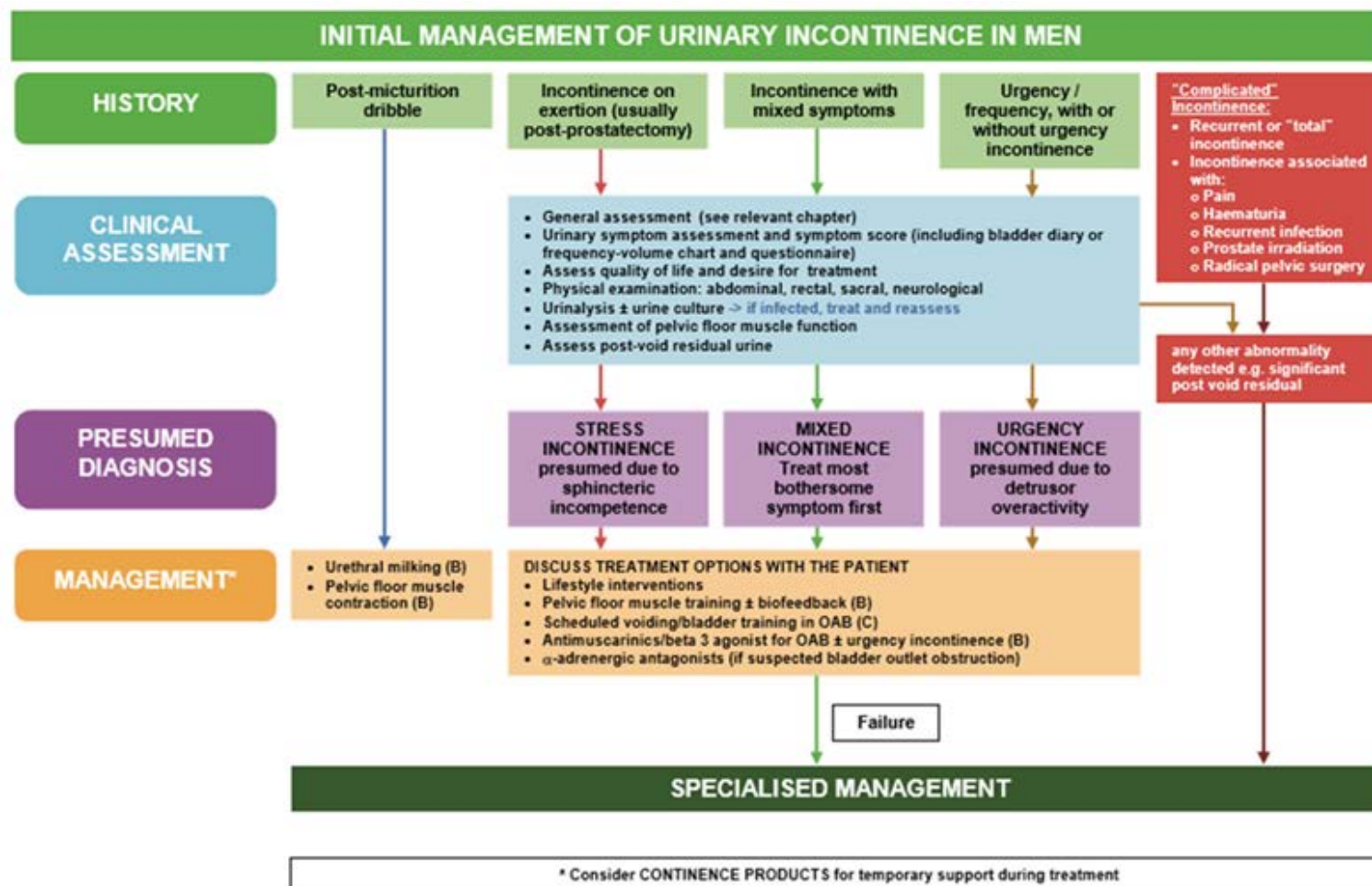
For men with post-micturition dribble, this requires no assessment and can usually be treated by teaching the man how to do a strong pelvic floor muscle contraction after voiding, or manual compression of the bulbous urethra directly after micturition. (GR B)

For men with stress, urgency or mixed urgency / stress incontinence, initial treatment should treat the most bothersome symptom first in men with symptoms of mixed incontinence and include:

- Lifestyle interventions (e.g. weight loss GR B)
- Supervised pelvic floor muscle training for men with post radical prostatectomy SUI accelerates recovery time (GR B)
- Scheduled voiding regimen for OAB (GR C)
- Anticholinergic/ $\beta 3$  agonist drugs for OAB symptoms with or without urgency incontinence (GR B) if the patient has no evidence of significant post-void residual urine
- $\alpha$ -adrenergic antagonists ( $\alpha$ -blockers) can be added if it is thought that there may also be bladder outlet obstruction (GR C)



Figure 5 – ICS Initial management of urinary incontinence in men







Should initial treatment be unsuccessful after a reasonable time (for example, 8-12 weeks), specialist advice is highly recommended.

Additional testing may be performed, such as

- cytology,
- cystourethoscopy
- and urinary tract imaging

If additional testing is normal then those individuals can be treated for incontinence by the initial or specialised management options as appropriate.

If symptoms suggestive of detrusor overactivity, or of sphincter incompetence persist, then urodynamic studies are advisable in order to arrive at a precise diagnosis, prior to invasive treatment.

Recommended options:

For sphincter incompetence

- artificial urinary sphincter (GR B).

- male sling (GR C).

For refractory idiopathic detrusor overactivity (with intractable overactive bladder symptoms)

- Botulinum toxin A (GR B)
- SNS (GR C),

Poor bladder emptying due to detrusor underactivity

- intermittent catheterisation (GR B/C).

Bladder outlet obstruction

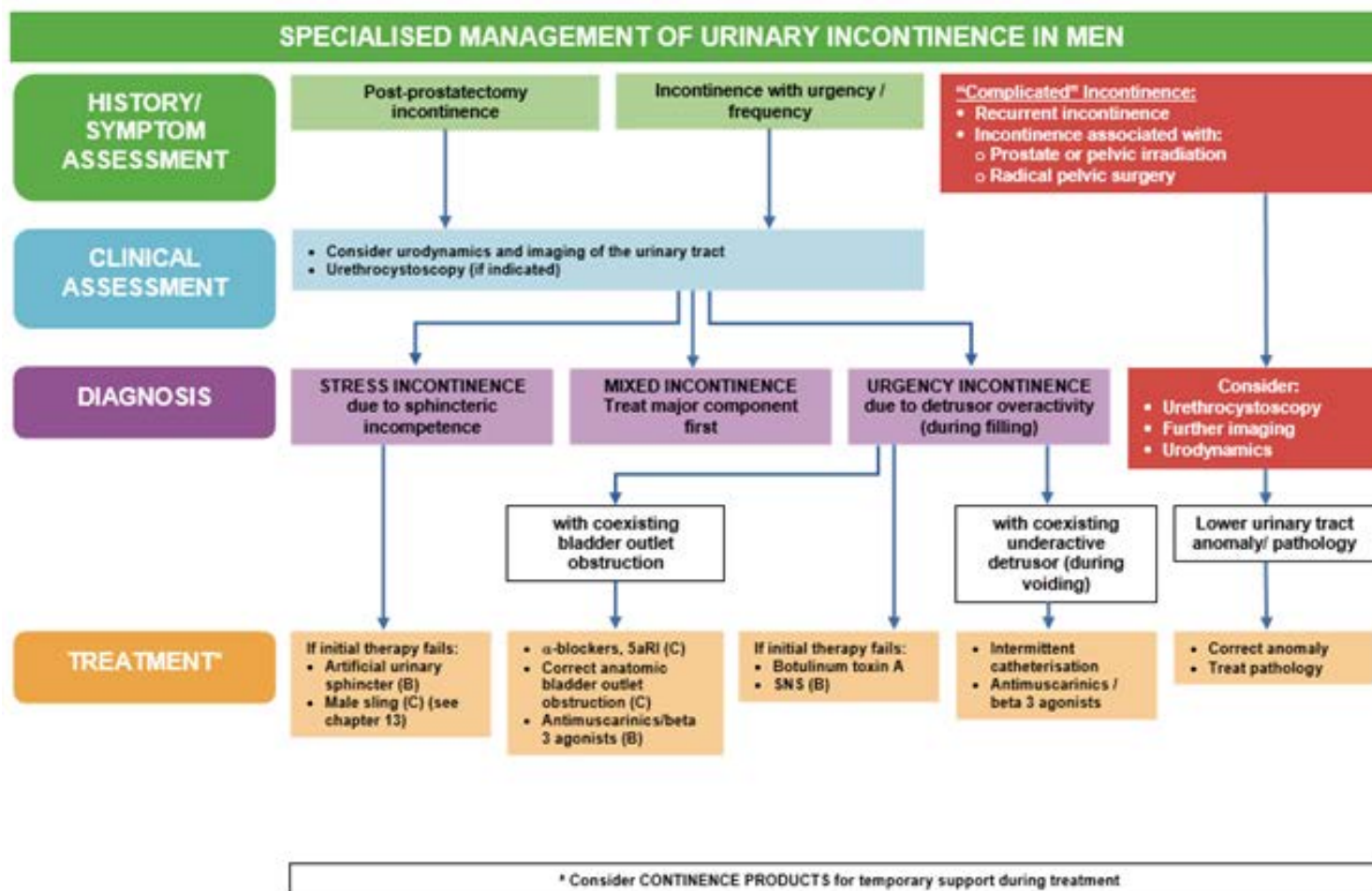
- surgical treatment to relieve obstruction (GR B)
- $\alpha$ -blockers and/or 5 $\alpha$ - reductase inhibitors would be an optional treatment (GR C)

Overactive bladder symptoms

- anticholinergics in combination with  $\alpha$ -blocker (GR B).



Figure 6 – ICS Specialised management of urinary incontinence in men





### 2.4.7 Care pathway for the management of urine incontinence in women

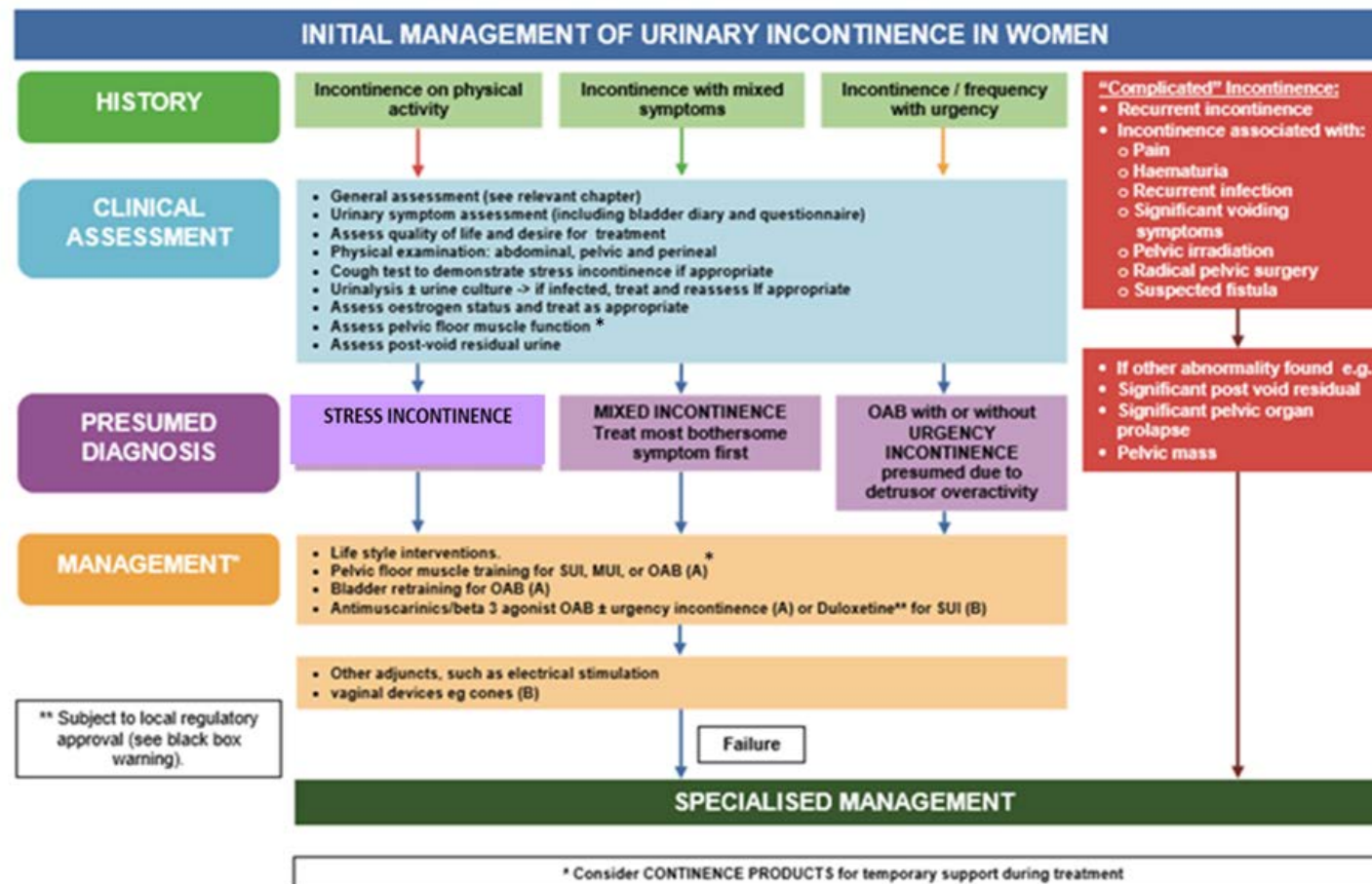
Initial assessment should aim to distinguish women with 'complicated' (see red box algorithm Figure 7) and women with SUI, UI, or MUI. Abdominal, pelvic and perineal examinations should be a routine part of physical examination. Women should be asked to perform a "stress test" (cough and strain to detect leakage likely to be due to sphincter incompetence). Any pelvic organ prolapse or urogenital atrophy should be assessed. Vaginal or rectal examination allows the assessment of voluntary pelvic floor muscle function, an important step prior to the teaching of pelvic floor muscle training.

ICS recommends the following: Clinicians should offer and provide the most intensive health professional-led PFMT programme possible within service constraints (GR A). Although studies are limited, there does not appear to be clear benefit for adding other modalities (i.e. motor learning, abdominal- or hip-muscle training, intra-vaginal resistance device) to PFMT (GR B). There is no clear benefit from adding clinic- (GR A) or home-based biofeedback (GR B) to a PFMT program.

Initial treatment includes

- Lifestyle advice:
  - Caffeine reduction for OAB (GR B)
  - Weight reduction (GR A)
- PFMT: based on sound muscle training with correct confirmed contraction prior to training with use of the 'Knack' (pelvic floor muscle bracing against increased intra-abdominal pressure e.g. coughing).
  - Supervised PFMT\* for SUI (GR A)
  - Supervised vaginal cones training for SUI (GR B)
  - Supervised bladder training (GR A) for OAB
  - PFMT ideally to include training of abdominal, vertebral and back muscles learned by a physiotherapist
- Scheduled voiding regimes
- Behavioural therapies
- Medication.
  - Anticholinergics/ $\beta 3$  agonist for OAB symptoms with or without urgency incontinence (GR A)
  - duloxetine may be considered for SUI (GR B)
  - Some women with significant pelvic organ prolapse can be treated by vaginal devices that treat both incontinence and prolapse (incontinence rings).
- ICS definition: A programme of supervised PFMT includes assessment of the woman's pelvic floor muscles and her ability to contract these muscles; education about the pelvic floor muscles and how they support the pelvic organs; instruction in how to correctly perform pelvic floor muscle exercises and "the Knack". An individualised exercise programme is prescribed for the woman to follow. Adjuncts to PFMT (such as biofeedback) or other physical therapies (such as neuromuscular EStim) may be used. These therapies aim to improve PFM strength, endurance, coordination and function. Other forms of physical therapy involving diaphragmatic aspiration are emerging.

Figure 7 – ICS Initial management of urinary continence in women



\* Pelvic floor assessment and training to include the core muscles: abdominal, vertebrae and back. Figure adapted from ICS 2017 Abrams, P., et al., Incontinence 6th Edition. ICI-ICS. International Continence Society, Bristol UK. Vol. ISBN: 9780956960733. 2017. ISBN: 9780956960733. 2519-2519.



Women who have “complicated” incontinence may need to have additional tests such as cytology, urodynamics, cystourethroscopy or urinary tract imaging. If these tests are normal then they should be treated for incontinence by the initial or specialised management options as appropriate. For women resistant to initial treatment urodynamic testing should be performed if results may change management. Systematic assessment for pelvic organ prolapse is highly recommended and women with coexisting pelvic organ prolapse should have their prolapse treated as appropriate.

#### Treatment options for SUI

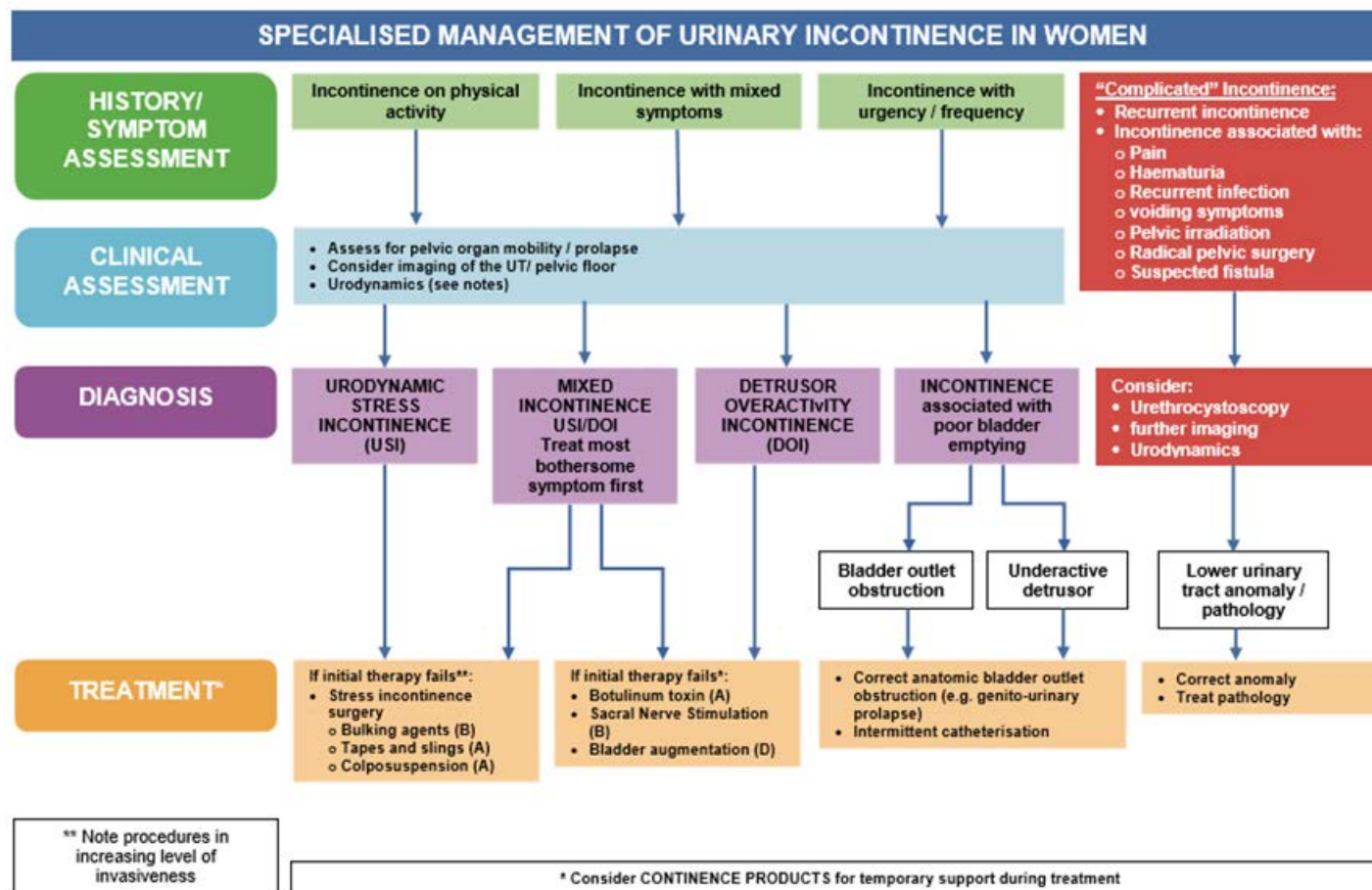
- Full range of non-surgical treatments
- Colposuspension procedures (GR A)
- Bladder neck/sub-urethral sling operations (GR A)

Potential risks and complications should be discussed with the individual. The correction of symptomatic pelvic organ prolapse may be desirable at the same time.

- For selected patients injectable bulking agents (GR B)
- Artificial urinary sphincter (GR C)
- Treatment options for UUI
- Botulinum toxin A (GR A)
- Sacral nerve stimulation (GR B)
- Bladder augmentation/intestinal cystoplasty (GR D).



Figure 8 – ICS Specialised management of urinary incontinence in women







## 2.5 Management of urinary incontinence in the frail elderly and the cognitively impaired

Although most of the above described management for women and men applies similarly to the healthy older patient, the expectations of assessment and treatment in the frail elderly and cognitively impaired will need to be tailored to fit their specific circumstances. Frail patients often have underlying conditions and comorbidities, and those need appropriate treatment in line with good clinical practice.

The ICS recognises that evidence is lacking on effectiveness of treatment in this 'growing' population. Nevertheless, therapeutic nihilism is not acceptable and standards of care should be similar as those of younger persons. Treatment should be attempted taking into account likely benefits, harms, feasibility, expectations and outcomes.

Cognitive frailty contains a heterogeneous groups of conditions such as mild impairment to severe dementia. A diagnosis of the cognitive impairment is therefore essential. Incontinence in dementia is recognised as a challenge and adds to the caregiver burden and the physician's burden, influencing decisions to relocate people to care homes (incontinence is associated with a reduced quality of life and impaired nutrition and mobility in older people with dementia). In vascular dementia, LUTS usually precede severe mental failure <sup>[9]</sup> whereas In Alzheimer's disease patients, UUI usually correlates with disease progression (late-stage dementia).

Due to co-morbidities, patients often use several drugs and these should be carefully checked for their anticholinergic side-effects. Elderly are sensitive to the effects of the medications on cognition; there is an association of cognitive impairment and higher rates of incident dementia diagnosis associated with high anticholinergic load and long exposure in older persons in epidemiological studies.

### Recommendations for practice from ICS:

- Family caregivers or residential and/or nursing staff dealing with different levels of UI (mild, moderate, severe, catheter managed) have different **educational needs** and require **different levels of support**.
- Interventions to support family caregivers of individuals with UI may need to be adapted to suit formal caregivers or staff in **long-term care** so that they accommodate the organisational context.
- An **individualised approach** is recommended to meet the needs and preferences of older people in long-term care.
- Interventions or approaches to caring for an individual with UI and **cognitive impairment** need to be tailored to the person's unique abilities and disabilities.
- Interventions for UI should be **theory-based, multicomponent, interdisciplinary, and person-centred**.

### 2.5.1 *Conservative options*

A drug history should be taken to identify drugs that can affect UI. New medication associated with the development or worsening of symptoms should be evaluated. Bowel management should be assessed and constipation addressed.

**Lifestyle interventions** No recommendations are possible regarding lifestyle interventions for UI in the frail elderly (LE 4).

### ***Pelvic floor muscle training***

- Biofeedback-assisted PFMT in combination with BIT reduces UI in homebound older adults (LE 2).
- Functional training in combination with PFMT reduces UI and improves walking time in frail older women (LE 2).

***Transcutaneous Posterior tibial nerve stimulation (T-PTNS)***

- is a safe treatment option and may be offered to frail older adults with UI or urinary symptoms however definitive evidence of effectiveness is needed (GR C).

***Scheduled voiding regimens*****Bladder training**

- It is uncertain whether bladder training reduces UI in frail older persons (LE 4).

**Timed voiding**

- It is uncertain whether timed voiding reduces UI in frail older persons (LE 4).

Habit training is a toileting schedule matched to the individual's voiding pattern based on their voiding diary. The toileting schedule is assigned to fit a time interval that is shorter than the person's normal voiding.

- It is uncertain whether habit retraining reduces UI in frail older persons (Level of Evidence 4).

Prompted voiding (to teach people to initiate their own toileting through requests for help)

- is effective in the short-term treatment of daytime UI in nursing home residents and home-care clients when caregivers comply with the protocol (LE 1).
- is ineffective and should not be used for people who need the assistance of more than one person to transfer, cannot follow a onestep command, have less than a 20% reduction in wet checks or less than a 66% appropriate toileting rate after a three-day trial; these people should be managed with "check and change" (LE 1).

**Toileting aids** are important to consider especially in the frail elderly as they can help overcome UI due to problems of e.g. mobility, access, and toilet proximity.

- Interventions combining toileting and functional training decrease urine loss and improve endurance in nursing home residents (LE 1).

**Containment products** should be chosen carefully. Incontinence-associated dermatitis, a common type of irritant contact dermatitis seen in patients with urinary or faecal incontinence, should be avoided by assessment and timely change of containment products. Mechanical factors such as traumata and friction may aggravate the lesions. The fragile skin in elderly patients is more prone to developing incontinence associated dermatitis. Gentle cleansing, use of hydrating topical agents and application of barrier products are the main elements in the prevention and treatment of incontinence associated dermatitis <sup>[27]</sup>.

***2.5.2 Pharmacological treatment***

**Anticholinergic drugs** in the elderly are effective but are known to have a negative effect on cognitive functioning. The following general recommendations for elderly frail patients should be observed:

- Polypharmacy increases the chance of adverse reactions to drug therapy (LE 1)
- Adverse drug events are more common in the frail elderly (LE 2)
- Drug-drug and drug-disease interactions are common in frail older persons (LE 1-3)
- Age-related changes in pharmacokinetics affect anticholinergic drugs for UI and should be incorporated into treatment planning (LE 1-2).
- The effect on cognitive function is cumulative (the anticholinergic cognitive burden scale) and increases with the length of exposure (LE 3).

Therefore, it may be advisable to start with a lower dosage as drugs may be effective at lower doses in frailer compared with healthier older persons (LE 3).





Evidence is lacking for this frail population and there is insufficient evidence to determine the efficacy, tolerability, and safety of the following agents (LE 4): a) Intravesical oxybutynin b) Transdermal oxybutynin c) Trospium d) Tolterodine e) Darifenacin f) Solifenacin g) Mirabegron h) Duloxetine i) Oral and topical oestrogen. The effect of cholinergic load on persons with mild dementia is uncertain (level 3). Treatment of overactive bladder with anticholinergics is considered inappropriate for frail older people according to the Beer's criteria (Level 3-4)<sup>[28]</sup>.

**Table 13 – Summary of evidence for drugs in the frail elderly**

Drug	Level of evidence	Summary of Evidence
Oxybutynin	2	Short-term treatment with oxybutynin-IR has small to moderate efficacy in reducing urinary frequency and urgency UI when added to behavioural therapy in long term care residents
	1	Low dose oxybutynin-ER does not cause delirium in cognitively impaired nursing home residents
	3	Oxybutynin-IR has been associated with cognitive adverse effects in persons with dementia and/or Parkinson's disease
	3	Oxybutynin has been associated with tachycardia ( not associated with QTc prolongation (LoE 3) or ventricular arrhythmia (LoE 2))
Solifenacin	2	Oxybutynin is less effective in persons with impaired orientation, cerebral cortical under-perfusion, and reduced bladder sensation
	2	Oxybutynin is less well tolerated, versus solifenacin, in older people
Solifenacin	2	Solifenacin (5mg/day) is associated with no impairment of cognition in older persons with mild cognitive impairment versus placebo
	1	Fesoterodine is effective in ameliorating the symptoms of OAB in robust community dwelling and medically complex older people
Tolterodine	4	Has been associated with cognitive impairment
	3	Has been associated with tachycardia



### 2.5.3 Surgical treatment in the frail older person

Information on surgical management of the frail elderly is still scarce. Surgical management of SUI in elderly women is the same as in younger stress-incontinent patients. The minimally invasive mid-urethral sling procedures have been used extensively. For men, the choice of surgical

intervention, mostly due to urinary incontinence after radical prostatectomy, is decided by incontinence severity rather than age or comorbidity. However, frailty, indicating decreased reserve and resistance especially in the above 80 years old, is associated with increased complications at surgery. The level of 'limited' evidence including risks related to surgery, and the ICS recommendations are presented in

Table 14 and Table 15.

**Table 14 – ICS Level of evidence for incontinence surgery in the frail older person**

Intervention	Level of evidence	Summary of Evidence
Gynaecological surgery women	4	No studies were identified regarding gynaecological surgery in institutionalised elderly women
	3	Exogenous administration of oestrogen is ineffective in promoting wound healing after gynaecological surgery in older women
	3	Injection of bulking agents for SUI appears to give minor benefit in women, however the technique is minimally invasive and age does not appear to correlate with outcomes
Injection of onabotulinumtoxin A	4	This might be an option in patients with idiopathic or neurogenic overactive bladder although risk of residual urine and a lower long-term success rate have been described
Quality of life	4	No studies were identified that evaluate functional or quality of life outcomes after UI surgery in the frail older
Risks of the surgical intervention	2	Risks of morbidity and mortality for frail patients undergoing anti-UI procedures are similar to those of other major non-cardiac surgical procedures
	2-3	Surgical mortality risks are still low in elderly persons, and when deaths do occur, they are often due to cardiac or cancer complications.
	2-3	Operative mortality is inconsistently associated with increased age, and most studies do not uniformly control for comorbid conditions
Pain control	2	Patient-controlled analgesia provides adequate pain control and sedation and increased patient satisfaction compared with standard fixed and time-administered medications in cognitively intact geriatric patients
	3	Choice of agent for patient-controlled analgesia may affect postoperative cognition.

**Table 15 – ICS Recommendations for incontinence surgery in the frail older person**

Grade of recommendation	Recommendations
A	<p>Preoperative risk should be stratified using established indices</p> <p>Programmes to prevent post-operative delirium should be utilised</p> <p>Proactive use of established measures to diagnose delirium should be in place</p> <p>Proactive preventative approaches to hospitalisation-related functional impairment should be used.</p> <p>Specialised care units may improve selective outcomes for frail older patients</p>
B	<p>Urodynamic evaluation should be done before considering surgical treatment of UI in frail older persons</p> <p>Patient controlled analgesia can be used in cognitively-intact frail older persons</p> <p>Analgesic agents associated with delirium (e.g., meperidine) should be avoided</p> <p>Pain assessment in cognitively impaired persons should use measures specially-designed for this population</p>
C	<p>Age alone is not a contraindication to surgical treatment of UI</p> <p>Validated frailty scales may aid prognostication and planning from post-surgical care in frail older adults</p> <p>Ensure adequate post-operative nutrition, especially in patients who cannot take oral feeding or who become delirious</p> <p>Discharge planning should begin before surgery takes place</p> <p>Long-term outcomes before the operation should be discussed with the patient</p>

Care pathway for the management of urine incontinence in frail older women and men

Interventions for frail older people should be tailored to:

- co-morbid disease
- current medications
- and functional and cognitive impairment

Investigation and management should take into account:

- degree of bother to the older person and/or caregiver
- the goals for care
- the degree that the older person is able to undertake any intervention
- the overall prognosis and life expectancy

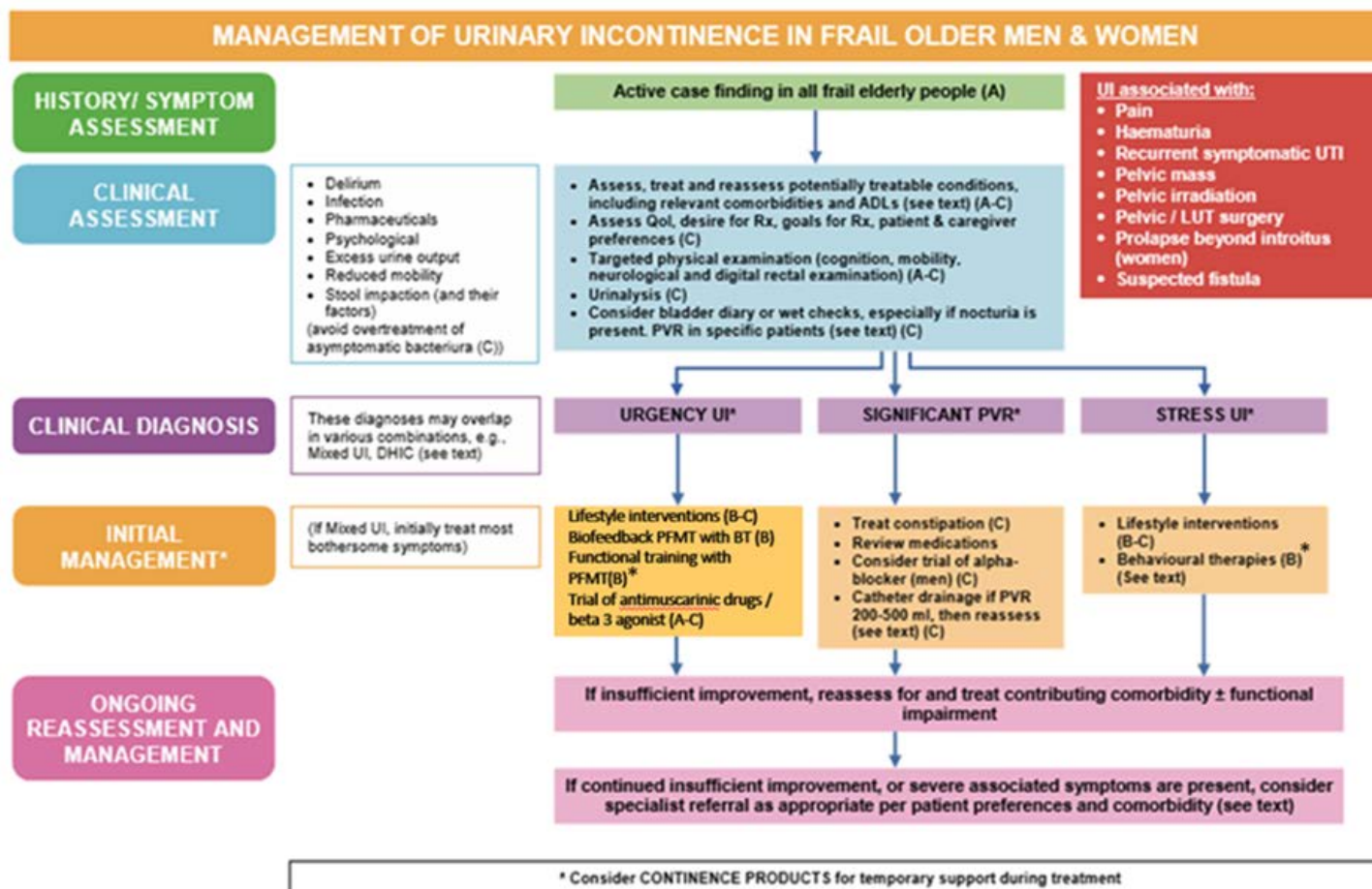
Effective management to meet the goals of care should be possible for most frail older people. PFMT in combination with bladder training should be started whenever possible and functional training will improve walking and general strength.

The care pathway is summarised in the algorithm of Figure 9 and the ICS grade of recommendation presented in Table 16.

In some frail older persons the only possible outcome may be containment; management with continence products, especially for people with minimal mobility (require assistance of > 2 people to transfer), advanced dementia (unable to state their name), and /or nocturnal urinary (and faecal) incontinence.

If initial management fails to achieve the desired goals, the next steps are specialist reassessment and treatment of contributing comorbidity and/or functional impairment.

Figure 9 – ICS Management of urinary incontinence in frail older women and men



\* Behavioural therapy and pelvic floor assessment and training to include the core muscles: abdominal, vertebrae and back. Figure adapted from ICS 2017 Abrams, P., et al., Incontinence 6th Edition. ICI-ICS. International Continence Society, Bristol UK. Vol. ISBN: 9780956960733. 2017. ISBN: 9780956960733. 2519-2519.


**Table 16 – ICS Recommendations for assessment and treatment of UI in frail women and men**

Grade of recommendation	History and symptom assessment	Conservative treatment	Drug treatments
A	<ul style="list-style-type: none"> <li>Active case finding</li> <li>Functional assessment (mobility, transfers, manual dexterity, dressing and undressing ability, ability to toilet)</li> <li>Evaluation for bowel “alarm” symptoms (red box algorithm)</li> </ul>	<ul style="list-style-type: none"> <li>Prompted voiding for frailer, more impaired older people</li> </ul>	<ul style="list-style-type: none"> <li>Anticholinergics may be added to conservative therapy of urgency UI (GR A-C, depending on agent)</li> <li>DDAVP (vasopressin) has a high risk of severe hyponatraemia in frail older persons and should not be used outside specialist centres or without very careful monitoring and long term followup</li> </ul>
B	<ul style="list-style-type: none"> <li>Define co-morbid conditions (blue box algorithm)</li> <li>A screening test for depression</li> <li>Urogenital atrophy does not, in itself, cause urinary incontinence and should NOT be treated for this purpose</li> <li>To assess bother patient / caregiver</li> <li>Set goals for care: dryness, decrease in specific symptoms, quality of life, reduction of comorbidity, lesser care burden</li> </ul>	<ul style="list-style-type: none"> <li>Bladder training for more fit alert persons</li> </ul>	<ul style="list-style-type: none"> <li>Anticholinergics may be added to conservative therapy of urgency UI</li> </ul>
C	<ul style="list-style-type: none"> <li>Physical examination should include a rectal examination for faecal loading or impaction Cognitive assessment (to assist in planning and management)</li> <li>Set goals for likely cooperation with management</li> <li>Urinalysis to screen for haematuria</li> <li>Treatment of otherwise asymptomatic bacteriuria/pyuria is not beneficial</li> <li>Treatment asymptomatic bacteriuria may cause harm by increasing the risk of antibiotic resistance and severe adverse effects. e.g., Clostridium difficile colitis</li> <li>Wet checks can assess urinary incontinence frequency in long-term care residents</li> <li>PVR test in selected at risk patients (see ICS)</li> </ul>	<ul style="list-style-type: none"> <li>Initial treatment should be individualised</li> <li>For the select cognitively intact older person with UI or FI, pelvic floor muscle therapy can be considered, but there are few studies</li> <li>Conservative and behavioural therapy for UI includes lifestyle changes</li> </ul>	<ul style="list-style-type: none"> <li>Anticholinergics may be added to conservative therapy of urgency UI</li> <li>Alpha-blockers may be cautiously (dose titration with regular review) considered in frail men with suspected prostatic obstruction</li> <li>Trial with catheter may be considered for PVR &gt; 200-500 ml if the PVR is felt to contribute to UI or urinary frequency</li> </ul>
D			<ul style="list-style-type: none"> <li>Frail older people with urgency urinary incontinence also may have detrusor underactivity during voiding with a high PVR but without outlet obstruction. There is no evidence that anticholinergics are less effective or cause retention in this situation</li> </ul>



The type of specialist will depend on local resources and the reason for referral: surgical specialists (urologists, gynaecologists, colorectal surgeons), gastroenterologists, geriatricians or physical therapist (functional and cognitive impairment); or continence nurse specialists (homebound patients). Referral decisions should consider goals of care, patient/caregiver desire for invasive therapy and estimated remaining life expectancy.

Age per se is not a contraindication to UI surgery (GR C), but before surgery is considered, all patients should have:

- Evaluation and treatment for any comorbidity, medications, and cognitive or functional impairments contributing to UI that could compromise surgical outcome (e.g., dementia that precludes patient ability to use artificial sphincter) (GR C).
- Adequate trial of conservative therapy, including pharmacological therapies where relevant (GR C).
- Discussion (including the caregiver) to ensure that the anticipated surgical outcome is consistent with goals of care in the context of the patient's remaining life expectancy (GR C).
- Urodynamic testing because clinical diagnosis may be inaccurate (GR B).
- Preoperative assessment and perioperative care to establish risk of, and to minimise the risk of common geriatric post-operative complications such as delirium and infection (GR A), dehydration and falls (GR C).

## 2.6 Management of urinary incontinence in children

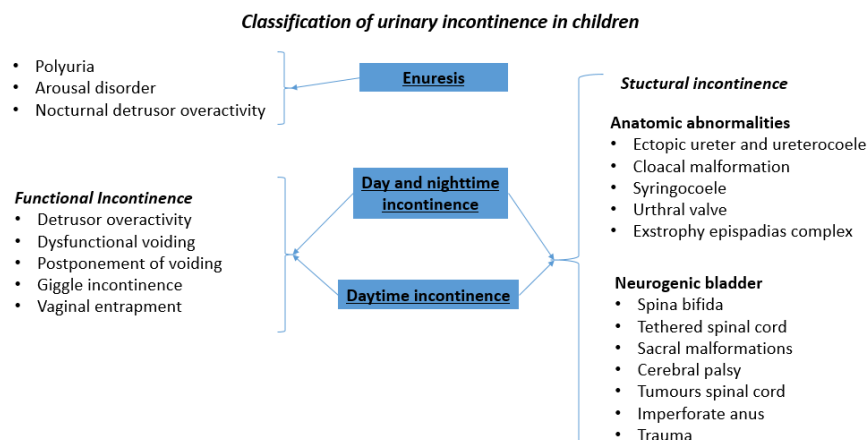
Management of UI in children is complex and involves the parental or caregiver's involvement and consent to assessment and treatment.

### 2.6.1 Initial assessment

Diagnosis relies on history-taking and simple non-invasive examinations to differentiate monosymptomatic enuresis and patients with daytime symptoms. It is essential to exclude daytime voiding symptoms, overactive bladder, dysfunctional voiding, and urinary tract infections <sup>[15]</sup>. A detailed investigation of voiding and bowel habits using **bladder and bowel diaries** and **structured and validated questionnaires** is performed. The social environment, the general and behavioural **development** is studied. **Physical examination** for palpable bladder, faecal loading, excluding anatomic and neurogenical causes. A **urine analysis and culture** is performed. Children should be **referred** when: recurrent and febrile urinary infection, voiding symptoms or poor bladder emptying, urinary tract anomalies, previous pelvic surgery, neuropathy, bowel dysfunction not responsive to treatment, or comorbid behavioural disorders (e.g. ADHD). The classification of UI in children is presented in Figure 10.



**Figure 10 – Classification of urinary incontinence in children**



## 2.6.2 Initial management

The initial management pathway is summarised in Figure 11 and should include the child's social environment and general and behavioural development. Physical examination should be done to evaluate the function of the pelvic floor muscles, detect a palpable bladder, faecal loading and exclude anatomic and neurogenical causes. Urine analysis and culture is sufficient to exclude the presence of infection. If possible, the child should be observed voiding.

Referrals for specialist treatment are recommended for children who have complicated incontinence as summarised in the red box below.

On the basis of the initial general assessment a management strategy is started either for NE, or urgency incontinence and children with other problem are referred for specialist care. Treatment cure rates are presented in Table 17.

### 2.6.2.1 Mono-symptomatic nocturnal enuresis

Primary enuresis is mostly due to an altered antidiuretic hormone profile, arousal failure, and delayed bladder maturation [15]. In secondary enuresis, psychological causes should also be taken into consideration. A good functional assessment of the PFM is important. For mono-symptomatic (no other urinary symptoms) NE treatment consists of:

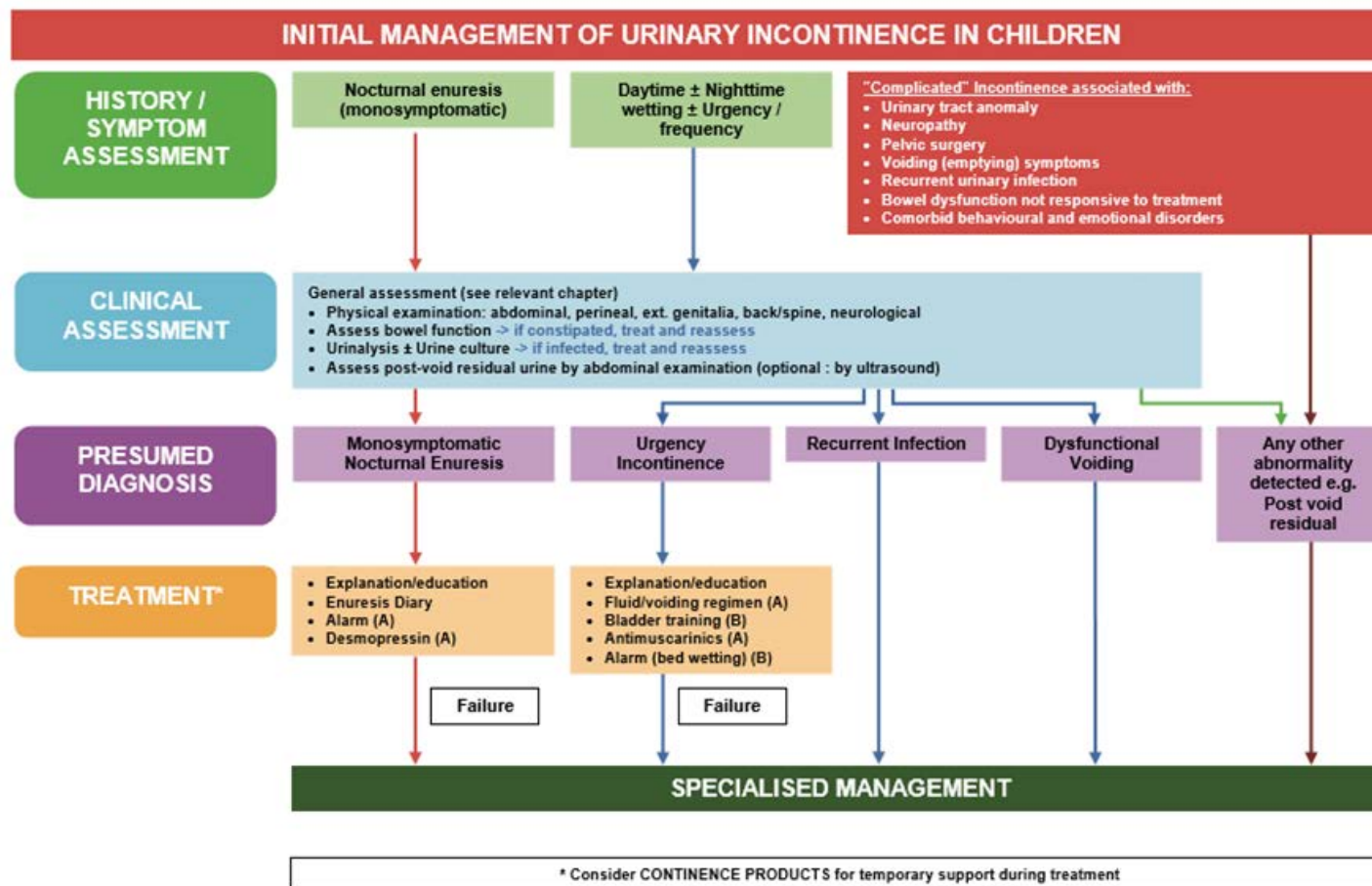
- Parental and child counselling and motivation
- Review of bladder diary with attention to night-time polyuria
- Age appropriate education and demystification or explanation
- PFM education and training (inclusive of core muscles)
- A choice between either bed wetting alarm (GR A) or anti-diuretic hormone analogues of desmopressin (GR A). It may be a parental and child choice if advantages and disadvantages are well explained.





### 2.6.2.2 Daytime incontinence

Figure 11 – ICS Initial management of urinary incontinence in children







Daytime incontinence should be managed holistically including:

- Counselling, timed voiding, behaviour modification and bowel management when necessary (GR B)
- Anticholinergics may be used if the child has OAB symptoms (GR A)

**Table 17 – Response and cure of different treatment modalities**

Treatment	Full response while on medication	Cure rates 6 months after cessation of treatment
Alarm treatment	65%	43%
Desmopressin	31%	22%
Dry-bed training	40%	18%
Imipramine		17%

### 2.6.3 Specialised management

In complex cases with a suspicion of underlying congenital malformations or systemic or endocrine diseases and in children refractory to initial therapy without neurogenic or anatomical abnormalities further assessment is advised. The details with grade of recommendation are summarised in Figure 12. Children are assessed with **urine flow** when old enough, together with **ultrasound** of bladder and rectum and post-void residual volume and upper urinary tract. Depending on the presenting problem, and resistance to treatment, **urodynamics** (voiding cystourethrogram, video-urodynamics), **cystoscopy** and **spinal imaging** should be considered when the results would alter the management.

- If the type and severity of lower tract dysfunction cannot be explained by clinical findings or in the presence of possible relevant neuropathy or urinary tract anomalies. (GR B)
- If invasive treatment is under consideration, for example, stress incontinence surgery if there is sphincteric incompetence, or bladder augmentation if there is detrusor overactivity. (GR B) • If upper tract dilation exists and is thought to be due to bladder dysfunction. (GR A)

- Invasive urodynamic studies are generally not recommended if the child has normal upper tract imaging and is to be treated by noninvasive means. (GR B)
- Spinal Imaging (US/X-ray/MRI) may be needed if a bony abnormality or neuro-logical condition is suspected. (GR A)

The treatment of incontinence associated with urinary tract anomalies is complex and cannot easily be dealt with in an algorithm. In many children more than one pathology demands treatment. If there are complex congenital abnormalities present, the treatment is mostly surgical and it should be individualised according to the type and severity of the problem.

Initial treatment should be non-surgical:

- Continue and intensify PFM education and training (inclusive of core muscles) especially for detrusor overactivity
- For refractory enuresis, P-PNTS can be useful
- For SUI: PFMT (GR C).
- For OAB symptoms: fluid/voiding regimens and anticholinergics (GR A).
- For voiding dysfunction: timed voiding, voiding re-education, PFM relaxation (+/- biofeedback), alpha-blocker therapy, and intermittent catheterisation (when PVR >30% of bladder capacity) (GR A/B).
- For bowel dysfunction: high fibre diet and laxatives as appropriate, PFM relaxation (+/- biofeedback), and transanal irrigation in severe cases (GR A).

The child's progress should be assessed and, if quality of life is still significantly impaired, or if the upper urinary tracts are at risk, surgical treatment is likely to be necessary. If surgical treatment is required, then urodynamic studies are recommended to confirm the diagnosis.



For urodynamic stress incontinence:

- colposuspension, (GR B)
- sling surgery (GR B)
- bulking agent injection (GR C)
- AUS (GR B)

For detrusor overactivity or poor compliance:

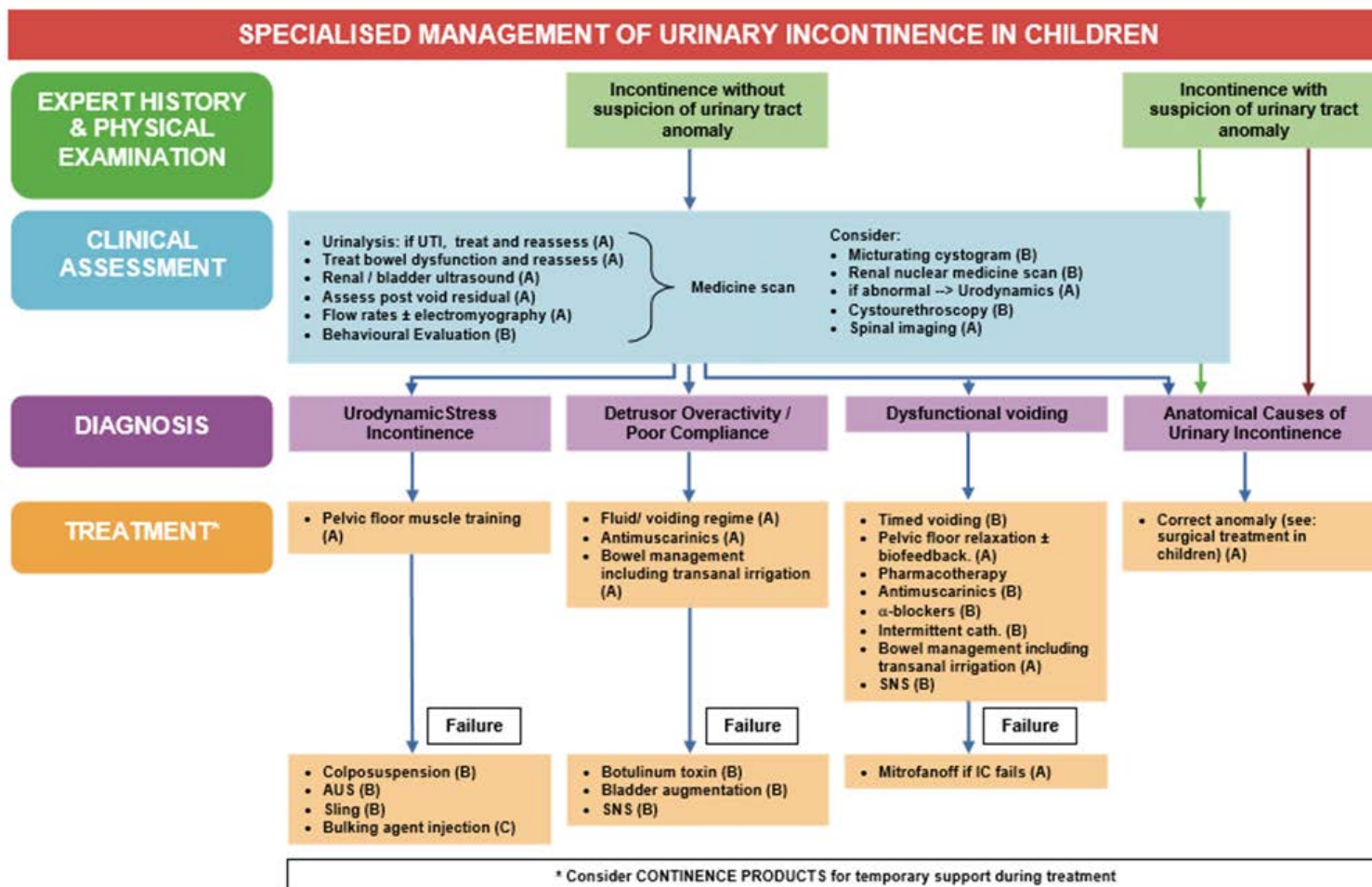
- botulinum toxin (for detrusor overactivity, and off-label) (GR B)
- bladder augmentation may be performed (GR B)

Dysfunctional voiding:

- If the child cannot do intermittent catheterisation then a Mitrofanoff channel may be needed (GR A).



Figure 12 – ICS Specialised management pathway for urinary incontinence in children





## 2.7 Management of faecal incontinence

### 2.7.1 Initial clinical assessment

Adult patients with faecal incontinence present with a variety of symptom complexes. As many people are reluctant to admit to having faecal incontinence, it is important to proactively enquire about it, especially in known high risk groups (such as older community-living individuals, post-partum women who might have had an obstetric injury and patients with loose stools). History will include symptoms such as loose stools and urgency, the type and severity of bowel incontinence, systemic disorders, neurological disorders, and anorectal surgeries (e.g., haemorrhoidectomy), obstetric history for women, medications, diet, chronic straining, cognitive status, and effects of symptoms on quality of life.

**Table 18 – Drugs that may exacerbate faecal incontinence and loose stools**

Drugs and mechanism	Examples
Drugs altering sphincter tone	Nitrates Calcium channel antagonists Beta-blockers Sildenafil SSRIs
Broad spectrum antibiotics	Cephalosporins Penicillins Macrolides
Topical drugs applied to anus	Diltiazem gel Betanechol cream Botulinum toxin A injection
Drug causing profuse loose stools	Laxatives Metformin Orlistat SSRIs Magnesium-containing antacids Digoxin
Constipating drugs	Loperamide Opioids Tricyclic antidepressants Aluminium-containing antacids Codeine
Tranquilisers or hypnotics	Benzodiazepines Tricyclic antidepressants SSRIs Anti-psychotics

*From Nice 49*



**Table 19 – Underlying clinical problems that should be addressed when starting FI management**

Underlying clinical problems of FI that should be addressed	To address
Faecal loading	Constipation
Infective and inflammatory bowel disease; irritable bowel syndrome	Start appropriate treatment
Warning signs of lower gastrointestinal cancer	To refer
Rectal prolaps	To refer
Third degree haemorrhoids	To refer
Acute anal sphincter injury: Obstetric and other trauma	To refer to surgeon
Acute disc prolaps e.g. Cauda equine syndrome	To refer to surgeon
Dyssynergia of the pelvic floor / anal sphincter	Refer
Poor functioning of PFM and core muscles	Physiotherapist

Assessing the type of bowel incontinence may help identify an aetiology.

- Anal incontinence is the involuntary loss of faeces and/or flatus and/or mucus).
- Faecal incontinence is the involuntary loss of faeces. Flatus incontinence is the involuntary loss of rectal gas, which may indicate rectal sensory impairment and/or anal sphincter dysfunction.
- Mucus incontinence is the involuntary loss of mucus only.

Some subtypes of faecal incontinence are

- urgency faecal incontinence, which is the involuntary loss of faeces due to an inability to defer defaecation, once the desire is perceived, for long enough to reach a toilet. Urgency faecal incontinence is often a symptom of external anal sphincter dysfunction. The symptom of urgency does not necessarily result in urgency faecal incontinence.
- Functional faecal incontinence is due to limitations in mobility or toileting ability or delayed assistance.

- Passive faecal incontinence, incontinence without forewarning, is typically related to internal anal sphincter dysfunction or poor closure of the external sphincter due to rectal prolapse or stage III/IV haemorrhoids.
- Flatus incontinence is often the first signal of lower gastrointestinal dysfunction.

Physical examination by the primary care physician will include anal inspection, abdominal palpitation, a brief neurological examination, digital rectal examination and by the second line physician usually procto-sigmoidoscopy or colonoscopy. A functional assessment of the PFM, the abdominal and back muscles should be performed; use of specialised equipment such as a manometric probe is advised.

- Further diagnostic testing needs to be considered if the patient has symptoms such as an unexplained change in bowel habit, weight loss, anaemia, rectal bleeding, severe or nocturnal diarrhoea, or an abdominal or pelvic mass and bowel pathology when organic conditions such as cancer, inflammatory bowel disease, a recto-vaginal fistula, full thickness rectal prolapse, or cloacal deformity are suspected. Condition specific management is indicated for these patients.
- Reversible factors (such as inadequate access to toilets and side effects of medications resulting in loose stools) should be assessed and addressed at the outset.

Some initial management can often be performed in primary care. After environmental factors and local or systemic pathology have been excluded, initial interventions include:

- Discussion of options and goals of management with the patient
- Provision of patient or caregiver information and education (GR A)
- Adjustment of diet and fluid advice, fibre intake (GR A)
- Establishing a regular bowel habit (GR C) or urgency training if relevant (GR C)



- Anti-diarrhoeal medication (loperamide) can help if stools are loose (GR B)
- Use of continence products including various types and sizes of absorbent pads, briefs, etc., to contain leaked faeces and prevent skin damage
- Odour control and laundry needs as well as disposable gloves are needed
- Provide advice on practical coping skills when incontinence occurs (GR C)
- Toileting aids are important to consider as they can help overcome FI due to problems of e.g. mobility, access, and toilet proximity. Examples are commodes, bedpans, raised toilet seats, bottom wipers, bars and frames, bidets, and bed protective sheaths

Further primary care management by medical personnel trained or specialised in incontinence is mentioned below under specialised management.



Figure 13 – ICS Conservative management of faecal incontinence

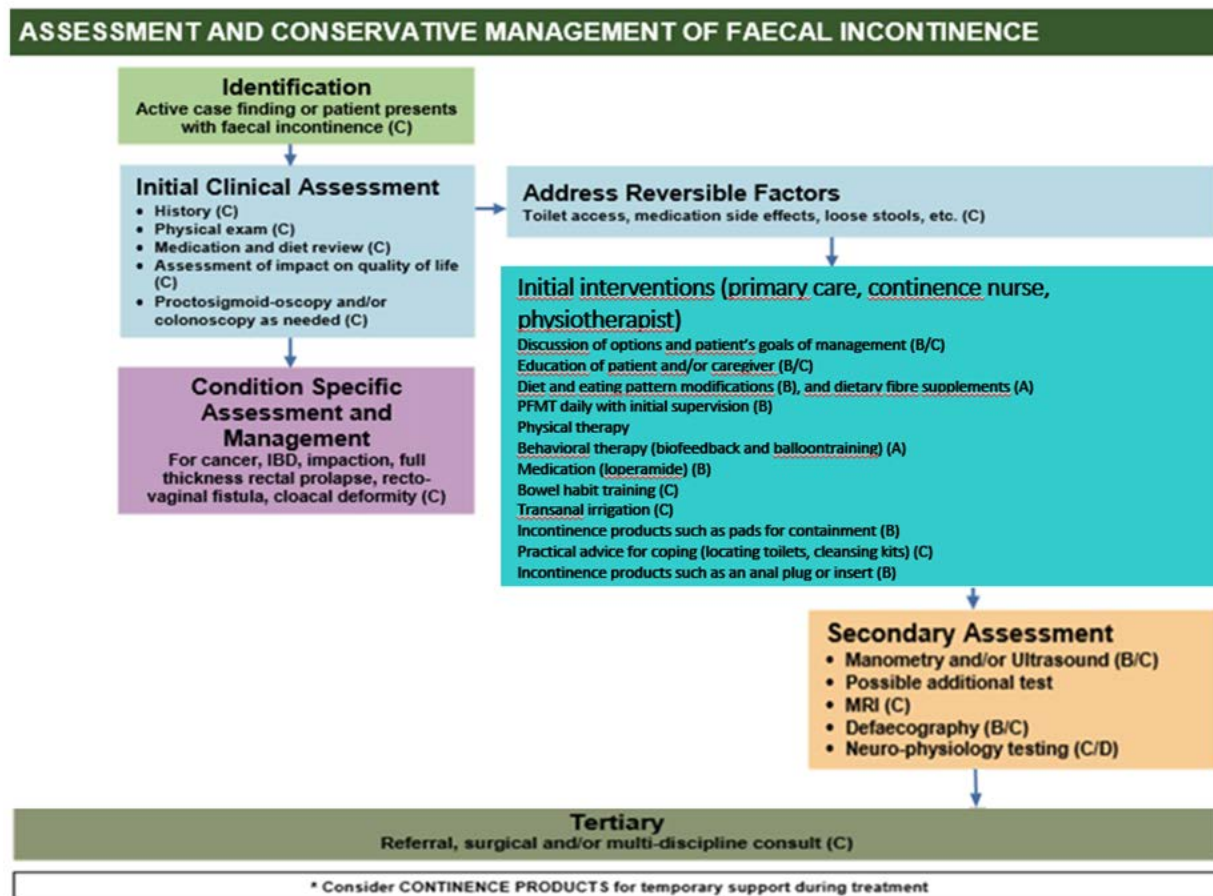


Figure adapted from ICS 2017 Abrams, P., et al., Incontinence 6th Edition. ICI-ICS. International Continence Society, Bristol UK. Vol. ISBN: 9780956960733. 2017. ISBN: 9780956960733. 2519-2519.





### 2.7.2 Specialised management (primary or secondary care)

If initial interventions fail to improve symptoms after 8-12 weeks, consideration should be given to referral to an incontinence specialist (e.g., gastroenterologist, continence nurse (primary care), advisor physiotherapist (primary care), or colorectal surgeon) for other interventions or further assessment.

- Pelvic floor muscle training (PFMT) – contraction of pelvic floor muscles, multiple times per day to improve strength of contraction and relaxation and increase awareness of anorectal muscle function. (GR C)
- Biofeedback therapy – behavioural treatment designed to enhance the strength of sphincter contraction and relaxation, and improve rectal sensation using specialised equipment. Biofeedback therapy can be combined with PFMT to improve strength. (GR B)
- Transanal Irrigation, balloon training to maximise bowel emptying and dyssynergic bowel pattern and minimise faecal incontinence primarily in patients with incomplete elimination, passive faecal incontinence, or faecal incontinence with defaecation difficulty, or dyschezia (GR C)
- Antegrade continence enemas can be used for severe anorectal malformations and Hirschprung disease.

Further secondary investigations include a variety of anorectal investigations, including manometry, anal ultrasound, and possibly MRI, defaecography, and neurophysiological testing can help to define structural or functional abnormalities of anorectal function and guide management if initial and/or secondary interventions are ineffective.

Faecal incontinence that fails to respond to initial and secondary management requires specialised consultation by a gastroenterologist, colorectal surgeon, urogynaecologist, and/or a multi-disciplinary team.

### 2.7.3 Surgery for faecal incontinence

In general, patients referred for surgical management of faecal incontinence must either have failed conservative therapy or not be candidates for conservative therapy due to severe anatomic or neurological dysfunction. ICS promotes physiotherapy, lifestyle interventions, and PFMT pre-operative and post-operative and this has good results on avoiding relapses.

- Prior to surgical management of faecal incontinence, the integrity of the anal sphincter complex should be assessed. This assessment is best performed with endoanal ultrasound, though pelvic MRI may also be useful. Ancillary tests include anal manometry, electromyography, and defaecography.
- If the patient has persisting faecal incontinence, he or she should undergo repeat assessment, including endoanal ultrasound.

The following are ICS recommendations:

- The surgical approach is influenced by the presence and magnitude of an anatomical anal sphincter defect. If no defect is present, or if the sphincter defect is minimal, options include SNS and biomaterial injection therapy. Acute anal sphincter repair is usually required following obstetric or direct trauma. End to end or overlapping repair may be performed. When possible the internal anal sphincter should be separately repaired. (GR C)
- Patients with rectal prolapse, rectovaginal fistula or cloacal deformity often have associated faecal incontinence. Initial therapy should be directed at correction of the anatomical abnormality. (GR C)
- For patients with moderate sphincter defects, sphincteroplasty, SNS or biomaterial injection therapy can each be considered. For patients with large sphincter defects (>120 degrees), sphincteroplasty is likely to be the best option, though a pudendal nerve electrotherapy trial for sacral nerve stimulation (SNS) can be considered. (GR C)





- Patients with sphincter defects of greater than 180° or major perineal tissue loss require individualised treatment. In some cases, initial reconstruction can be performed. Should incontinence persist, alternatives include stimulated muscle transposition (usually graciloplasty) artificial anal sphincter implantation, or sacral nerve stimulation. (GR C)

Management of failed surgery recommendations:

- For patients who remain incontinent following sphincteroplasty, repeat endoanal ultrasound should be undertaken to reassess the status of the repair. If no defect is present, or if the sphincter defect is minimal, options include SNS and biomaterial injection therapy. If there is a large persisting sphincter defect, repeat sphincteroplasty can be considered. (GR C)
- Patients who have failed SNS can be considered for biomaterial injection therapy or sphincteroplasty if a sphincter defect is present. Other alternatives include stimulated graciloplasty and implantation of an artificial anal sphincter. (GR C)

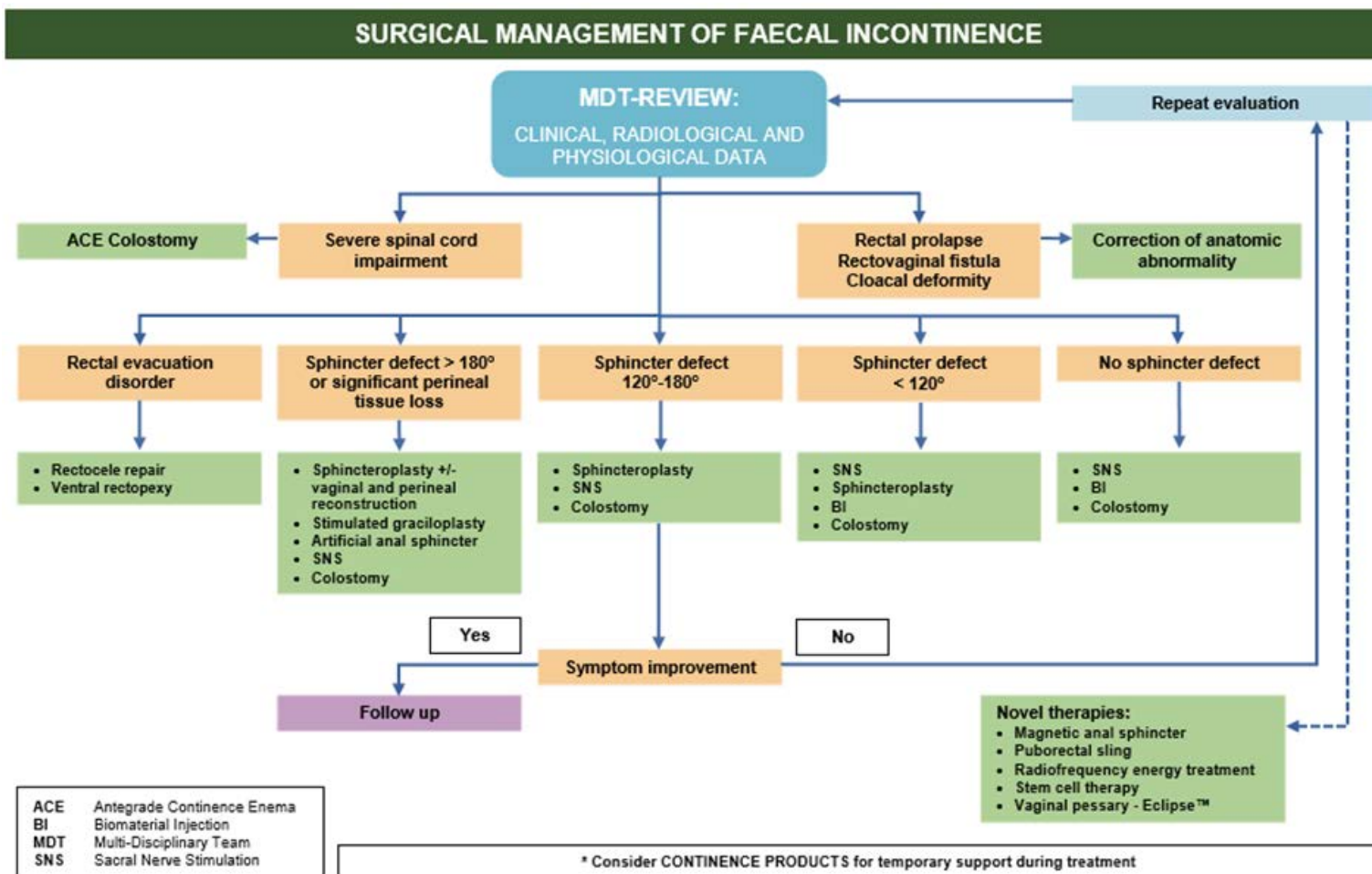
- Patients who fail surgical therapy for faecal incontinence, or who do not wish to undergo extensive pelvic reconstruction, should consider placement of an end sigmoid colostomy. (GR C) While this procedure does not restore continence, it does restore substantial bowel control and appears to improve social function and quality of life. Novel therapies can also be considered under protocol: PTNS, the magnetic anal sphincter, a new surgical technique called SECCATM, vaginal pessary (EclipseTM) and sling procedures. (GR D)

Management of Individuals with congenital abnormalities:

- The abnormalities may be amenable to surgical repair. Often this will involve both laparoscopic abdominal and perineal approached. Poor functional outcomes may be treated by an Antegrade Continence Enema procedure or colostomy. Patients with cauda equina type neurological disorders, either congenital or acquired, should be considered for an this procedure or colostomy. (GR C)



Figure 14 – ICS Surgical management of faecal incontinence





#### *2.7.4 Care pathway for the management of faecal incontinence in frail older women and men*

In some frail older persons the only possible outcome may be containment; management with continence products, especially for people with minimal mobility (require assistance of > 2 people to transfer), advanced dementia (unable to state their name), and /or nocturnal urinary and faecal incontinence.

The most common types of faecal incontinence in frail older people are related to urgency and passive leakage. Passive leakage can refer to leakage, seepage and staining following bowel movements that are not associated with faecal urgency and may also occur with faecal impaction. Because constipation and impaction often contribute to faecal incontinence in older adults, these are considered separately in the algorithm.

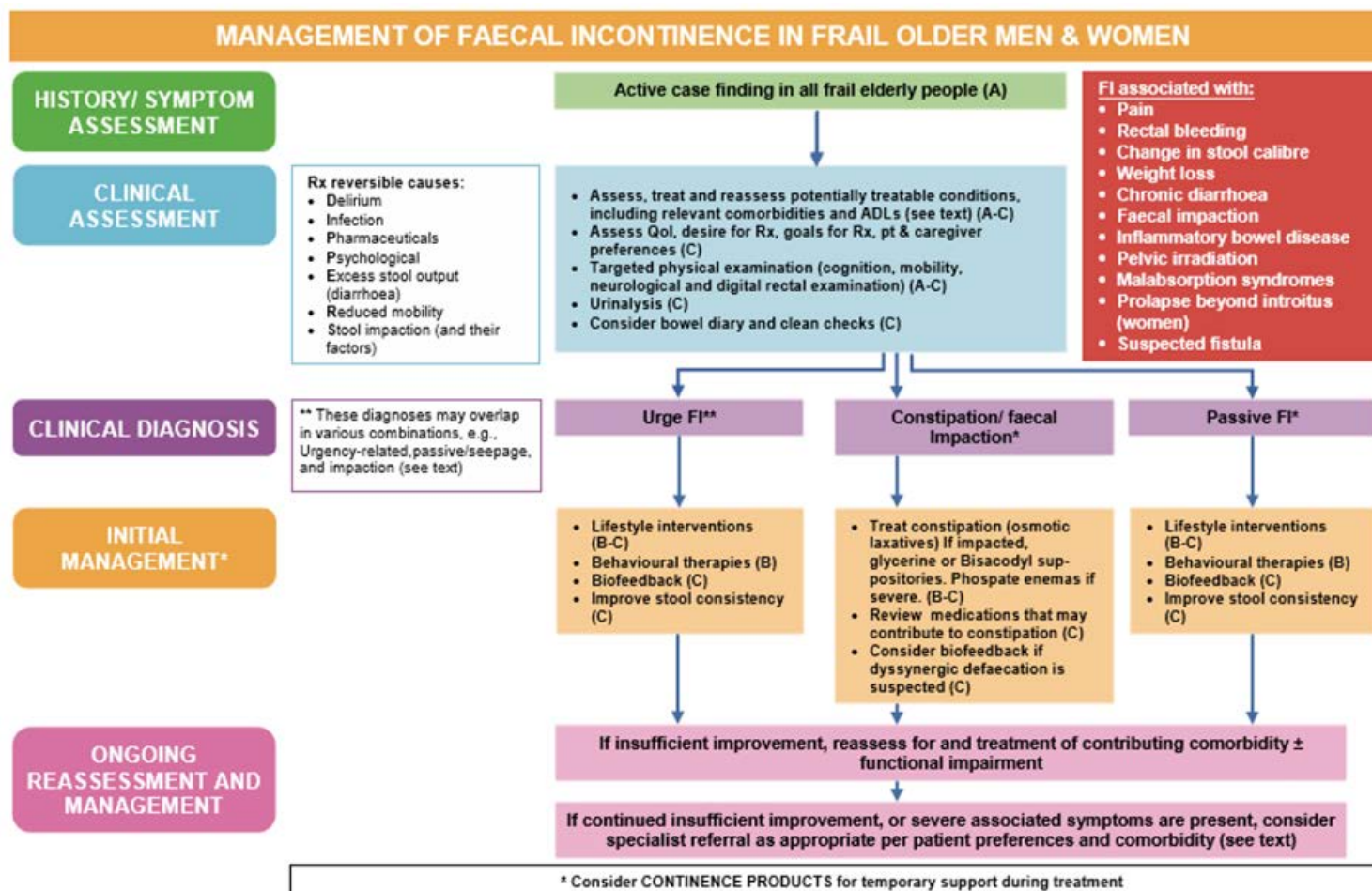
Optimal faecal incontinence management is usually possible with the approaches in Table 20. If initial management fails to achieve the desired goals, the next steps are specialist reassessment and treatment of contributing comorbidity and/or functional impairment.

Age per se is not a contraindication to UI or FI surgery (GR C), but before surgery is considered, all patients should have:

- Evaluation and treatment for any comorbidity, medications, and cognitive or functional impairments contributing to UI that could compromise surgical outcome (e.g., dementia that precludes patient ability to use artificial sphincter) (GR C).
- Adequate trial of conservative therapy, including pharmacological therapies where relevant (GR C).
- Discussion (including the caregiver) to ensure that the anticipated surgical outcome is consistent with goals of care in the context of the patient's remaining life expectancy (GR C).
- Urodynamic testing or anorectal manometry, because clinical diagnosis may be inaccurate (GR B).
- Preoperative assessment and perioperative care to establish risk of, and to minimise the risk of common geriatric post-operative complications such as delirium and infection (GR A), dehydration and falls (GR C).



Figure 15 – ICS Management of faecal incontinence in frail older women and men



**Table 20 – ICS recommendations for assessment and treatment of faecal incontinence in frail older women and men**

Grade of recommendation	History and symptom assessment	Conservative treatment	Drug treatments
A	<ul style="list-style-type: none"><li>• Active case finding</li><li>• Functional assessment (mobility, transfers, manual dexterity, dressing and undressing ability, ability to toilet)</li><li>• Evaluation for bowel “alarm” symptoms (red box algorithm)</li></ul>	<ul style="list-style-type: none"><li>• Prompting to go to the toilet for bowel movement for frailer, more impaired older people</li></ul>	
B	<ul style="list-style-type: none"><li>• Define co-morbid conditions (see Figure 15)</li><li>• A screening test for depression</li><li>• To assess bother patient / caregiver</li><li>• Set goals for care: decrease in specific symptoms, quality of life, reduction of comorbidity, lesser care burden</li></ul>	<ul style="list-style-type: none"><li>• Bowel training for more fit alert persons</li><li>• Improving stool consistency can be done with dietary fibre and supplementary fibre</li></ul>	<ul style="list-style-type: none"><li>• Loperamide may be considered for diarrhoea at low doses to improve stool consistency. However, close monitoring for constipation and impaction is needed.</li></ul>
C	<ul style="list-style-type: none"><li>• Physical examination should include a rectal examination for faecal loading or impaction</li><li>• Cognitive assessment (to assist in planning and management)</li><li>• Set goals for likely cooperation with management</li></ul>	<ul style="list-style-type: none"><li>• Initial treatment should be individualised</li><li>• For the select cognitively intact older person with FI, pelvic floor muscle therapy can be considered to avoid neural deterioration and sacropenia</li></ul>	
No grading	<ul style="list-style-type: none"><li>• Stool studies for infectious causes and testing for malabsorption syndromes.</li><li>• Suspected stool impaction/loading on digital rectal examination consider an abdominal x-ray</li></ul>	<ul style="list-style-type: none"><li>• For the select cognitively intact older with FI, biofeedback, balloon training and PTNS may be considered, but few studies exist among frail older adults.</li></ul>	



## 2.8 Management of neurological incontinence

### 2.8.1 Management of neurogenic urinary incontinence

The management of neurological urinary incontinence depends on the mechanisms producing incontinence which is defined by the site and extent of the nervous system abnormality. An initial assessment will classify the neurogenic incontinence patient into one of four groups. History and physical examination are important in helping distinguish these groups:

- peripheral lesions (as after major pelvic surgery) including those with lesions of the cauda equina (eg. lumbar disc prolapse)
- sacral spinal cord lesions involving the sacral micturition centre
- suprasacral spinal cord lesions (suprasacral infrapontine spinal cord lesions)
- central lesions of the brain or brain stem (stroke, Parkinson's disease, multiple sclerosis)

The assessment should be made using

- Questionnaires, urinalysis, bladder diary, uroflowmetry with assessment of PVR, and imaging of the urinary tract (ultrasonography)
- Invasive urodynamics should be used as part of the initial assessment in select patient populations (e.g. meningomyelocele)

- Due to increasing data on organ cross-sensitisation and the debilitating effect of faecal incontinence on quality of life, a history of bowel function should be also included

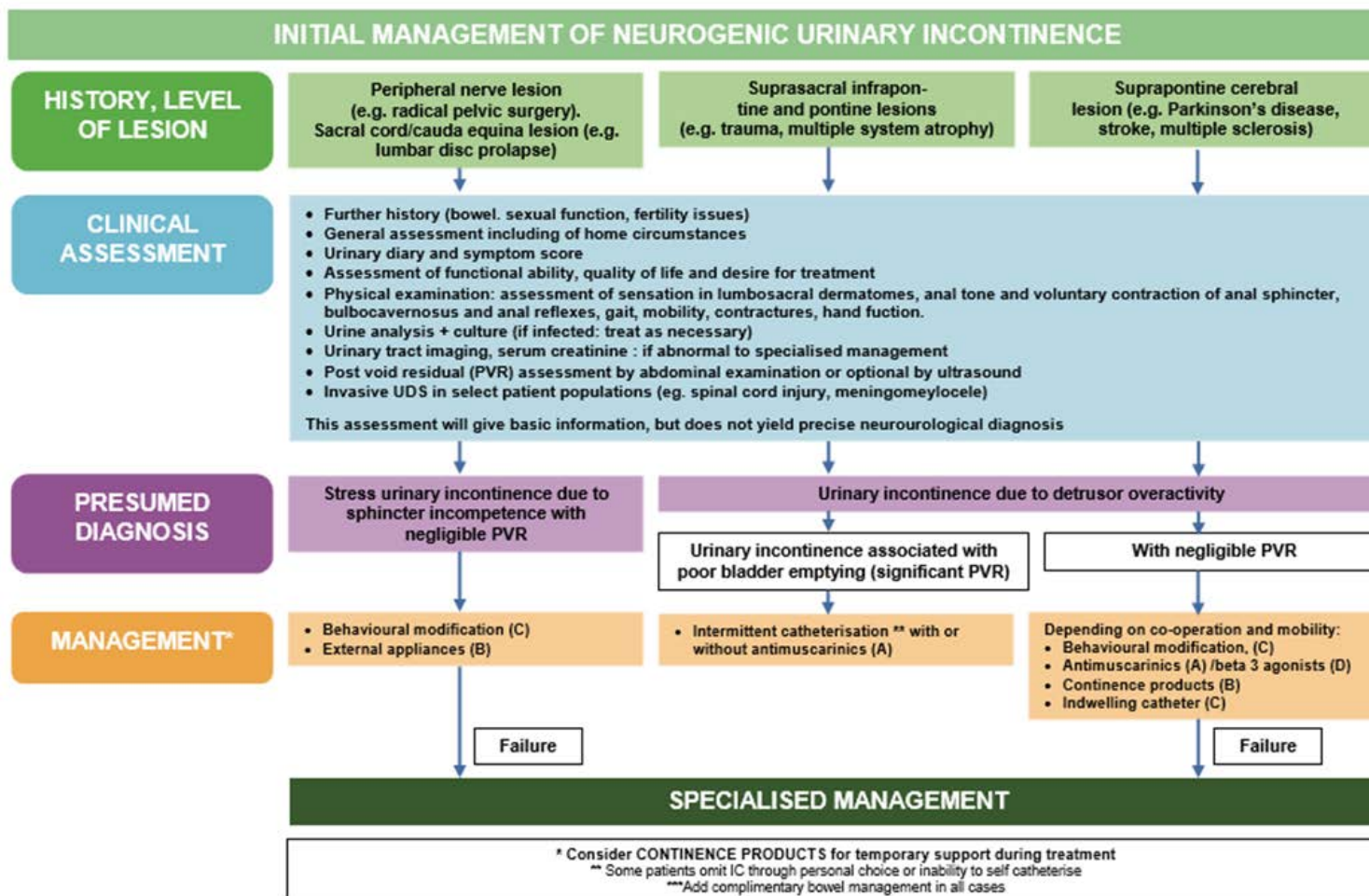
The initial treatment recommendations (Figure 16) from ICS are as follows:

- Physiotherapy should be started after functional assessment.
- Electrical stimulation can be considered.
- Patients with peripheral nerve lesions (e.g. denervation after pelvic surgery) and patients with spinal cord lesions (e.g. traumatic spinal cord lesions) should receive specialised urological management (GR A).
- Initial treatment for patients with incontinence due to suprapontine pathology, like stroke; need to be assessed for degree of mobility and ability to cooperate. Initial recommended treatments are behavioural therapy (GR C) and anticholinergic drugs for presumed detrusor overactivity (GR A). If incontinence persists and if operative procedures are not indicated then continence products (GR B) or catheters (GR C) may be necessary on a long-term basis. Continence products can also be necessary in non-cooperative or less mobile patients.
- Pharmacological detrusor relaxation and/or antibiotics may be useful in cases of persistent bypass leakage and/or recurrent UTI (patients with continuous drainage).
- In all cases, bowel management should complement management of NLUTD.





Figure 16 – ICS Initial management of neurogenic urinary incontinence





Specialised assessment is needed in most patients with neurogenic urinary incontinence:

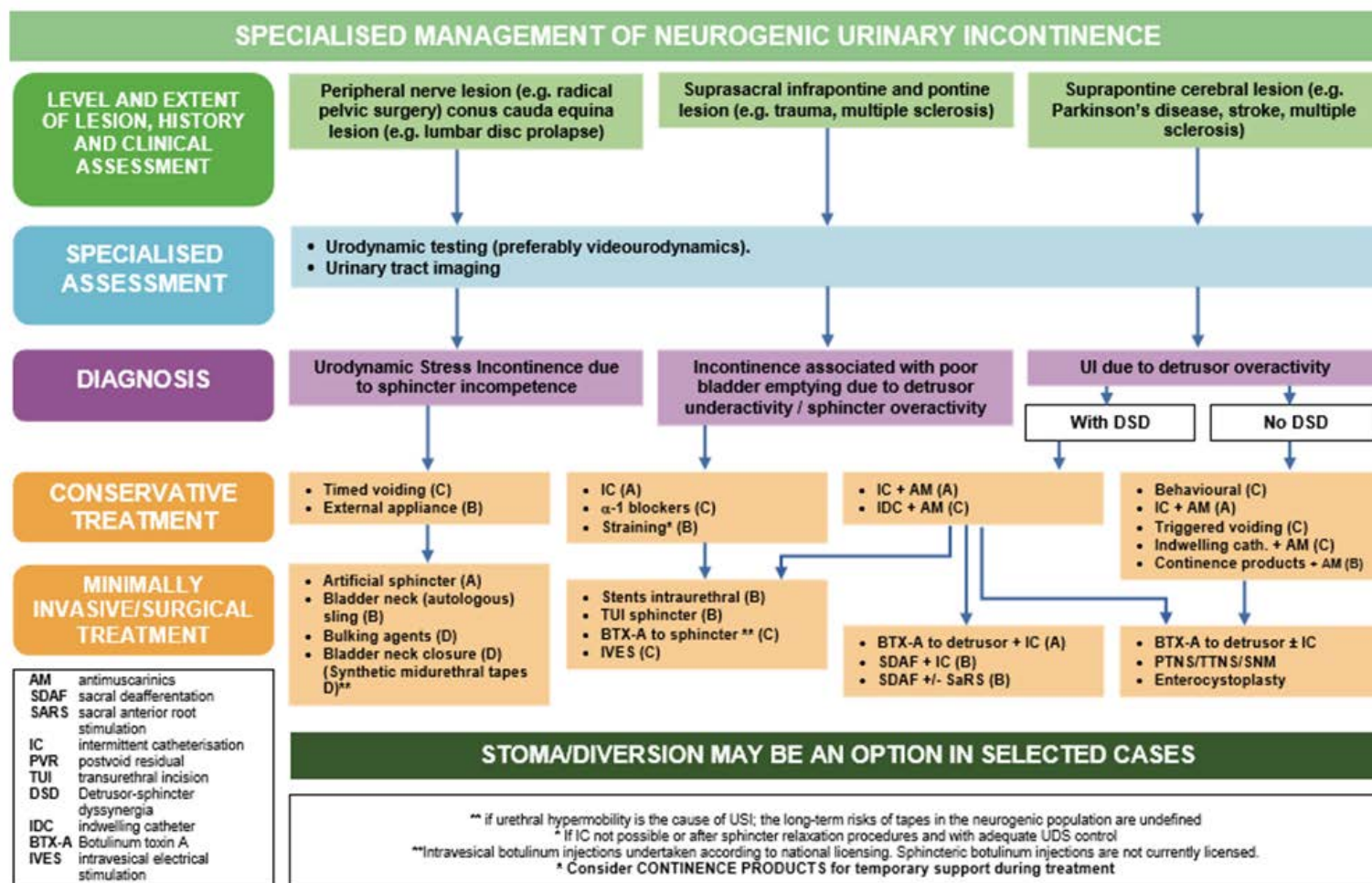
- Invasive urodynamic studies should be used with videourodynamics if available when surgical interventions are planned or when the “bladder may be unsafe”.
- Upper tract imaging is needed in some patients and more detailed renal function studies will be desirable if the upper tract is considered in danger: high bladder pressure, upper urinary tract dilation, recurrent or chronic upper tract infection, (major) stones, (major) reflux.
- In patients with peripheral lesions, clinical neurophysiological testing may be helpful for better definition of the lesion.

For specialised management, conservative treatment is the mainstay (GR A). Management of neurogenic urinary incontinence has several options. The algorithm details the recommended options for different types of neurological dysfunction of the lower urinary tract. The dysfunction does not necessarily correspond to one type/level of neurological lesion and is defined best by urodynamic studies. One should always ascertain that the management ensures a safe lower urinary tract (storage at low pressure and complete emptying) Both urinary and bowel function should be assessed together if both systems are affected, as symptoms and treatment of one system can influence the other, and vice versa (GR A).





Figure 17 – ICS Specialised management of neurogenic urinary continence





Treatment options are often used in combination and are summarised in Table 21.

**Table 21 – ICS recommendations for treatment of neurogenic urinary incontinence**

Grade of recommendation	Conservative treatment	Minimally invasive treatments	Surgical treatment
A	Intermittent catheterisation Anticholinergics	Botulinum toxin for detrusor	Artificial sphincter
B	Continence products Bladder expression		Stents intraurethral TUI sphincter Sacral deafferentation Sacral anterior root stimulator Enterocystoplasty Bladder neck sling
C	Alpha-1-adrenergic blockers Oral cannabinoid agonists (MS) Triggered voiding Timed voiding Behavioural therapy Indwelling catheter	Botulinum toxin for: sphincter Intravesical electrical stimulation PTNS/TTNS SNM (stable disease only)	a.
D	Beta-3-agonist alone or as an add-on to anticholinergics		Sub-urethral tapes Bulking agents Bladder neck closure

### 2.8.2 Management of faecal incontinence in neurological patients

Patients with known neurological disease may present with symptoms related to neurological bowel dysfunction, such as; difficulty in defaecation, constipation and faecal incontinence which disturb their activities of daily living and impair quality of life. Many have permanent impairments and functional limitations and disabilities, which are due to neurological deficits and complications.

The initial assessment should include a history, a physical examination with a functional assessment, environmental factors, and basic investigations:

The history:

- Neurological diagnosis and functional level
- Previous and present lower gastrointestinal (LGIT) function and disorders
- Severity of neurogenic bowel dysfunction
- Current bowel care and management including diet, fluid intake, medications affecting bowel functions
- Co-morbidity / complication e.g., urinary incontinence, autonomic dysreflexia, pressure ulcers, sexual dysfunction
- Patient's satisfaction, needs, restrictions and quality of life
- Environmental factors and barriers and facilitators to independent bowel management.

Physical examination:

- Cognitive function; motor, sensory and sacral reflexes – voluntary anal sphincter contraction, deep perianal sensation, anal tone, anal and bulbo- cavernosus reflexes
- Spasticity of the lower limbs
- Abdominal palpation for faecal loading and rectal examination



- Functional assessment: Hand and arm use, fine hand use, mobility – maintaining body position, transfer and walking ability.

Environmental factors assessment: toilet accessibility; devices for bowel care and mobility; caregiver support and attitude.

Basic investigations: Stool examination, plain abdominal X-Ray

The initial management consists of:

- Continence products and anal plugs or faecal collectors (rectal tubes, catheters, trumpets, rectal pouches) can be helpful in patients who have less anal sensation
- Patient education and goals-setting to achieve complete defaecation on a regular basis and faecal continence based on right time, right place, right trigger and right consistency with adequate fibre diet and fluid intake;
- Appropriate trigger according to preservation of sacral (anorectal) reflex – digital rectal stimulation (GR C);
- suppository and enema (GR B);
- if no anorectal reflex, manual evacuation (GR B);
- abdominal massage (GR C) can also be helpful

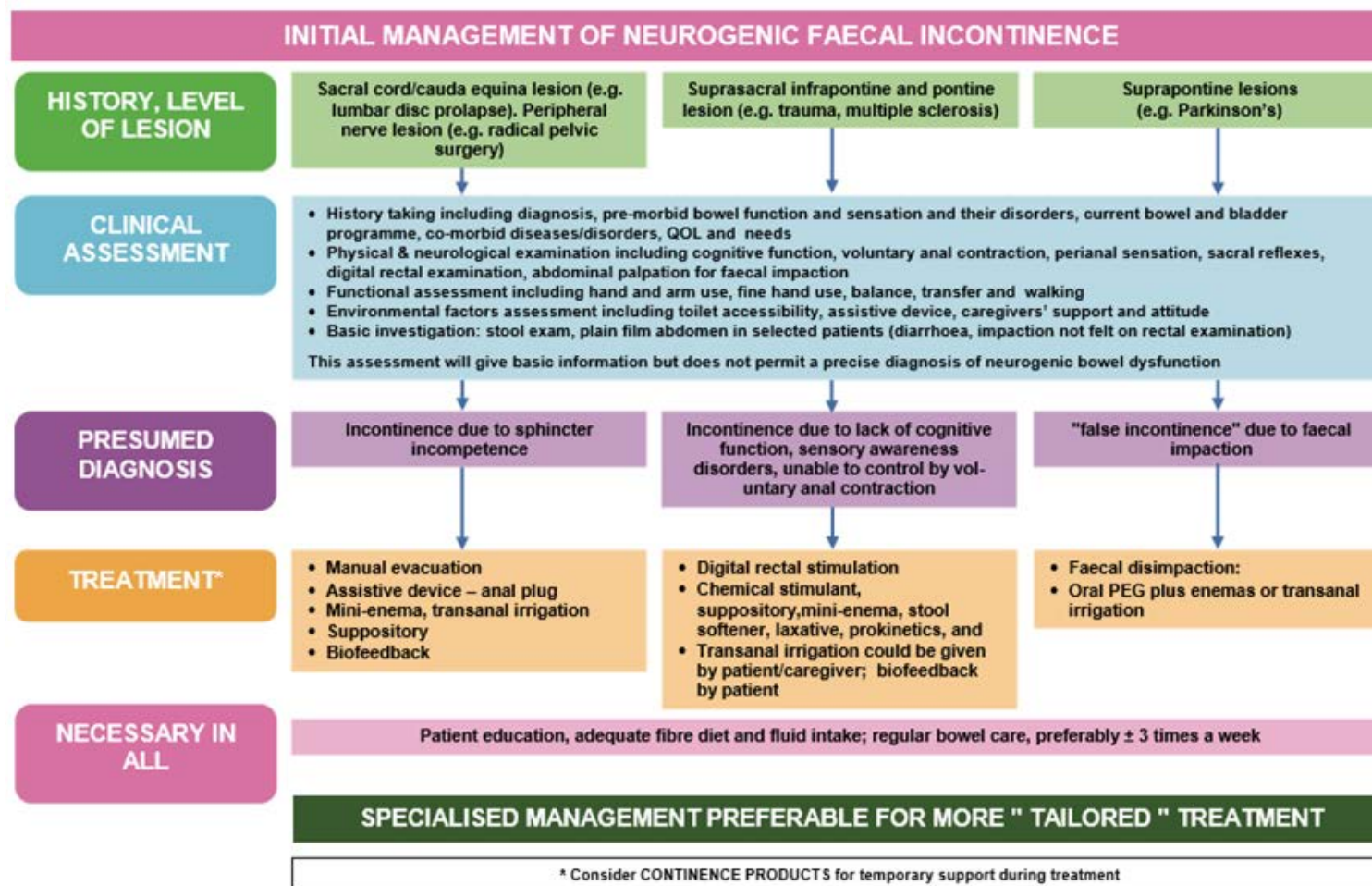
- Prescribe medications – stool softener, laxative, prokinetic agents, anti-diarrhoeal drugs as necessary
- Assistive techniques may be necessary for
- Defaecation – transanal irrigation (GR A)
- For incontinence – anal plug (GR C)

The algorithm does not apply to management in acute neurological patients that need regular bowel emptying.

Specialised management will be needed if initial management is unsuccessful to look for comorbidity and certainly before performing invasive treatment



Figure 18 – ICS Initial management of neurogenic faecal incontinence





- Do not assume that all symptoms are due to neuropathy, e.g. women with neurological pathology might have had childbirth injury to the sphincter
- Special investigations: manometry, endoanal ultrasound, (dynamic) MRI, (needle) EMG. These specific bowel functional tests and electro-diagnostic tests must be considered optional, as their value in neurological pathology is not sufficiently demonstrated so far.

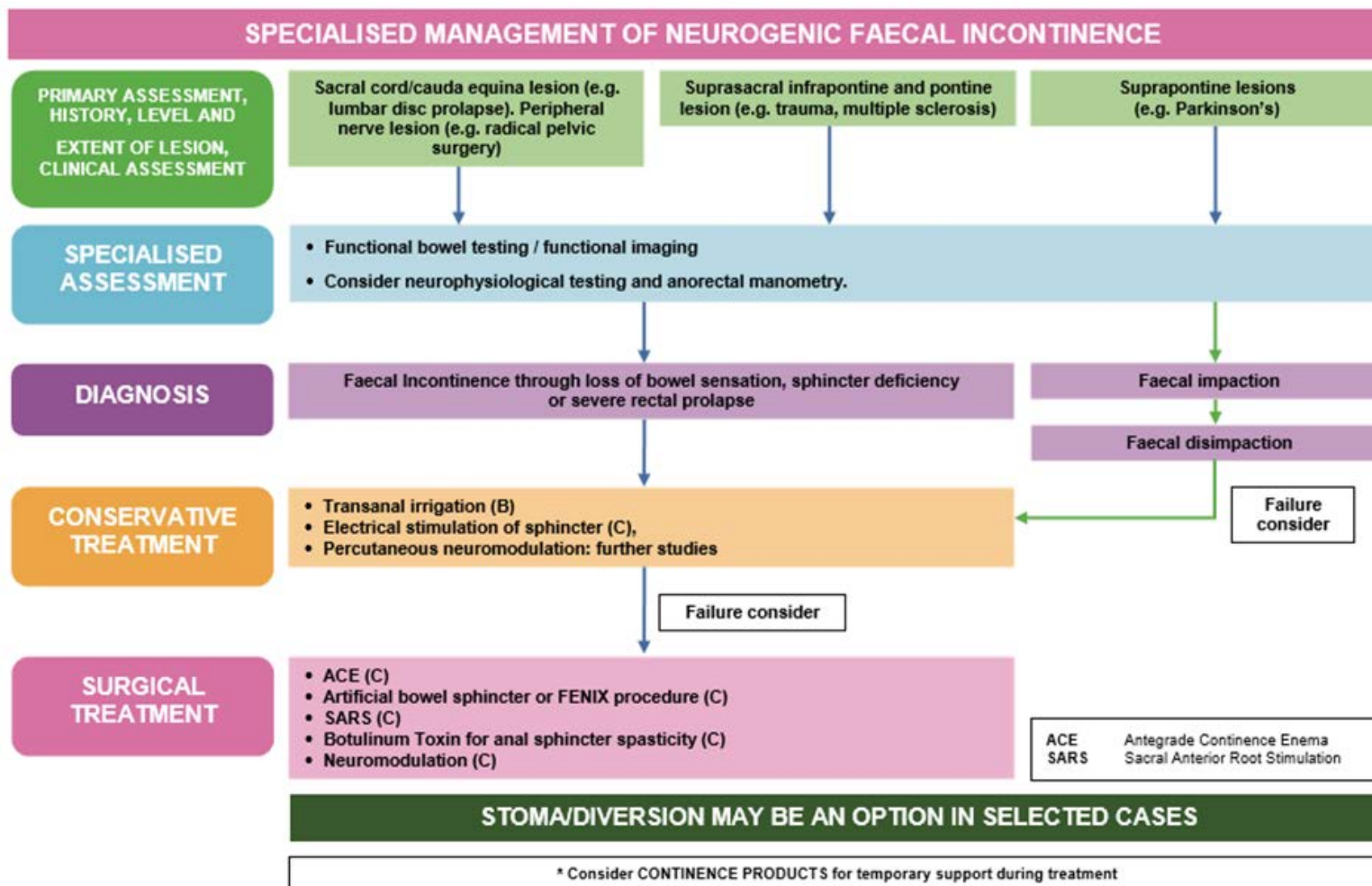
Specialised treatment consists of:

- Conservative treatment for neurological faecal incontinence is also the mainstay for specialised management, (GR C).
- Management of neurological incontinence does not include very extensive treatment modalities and many conservative interventions are still empirical.
  - Transanal irrigation (GR B).
  - Electrical stimulation sphincter, (GR C).
  - Percutaneous neuromodulation and sacral nerve stimulation: further research is required (GR D).
- Surgical management of neurogenic faecal incontinence has different options which need a very strict patient selection
  - Antegrade Continence Enema (GR C).
  - Artificial bowel sphincter or FENIX implant procedure (a small, flexible band of interlinked titanium beads with magnetic cores) (GR C).
  - Sacral Anterior Root Stimulation (GR C).
  - Botulinum Toxin (GR C).
  - Neuromodulation (GR C).
- It is recommended that urinary and bowel function are assessed simultaneously if both systems are affected, as symptoms and treatment of one system can influence the other and vice versa (GR A).





Figure 19 – ICS Specialised management of neurogenic faecal incontinence





General strong recommendation from ICS are as follows:

- Patients with known neurological disease often need evaluation to exclude bladder dysfunction, not only if symptoms occur, but as a standard assessment as neurogenic bladder has a high prevalence in the particular disease.
- A possible neurological cause of “idiopathic” incontinence should always be considered. Diagnostic steps to evaluate this include basic assessments, such as history and physical examination, urodynamics and specialised tests.
- Incontinence in neurological patients does not necessarily relate to the neurologic pathology. Other diseases such as prostate pathology, pelvic organ prolapse, might have an influence. These factors should be evaluated as potential primary or contributory causes.
- Extensive diagnostic evaluation is often useful and necessary to tailor an individual treatment based on complete neurofunctional data. This may not be needed in every patient e.g. patients with suprapontine lesions or in patients where treatment will consist merely of bladder drainage when the person is frail or has limited life expectancy.
- There is often a need to manage both bladder and bowel dysfunction simultaneously.

### 3 REIMBURSEMENT FOR INCONTINENCE IN BELGIUM

This chapter starts with an overview of the reimbursement and payments by RIZIV – INAMI for physiotherapy, medication, surgery and materials for patients with incontinence. The chapter then continues with a description of the reimbursement or payments by the federated instances. Subsequently, we briefly describe the financial intervention by some of the complementary insurances of sickness funds. The chapter ends with a short paragraph on other compensations for incontinence patients in Belgium.

#### 3.1 Overview of RIZIV – INAMI reimbursement/payments for patients with incontinence

##### 3.1.1 *Reimbursement of physiotherapy sessions for pelvic re-education*

For frequent pathology, RIZIV – INAMI reimburses up to 18 physiotherapy sessions per calendar year and per indication. If more sessions are needed, a request can be done at the advising physician of the sickness fund. For F-pathology, up to 60 sessions can be reimbursed. Also for F-pathology a request has to be done at the advising physician.

A prescription by a physician is required for the patient to obtain reimbursement and for the physiotherapist to be allowed to perform the therapy. A prescription must include the following elements:

- A diagnosis or indication
- The number of sessions needed
- If the patient cannot go to the physiotherapists' practice, that the physiotherapy should take place at the patient's home



If the physiotherapist adheres to the RIZIV – INAMI tariffs, a patient (without preferential reimbursement status) pays €5.48 out of pocket per session at the physiotherapists' practice and €7.06 for a session at home. For patients who benefit from a preferential reimbursement status, these amounts are reduced. Out-of-pocket payments are higher when the physiotherapist does not adhere to the official RIZIV – INAMI tariffs.

If a physician wants to obtain an advice of a physiotherapist, a functional evaluation can be requested by prescribing a “consultative physiotherapeutic exam”. In this case, the physician receives a report with a proposal treatment if applicable.

### *3.1.2 Reimbursement of continence nurse consultation*

There is currently no RIZIV – INAMI reimbursement for a consultation with a nurse for incontinence. Continence nurse is so far no recognised specialty.

### *3.1.3 Reimbursement of medication for incontinence*

The main medication reimbursed by RIZIV – INAMI for UI is oxybutynin 5mg immediate release formulation, which has considerable side effects. The newer anticholinergics (darifenacine, fesoterodine, propiverine, solifenacine, tolterodine), that have an improved side effect profile and better dosing schedule, are only reimbursed when prescribed in second line for patients with urgency incontinence as a result of neurological disorder (cerebral lesion or spinal cord lesion) and when no benefit is achieved with oxybutynin. When prescribed in second line for these indications, they cost the patient only about 5€ per month. However, in other cases, these newer drugs cost the patient 30€ to 50€ per month.




**Table 22 – Overview of reimbursement of incontinence medication**

Drug	Dosage	Brand name	N° tablets	Price	Reimbursed (No or category)	Regular (/Preferential) reimbursement *	Immediate release	Extended release
Darifenacin	7.5 mg once daily	Emselex®	28	26.85	No			X
	15 mg once daily		28	44.03	B <sup>£</sup>	14.8 (9.8)		X
			98	131.32	B <sup>£</sup>	14.8 (9.8)		
Fesoterodine	4 mg once daily	Toviaz®	28	50.01	B <sup>£</sup>	11.9 (7.64)		X
			84	109.87	B <sup>£</sup>	14.8 (9.8)		
	8 mg once daily		28	55.39	B <sup>£</sup>	11.9 (7.90)		x
			84	121.96	B <sup>£</sup>	14.8 (9.8)		
			100	134.52	B <sup>£</sup>	14.8 (9.8)		
Oxybutynin	5 mg	Ditropan®	30	8.23	B <sup>\$</sup>	2.21 (1.92)	X	
					Cat cx	3.81 (3.81)		
			100	12.56	B <sup>\$</sup>	4.40 (3.64)	X	
					Cat cx	8.6 (8.6)		
		Oxybutinin EG®	30	6.32	B <sup>\$</sup>	0.56 (0.33)	X	
					Cat cx	1.78 (1.78)		
			100	8.79	B <sup>\$</sup>	1.47 (0.88)	X	
					Cat cx	4.7 (4.7)		
	36 mg/patch 2/week	Kentera®	8	45.81	No			X
			24	98.05	No			X
Propiverine	5 mg twice daily	Mictonet®	56	25.90	No		X	
			168	57.29	No		X	
	15 mg once to twice daily		56	25.90	No		X	
			168	57.29	No		X	
	30 mg once daily		28	25.90	No			X
			84	57.29	No			X
Solifenacin	5 mg once daily	Vesicare®	30	54.72	No			X



			90	114.97	B <sup>£</sup>	14.8 (9.8)	X
			200	201.00	No		X
	10 mg once daily		30	80.00	No		X
			90	152.87	B <sup>£</sup>	14.8 (9.8)	X
Tolterodine	2 mg		56	47.45	No	X	
	4 mg once daily	Detrusol®	56	41.35	B <sup>£</sup>	10.79 (6.42)	X
		Tolterodine Teva®	28	20.98	B <sup>£</sup>	5.67 (3.40)	X
		Tolterodine Teva®	84	29.84	B <sup>£</sup>	8.05 (4.79)	X
		Tolterodin Sandoz®	28	20.88	B <sup>£</sup>	5.64 (3.38)	X
		Tolterodin Sandoz®	84	41.35	B <sup>£</sup>	10.79 (6.42)	X
		Urolina®	28	17.25	No		X
		Urolina®	84	25.31	B <sup>£</sup>	6.98 (4.15)	X
Mirabegron	25 mg	Betmiga®	30	54.72	No		X
		Betmiga®	90	130.00	No		X
	50 mg	Betmiga®	30	54.72	No		X
		Betmiga®	90	130.00	No		X

\* “Remgeld reguliere tegemoetkoming” – “ticket modérateur intervention régulière”; “remgeld verhoogde tegemoetkoming” – “ticket modérateur intervention majorée”

£ Category B: Chapter IV § 268

\$ Category B: Chapter IV § 195

Source: based on BCFI – CBIP website



### *3.1.4 Reimbursement of technical medical interventions, implants and other invasive medical devices*

A range of surgical procedures, implants and other invasive medical devices are reimbursed by RIZIV – INAMI. They are listed in the appendix of the chapter on data analysis.

### *3.1.5 Reimbursement/payments for incontinence materials*

Finally, RIZIV – INAMI intervenes for the purchase of incontinence materials. In this section we make an overview of covered materials, either through the “large lump sum for incontinence”, the “small lump sum for incontinence” or reimbursements upon prescription.

According to the classification of Cottenden e.a. (2013) <sup>[29]</sup>, continence products can be divided into (1) those that are intended to manage urinary retention and or contain incontinence (urinary and or faecal) and (2) those intended to assist with toileting. In the following paragraph we use this classification to give an overview of RIZIV – INAMI interventions.

**(1) Containment/control products** can be further subdivided into three overlapping classes (see Figure 20): those for urinary retention (depicted in the red circle), urinary incontinence (blue circle), and faecal incontinence (green circle). A patient experiencing both problems will need two products (one from each circle) or one product from the intersection of the two circles.

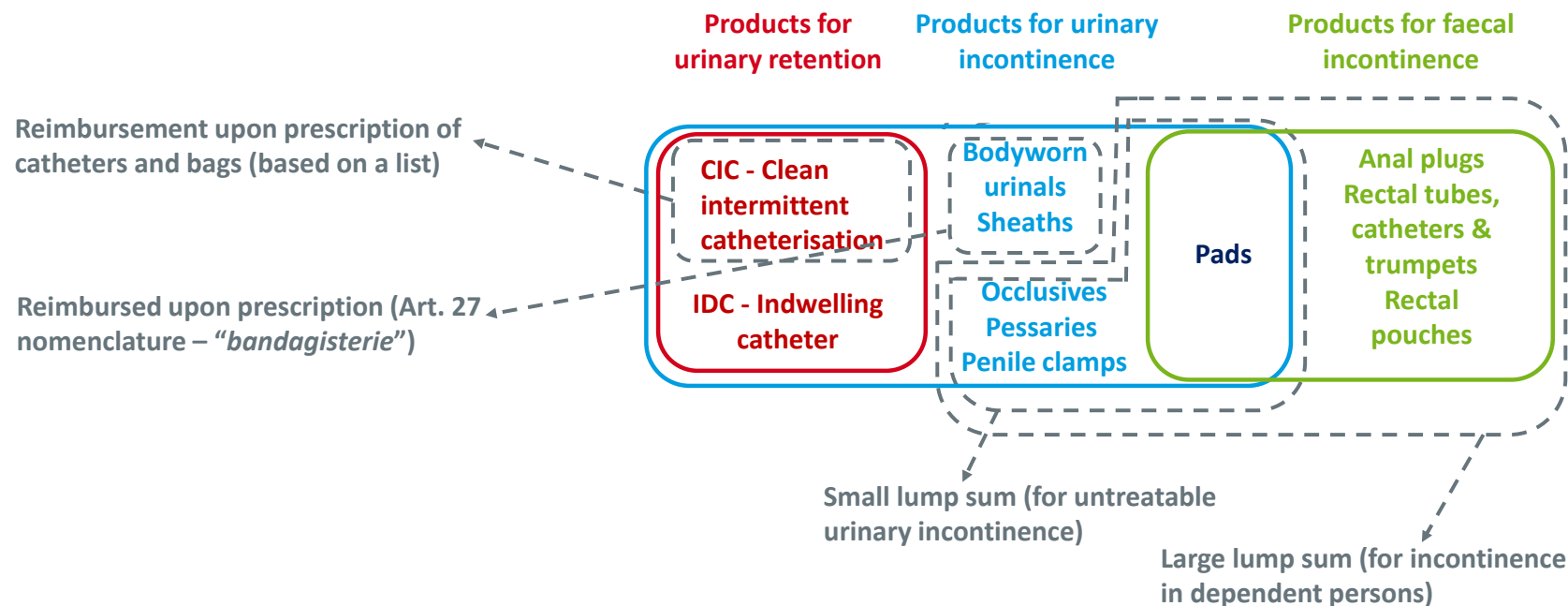
RIZIV – INAMI intervenes in different ways for the containment/control products:

- for materials used with clean intermittent catheterisation (CIC), as well as for sheaths, there is separate reimbursement upon prescription
- all other materials used for incontinence\* can be covered by either the small lump sum for untreatable UI or the large lump sum for incontinence in dependent persons, if the patient is eligible for one of these lump sums.

(\* Note that there is no detailed statement on what the lump sums precisely intend to cover - this likely has been a deliberate choice of the decision-makers.)



Figure 20 – Overview of RIZIV – INAMI reimbursement for incontinence materials – part 1: containment/control products



	Large lump sum	Small lump sum
CIC – self-catheterisation	X	X
CIC – by third person	✓	X
IDC	X	X
Sheaths	✓	X

X Cannot be combined    ✓ Can be combined

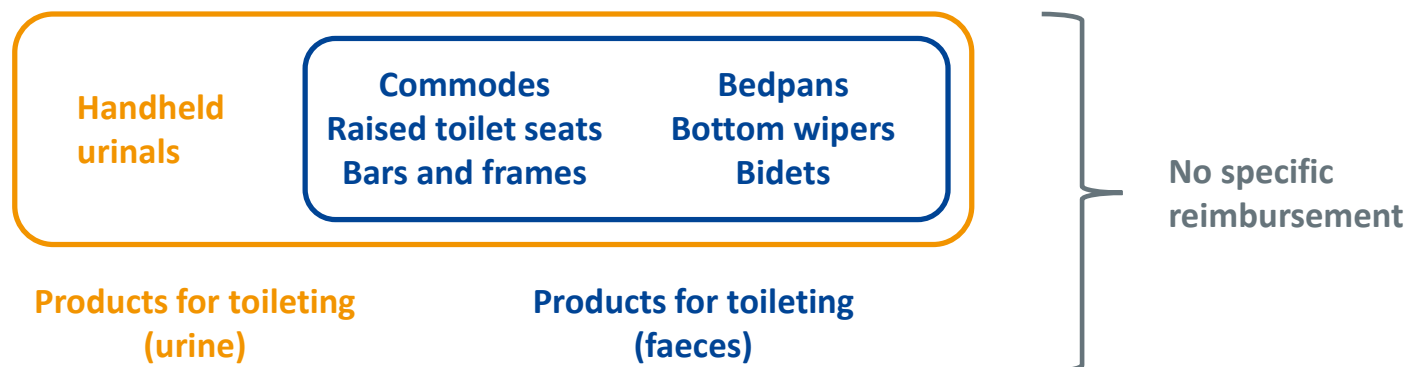
CIC= Clean intermittent catheterisation ('intermitterende katheterisatie'; 'sondage intermittent'); IDC= Indwelling catheter ('verblijfskatheter'; 'sonde à demeure'). Note that CIC should be used in preference to an IDC if it is clinically appropriate and a practical option for the patient.



The matrix at the bottom of Figure 20 shows which of the specific reimbursements can be combined with any of the lump sums. The small lump sum cannot be granted to persons who get a reimbursement for material used in CIC or IDC or for sheaths. The large lump sum cannot be granted to persons who do self-catheterisation or use IDCs, but can be granted to persons who get CIC by a third person or who use sheaths.

**(2) Toileting aids**, as classified by Cottenden e.a. (2013), are depicted in Figure 21. There is no specific RIZIV – INAMI reimbursement for toileting aids. As there is no detailed statement on what the incontinence lump sums intend to cover, it is unsure whether they are supposed to be covered or not by the lump sums.

**Figure 21 – Overview of RIZIV – INAMI reimbursement for incontinence materials – part 2: products to assist with toileting**



Source of classification: adapted from Cottenden e.a. (2013) <sup>[29]</sup>



### 3.1.5.1 *The “large lump sum” for incontinence in dependent persons*

- The lump sum for incontinence in dependent persons (persons with high care need) covers “incontinence material”.
  - Persons eligible for this large lump sum are, during at least four of the last twelve months preceding the award:
    - entitled to lump sum B or C for home nursing (see Table 25 for the conditions for home nursing lump sums). It is sufficient that the advisory physician of the sickness fund gives his/her permission for home nursing at lump sum B or C, the patient does not necessarily need to get home nursing.
    - AND have a score 3 or 4 on the criterion Incontinence on the Katz scale. The Katz scale (see Table 23) measures washing, clothing, transfer and mobility, toilet visit, incontinence and eating.
      - Score 3 for Incontinence means incontinence for urine or faeces (see Table 24 for details)
      - Score 4 for Incontinence means incontinence for urine and faeces (see Table 24 for details).
  - The patient may not have received an incontinence lump sum in the last 12 months. (Note that at the time of writing this report, a proposal is being developed by RIZIV – INAMI, which would make it possible to grant a large lump sum to a person who has received a small lump sum in the preceding 12 months, with a pro rata adjustment of the large lump sum.)
- In contrast to the small lump sum, also patients with “treatable” incontinence can be eligible for the large lump sum; however treatment options will be limited given the limited mobility of the patient, e.g. physiotherapy will often not be possible.
  - The last day of above mentioned four months, the patient has to stay at home, and thus not in a care institution for which the health insurance financially intervenes:
    - general or psychiatric hospital
    - Nursing homes (RVT/MRS), except for stay in centre for daycare,
    - Homes for the elderly (ROB/MRPA),
    - Psychiatric care home (PVT/ MSP),
    - Initiatives for sheltered living (initiatief voor beschut wonen/habitations protégées) or certain rehabilitation centres.
    - Staying in an institute of VAPH, AVIQ-Handicap, PHARE or DPB, is allowed, as long as there is no financial intervention of RIZIV – INAMI.<sup>a</sup>
  - The incontinence lump sum can be cumulated with the care lump sum for chronic patients, the palliative care lump sum and the lump sum for patients in persistent vegetative state (PVS).

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<sup>a</sup> VAPH, Vlaams Agentschap voor Personen met een Handicap ; AVIQ, l'Agence pour une Vie de Qualité (Région wallonne) ; PHARE, Personne Handicapée Autonomie Recherchée (Région de Bruxelles-Capitale) ; VAPH, Vlaams Agentschap voor Personen met een Handicap (Région flamande) ; DPB, Dienststelle für Personen mit Behinderung (Communauté germanophone)



- Entry procedures:
  - Automatic granting via the Katz scale evaluation done by the home care nurse. This evaluation is sent to the advisory physician of the sickness fund and the lump sum is granted automatically on this basis.
  - An alternative entry is possible for people who do not call upon home nursing, but on informal caregivers. These persons can get the lump sum on the basis of a statement written by a physician. For this large lump sum, any physician can write the statement (GP, urologist, geriatrician,...). (Note that at the time of writing this report, a form is worked out by RIZIV – INAMI that combines the form for the small lump sum and the Katz scale to avoid that each physician has to write a statement based on his/her own inspiration.)
  - The lump sum is granted for 1 year, after which it can be “renewed” by automatic granting or a new statement by the physician. <sup>[30]</sup>



Table 23 – Katz evaluation scale (for French version see appendix)

Evaluatieschaal					
Criterium	Score	1	2	3	4
Zich wassen		kan zichzelf helemaal wassen zonder enige hulp	heeft gedeeltelijke hulp nodig om zich te wassen boven of onder de gordel	heeft gedeeltelijke hulp nodig om zich te wassen zowel boven als onder de gordel	moet volledig worden geholpen om zich te wassen zowel boven als onder de gordel
Zich kleden		kan zich helemaal aan- en uitkleden zonder enige hulp	heeft gedeeltelijke hulp nodig om zich te kleden boven of onder de gordel (zonder rekening te houden met de veters)	heeft gedeeltelijke hulp nodig om zich te kleden zowel boven als onder de gordel	moet volledig worden geholpen om zich te kleden zowel boven als onder de gordel
Transfer en verplaatsingen		is zelfstandig voor de transfer en kan zich volledig zelfstandig verplaatsen zonder mechanisch(e) hulpmiddel(en) of hulp van derden	is zelfstandig voor de transfer en voor zijn verplaatsingen, mits het gebruik van mechanisch(e) hulp-middel(en) (kruk(ken), rolstoel, ...)	heeft volstrekte hulp van derden nodig voor minstens één van de transfers en/of zijn verplaat-singen	is bedlegerig of zit in een rolstoel en is volledig afhankelijk van anderen om zich te verplaatsen
Toiletbezoek		kan alleen naar het toilet gaan, zich kleden en zich reinigen	heeft hulp nodig voor één van de drie items: zich verplaatsen of zich kleden of zich reinigen	heeft hulp nodig voor twee van de drie items: zich verplaatsen en/of zich kleden en/of zich reinigen	heeft hulp nodig voor de drie items: zich verplaatsen en zich kleden en zich reinigen.
Continentie		is continent voor urine en faeces	is accidenteel incontinent voor urine of faeces (inclusief blaassonde of kunstaars)	is incontinent voor urine (inclusief mictietraining) of voor faeces	is incontinent voor urine en faeces
Eten		kan alleen eten en drinken	heeft vooraf hulp nodig om te eten of te drinken	heeft gedeeltelijke hulp nodig tijdens het eten of drinken	de patiënt is volledig afhankelijk om te eten of te drinken

- in geval van een score 2 voor het criterium 'continentie': bij de rechthebbende een combinatie van nachtelijke urine-incontinentie en occasionele

urine-incontinentie overdag werd vastgesteld: ..... JA ☐ NEE ☐ (1)

en stelt de adviserend geneesheer ervan in kennis dat hij/zij bij de rechthebbende begint met de verzorging:

op datum van .....  
gedurende een periode die eindigt op .....

Indien verzorging werd voorgeschreven, identificatie van de voorschrijvende geneesheer:

naam: ..... RIZIV-nummer : ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Op basis van bovenstaande evaluatieschaal wordt *forfait A* / *forfait B* / *forfait C* (2) aangevraagd, wordt toiletverzorging ter kennis gegeven (2).



**Table 24 – Scores 1 to 4 for incontinence on the Katz scale****Score 1: Is continent for urine and faeces****Score 2: Is accidentally incontinent for urine or faeces (including bladder catheter or artificial anus):**

- occasionally = at irregular intervals during 24 hrs, undeliberate urine and/or faecal loss, e.g. in case of stress incontinence or dribbling;
  - only night incontinence = score 2;
  - night incontinence and occasional urine incontinence during the day = score 2.
- patient has an artificial anus,
- OR urostomy;
- OR indwelling catheter.
- patient does self-catheterisation.

**Score 3: Incontinent for urine (including patients on miction training) or for faeces:**

- continuously suffering from undeliberate urine or faeces loss;
- OR be on miction training = this is not actually a training intervention nor a treatment, but a care regimen where the patient gets support to go to toilet minimum 4 times a day (mentioned in the nursing file) (note that it is not the nurse that has to do this 4 times a day, but an informal carer);
- OR catheterisation by health professional or other carer;
- patient shows permanent inappropriate behaviour when going to toilet, for urine or faeces.

**Score 4: Incontinent for urine and faeces:**

- continuously suffering from undeliberate loss of urine and faeces;
- patient shows permanent inappropriate behaviour when going to toilet, for urine and faeces.

Source: <sup>[32]</sup>

**Table 25 – Conditions for home nursing lump sum A, B and C**

Conditions for home nursing lump sum A :

- minimum one nursing visit with hygienic care per care day
- be dependent for washing and clothing (score 3 or 4), and
- dependent for transfer and mobility\* and/or for toilet visit (score 3 or 4);

Patients entitled to lump sum A are entitled to at least one nursing visit per day. There is no maximum number of visits. Several visits are possible, however, the lump sum, which is on daily basis, does not change.

Conditions for home nursing lump sum B :

- minimum one nursing visit with hygienic care per care day
- be dependent for washing and clothing (score 3 or 4), and
- dependent for transfer and mobility and for toilet visit (score 3 or 4); and
- dependent for continence and/or nutrition (score 3 or 4);

Patients entitled to home nursing lump sum B are entitled to at least one nursing visit per day. There is no maximum number of visits. Several visits are possible, however, the lump sum does not change.

Conditions for home nursing lump sum C :

- minimum one nursing visit with hygienic care per care day
- be dependent for washing and clothing (score 4), and
- dependent for transfer and mobility and for toilet visit (score 4); and
- dependent for continence and nutrition (at least one of these two criteria should have score 4 and the other minimum 3).

Patients entitled to home nursing lump sum C are entitled to min. 2 nursing visits per day. There is no maximum number of visits. More than 2 visits are possible, however, the home nursing lump sum does not change.

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\* 'Transfer' means each change in position (from lying to standing, from sitting to standing, from lying to sitting, and vice versa); 'mobility' means going from one point to another.



### 3.1.5.2 The “small lump sum” for untreatable urinary incontinence

The small lump sum for untreatable urinary incontinence covers urinary incontinence only. Similar as for the large lump sum, there is no detailed statement on what the small lump sum precisely intends to cover. It is precised however that both lump sums find their legal basis in the coordinated law of 14 July 1994, Art. 34, 14° on the compulsory insurance, which mentions coverage of “materials and care products” for patients, taken care of at home, who suffer from a severe condition or who get palliative care.

Conditions for the small lump sum are:

- Patients suffering from an incurable form of urinary incontinence (“After exclusion of treatable causes for incontinence and attempt for treatment, still permanent incontinence.”)
- Not having received an incontinence lump sum in the last 12 months
- Staying at home and thus not in a care institution for which the health insurance financially intervenes:
  - general or psychiatric hospital
    - except for stay in acute ward A, C, D, E, G, K, L M, N at general hospitals, as well as day care nursing or night care nursing service at general or psychiatric hospitals
  - Nursing homes (RVT/MRS), except for stay in centre for daycare,
  - Homes for the elderly (ROB/MRPA),
  - Psychiatric care home (PVT/ MSP),
  - Initiatives for sheltered living (initiatief voor beschut wonen/habitations protégées) or certain rehabilitation centres.

- Staying in an institute of VAPH, AVIQ-Handicap, PHARE or DPB, is allowed, as long as there is no financial intervention by RIZIV – INAMI.<sup>b</sup>
- Not having received a RIZIV – INAMI fee for self-catheterisation (from the list with catheters for self-catheterisation) or incontinence material or any other material in art. 27 of the nomenclature (urine bags, catheters, ...). (Currently an exception is being developed for persons who got reimbursement through art. 27 for ostomy material so that ostomy patients who continue to suffer from losses are also eligible for the small lump sum. Another exception would hold for code 641524 which covers incontinence materials used during hospital stay. These exceptions however are under preparation and thus not definite yet.)
- Request procedure:
  - The GP fills out the request form (see Figure 22). The possibility to fill out the form will possibly be expanded to urologists, paediatricians, geriatricians and gynaecologists. However, this proposal has not yet been formally accepted.
  - If the advising physician of the sickness fund of the patient has to agree to the form. In practice, the form is by default approved, if the administrative conditions are met.
  - The approval is valid for 3 years, but the sickness fund checks yearly whether the administrative conditions are still met.<sup>[33]</sup> (Note that at the time of writing this report, a proposal is being developed by RIZIV – INAMI to extend the validity of the approval to lifetime (for as long as the other conditions are met) for persons of 75 years or older.)

<sup>b</sup> VAPH, Vlaams Agentschap voor Personen met een Handicap ; AVIQ, l'Agence pour une Vie de Qualité (Région wallonne) ; PHARE, Personne Handicapée Autonomie Recherchée (Région de Bruxelles-Capitale) ; VAPH,

Vlaams Agentschap voor Personen met een Handicap (Région flamande) ; DPB, Dienststelle für Personen mit Behinderung (Communauté germanophone)



**Figure 22 – Request form for the small lump sum (for French version see appendix)**

FORMULIER AANVRAAG « ONBEHANDELBARE INCONTINENTIE-FORFAIT »

Voor thuiszorg door de huisarts in te vullen  
Naar de adviserend geneesheren te sturen

1. Identificatie van de patiënt

2. Evaluatie

• Anamnese

- Incontinentie is continu
- Incontinentie is intermitterend
- Stress incontinentie
- Urge incontinentie
- Urinaire incontinentie en ook faeces incontinentie

• Objectieve gegevens

> Klinisch onderzoek ter opzoeken van

1. fecaloma
2. globus vesicalis
3. prostatiche hypertrofie
4. gynecologische prolaps
5. anale hypotonus

> Technische onderzoeken :

- Urine

Eventuele specialistische onderzoeken :

- (uro, genyco, geriater)

> Eventuele intercurrente factoren :

- sommige geneesmiddelen
- omgevingsfactoren
- gevorderde dementie

> Therapie :

- Medicatie
- Kine
- Heelkunde

3. Na uitsluiting van behandelbare oorzaken van incontinentie en poging tot therapie toch blijvende incontinentie.  
Daarom vraag ik voor De heer/Mevr. .... de toekenning van het forfait aan de adviserend geneesheer.

Stempel en handtekening van de huisarts

Datum

Both lump sums can be granted to children, as long as they meet the conditions. In practice, (some) sickness funds impose a minimum age of 3 years.

Persons with a handicap are also entitled to the RIZIV – INAMI lump sums. The extent to which the RIZIV – INAMI lump sums can be combined with the payments by federated instances for incontinence is detailed in the section below on “Reimbursement by federated instances”.

### 3.1.5.3 Reimbursement of penile sheaths and bodyworn urinal for male incontinence

Reimbursement of penile sheaths and bodyworn urinals for male incontinence is based on the fee list of RIZIV – INAMI nomenclature Article 27. The list contains urinary incontinence material that can be used by male patients, notably condom catheters (sheaths) and the material used with it: urine bags (for day or night), fixing material and protecting film for the skin, as well as a bodyworn urinal.

- Per 3 months, a patient is entitled to:
  - 90 condom catheters
  - 20 leg bags for day use
  - 20 bags or 1 container for night use
  - 1 flacon of barrier film
- Per 6 months a patient is entitled to 1 fixing belt
- Article 27 also comprises a hospital lump sum on day basis for the use of the above materials in hospital. <sup>[34]</sup>

Reimbursement for this material can be cumulated with the “large lump sum”, but not with the “small lump sum”.



### 3.1.5.4 Reimbursement of catheters for self-catheterisation

Reimbursement of catheters for self-catheterisation is based on a list of non-implantable medical devices. The reimbursement was recently expanded. According to the new rules, a patient is entitled to a max. of 5 catheters per day, for the following indications:

- Retention bladder with an important post-mictional residue ( $\geq 100$  ml) following an acquired or congenital medullary injury
- Retention bladder with an important post-mictional residue ( $\geq 100$  ml) in case of peripheral neuropathy
- Paraplegia or paraparesis, tetraplegia or tetraparesis in case when aggravation of incontinence is avoided by the combination of parasympatholytic medication and self-catheterisation
- Urine retention in absence of separate neurologic injury: substitution bladder; bladder enlargement

When the patient is younger than 18 years, the condition of 100 ml post-mictional residue does not apply.

In case of following indications, the patient is entitled to max. 8 catheters per day:

- Retention bladder  $\leq 300$  ml
- Neurogenic bladder in children under 18 years

Only the catheters listed are reimbursed. 3 types of catheters are on the list:

- Dry catheters
- Pre-lubricated catheter
- Pre-lubricated catheter with one or more other additional functions (more advanced catheters)

The reimbursement amount per catheter and the amount at charge of the patient are listed in Table 26.

**Table 26 – Reimbursement per catheter for self-catheterisation**

	Max. reimbursement per catheter (€)	Max. amount at charge of patient per catheter (€)
Dry catheter	1	0
Pre-lubricated catheter	2.7	0
More advanced catheter	2.7	1

The reimbursement procedure is as follows:

- A specialist physician sends a reimbursement request form to the advisory physician of the sickness fund of the patient.
- The advisory physician sends back an authorisation, which is valid for a period of 1 year. The authorisation can be extended for a new period of max. 5 years (for patients entitled to reimbursement for max. 5 catheters per day) or max. 1 year (for patients entitled to reimbursement for max. 8 catheters per day).
- The physician consequently prescribes the catheters. It is the specialist physician that has to write the first prescription. Following prescriptions can be done by the treating physician (e.g. GP).
- On the basis of the authorisation and the prescription, the pharmacist delivers the catheters to the patient and the patient is directly reimbursed. <sup>[35]</sup>



### 3.2 Reimbursement/payments by federated instances – for persons with a handicap

In addition to the grants paid by RIZIV – INAMI, patients with a handicap recognised as such by the federated instances can get an additional grant or reimbursement for the expenditures on (mainly) incontinence absorbent material.

The concerned federated instances and the covered population are the following:

- “Vlaams Agentschap voor Personen met een Handicap” (VAPH): covers the Flemish speaking community, i.e. persons living in Flanders and the Dutch speaking living in the Brussels capital region
- “Agence Wallonne pour l’Intégration des Personnes Handicapées” (AWIPH) is now part of “Agence pour une Vie de Qualité” (A.V.I.Q): covers the persons living in Wallonia (except the German-speaking community)
- “Personne Handicapée Autonomie Recherchée” (PHARE) from the COCOF (‘Franse Gemeenschapscommissie’/Commission communautaire française): covers the French speaking living in Brussels Capital Region
- “Office pour une vie autodéterminée de la région germanophone” (OVA) : covers the persons from the German-speaking community.

#### 3.2.1 VAPH – Flemish community

VAPH subsidises incontinence material (absorbent and protecting material) for persons with a handicap. In the past, persons had to justify their expenses with purchase receipts, but this system was abandoned. Currently VAPH pays yearly lump sums to incontinence patients and does no longer demand for justification of expenditures. Following a cost study, the grant levels were reviewed accordingly.

The lump sums are currently differentiated according to a combination of the following factors:

- age
- type of incontinence

degree of incontinence (see Table 27 and Figure 23).

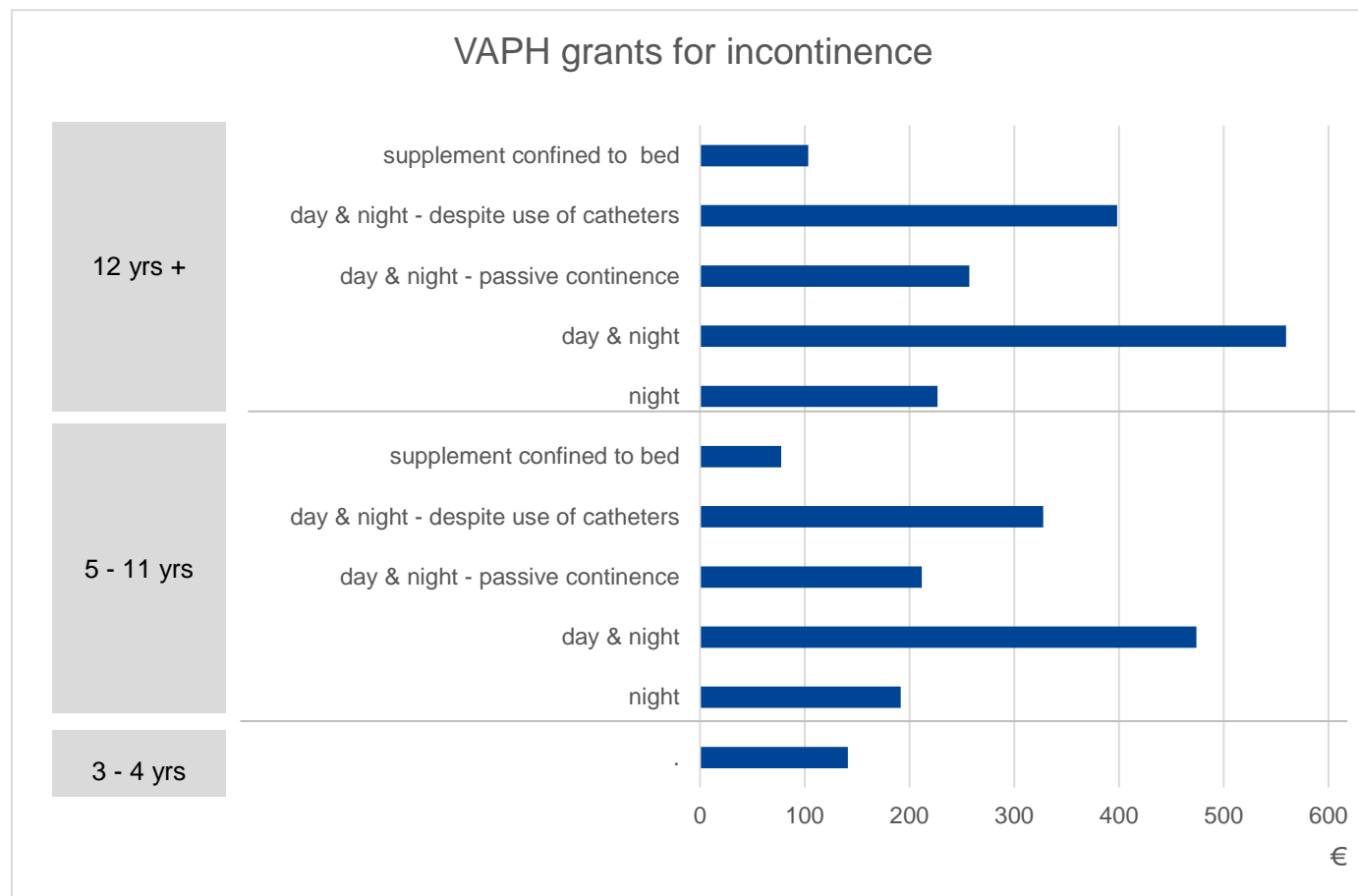
The lump sums are granted regardless of whether the patient received a RIZIV – INAMI lump sum for incontinence. However, when the VAPH grant levels were determined, the level of the RIZIV – INAMI small lump sum was taken into account. This makes for instance that the VAPH grant for patients using catheters was set relatively high, as these patients are not eligible for a RIZIV – INAMI lump sum for incontinence.

**Table 27 – VAPH lump sums for incontinence material**

Age category		VAPH yearly lump sum (€)
3 – 4 years	children with:	141.10
	<ul style="list-style-type: none"><li>• faecal incontinence or</li><li>• faecal and urinary incontinence (day and night)</li></ul>	
5 – 11 years	incontinence at night	191.50
	incontinence, day and night	473.70
	incontinence, day and night, passive continence:	211.65
	<ul style="list-style-type: none"><li>• person who does not get/recognise a signal when urine will be released but who is conditioned to go to toilet at regular times (with or without toileting assistance from another person); or</li><li>• person who gets/recognises a signal when urine will be released and uses the toilet but is imposed fixed toilet times structure because of behavioural problems or need for structure</li></ul>	
	incontinence, day and night, despite the use of catheters	327.55
	supplement for incontinent persons (5 to 11 year) permanently bedridden	77.50
12 years and older	incontinence at night	226.77
	incontinence, day and night	559.37
	incontinence, day and night, passive continence (see above)	257.01
	incontinence, day and night, despite the use of catheters	398.11
	supplement for incontinent persons (12 years and older) permanently bedridden	103.34



Figure 23 – VAPH grants for incontinence







In order to obtain the grant,

(1) a physician has to fill out a form specifically on incontinence. <sup>[36]</sup>  
According to VAPH, the objective of the form is twofold:

- to provide the necessary information about severity of the condition, material needs and impact on daily living, in order to determine the right lump sum category
- to make the patient and physician think about possible treatments. <sup>[37]</sup>; <sup>[38]</sup>

(2) in addition, the patient needs a report by a multidisciplinary team (this report is only needed once and can be used to request financial intervention for other medical aids or adjustments as well).

Such multidisciplinary team includes at least a physician, a master of psychology or pedagogy, a bachelor social work or social nursing, an expert in medical aids. These multidisciplinary teams exist as part of:

- the social services of the sickness funds (“Dienst Maatschappelijk Werk”, “Service Social”)
- Rehabilitation centres
- Consultation offices
- Centers for developmental disorders
- Student guidance centres
- Observation and treatment centres
- K-services in hospitals
- Mental health care centres (CGG-SSM)

- Centres for orientation and observation

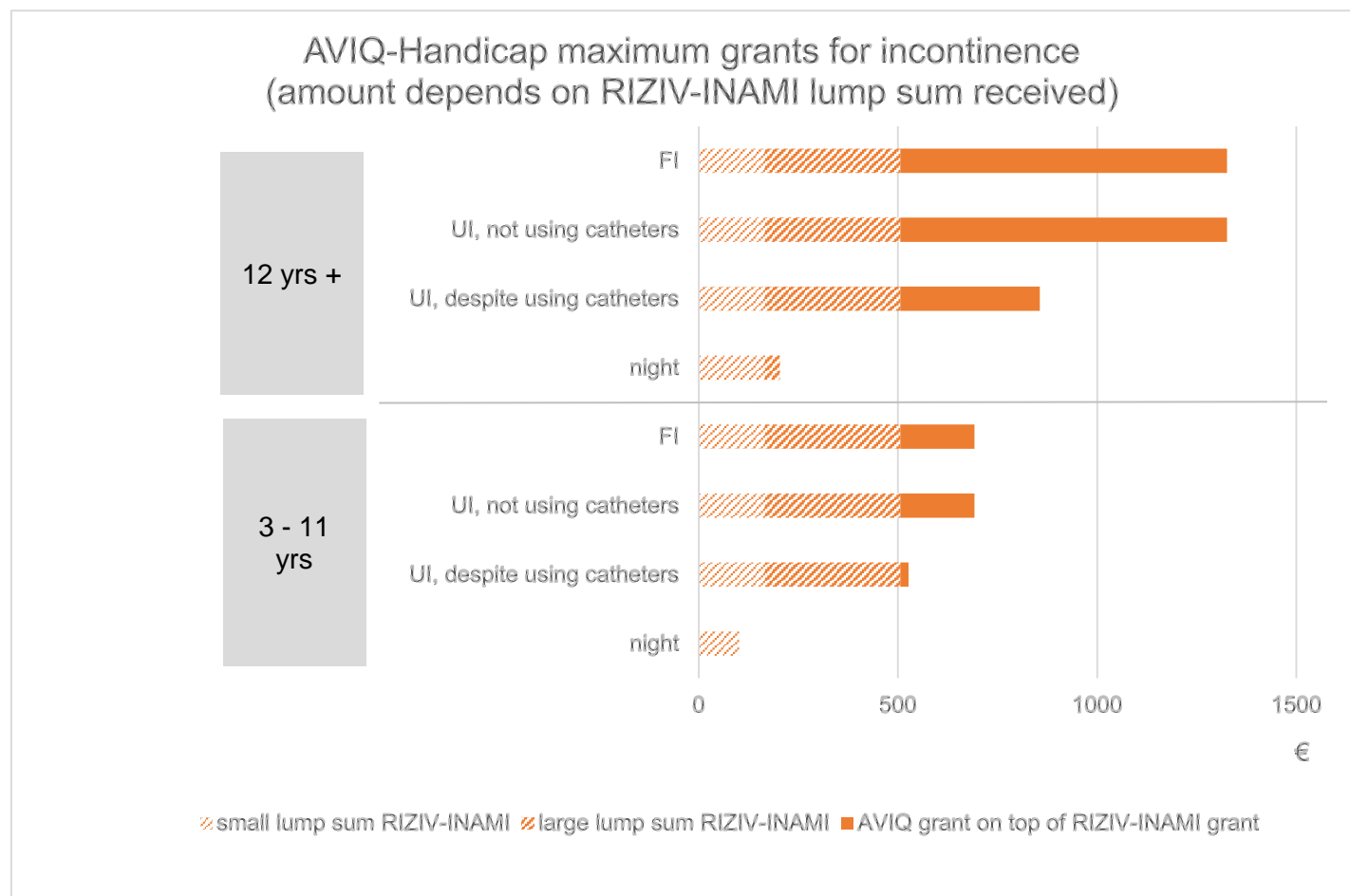
Furthermore, the “Bijzondere Bijstandsc commissie” (BBC) of the VAPH can pay an extra allowance to people who can prove that they spend more than 300€ on top of the yearly lump sum they receive from the VAPH. <sup>[39]</sup>

### 3.2.2 AWIPH – AVIQ-Handicap – French Community

In the context of “Aide matérielle à l’intégration”, AVIQ-Handicap can grant a payment to persons with incontinence, on the condition that the RIZIV – INAMI lump sum (the large or the small one, or none, depending on eligibility) has been fully exhausted. The person has to prove his/her expenditures with purchase receipts. <sup>[40]</sup>, <sup>[41]</sup>

**Table 28 – AWIPH grants for incontinence material**

Age category		Payment ceiling (€)
3-11 yrs	6-11 yrs night incontinence	102.00 + VAT
	3-11 yrs urinary incontinence and using catheters	527.00 + VAT
	3-11 yrs urinary incontinence not using catheters And/or faecal incontinence	692.00 + VAT
12+ yrs (or <12 yrs that need large size material)	Night incontinence	204.00 + VAT
	Urinary incontinence and using catheters	856.00 + VAT
	Urinary incontinence not using catheters And/or faecal incontinence	1 326.00 + VAT

**Figure 24 – AVIQ-Handicap maximum grants for incontinence**

*Note: VAT to be added on top of the mentioned amount*



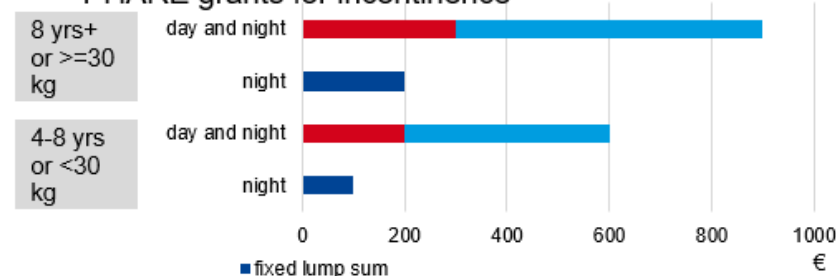
### 3.2.3 PHARE (*Personne Handicapée Autonomie Recherche*)

For the French speaking living in Brussels Capital Region, PHARE grants lump sums for incontinence material to children as well as adults. The lump sums are differentiated according to whether the incontinence only occurs at night, or also during the day. For night incontinence, a lump sum is paid and no justification of expenditures is required. For night and day incontinence, the first part of the payment (200€ for children <8; 300€ for 8+) of the maximum payment (600€ and 900€, respectively) is paid as a lump sum without justification of expenditures. For the second and third payment (each time of 200€ and 300€ respectively) the patient must prove his or her expenditures. <sup>[42]</sup>

**Table 29 – PHARE lump sums for incontinence material**

Age category		Lump sum (€)	Payment ceiling for payments upon justification of expenditures(€)
4-8 yrs (or =< 30 kg)	Night incontinence	100	
	Night and day incontinence		600
8+ yrs (or > 30 kg)	Night incontinence	200	
	Night and day incontinence		900

### PHARE grants for incontinence



### 3.2.4 German Community

Since 2000, the «Office pour une Vie Autodéterminée de la région germanophone» (OVA) no longer intervenes in incontinence materials as in their opinion the materials are covered by RIZIV – INAMI and the sickness funds. <sup>[43]</sup>

## 3.3 Financial interventions by complementary insurance of sickness funds

Many sickness funds give extra benefits to their members with incontinence, e.g. in the form of a discount on the purchase cost of incontinence material on the condition that it is bought in a healthcare shop associated to the sickness fund.

## 3.4 Other compensations

Other compensations for incontinence material exist in Belgium, such as:

- Some municipalities grant an allowance to patients with incontinence, as a compensation for the extra costs they bear for waste disposal.
- A reduced VAT of 6% applies to incontinence products.



## 4 INCONTINENCE IN BELGIUM: DATA OVERVIEW

### 4.1 Introduction

In this chapter we aim to give an overview of:

- The number of patients receiving one of the two RIZIV – INAMI lump sums for incontinence to explore the socio-demographics of the patients receiving an incontinence lump sum to examine whether the reimbursement is currently accessible to all layers of the population.
- The number of patients being in treatment for incontinence (drugs, interventions, materials), based on reimbursement data.
- The number of patients hospitalized for incontinence based on hospital administrative data.

### 4.2 Methods

#### 4.2.1 MZG-RHM 2014: hospitalisations for incontinence

##### Data source

All Belgian general, non-psychiatric hospitals are legally bound to submit twice a year a large, standardized set of data on all inpatient (hospitalisation of minimum one night) and day-care hospital stays (admission and discharge occurring the same day) and emergency room contacts to the Federal Public Service for Health, Food Chain Safety and Environment (FPS Public Health): the Minimal Hospital Data or 'Minimale Ziekenhuis Gegevens' – 'Résumé Hospitalier Minimum' (MZG – RHM).

KCE has access to the MZG – RHM within the Technical Cell (TCT) data. 'Technische Cel – Cellule Technique' (<https://tct.fgov.be>) created in the [Law of 29 April 1996](#), is a common service of the RIZIV– INAMI and FPS. Its

mission is to collect, link, validate and anonymize data relating to hospitals. The TCT links the Minimal Hospital Data (MZG – RHM) to the Sickness Funds reimbursement data in-hospital for the analysis of links between health care insurance reimbursements and treated pathologies for the elaboration of financing rules, accreditation standards and quality conditions in the context of an effective health policy. Access of the KCE to the Technical Cell data is regulated in the same law as the Technical Cell.

The MZG – RHM include a.o. administrative and medical data. Administrative data of interest for the present study were patient demographics (age, sex), type of hospital stay (inpatient or day-care) and hospital identification. The hospital identification allowed to determine the number of hospitals in which certain procedures were performed but was not used as such. Medical data of interest were principal and secondary diagnoses of the patient recorded for each of his/her hospital stay, procedures administered during the hospital stay, Major Diagnostic Category (MDC), All Patient Refined Diagnosis Group (APR-DRG) and severity of illness (SOI) of the hospital stay (see Box 1).

Hospitalisations analysed in the present study were discharged in 2014, which was the most recent available data registration year at the time of analysis. Before 2015 when Belgium turned to ICD-10-BE (International Classification of Diseases-10<sup>th</sup> Revision-Belgium), diagnoses and procedures were still coded according to the ICD-9-CM classification (International Classification of Diseases-9th Revision-Clinical Modification). APR-DRG version 28 is the version used for 2014 discharges in Belgium.



### Box 1 – APR-DRG classification system [44, 45]

Belgium imported the 3M™ **All Patient Refined-Diagnosis Related Group** (APR-DRG) grouper from the United States to assign each hospital stay to an APR-DRG. APR-DRGs were defined to be clinically coherent groups of patients expected to require similar costs. The 28th version consists of 320 APR-DRGs, grouped into 25 **Major Diagnostic Category** (MDC). Except rare specific exceptions, each APR-DRG is divided into four levels of **severity of illness** (SOI). The severity of illness is the extent of physiologic decompensation or organ system loss of function and the four possible levels are 1=minor, 2=moderate, 3=major, 4=extreme.

Patients are allocated to an APR-DRG-SOI group on the basis of their principal diagnosis, secondary diagnoses and procedures, age and sex. For some APR-DRGs other characteristics may be used (e.g. type of discharge for burns groups or weight at birth for some paediatric groups).

### Data preparation

A preliminary data transformation consisted in applying the following filters:

- Step 1: Excluding ambulatory emergency contacts for the focus was on hospitalisations.
- Step 2: Excluding complete psychiatric stays, which are registered according a simplified layout impeding the exploitation of diagnoses and procedures.
- Step 3: Excluding newborns (younger than 28 days) who stay with the mother, babies being out of scope.

Data were corrected for three hospitals. We replicated their registration data of 2013 to 2014 because the APR-DRG attribution by the 3M grouper software was flawed due to lacking pathology information and 2014 data were unexploitable.

The number of stays added or subtracted at each step are given in Table 30.

Table 30 – Data transformation process

Step	Exclusion/correction criterion	Number of stays of at least one high registered for 2014	Number of day-care stays registered for 2014	Total number of stays registered for 2014
<b>MZG – RHM 2014</b>		1 980 891	5 194 823	7 175 714
<b>Step 1</b>	Ambulatory emergency contacts		- 2 369 525	- 2 369 525
<b>Step 2</b>	Complete psychiatric stays	- 49 548	- 4 027	- 53 575
<b>Step 3</b>	Newborns who stay with the mother	- 103 203	- 63	- 103 266
<b>Step 4</b>	Corrections for 3 hospitals	+ 585	- 1176	- 591
<b>Total</b>		1 828 725	2 820 032	4 648 157

### Data selection

Hospital stays were selected if at least one (principal or secondary) diagnosis registered during the stay belonged to one of the following list of ICD-9-CM diagnosis codes:

#### Urinary incontinence:

- 307.6 ENURESIS
- 625.6 STRESS INCONTINENCE, FEMALE



- 788.3x URINARY INCONTINENCE, corresponding to the following 5 digits codes:
  - 788.30 URINARY INCONTINENCE, UNSPECIFIED
  - 788.31 URGE INCONTINENCE
  - 788.32 STRESS INCONTINENCE, MALE
  - 788.33 MIXED INCONTINENCE (MALE) (FEMALE)
  - 788.34 INCONTINENCE WITHOUT SENSORY AWARENESS
  - 788.35 POST-VOID DRIBBLING
  - 788.36 NOCTURNAL ENURESIS
  - 788.37 CONTINUOUS LEAKAGE
  - 788.38 OVERFLOW INCONTINENCE
  - 788.39 OTHER URINARY INCONTINENCE
- 788.91 FUNCTIONAL URINARY INCONTINENCE.

#### Faecal incontinence:

- 307.7 ENCOPRESIS
- 787.6x INCONTINENCE OF FECES, corresponding to the following 5 digits codes:
  - 787.60 FULL INCONTINENCE OF FECES
  - 787.61 INCOMPLETE DEFECATION
  - 787.62 FECAL SMEARING
  - 787.63 FECAL URGENCY.

#### **Methods**

Inside the primary selection, descriptive analyses were mostly run on hospital stays presenting a principal diagnosis included in the selection list.

All data transformation and analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA). <sup>[46]</sup>

For the determination of crude rate of incidence of admissions for incontinence in the Belgian population, the 'midyear' population 2014-2015 was chosen (average of populations 2014 and 2015 which are provided by Statbel, the Belgian statistical office).

#### *4.2.2 EPS 2008-2015: sample of health insurance reimbursements and population data*

##### **Data source**

The 'InterMutualist Agenstchap – Agence InterMutualiste' (IMA – AIM) is a non-profit organisation that manages and analyses information on all reimbursements related to the compulsory health insurance. These data, transmitted by the 7 Belgian sickness funds, cover all reimbursed services (consultations, pharmaceuticals, diagnostic and therapeutic procedures) and some patient socio-demographic characteristics as well as social security related data to the extent they influence reimbursement. They are called the IMA – AIM data.

The analyses for the present study are performed on a subset of the IMA – AIM data, the 'Echantillon Permanent – Permanente Steekproef' (EPS). This sample follows the reimbursed health expenditures for a group of people over the years, currently from 2002 to 2016 in release 12. This group is composed of randomly drawn members of the Sickness Funds (approximately 1 in 40 for members younger than 65, and 1 in 20 for members aged 65 and older). The purpose of the larger sample of the 65 years and older is to increase the precision for this group, which has relatively more health expenditures. The [Program Law of 27 December 2005](#) gave a permanent access via a secure connection to the KCE as well as other organisations such as the FPS Public Health or the RIZIV – INAMI, to use the data within the boundaries of their legal missions.



## Data selection

The list of selection criteria built up to extract information pertaining to urinary and faecal incontinence can be found in Appendix 3. The aim was to analyse the drugs, material and interventions reimbursed to incontinent patients and estimate the prevalence of these patients. Socio-demographics of patients benefiting from an incontinence lump sum were also examined.

The extraction was done in two steps. A first step consisted in extracting reimbursements data. Claims data were extracted using the list of selection codes for 2015, the most recent year available at the time of the present study. Data of small and large incontinence lump sums were extracted from 2008 to 2015 to look at the evolution of these lump sums through time.

In a second step, population data from 2015 were retrieved for all patients whose reimbursement records were selected in the first step.

## Data transformation

Data cleaning consisted in discarding records of a same RIZIV – INAMI billing code whose number of times registered a same day was negative or null. Such records result from data corrections (e.g. cancellation of an intervention wrongly registered).

Technical definitions of variables derived from EPS population variables are given in Appendix 4.

## Methods

As data were drawn from the EPS, it was necessary to take the sampling design into account to generalize results. The EPS sampling design is actually stratified by age and sex, which means that an individual aged 65 years or more has a probability of 1/20 to be drawn from the group of individuals with the same age and sex. Appropriate methods to calculate results based on EPS that would be generalizable to the whole population

are survey methods. These methods take the stratified sampling design into account, weighting each observation while calculating parameter estimates (e.g. mean, median, frequencies) as well as a precision of these estimates (sampling error). The weight used is the inverse of the sampling probability of each individual in his/her stratum (e.g. 20 for people aged 65 or older). For the present study, analysed variables are presented with their 95% confidence intervals (95% IC).

More information on sampling methods can be found in KCE report 2008 “Coupling of the Permanent Sample with the Hospital Data: Feasibility and data representativeness study”.<sup>[47]</sup>

The EPS allows to estimate the prevalence of patients with urinary or faecal incontinence who received a reimbursed treatment for incontinence. Each patient who received a reimbursement for a drug for urinary frequency or incontinence and/or material for urinary incontinence (implants, material covered by article 27 and/or self-catheterization) and/or received a small incontinence lump sum was considered to have urinary incontinence. Each patient who received a reimbursement for an implant for faecal incontinence or was operated for faecal incontinence was considered having faecal incontinence. Note that some patients may suffer from both indications. When patients received a large incontinence lump sum and/or were reimbursed for a complex monodisciplinary pelvic floor rehabilitation<sup>c</sup> without any further indication on the incontinence, we decided to distribute them between urinary and faecal incontinence according to the proportion found in patients with a defined incontinence.

All data transformation and analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA).<sup>[46]</sup> The estimates and %95 IC of the standard deviation of the age (Table 35) were programmed according to the Taylor series linearization method (<http://support.sas.com/kb/45/701.html>). No correction for finite population was introduced as the size of the EPS is less than 5% of the total population.

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<sup>c</sup> RIZIV – INAMI billing code 558132\_558143, see Appendix 4 for full Dutch and French description)





#### 4.2.3 RIZIV – INAMI data: numbers and amounts reimbursed for incontinence (lump sums, therapeutic interventions, implants or drugs)

##### Doc N (Document N)

Doc N are aggregates of the reimbursement data of all reimbursed services transmitted by the 7 Belgian sickness funds to the RIZIV – INAMI on a monthly basis including counts and reimbursed amounts for all RIZIV – INAMI billing codes. KCE regularly receives updates from the RIZIV – INAMI.

This data source was used to examine the most frequent surgical procedures performed for incontinence in 2016 (last available year) as well as to study the evolution of incontinence lump sums and complex monodisciplinary rehabilitation of the pelvic floor, in number and reimbursed amounts, between 2008 and 2016.

##### Farmanet – Pharmanet

The database Farmanet – Pharmanet managed by the RIZIV – INAMI contains the reimbursement information on all reimbursed pharmaceuticals delivered in public pharmacies by prescriber and patient.

We requested to the RIZIV – INAMI for an aggregated extraction of the annual number of patients, volumes expressed in (Defined Daily Doses) DDDs and reimbursed amounts concerning all 6 reimbursed drugs for urinary frequency and incontinence (ATC<sup>d</sup> chemical subgroup= G04BD) between 2008 and 2017 (last available year). These drugs were Oxybutynin, Solifenacin, Flavoxate, Fesoterodine, Tolterodine, Darifenacin.

<sup>d</sup> Anatomical Therapeutic Chemical/Defined Daily Dosis (ATC/DDD) system classification is an international standard for drug utilization studies, developed and maintained by the World Health Organisation) WHO

## 4.3 Data on diagnosis and treatment

### 4.3.1 MZG-RHM 2014: hospitalisations for incontinence

#### Data selection

Among the 4 648 157 hospital stays discharged in 2014 and filtered as explained in section 4.2.1, 51 904 stays (1.2%) presented at least one (principal or secondary) diagnosis code from the incontinence selection list of ICD-9-CM codes (see section 4.2.1). Urinary incontinence was registered in 36 554 cases (93.4%) and faecal incontinence in 15 350 cases (29.6%); 11 784 cases (22.7%) presented both types of incontinence.

When only principal diagnosis was retained for selection, 7 596 hospital stays (0.16% of the data source) were retained: 7 133 (93.9%) admissions due to urinary incontinence and 463 (6.1%) due to faecal incontinence. In 0.36% of the urinary cases (26/7 133), patients also suffered from faecal incontinence during their stay. The proportion of cases admitted for faecal incontinence also suffering from the urinary type during the stay was 9.1% (42/463).

#### Patient demographics

In 85.9% of the hospital stays, the patient admitted for incontinence was a woman (in 2 admissions (<0.1%) the sex was registered as changed). The mean age was 57.3 years (min=0.5 year, P25=47, median=57, P75=69, max=98).

As seen in Figure 25, adult women were admitted at a slightly younger age than men. Men were 58 year old on average (min=2, P25=48, median=67, P75=76, max=93) versus 57.2 years for women (min=0.5, P25=47, median=56, P75=68, max=98), whereas more boys than girls were admitted below 20 years of age (169 vs 86 or a proportion of 64.9% boys; see also

Collaborating Centre for Drug Statistics Methodology (<https://www.whocc.no/>). The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults.

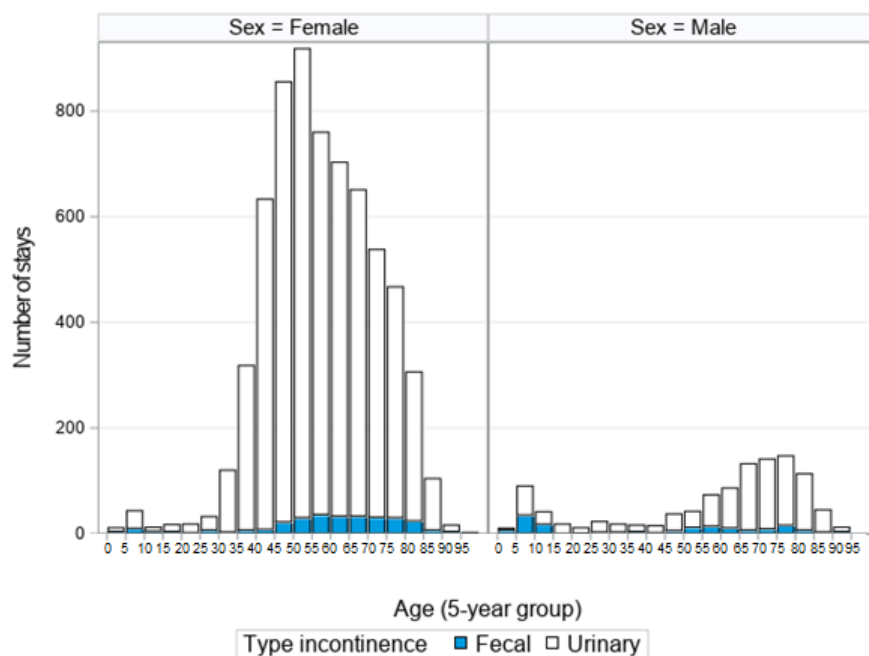




Figure 26). Women represented 87.2% of the cases admitted for urinary incontinence and represented 65% of those admitted for faecal incontinence.

Patients admitted for urinary incontinence were 57.6 years old on average (min=3, P25=34, median=57, P75=69, max=95) and 53 years old for faecal incontinence (min=6, P25=42, median=59, P75=72, max=98).

**Figure 25 – Distribution of sex and age at admission for faecal and urinary incontinence (2014)**



**Figure 26 – Distribution of sex and age at admission for faecal and urinary incontinence (2014): patients aged 0 – 20 years**

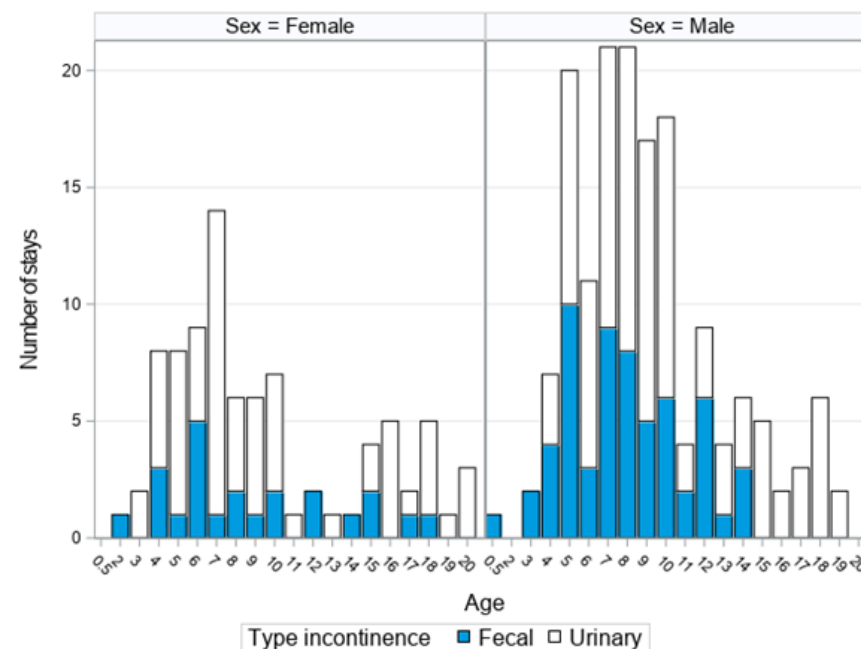




Table 31 shows the crude incidence rate of admissions for urinary and faecal incontinence in the Belgian population for the year 2014. The urinary incidence was the highest among women aged 40-79. In men for the same incontinence type, more admissions occurred in age class 70-89 years. Faecal incontinence incidence rate culminated in women aged 60-80 and in men above 90 years (note that the rate is calculated with only 4 admissions occurring in men of that age). To a lesser extent, faecal incontinence was also relatively higher in boys below the age of 10.

**Table 31 – Crude incidence rate of admissions for urinary incontinence per 100 000 population per incontinence type, sex and age (2014)**

Age (years)	Urinary incontinence			Faecal incontinence		
	Female	Male	Total	Female	Male	Total
0-9	6.4	8.8	<b>7.6</b>	2.2	6.4	<b>4.3</b>
10-19	3.3	6.5	<b>4.9</b>	1.5	2.8	<b>2.2</b>
20-29	5.9	4.3	<b>5.1</b>	1.3	0.6	<b>0.9</b>
30-39	59.2	3.7	<b>31.3</b>	1.4	1.0	<b>1.2</b>
40-49	188.2	5.5	<b>95.7</b>	3.9	1.0	<b>2.4</b>
50-59	207.3	11.6	<b>109.4</b>	8.5	3.3	<b>5.9</b>
60-69	202.1	32.9	<b>119.5</b>	10.4	3.0	<b>6.7</b>
70-79	209.3	71.0	<b>146.9</b>	13.5	6.8	<b>10.5</b>
80-89	117.6	77.6	<b>102.8</b>	9.6	5.2	<b>8.0</b>
90+	19.1	33.8	<b>22.9</b>	7.3	16.9	<b>9.8</b>
<b>Grand Total</b>	<b>109.4</b>	<b>16.6</b>	<b>63.8</b>	<b>5.3</b>	<b>3.0</b>	<b>4.1</b>

### Diagnoses

The percentage of day care admissions, parameters of age distribution and percentage of female admissions are given for each principal diagnosis in Table 32.

Most cases of urinary incontinence are due to female stress incontinence ( $5402/7133 = 75.7\%$ ). Full incontinence accounts for two thirds of faecal incontinence cases ( $306/463 = 66.1\%$ ).


**Table 32 – Number of admissions, admission type (day care or inpatient), age and sex per principal diagnosis (2014)**

Principal diagnosis	Admissions		Age							Sex	
	Number	% Day care	Mean	SD*	Min	P25	Median	P75	Max	% Female	
Urinary incontinence	7 133	51%	57.6	15.6	3	47	57	69	95	87.9%	
625.6 Stress incontinence, Female	5 402	25.6%	57	13.1	10	47	55	67	93	100%	
788.3x Urinary incontinence**	1 707	58.5%	59.8	21.3	3	50	65	75	95	47.4%	
788.30 unspecified	472	68.6%	59.6	23	3	8	50	66	76	44.1%	
788.31 urge	394	80.7%	61.9	18.7	5	24	53	65	76	49%	
788.33 mixed (female/male)	345	28.4%	61.7	14.5	8	37	51	63	73	91.3%	
788.32 stress, male	183	43.2%	69.3	9.6	15	54	60	70	76	0%	
788.39 other	137	48.9%	61.1	21.3	4	7	53	67	76	38.7%	
788.36 nocturnal enuresis	94	63.8%	24.3	26.2	4	5	8	10	26	26.6%	
788.35 post-void dribbling	35	100%	45	17.9	7	7	32	47	56	8.6%	
788.38 overflow	31	45.2%	73.6	11.6	45	54	63	76	83	29%	
788.37 continuous leakage	16	25%	71.2	12.2	45	45	66.5	73	80	18.8%	
788.91 Functional urinary incontinence	18	44.4%	68	21.7	5	57	73.5	82	89	33.3%	
307.6 Enuresis	6	33.3%	7.3	2	4	6	8	9	9	100%	
Faecal incontinence	463	33.5%	53	25.1	0.5	42	59	72	98	65.0%	
787.6x Faecal incontinence	432	54.4%	56	23	0.5	48	60	73	98	68.1	
787.60 Full incontinence	306	44.4%	57.7	23.1	4	49	63	75	98	72.9%	
787.62 Fecal smearing	49	79.6%	50.2	24.2	2	39	56	67	84	46.9%	
787.63 Fecal urgency	43	97.7%	56.6	15.5	22	48	58	70	81	60.5%	
787.61 Incomplete defecation	34	52.9%	48.3	25.3	0.5	38	53	65	84	64.7%	
307.7 Encopresis	31	3.2%	10.5	10.9	3	5	8	12	63	22.6	

\* SD: standard deviation - \*\* 788.34 Incontinence without sensory awareness was not found in the database.



At first glance, Table 32 reveals that half of the cases of urinary incontinence were treated in day-care (51%) versus only a third of the cases admitted for faecal incontinence (33.5%). Nevertheless, within each group, this percentage varied with the sex and the patient principal diagnosis.

Male urinary incontinence interventions tend to be more easily performed in a day-care setting than female incontinence. Only a quarter of the admissions for female stress incontinence (ICD-9-CM code 626.5) were done in day care. On the contrary 43% of admissions for male urinary stress incontinence were done in day care (code 788.32). All principal diagnoses of urinary incontinence considered, male patients were admitted in day care in 69.8% of the cases versus 28.2% for female patients (not shown in table). In the faecal incontinence group, admission rates were similar between both sexes (49.4% in men versus 51.8% in women).

Forty-four percent of the cases of full faecal incontinence (code 787.60), the most frequent form of faecal incontinence treated in hospital, were admitted in day care. Cases presenting a principal diagnosis of smearing (code 787.62) or urgency (code 787.63) were mostly admitted in day care. Encopresis was almost never treated in day care (3.2%).

While the principal diagnosis explains the reason for the admission, APR-DRG and MDC reflect the hospitalisation as a whole, taking into account possible comorbidities, possible adverse events having occurred during the

stay, etc. Moreover a hospitalisation may also be the opportunity to administer a treatment for a benign condition not directly related to the incontinence, possibly decreasing the probability of being admitted in day care. Therefore, it is relevant to examine the proportion of day-care stays broken down by MDC, such as presented in Table 33.

In our selection, the gynaecologic MDC 13 contains only admissions with female stress incontinence (code 626.5). For all stays in the MDC 00 group ('any remaining stay' group), a surgical procedure was performed with no relation with the principal incontinence diagnosis (in our study: 76 stays for diagnosis 787.6 Faecal incontinence, 50 stays for diagnosis 788.3 Urinary incontinence and 11 stays for diagnosis 625.6 Female stress incontinence). Contrary to other MDCs, this group represents by definition a heterogeneous population. Nevertheless its results are given in Table 33 for completeness.

MDC 19 Mental diseases and disorders contains the admissions for (diurnal) enuresis (code 307.6) and encopresis (code 307.7), which are not considered to belong to purely urinary (contrary to nocturnal enuresis) or digestive conditions. As encopresis does not share the same medical specialism and the same therapeutic modalities with the other forms of faecal incontinence, this may explain the differences in percentage of day-care admission.

**Table 33 – Number of admissions, admission type (day care or inpatient), age and sex per MDC (2014)**

Principal diagnosis	Admissions				Age					Sex
	Number	% Day care	Mean	SD*	Min	P25	Median	P75	Max	% Female
Urinary incontinence										
13 Diseases & disorders of the female reproductive system	5 391	25.5%	57	13.1	10.0	47	55	67	93	100%
11 Diseases & disorders of the kidney & urinary tract	1 675	58.9%	60.1	21.3	3.0	51	66	75	95	46.6% <sup>†</sup>
Faecal incontinence										
06 Diseases & disorders of the digestive system	356	56.4%	54.9	24.5	0.5	45	59.5	74	98	63.8%
Stays with any type of incontinence										
00 Remaining group**	137	42.3%	57.8	15.7	8	49	59	69	90	82.5%
19 Mental diseases and disorders	37	8.1%	10	10	3.0	6	8	10	63	35.1%

\* SD: standard deviation - † 2 admissions with changed sex recorded accounted for 0.1%. \*\* see Appendix 1 for APR-DRG belonging to MDC 00.

Results by APR-DRG are presented in Appendix 1.

### Procedures

Similarly as for the percentage of day-care admissions in the previous section, it is more judicious to examine the type of procedures administered during the stay per MDC or APR-DRG instead of principal diagnosis.

Obviously as seen in Appendix 1, major surgical procedures are not performed during a day care hospitalisation.

The list of the 10 most frequent procedures performed by MDC can be found in Appendix 2. In MDC 13, which corresponds to female stress incontinence (see previous section on diagnostics), code 59.79 'Other repair of urinary stress incontinence' is the most frequent of all procedures performed (71.7%).

This code represent 20% of all procedures for the other cases of urinary incontinence, preceded by 57.32 'Other cystoscopy' (31%), which is coded for a transurethral cystoscopy without urethral biopsy, not to control haemorrhage and not as a retrograde pyelogram.

Colonoscopies (18%) and endoscopic procedures such as biopsies of large or small intestines (13% and 7%, respectively), other endoscopies of small intestine (7%) and polypectomies of large intestine (4%) are the most frequent procedures performed in case of faecal incontinence.



## Key Points

- **Number of admissions and demographics**
  - There were 7 596 admissions for incontinence in 2014, from which 94% for urinary incontinence. The number of admissions for urinary and faecal incontinence were respectively 63.8 and 4.1 per 100 000 population.
  - Out of 100 000 women, there were 109 admissions for urinary incontinence and 5 for faecal incontinence while respectively 17 and 3 admissions occurring per 100 000 men for the same reasons.
  - On average, patients were 52.7 years old when admitted for urinary incontinence and 53 years old when admitted for faecal incontinence. A paediatric subgroup consisted in children below the age of 10.
- **Diagnostics**
  - Three out of four admissions for urinary incontinence were due to female stress incontinence while full incontinence accounted for two thirds of the faecal incontinence admissions. Enuresis and encopresis, two paediatric conditions, were not frequently admitted to hospital.
- **Day care setting and treatment**
  - Other repair of stress incontinence as well as cystoscopies were found among the most frequent procedures administered for urinary incontinence. In faecal incontinence, the most frequent procedures were colonoscopies and endoscopic interventions with or without biopsy.
  - Treatment of urinary incontinence was more often performed in day care in men (70%) than in women (28%). No noticeable sex difference was seen in proportion of day care treatment for faecal incontinence (49% in men versus 52% in women).

## 4.3.2 EPS 2008-2015: sample of health insurance reimbursements and population data

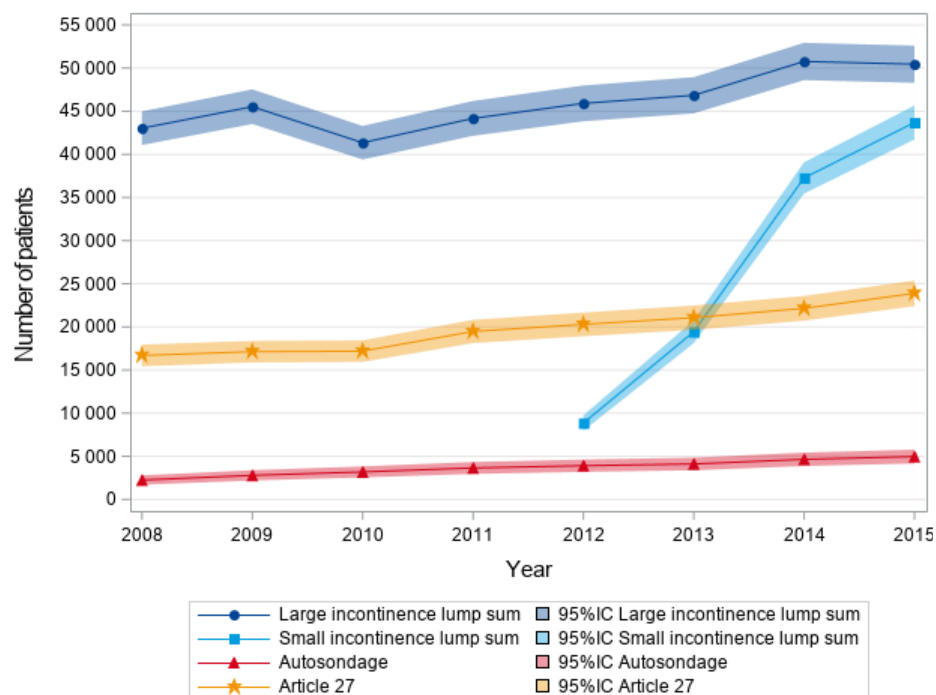
### Evolution of lump sums since 2008

Figure 27 shows that the small lump sum was complementary to already existing reimbursement systems, at least until 2015. The number of patients receiving the small lump sum introduced in 2012 rose steeply and nearly caught up with the number of patients benefiting from a large lump sum within the EPS. As seen below in Figure 29, based on Doc. N, from 2016 onwards the number of patients with a small lump sum has outgrown those with a large one.

The number of patients getting reimbursement for self-catheterisation (autosondage) material or incontinence material covered by article 27 (urine bags, catheters, penile sheaths...) did not immediately decrease after the introduction of the small lump sum.



**Figure 27 – Evolution of number of patients benefiting from a small or large incontinence lump sum, or from reimbursements for self-catheterisation material or incontinence material covered by article 27 (extrapolated from EPS 2008 – 2015)**



### Characteristics of patients receiving incontinence lump sums

The number of patients who received a lump sum for incontinence and the corresponding percentage within the EPS 2008 – 2015 are presented in Table 34.

Note that very few patients had 2 lump sums recorded within the same year (98 patients=0.46%). It is impossible to know if this resulted from registration flaws, errors in reimbursement condition application or another reason. Patients with one of each lump sum (n=72)<sup>e</sup> were categorized as having received a large one. (The remaining 26 out of 98 received twice the same lump sum in a single year.)

<sup>e</sup> In many of these cases, both small and large lump sums were recorded on the first of January.



**Table 34 – Number of patients and percentage of insured persons benefiting from incontinence lump sums per year (extrapolated from EPS 2008 – 2015)**

Incontinence lump sum	2008	2009	2010	2011	2012	2013	2014	2015
<b>Number of patients (95% IC)</b>								
Large	43 040 (41 088,44 992)	45 540 (43 532,47 548)	41 360 (39 417,43 303)	44 180 (42 160,46 200)	45 920 (43 849,47 991)	46 860 (44 761,48 959)	50 780 (48 618,52 942)	50 460 (48 306,52 614)
Small					8 860 (7 970,9 750)	19 440 (18 122,20 758)	37 280 (35 472,39 088)	43 700 (41 737,45 663)
No lump sum	10 723 920 (10 721 968,10 725 872)	10 815 700 (10 813 692,10 817 708)	10 908 020 (10 906 077,10 909 963)	10 985 540 (10 983 520,10 987 560)	11 039 280 (11 037 033,11 041 527)	11 083 820 (11 081 354,11 086 286)	11 114 560 (11 111 767,11 117 353)	11 162 120 (11 159 234,11 165 006)
<b>TOTAL (Belgium)</b>	<b>10 766 960</b>	<b>10 861 240</b>	<b>10 949 380</b>	<b>11 029 720</b>	<b>11 094 060</b>	<b>11 150 120</b>	<b>11 202 620</b>	<b>11 256 280</b>
<b>Percentage insured persons with incontinence lump sums % (95% IC)</b>								
Large	0.40 (0.38,0.42)	0.42 (0.40,0.44)	0.38 (0.36,0.40)	0.40 (0.38,0.42)	0.41 (0.40,0.43)	0.42 (0.40,0.44)	0.45 (0.43,0.47)	0.45 (0.43,0.47)
Small					0.08 (0.07,0.09)	0.17 (0.16,0.19)	0.33 (0.32,0.35)	0.39 (0.37,0.41)
No lump sum	99.60 (99.58,99.62)	99.58 (99.56,99.60)	99.62 (99.60,99.64)	99.60 (99.58,99.62)	99.51 (99.49,99.53)	99.41 (99.38,99.43)	99.21 (99.19,99.24)	99.16 (99.14,99.19)
<b>TOTAL (Belgium)</b>	<b>100.00</b>	<b>100.00</b>	<b>100.00</b>	<b>100.00</b>	<b>100.00</b>	<b>100.00</b>	<b>100.00</b>	<b>100.00</b>

Except for the few flaws mentioned above, the number of patients corresponds to the number of lump sums reimbursed drawn from the RIZIV – INAMI Document N. One of the added values of the detailed EPS data compared to the exhaustive but aggregated Document N data is the availability of patient demographics (Table 35) and socio-economic and health-related characteristics (Table 37).




**Table 35 – Demographics of patients benefiting from an incontinence lump sum (extrapolated from EPS 2015)**

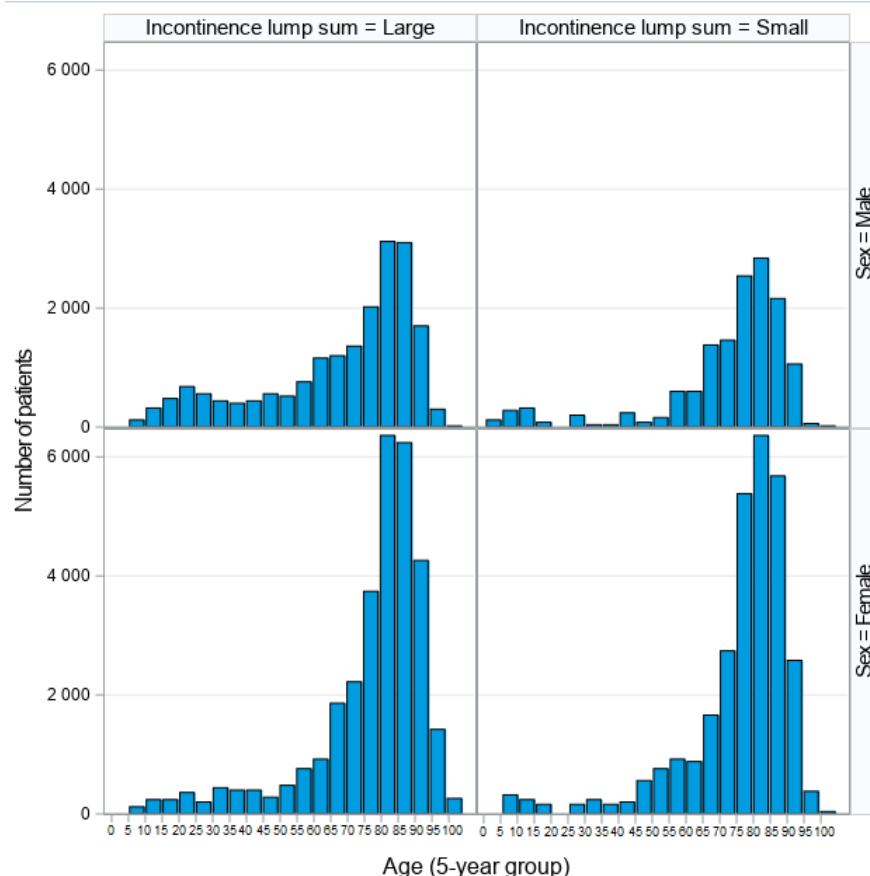
Incontinence lump sum	Age in years (95% CI)						Sex (95% CI)	
	Mean	SD	Min	P25	Median	P75	Max	% Female
Large	73.4 (72.3,74.4)	20.34 (18.13,22.54)	5	66.4 (64.5,68.3)	80.0 (79.4,80.7)	86.5 (86.0,87.0)	105	61.8 (59.7-64.0)
Small	74.4 (73.4,75.4)	17.50 (14.60,20.41)	3	69.8 (68.6,71.0)	78.6 (78.0,79.2)	84.6 (84.1,85.0)	101	67.3 (65.2-69.5)
No lump sum	41.1 (41.1,41.2)	23.67 (23.58,23.76)	0 (0,<0.01)	21.3 (21.2,21.4)	40.7 (40.6,40.9)	58.8 (58.7,58.9)	112	50.7 (50.6-50.9)
<b>TOTAL (Belgium)</b>	<b>41.4</b> <b>(41.3,41.5)</b>	<b>23.82</b> <b>(23.74,23.91)</b>	<b>0</b>	<b>21.4</b> <b>(21.3,21.6)</b>	<b>41.0</b> <b>(40.9,41.2)</b>	<b>59.2</b> <b>(59.1,59.3)</b>	<b>112</b>	<b>50.9</b> <b>(50.7-51.0)</b>

On average, patient age did not differ between incontinence lump sum categories (the 95% confidence intervals are overlapping). Patients receiving a lump sum were globally older than the general EPS population (Table 35).

When age histograms are presented by lump sum and sex (Figure 28), the shape of the distributions reveal that the paediatric proportion of the population receiving a large lump sum is larger in males compared to females. The same difference between sexes was observed in the population hospitalized for incontinence in section 4.3.1 (Figure 25 and Figure 26): more boys were hospitalized than girls.



**Figure 28 – Age distribution of patients receiving an incontinence lump sum, per lump sum and sex (extrapolated from EPS 2015)\***



\*Note: since frequency of patients is broken down by sex and age, which corresponds to the EPS sampling design, no confidence intervals are needed.

**Table 36 – Percentage and number of patients by geographic location benefiting from an incontinence lump sum (extrapolated from EPS 2015)**

Incontinence lump sum	Flanders	Brussels	Wallonia	Abroad	Missing value
Large	61.08 (58.97,63.19)	5.79 (4.79,6.79)	32.86 (30.82,34.89)	0.08 (0.00,0.19)	0.20 (0.02,0.37)
Small	86.32 (84.69,87.95)	1.19 (0.69,1.69)	12.45 (10.88,14.02)	- (0.00,0.14)	0.05 (0.00,0.14)
No lump sum	57.10 (56.93,57.28)	9.83 (9.72,9.93)	31.26 (31.10,31.43)	1.61 (1.56,1.65)	0.20 (0.18,0.22)
<b>TOTAL (Belgium)</b>	<b>57.23 (57.06,57.41)</b>	<b>9.77 (9.67,9.88)</b>	<b>31.20 (31.04,31.36)</b>	<b>1.59 (1.55,1.64)</b>	<b>0.20 (0.18,0.22)</b>

Table 36 presents the number of patients by geographic location per incontinence lump sum, knowing that the percentage of each of the three regions are very slightly underestimated due to the presence of patients living abroad and missing values, except for small lump sums which only concerns Belgian residents.

Almost 9 patients out of 10 receiving a small lump sums lived in Flanders (86.32% (95% IC: 84.69, 87.95)). The underuse of small lump sum observed in the two other regions was particularly visible in Brussels where only 1.19% (IC 95%: 0.69, 1.69) of the beneficiaries of a small lump sum resided. Walloon residents represented 12.45% (95% IC: 10.88, 14.02) of these beneficiaries. The geographic distribution of beneficiaries of a large lump sum was somehow better balanced with 61.08% (95% IC: 58.97, 63.19) of the patients living in Flanders and 32.86% (95% IC: 30.82, 34.89) in Wallonia. Nevertheless, patients living in Brussels were also underrepresented with 5.79% (95% IC: 4.76, 6.79) of the large lump sum beneficiaries.



A short exploration of the data learned that the proportion of beneficiaries of small lump sums living in Flanders who were administered nursing home care was not exceptionally higher than expected. This observation invalidated the assumption that regional differences were due to home care nurses seeing to inform patients about the small incontinence lump sum and/or general practitioners about their patients need and the existence of the small incontinence lump sum.

Some areas with a higher proportion of socio-economically underprivileged population with a restricted health literacy may face a lower access to the incontinence small lump sum, but this is probably not the sole explanation of such a difference. Exploration of pockets of underuse (e.g. in large cities or isolated rural areas) was considered beyond the scope of the present project.

**Table 37 – Socio-economic and health-related characteristics of patients benefiting from an incontinence lump sum (extrapolated from EPS 2015)**

	Entitlement to B or C nursing care lump sum (95% CI)	Home care (95% CI)	Entitlement to preferential reimbursement (95% CI)	Handicap recognition (95% CI)	Chronic illness status (95% CI)	Entitlement to physiotherapy major coverage (E list) (95% CI)	Global Medical File* (95% CI)
Incontinence lump sum	% YES	% YES	% YES	% YES	% YES	%YES	%YES
Large	91.3 (90.1,92.6)	89.1 (87.6,90.7)	66.6 (64.7,68.6)	12.7 (11.0,14.4)	85.4 (83.9,86.9)	29.9 (27.8,31.9)	55.3 (53.1,57.4)
Small	5.4 (4.4,6.3)	60.4 (58.1,62.6)	56.5 (54.2,58.7)	4.0 (3.0,5.1)	59.5 (57.2,61.7)	8.9 (7.6,10.2)	71.1 (69.0,73.1)
No lump sum	0.1 (0.1,0.2)	6.2 (6.1,6.2)	17.6 (17.4,17.7)	0.72 (0.69,0.74)	9.1 (9.0,9.2)	1.0 (1.0,1.0)	43.1 (42.9,43.2)
<b>TOTAL (Belgium)</b>	<b>0.57 (0.55,0.59)</b>	<b>6.7 (6.7,6.8)</b>	<b>17.9 (17.8,18.1)</b>	<b>0.78 (0.75,0.81)</b>	<b>9.7 (9.6,9.7)</b>	<b>1.16 (1.13,1.20)</b>	<b>43.2 (43.0,43.4)</b>

\*Patients are considered having a global medical file only if they had at least one of the codes listed in Appendix 4 billed during the year. This definition is stricter than the one used in the IMA – AIM Atlas (<http://www.aim-ima.be/Atlas>) that combines billing codes and contacts with general practitioners. In 2015, the percentage of the population with a global medical file calculated in the IMA – AIM Atlas reached 63.2%.



As expected, almost all of the patients receiving a large incontinence lump sum in 2015 (91.3%) were entitled to a **B or C nursing care lump** that same year as it is one of the conditions to get access to the large incontinence lump sum. An alternative access track to the lump sum has been created for patients who do not call upon the services of a home nurse. These patients can obtain the large lump sum on the basis of a written statement by a physician; this explains that 9% of the patients did not have a B or C nursing care lump sum.

As 60% of the patients who get a small lump sum also get home care, it is well possible that home care nurses play an important role in communicating about the small lump sum to their patients.

The proportion of patients entitled to a **preferential reimbursement** were somewhat higher in those benefiting from a large rather than a small incontinence lump sum (66.6% vs 56.5%). The entitlement to a preferential reimbursement is indeed an indication of a vulnerable population, whether due to a particular situation (orphans, people with disability, ....) or a very low income.

Logically, compared to beneficiaries of the small incontinence lump sums, beneficiaries of the large lump sum were more numerous to have a handicap recognized (12.7% vs 4%), a chronic illness recognized (85.4% vs 59.5%) and to be entitled to a major coverage of their physiotherapy interventions (29.9% vs 8.9%) due to a pathology belonging to list E (e.g. Parkinson disease, Guillain Barré syndrome, spina bifida, burns). Considering that the small incontinence lump sum must be granted by a general practitioner, it also seems coherent that an even larger proportion of patients with such a lump sum had a global medical file, opened or extended during the same year which indicates a better follow-up of their health in general (71.1% vs 55.3% for those with a large lump sum and vs 43.1% of the remaining population, see note under Table 37 for the apparently low global percentage of patients with a global medical file).

### Estimation of the prevalence of patients treated for incontinence

In 2015, we estimated that a total of 208 120 patients (95% IC: 203 652, 212 588) patients were reimbursed for some treatment for incontinence, whether urinary or faecal or received an incontinence lump sums. This represents 1.85% (95% IC: 1.81, 1.89) of the Belgian population covered by the national health insurance.

Table 38 presents the different subgroups of these patients according to the type of reimbursements they received.

**Table 38 – Number and percentage of patients reimbursed for incontinence in 2015 (extrapolated from EPS 2015)**

Incontinence sum	lump	Number of patients (95% IC)	Percentage of Belgian insured population (95% IC)
Urinary Incontinence		161 940 (157 942,165 938)	1.44 (1.40,1.47)
Faecal incontinence		640 (368,912)	0.01 (0.00,0.01)
Urinary and faecal incontinences		980 (669,1 291)	0.01 (0.01,0.01)
Unspecified incontinence		44 560 (42 353,46 447)	0.40 (0.38,0.41)
No incontinence		11 048 160 (11 043 692,11 052 628)	98.15 (98.11,98.19)
<b>TOTAL (Belgium)</b>		<b>11 256 280</b>	<b>100.00</b>



We allotted the category “Unspecified incontinence” proportionally to other categories, urinary incontinence accounting for  $161\,940 / (161\,940 + 640 + 980) = 99.010\%$ , faecal incontinence for  $0.391\%$  and the group with both incontinenes for  $0.599\%$ . After allotting, the estimated number of patients treated (and reimbursed) for incontinence reached 206 059 patients for urinary incontinence, 814 for faecal continence and 1 247 patients suffering for urinary and faecal incontinenes; representing in total 207 306 patients with urinary incontinence and 2 061 patients with faecal incontinence.

### Key Points

- **Characteristics of patients receiving incontinence lump sums**
  - Patients receiving a lump sum were older than the general population (respectively for patients receiving a large lump sum and a small lump sum, mean ages were 73 years and 74 years and medians were 80 and 79 years). Sixty-two percent of the beneficiaries of a large lump sum were female against 67% of the beneficiaries of a small lump sum.
  - 91% of the patients receiving a large lump sum were entitled to a B or C nursing care lump sum, based on the Katz-scale evaluation by a home care nurse. This implies that 9% of patients receiving the large lump sum get access to it via a statement by a physician.
  - 5% of patients receiving a small lump sum were entitled to a B or C nursing care lump sum. This means that they were heavy care dependent but did not have a severe score on incontinence on the Katz-scale evaluation.
  - 60% of the patients receiving a small lump sum also get home care, suggesting that home care nurses may play an important role in communicating about the small lump sum to their patients.

- **13% of patients receiving a large lump sum are recognised as having a handicap. This is 4% for patients receiving a small lump sum.**
- **85% of patients receiving a large lump sum are recognised for having a chronic illness vs 60% of patients receiving a small lump sum. Respectively 30% vs 10% are entitled to a physiotherapy (E list) major coverage (30% vs 10%).**
- **67% of patients receiving a large lump sum are entitled to a preferential reimbursement vs 57% of patients receiving a small lump sum.**
- **Conversely, amongst those receiving a large lump sum there were less patients having a global medical file (GMF) opened or renewed (55%) compared to those receiving a small lump sum (71%), which seems related to the fact that the small incontinence lump sum must be granted by a general practitioner.**
- **Almost 9 patients out of 10 receiving a small lump sum lived in Flanders (86.5%) against 12.5% in Wallonia and only 1% in Brussels where the small lump sum seems therefore particularly underused. The geographic distribution of beneficiaries of a large lump sum was somehow better balanced: respectively 61%, 33% and (again only) 6% of patients living in Flanders, Wallonia and Brussels, respectively.**
- **Number of patients receiving a reimbursed treatment for incontinence**
  - **In 2015, the number of patients receiving a reimbursed treatment for urinary incontinence was estimated at around 207 300 patients (1842 per 100 000 population) whereas the number of patients receiving a reimbursed treatment for faecal incontinence averaged 2 050 patients (18 per 100 000 population). About 1 250 patients (11 per 100 000 population) belonged to both groups.**



#### 4.3.3 RIZIV – INAMI data: numbers and amounts reimbursed for incontinence (lump sums, therapeutic interventions, implants or drugs)

##### Evolution of incontinence lump sums

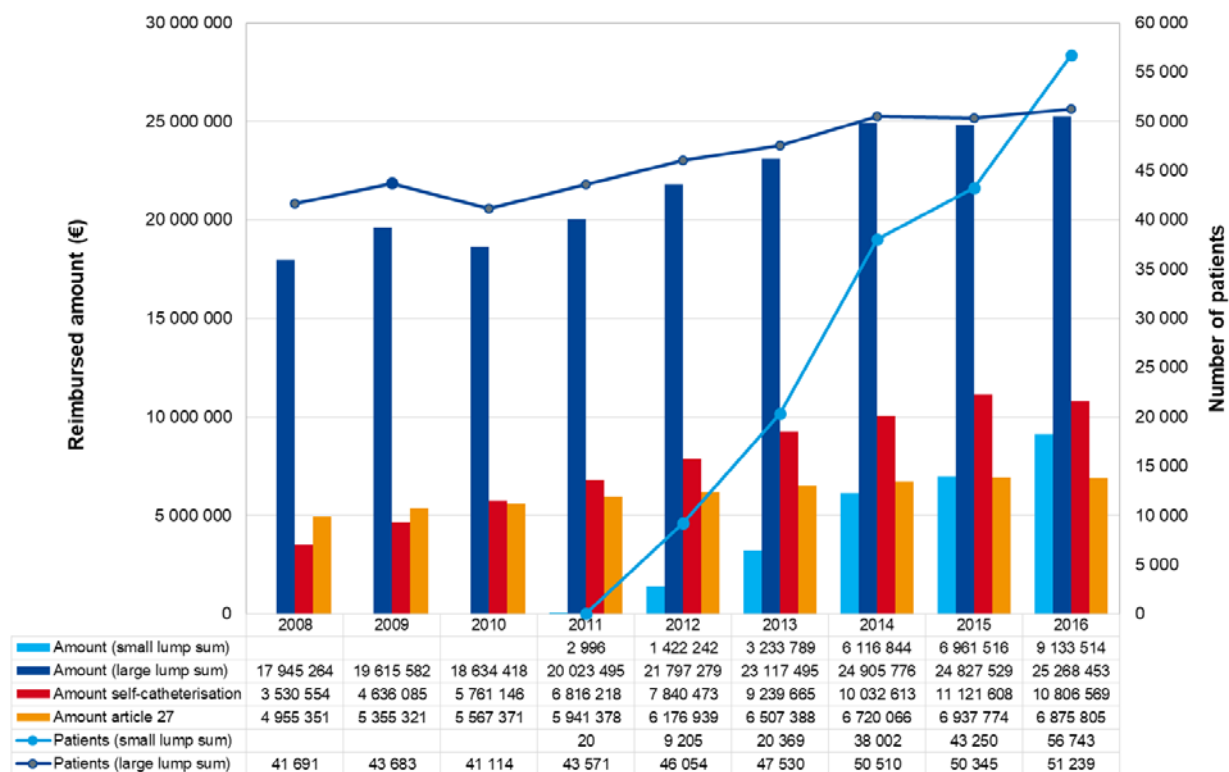
Figure 29 shows the 2008-2016 evolution in number<sup>f</sup> and amounts of incontinence lump sums as well as reimbursements for article 27 material and for self-catheterisation (monthly lump sum until 1 November 2017). As seen in section 3.1, the small lump sum cannot be granted to patients who get a reimbursement for material covered by article 27 (sheaths, urinals...) or self-catheterisation. The large lump sum and the self-catheterisation lump sum cannot be granted concurrently but the large lump sum and article 27 reimbursements can.

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<sup>f</sup> The annual number of incontinence lump sums is equivalent to the annual number of patients receiving them (except negligible data flaws covered in 4.3.2), contrary to the number of self-catheterization lump sums or article 27 material codes.



Figure 29 – Reimbursements for incontinence lump sums, for material of article 27 and self-catheterisation, and number of patients receiving an incontinence lump sums (2008-2016)



First, patients receiving a large lump sum were for the first time outnumbered by those receiving a small lump sums in 2016. The number of patients receiving a large lump sums seems to stabilize after 2014. The same phenomenon was observed in the reimbursements for self-catheterisation material and incontinence material covered by article 27 in 2016 (the RIZIV – INAMI Doc. N database does not allow to calculate the exact number of patients). The trend seems to start from 2016 onwards but have to be confirmed with data for 2017-2018.

Second, the actual numbers of incontinence lump sums confirm the robustness of the estimations based on the EPS in previous section 4.3.2, as they always are located inside limits of the 95% confidence intervals as calculated for 2008-2015 in Table 34 (except for the small number of patients (20) who received a small lump sum soon after the creation of this lump sum end November, who were too few to be selected by the sampling). Table 39 presents the actual percentage of covered by the national health insurance who received an incontinence lump sum between 2008 and 2016.

**Table 39 – Actual percentage of insured population benefiting from incontinence lump sums per year (Doc N 2008-2016 and number of individuals based on EPS 2015-2016)**

[illegible]





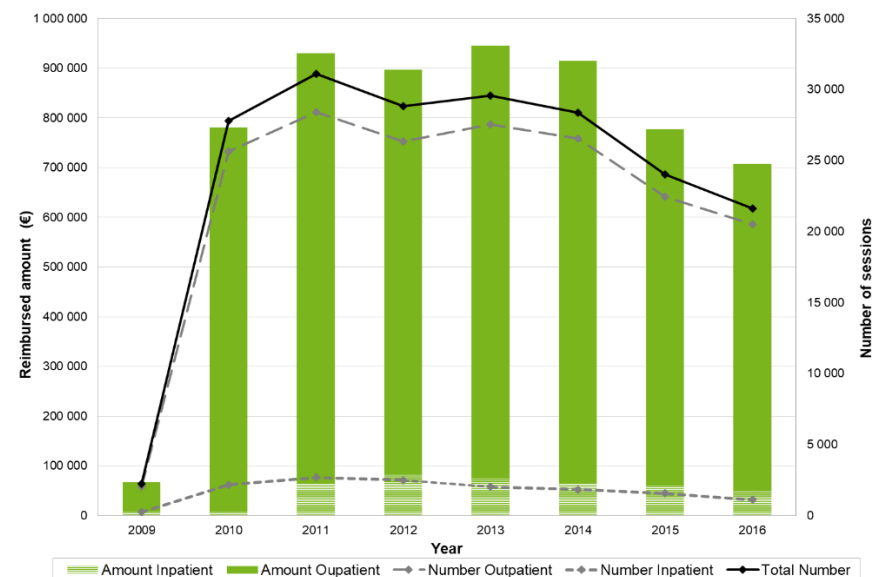
### Reimbursements of physiotherapy

Unfortunately, fee codes for first line physiotherapy are not specific enough to describe the use of physiotherapy in first line for incontinence in Belgium. Legally physicians have to mention the indication on the prescription of physiotherapy, but this information is not captured in the national databases.

In the second line, the only physiotherapy treatment that can be identified in the RIZIV – INAMI reimbursements is the ‘complex monodisciplinary rehabilitation of the pelvic floor for acute urinary or faecal incontinence’, prescribed by the treating medical specialist (outpatient code 558132 and inpatient code 558143). The prescription is not necessary when the rehabilitation is performed by a physician specialized in urologic rehabilitation. Sixty sessions may be billed during a maximum period of 6 months. Other physiotherapy delivered for incontinence treatment in second line cannot be identified as it cannot be distinguished from physiotherapy for other pathologies.

Figure 30 presents the number of sessions reimbursed and their reimbursed amounts since the creation of the codes on the 1st December 2009. The billing of those codes seems to decrease from 2014 onwards. In 2016, there were 21 628 (in- or outpatient) sessions reimbursed totalling € 707 704 whereas the number of sessions in 2013 amounted to 29 581 for a total amount reimbursed of € 945 084.

**Figure 30 – Amounts reimbursed and number of sessions of complex monodisciplinary rehabilitation of the pelvic floor (2009-2016)**



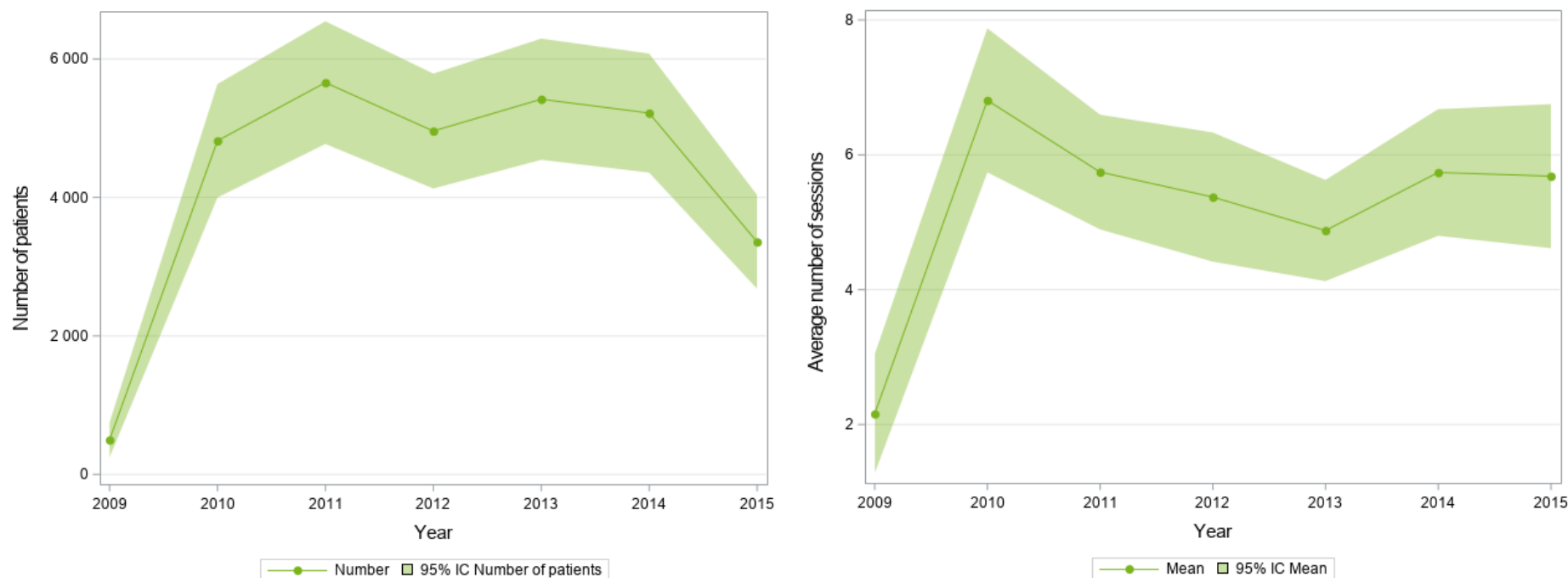
To determine whether the diminishing trend is due to a decrease in the number of patients or to a reduction in the average number of sessions per patient, the number of patients receiving complex monodisciplinary rehabilitation of the pelvic floor was extrapolated based on EPS data 2009-2015. Even if the 95% confidence intervals are large due to the low number of patients found in the EPS,



Figure 31 clearly shows that the number of beneficiaries of complex monodisciplinary rehabilitation of the pelvic floor tended to decrease since 2013. The average number of sessions per patient oscillated between 5 and 6 over the years while the median followed a similar curve as that of the

mean, oscillating between 3 and 4 sessions (chart not shown). The maximum number of sessions observed was 46 (in 2010). This low average number is in discrepancy with the maximum number of 60 sessions that is allowed.

**Figure 31 – Complex monodisciplinary rehabilitation of the pelvic floor: number of patients (left chart) and average number of sessions per patient (right chart) (extrapolated from EPS 2009-2015)**



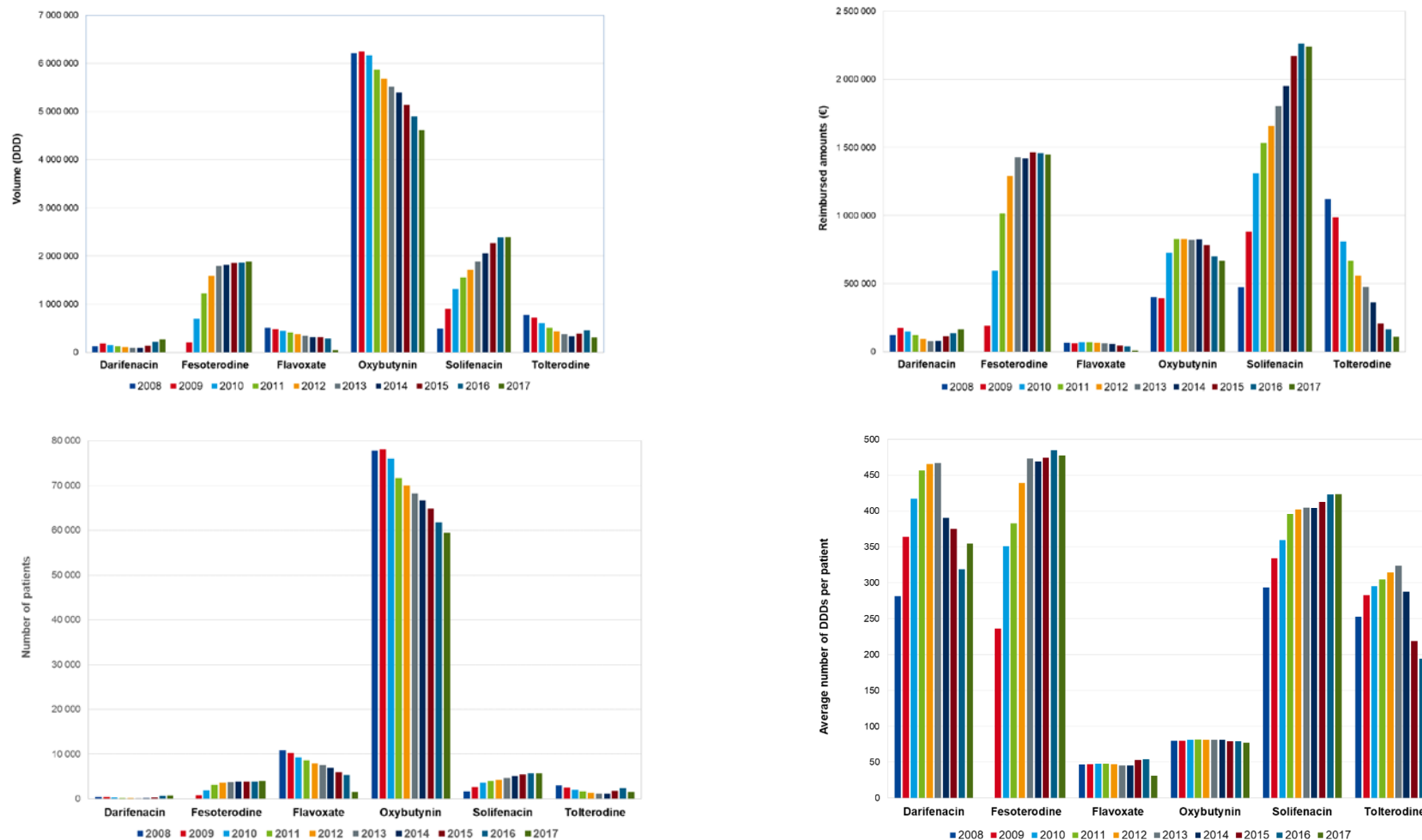


### Reimbursements of medication for urinary incontinence

The volume of Defined Daily Doses (DDDs) represented by the chemical subgroup of urinary frequency and incontinence drugs (ATC = G04BD) – at least those reimbursed (see section 3.X reimbursements for incontinence) - increased from 8 million DDDs in 2008 to remained stable around 10 million DDDs from 2013 onwards. Similarly, the reimbursements for these drugs rose from €2.2 million in 2008 to be around €4.7 million from 2013 onwards. Conversely, the number of patients concerned was 91 400 in 2008 decreasing to 71 600 in 2017. Detailed data are given in Appendix 5 and Figure 32.



**Figure 32 – Urinary frequency and incontinence drugs: Volume (DDD), reimbursements (€), number of patients and average number of annual DDDs per patient (RIZIV – INAMI Doc. N 2008 – 2017))**





Despite the decreasing number of patients over the period, oxybutynin was by far taken by the largest number of patients in 2017 and represented the first product in volume delivered: 59 464 patients for 4 613 58 DDDs (48.5%). Nevertheless, this product only represented €667 143 or 14.4% of the 2017 budget dedicated to the whole chemical subgroup of urinary frequency and incontinence drugs. Almost half of the budget (48.3%) went to solifenacin that took a skyrocketing share of the reimbursements between 2008 and 2017 (€2 239 720 for only 5 646 patients). Solifenacin is not only an expensive drug but the annual number of DDDs by patient is high; patients took 424 DDDs of solifenacin on average in that year (>1 dose a day) versus 78 DDDs for oxybutynin. The daily dose is one tablet a day of 5 or 10 mg tablets for solifenacin and 10 to 15 mg in 2 of 3 doses for oxybutynin but the WHO Collaborating Centre for Drug Statistics Methodology considers that for both products, one DDD equals 5 mg.

Since 2017, conditions to reimburse oxybutynin have been loosened compared to other reimbursed drugs of the group such as solifenacin, which are only reimbursed in neurogenic bladder due to cerebral lesion or a superior spinal cord injury and after therapy with oxybutynin failed. They are therefore prescribed as long-term therapy while oxybutynin may be prescribed temporarily. Oxybutynin can now be prescribed for UI in adults by any medical doctor on a regular prescription. Note that the Belgian distributor of Flavoxate stopped its marketing in 2014 and supplies lasted until 2017.

#### Reimbursements of interventions for urinary and faecal incontinences

A total amount of € 4 806 536 was reimbursed for the interventions performed in 2016 for urinary or faecal incontinence. As seen on Table 40, urinary incontinence accounted for €3 851 958 and faecal incontinence for €954 577.

**Table 40 – Number of interventions and reimbursements for incontinence (Doc N 2016)\***

RIZIV – INAMI codes		Label	Number	Reimbursed amount (€)
<b>Urinary incontinence</b>				
432751_432762	Transvaginal placement of synthetic sub-urethral sling for urine incontinence		6 465	2 220 792
262150_262161	Endoscopic treatment of urinary incontinence		2 089	377 007
431852_431863	Anterior colporrhaphy <u>or</u> posterior colpoperineorrhaphy with suturing of levator muscles		1 150	245 626
431491_431502	Amputation of cervix with vaginal repair surgery (Stumndorf procedure)		1 045	251 265
262555_262566	Review of the functioning of the neurostimulator for sacral nerve stimulation		940	30 255
431896_431900	Anterior colporrhaphy <u>and</u> posterior colpoperineorrhaphy with suturing of levator muscles		680	231 986
431373_431384	Surgical intervention for genitourinary prolapse with abdominal and vaginal approaches during a same intervention		483	139 973
262474_262485	Placement of a definitive epidural electrode for sacral nerve stimulation, including review of the functioning		214	22 403



262135_262146	Placement of an artificial uretral sphincter	184	86 758
432073_432084	Surgical intervention for urinary incontinence by one approach, either abdominal or vaginal	171	59 055
431911_431922	Intervention for uterine prolapse by vaginal approach with supravaginal cervix amputation, cardinal ligaments suture to the uterine isthmus and anterior colporrhaphy, including possible posterior colpoperineorrhaphy (Manchester Fothergill operation or variant)	148	65 345
432095_432106	Surgical intervention for urinary incontinence by abdominal and vaginal approaches (Steckel and derivatives)	134	58 473
262496_262500	Placement of a temporary epidural electrode connected to an external stimulator as trial therapy for sacral nerve stimulation, including control of the functioning	99	10 308
262511_262522	Removal of the temporary extension used for trial therapy of sacral nerve stimulation	74	3 814
260455_260466	Female bladder neck repair for urinary incontinence	58	20 307
262533_262544	Replacement of a definitive electrode for sacral nerve stimulation	53	4 958
260610_260621	Surgical repair of a vesicovaginal fistula	52	23 634
<b>TOTAL</b>			<b>3 851 958</b>
<b>Faecal incontinence</b>			
244156_244160	Surgical repair of rectal prolapse by abdomino-perineal or abdominal approach according to Loygues	1 824	877 768
244193_244204	Resection of rectal prolapse	108	26 017
244171_244182	Suture of Levator muscles for rectal prolapse	62	22 655
244392_244403	Repair of anal sphincter for incontinence (old tear or revision) unrelated to delivery	59	26 844
244215_244226	Anal cerclage for rectal prolapse	14	1 294
<b>TOTAL</b>			<b>954 577</b>

\* For original Dutch and French version see Appendix 3



### Reimbursements of implants for urinary and faecal incontinences

Appendix 6 shows the number and amounts reimbursed per implant for urinary and faecal incontinence. The total reimbursements in 2016 amounted to € 7 464 224, respectively € 5 789 723 and € 1 674 501 for urinary and faecal incontinence. To no surprise, the most frequent type of material used for urinary incontinence were the sets of (re)placements of suprapubic catheters (n=15 910 sets), followed by the synthetic sub-urethral slings (n=6 402 slings). For faecal incontinence, the most frequently used material was the one requested by the surgical repair of rectal prolapse according to Loygues, by endoscopy or open approach (n=1 746 kits). The examination of alternative coding practice explaining possible discrepancies between the number of procedures and the number of required sets related to the procedures was considered out of scope of the present project.

### Key Points

- **Incontinence lump sums**
  - In 2016, there were 51 239 patients receiving a total amount of € 25.3 million as large incontinence lump sum against 56 743 patients totalling € 9.1 million for the small incontinence lump sums.
- **Physiotherapy**
  - Medical fees for physiotherapy are not specific and do not allow the description of the use of physiotherapy for incontinence in Belgium.
  - Only complex monodisciplinary rehabilitation of the pelvic floor for acute urinary or faecal incontinence, prescribed by the treating medical specialist, is billed separately. In 2016, 21 600 such rehabilitation sessions were reimbursed for € 707 700 against 29 600 sessions for € 945 000 in 2013. This decrease was due to the diminishing number of beneficiaries over recent years. The annual average number of sessions per patient was estimated at 5 to 6 per year.
- **Medication**
  - Oxybutinin is by far the most frequently used drug for urinary frequency and incontinence. In 2017, more than 4.6 million DDDs were delivered to almost 60 000 patients, representing 78 annual days of treatment per patient, for an amount of approximately € 670 000.
  - Amongst the other anticholinergica, reimbursed only in neurogenic bladder due to cerebral lesion or a superior spinal cord injury, solifenacin gained ground over the years and was delivered to 5 650 patients in 2016, representing a volume of 2.4 million DDDs (424 annual days of treatment per patient) for an amount of approximately € 2.2 million.



- Interventions

- In 2016, an amount of €3.9 million was reimbursed for the interventions performed for urinary incontinence and almost € 1 million for the interventions for faecal incontinence, representing in total €4.8 million. The most frequent interventions for urinary incontinence were the placements of synthetic sub-urethral slings (n=6 500) followed by the endoscopic treatments (n=2 100). For faecal incontinence, the Loygues surgical repair of rectal prolapse was by far the most frequent intervention performed in 2016 (n=1 800).

- Implants

- Reimbursements for implants represented € 7.5 million, respectively €5.8 million and €1.7 million for urinary and faecal incontinence; the material mirroring the most frequent procedures.

#### 4.4 Estimating the number of people with untreated incontinence

In 2015, we estimated that 208 120 patients received an incontinence lump sum or were reimbursed for some form of treatment of incontinence. Among them, 93 595 people were entitled an incontinence lump sum (43 250 small and 50 345 large ones). There were thus 114 500 people treated and reimbursed (but not receiving any incontinence lump sum).

In the last Health Interview Survey 2013, 4.2% of the people aged 15 years or more (including persons in homes for the elderly ('woonzorgcentra', 'maisons de repos pour personnes âgées')) declared to have suffered from urinary incontinence during the last year. This represent more or less 400 000 people with urinary incontinence. This figure has probably increased till 2015 and must be topped up with people facing faecal incontinence only. Moreover, the result is probably underestimated due social desirability bias in the responses. On the other hand, the result also includes very light incontinence cases (as it reports people who have suffered at least once from urine loss during the 12 preceding months). We can thus state that **roughly 200 000 were identified as receiving neither a reimbursed treatment nor a lump sum for their incontinence in 2015.** This does not mean that they are not treated as physiotherapy specific to incontinence is not identifiable in the billing data, and as they can be prescribed a drug therapy outside reimbursed conditions at their own expenses.

Another indication that there is a large number of patients with incontinence remaining unnoticed from the health care system can be found in the 2013 Health interview survey. Among the respondent who revealed their urinary incontinence, **32% were not followed by a health care professional.** Nonetheless the results cannot be nuanced as the HIS includes no information on the severity of the incontinence encountered during the last year, their willingness to seek medical advice on their condition or their awareness of possible therapeutic modalities.





## 5 INTERNATIONAL PERSPECTIVE

### 5.1 Introduction

Decisions for healthcare services are based on multiple factors. Besides effectiveness and cost-effectiveness many other considerations can play a role to argument whether an intervention or an appliance justifies a claim on health insurance, like:

- Is the concerned condition an illness? (one of the possible arguments e.g. not to cover baby diapers or sanitary napkins);
- Is the intervention medically necessary or essential care? (one of the possible arguments e.g. not to cover pure aesthetic plastic surgery; or in vitro fertilisation);
- Is it a condition that has a very high prevalence in the population? (one of the possible arguments e.g. not to fully cover corrective eyeglasses)
- Is it an intervention with a very low cost that people can afford to pay for themselves? (one of the possible arguments e.g. not to cover simple walking aids)
- Is the condition considered the individual responsibility of the patient? (one of the possible arguments e.g. not to cover smoking-cessation interventions; or dietary advice)
- Is it financially feasible for the national health insurance to cover the intervention? (one of the possible arguments e.g. not to fully cover dental care).<sup>[48]</sup>

In the case of absorbent materials for incontinence, healthcare decision makers have a number of arguments to support reimbursement. Although incontinence is not life-threatening condition, it translates into reduced quality-of-life for patients, not only physically and psychologically but also socially. The costs to reimburse absorbent products might be recovered in the medium run as these products can delay the need for home care nursing and the need to move into residential care, and when it concerns younger persons, they can help them to get back at work. Unsurprisingly, in what we

will see, most of the countries analysed reimburse incontinence pads, but there are exceptions. In what follows we provide an overview of reimbursement of incontinence absorbent materials for patients living at home in a selection of countries. We examine whether or not absorbent materials are covered, under which conditions patients are eligible for reimbursement and under which modalities coverage takes place.

The chapter starts with an overview of the analysed set of countries. Consequently, we examine whether or not incontinence materials are included in the health benefit basket of the concerned countries. We then elaborate the indications and patient characteristics eligible for reimbursement. We continue with the reimbursement methods and the monetary amounts of reimbursement.

### 5.2 Methods

This chapter is mainly based on information from the websites of the reimbursement instances.

### 5.3 Selection of countries

Table 41 gives an overview of the analysed countries and corresponding health insurance systems selected for this report. A distinction can be made between countries with a social insurance system, predominantly funded by payroll contributions (like Belgium) versus countries with a national health insurance, funded by general taxation (like the United Kingdom).

For the countries with a social insurance scheme, we focus on the legal, mandatory insurance scheme, not on voluntary additional private insurance schemes. Similarly, for the UK and Italy, we focus on the services and benefits provided by the national health service, not on the private insurance schemes.

**Table 41 – List of analysed countries and health insurance systems**

Country	Considered health insurance or Social insurance	National Health Insurance
The Netherlands	Verplichte basisverzekering voor zorg (basispakket)	X
France	Couverture Maladie Universelle (CMU)	X
Germany	Gesetzliche Krankenversicherung (GKV)	X
Switzerland	Basic insurance according to Swiss Federal Law on Health Insurance <sup>9</sup>	X
United Kingdom	NHS England	X
Italy	National Benefit Catalogue of the Italian NHS	X
Australia	Australian Government Scheme - CAPS	X
Canada	Ontario Incontinence Supplies Grant Program	X

*Classification of countries (social insurance versus national health insurance) based on: <sup>[49]</sup>*

<sup>9</sup> Krankenversicherungsgesetz (KVG); la loi fédérale sur l'assurance-maladie (LAMal); legge federale sull'assicurazione malattia (LAMal)

## 5.4 Cross-country analysis

### 5.4.1 Absorbent materials: included or excluded from the health benefit basket

Table 42 gives a brief overview of whether or not absorbent materials for incontinence are part of the health benefit basket. To enable comparison with Belgium, the table starts with the national (federal) and regional (federated) levels in Belgium and then continues with the other countries.

In Belgium payments for incontinence material are granted at both the federal level (RIZIV – INAMI) and federated level (Flemish Community; French Community; French-speaking in Brussels). Only one community does not grant a payment for incontinence material: the German community.

In most of the foreign countries analysed, absorbent materials are covered by specific reimbursements. There is one exception: France. In France, absorbent materials for incontinence are not part of the L.P.P. ("Liste des Produits et Prestations Remboursables") and therefore not reimbursed by the statutory health insurance. There are however other ways for patients to get reimbursement for incontinence pads in France, notably through the following schemes:

- The health insurance funds (« caisses d'assurance maladie ») can cover expenses for absorbent materials as part of their extra-legal schemes, notably for chronic ill patients, for patients in home care and patients in an alternative setting to hospital care.
- Furthermore, for handicapped children entitled to l'Allocation d'Education de l'Enfant Handicapé, costs related to incontinence materials can be reimbursed by the "Commission des droits et de l'autonomie des personnes handicapées".



- Under certain conditions, persons above 60 years are entitled to an allowance for autonomy "Allocation Personnalisée d'Autonomie (A.P.A.), if they have a dependency level of 1 to 4 on the A.G.G.I.R. (Autonomie Gérontologique Groupe Iso-Ressources)-scale. The amount of the allowance varies in function of the G.I.R. level. Persons in category 4 (persons that need assistance for toilet and dressing and that once they are helped up can move themselves within the lodging) receive the lowest fee, whilst persons in category 1 (persons confined to bed or chair that have lost their mental, physical, locomotor and social autonomy that need a continuous presence of intervenients) receive the highest fee. Persons with a G.I.R. level of 5 or 6 are persons that are only very little dependent or not dependent.

**Table 42 – Inclusion or exclusion of absorbent materials for incontinence for patients living at home in the health benefit basket**

		Included	Excluded
BE	RIZIV – INAMI	√	
	VAPH	√	
	AVIQ Handicap	√	
	PHARE	√	
	German comm.		√
NL		√	
FR			√
DE		√	
CH		√	
UK		√	
IT		√	
AU		√	
CA		√	



### 5.4.2 Absorbent materials: eligible indications and age groups

Table 43 summarises the medical conditions and patient characteristics to be eligible for reimbursement of absorbent materials for incontinence. The table starts with the federal and federated levels in Belgium and continues with the criteria imposed in other countries.

**Table 43 – Eligibility criteria for reimbursement of absorbent materials**

Inclusion criteria		Excluded
<b>BE</b>	<b>RIZIV – INAMI large lump sum</b> Heavy care-dependent AND a score of 3 or 4 on incontinence on the Katz scale	Patients with a score of 1 or 2 on incontinence on the Katz scale: <ul style="list-style-type: none"><li>• Score 1: continent for urine and faeces</li><li>• Score 2: Accidentally incontinent for urine or faeces (including patients with bladder catheter or artificial anus:<ul style="list-style-type: none"><li>- occasionally = at irregular intervals during 24 hrs, undeliberate urine and/or faecal loss, e.g. in case of stress incontinence or dribbling;<ul style="list-style-type: none"><li>○ only night incontinence = score 2;</li><li>○ night incontinence and occasional urine incontinence during the day = score 2.</li></ul></li><li>- patient has an artificial anus, OR urostomy, OR indwelling catheter</li><li>- patient does self-catheterisation.</li></ul></li></ul>
	<b>RIZIV – INAMI small lump sum</b> <ul style="list-style-type: none"><li>• Untreatable incontinence</li></ul>	Patients who received other reimbursement for self-catheterisation or other incontinence material by RIZIV – INAMI (via nomenclature)
	<b>VAPH</b> <ul style="list-style-type: none"><li>• Persons with a handicap</li><li>• Common treatable forms of incontinence only when it is demonstrated that treatment is not a possibility, or that treatment was not successful.</li><li>• Min. 5 years. In very exceptional cases and under strict conditions an exception can be made for persons of 3-4 years.</li></ul>	By default are excluded: <ul style="list-style-type: none"><li>• Stress incontinence</li><li>• Urge incontinence</li><li>• Other types of light or occasional incontinence</li></ul> Other types of incontinence are excluded, when treatment is an option and has not yet been tried. "Not all types of incontinence are eligible. Many users can be helped



Inclusion criteria	Excluded
	with other solutions like advanced bowel and bladder control training, adapted urinary infection prevention or a small surgical procedure.”
<b>AVIQ Handicap</b> <ul style="list-style-type: none"><li>• Persons with a handicap</li><li>• In case the patient's expenditures exceed the RIZIV-INAMI lump sum</li><li>• Upon approval of the advising physician</li><li>• In case of a negative approval of the advising physician:<ul style="list-style-type: none"><li>○ Day and/or night incontinence, urinary and/or faecal resulting from<ul style="list-style-type: none"><li>▪ Neurological spinal lesions or (congenital or acquired) lesions of the lower urinary or intestinal apparatus</li><li>▪ Psychomotoric or mental development retardation</li><li>▪ Psychic illness</li></ul></li></ul></li></ul>	<ul style="list-style-type: none"><li>• Patients aged 3 to 5 years with nocturnal incontinence only</li><li>• Accidental leakages</li></ul>
<b>PHARE</b> <ul style="list-style-type: none"><li>• Persons with a handicap</li><li>• Prescription attesting day and/or night incontinence, urinary and/or faecal following<ul style="list-style-type: none"><li>○ Neurologic spinal lesions; or</li><li>○ Congenital or acquired lesions of the urinary or intestinal apparatus; or</li><li>○ Psychomotor, mental or psychologic development problems</li></ul></li><li>• Total or partial incontinence</li><li>• Temporary or irreversible incontinence</li><li>• Minimum age of 4 years</li></ul>	
<b>NL</b> <ul style="list-style-type: none"><li>• Long term incontinence;<ul style="list-style-type: none"><li>○ Faecal incontinence &gt; 2 weeks; or</li><li>○ Urinary incontinence &gt; 2 months</li></ul></li><li>• And incontinence severely disrupts daily life and long-term use is necessary;</li><li>• Incontinence that will not cure by itself and that cannot be treated.</li><li>• Or other incontinence, in case (and as long as) there is support of pelvic floor exercises, muscle exercises or bladder training.<ul style="list-style-type: none"><li>○ Reimbursement in this case starts from the moment the patient starts therapy.</li></ul></li></ul>	<ul style="list-style-type: none"><li>• Short term incontinence, e.g. after pregnancy or operation</li><li>• Enuresis nocturna</li><li>• If a patient is not willing to follow conservative therapy, the patient is not entitled to reimbursement. This restriction is only valid in situations where it is reasonable to expect therapy of a patient.</li></ul>



Inclusion criteria	Excluded
<ul style="list-style-type: none"> <li>○ The insurer can decide to restrict reimbursement to patients that are <b>willing</b> to follow conservative therapy (pelvic floor physiotherapy).</li> </ul> <hr/> <p><b>DE</b> Reimbursement for absorbent pads (disposable or re-usable) is provided for moderate, severe and most severe UI and FI.</p> <ul style="list-style-type: none"> <li>○ Indicative value for moderate UI: 100 to 200 ml in 4 hrs</li> <li>○ Indicative value for severe UI: 200 to 300 ml in 4 hrs</li> <li>○ Indicative value for most severe UI: &gt; 300 ml in 4 hrs.</li> </ul> <p>Medical aids for incontinence can be reimbursed in the above indications, when they meet one of the following aims:</p> <ul style="list-style-type: none"> <li>• Group 1: to enable participation to social life</li> <li>• Group 2: be important for the treatment of a disease (in case of treatment for decubitus 2, in patients being treated e.g. for prostate removal)</li> <li>• Group 3: to prevent serious functional damage or consequential damage (to prevent skin disease in patients with dementia or another severe functional disorder e.g. patients with partial paralysis after stroke and speech disorder who cannot give signal when they need to go to toilet)</li> </ul>	<ul style="list-style-type: none"> <li>• Light incontinence: &lt; 100 ml in 4 hrs</li> </ul> <hr/>
<p><b>CH</b></p> <ul style="list-style-type: none"> <li>• Medium incontinence: Urine loss 100-200 ml/4h             <ul style="list-style-type: none"> <li>○ Urge incontinence, mixed incontinence. Loss of medium to important urine volumes at irregular intervals, in case of overcharge and strong pressure on the bladder, with an incontrollable need to urinate</li> <li>○ Limitation: only incontinence caused by an illness or accident, like multiple sclerosis, paraplegia, cerebral palsy, Parkinson, dementia.</li> <li>○ The reimbursement applies to absorbent material for incontinence, mattress covers and net pants (urinary condoms are not reimbursed for this degree of incontinence)</li> </ul> </li> <li>• Severe incontinence: Urine loss &gt;200 ml/4h             <ul style="list-style-type: none"> <li>▪ Urge incontinence, reflex incontinence (réflexe spinal neurogène pathologique, avec insensibilité à la pression sur la vessie). Vidange vésicale complète soudaine, avec émission de gros volumes d'urine.</li> <li>▪ The reimbursement applies to absorbent material for incontinence, mattress cover, net pants and urinary condoms</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Light incontinence:             <ul style="list-style-type: none"> <li>○ urine loss &lt;100 ml/4h</li> <li>○ stress incontinence, urine loss in small quantities in certain situations where pressure is put on the bladder, e.g. sneezing, cough, laughing and sports</li> <li>○ "light incontinence" is not considered an illness by the LAMal (l'assurance maladie; Caisse-Maladie Assurance de base)</li> </ul> </li> </ul>



Inclusion criteria	Excluded
<ul style="list-style-type: none"> <li>Total incontinence: Incontrollable and continuous loss of urine or faeces</li> </ul>	
<b>IT</b> <ul style="list-style-type: none"> <li>Patients with stabilised incontinence</li> <li>Medical prescription is required; the physician specifies the model, size and number of pads needed on the basis of the reimbursement list</li> </ul>	
<b>UK</b> <ul style="list-style-type: none"> <li>Distinct criteria are set out by local clinical commissioning groups (CCG), e.g. <ul style="list-style-type: none"> <li>products may only be available for people with severe or long-term incontinence</li> <li>there may be a limit to a certain number of products per day.</li> <li>to qualify for incontinence products, the patient needs to be assessed (which may involve keeping a bladder diary for three days) and start a treatment plan</li> </ul> </li> </ul>	
<b>AU</b> <ul style="list-style-type: none"> <li>Permanent and severe urinary and/or faecal incontinence which is a result of <ul style="list-style-type: none"> <li>an eligible neurological condition</li> <li>or other condition listed.</li> </ul> </li> </ul> <p>Permanent and severe incontinence is defined as "the frequent and uncontrollable, moderate to large loss of urine or faeces which impacts on a person's quality of life and which is unlikely to improve with medical, surgical or clinical treatment."</p>	<ul style="list-style-type: none"> <li>Light incontinence</li> <li>Transient incontinence (not permanent);</li> <li>Incontinence that can be treated with an existing conservative treatment regime (e.g. pelvic floor exercises or bladder re-training), medication or surgery;</li> <li>Only night-time bed wetting (enuresis)</li> </ul>
<b>CA</b> <ul style="list-style-type: none"> <li>Children and youth between the ages of 3 to 18 years with chronic disabilities (physical or developmental)</li> <li>Only types of incontinence that cannot be treated</li> <li>Lasting longer than 6 months</li> <li>Some children under the age of 3 may be eligible for funding depending on their diagnosis (for example, Spina Bifida, Prune Belly Syndrome).</li> </ul>	<ul style="list-style-type: none"> <li>Enuresis (bedwetting)</li> <li>Encopresis (stool soiling) <ul style="list-style-type: none"> <li>It is considered a complication of constipation. There are many ways to resolve these problems and you should consult with your doctor.</li> </ul> </li> <li>Stress incontinence <ul style="list-style-type: none"> <li>This condition usually occurs in the older population and can usually be resolved with appropriate medical and/or rehabilitative interventions.</li> </ul> </li> </ul>



**A number of countries and regions explicitly exclude short term incontinence, enuresis nocturna, stress incontinence, urge incontinence or encopresis.**

- E.g. In Switzerland, stress incontinence is considered light incontinence and as such explicitly excluded from reimbursement.
- E.g. In the Netherlands, enuresis nocturna and short term incontinence (e.g. after pregnancy or after surgery) are explicitly excluded from reimbursement.
- E.g. in Canada Ontario, enuresis, encopresis and stress incontinence are excluded from reimbursement.
- E.g. VAPH in Flanders by default excludes stress incontinence, urge incontinence and other types of light or occasional incontinence.

**Several countries explicitly exclude light incontinence.**

- E.g. Germany excludes light incontinence defined as “urine loss < 100 ml in 4 hrs”.
- E.g. Switzerland also excludes light incontinence and applies the same definition as Germany.
- E.g. Australia (CAPS) excludes light incontinence, but no definition for it was found.
- E.g. The Netherlands explored the possibility to exclude light incontinence from reimbursement either by excluding the indication of stress incontinence or by excluding light pads from reimbursement. However the former CVZ left this idea as it concluded that both options might lead to a shift in prescription behaviour, either towards reimbursed indications, or to heavier pads.

**In the analysed countries that exclude light incontinence, no precise instructions have been found as to how physicians should distinguish light from heavier incontinence patients.**

- An indicative value is given of less than 100 ml urine loss per 4 hours (but it is unclear how healthcare practitioners should measure this).

**In some countries, patients are not entitled to reimbursement when they are not willing to follow conservative therapy (pelvic floor exercises).**

- E.g. In the Netherlands, in case of incontinence that is expected to be improved by treatment, patients need to follow pelvic floor exercises, muscle exercises or bladder training. Reimbursement in this case starts from the moment the patient starts therapy. If a patient is not willing to follow conservative therapy, the patient is not entitled to reimbursement. This restriction is only valid in situations where it is reasonable to expect therapy of a patient.
- E.g. In Flanders, common treatable forms of incontinence are only covered when it is demonstrated that treatment is not a possibility, or that treatment was not successful.

**In the Australian scheme indications are listed in a detailed list of eligible neurological and other conditions.**

Table 44 shows the detailed list of eligible indications in the Australian CAPS scheme, starting with the neurological conditions (category 1 to 7), followed by other conditions (category 8).





**Table 44 – List of eligible indications in the Australian CAPS scheme**

**CAPS - Eligible Neurological Conditions (Category 1 to 7)**

Category 1 – Spina Bifida and Syringomyelia	Category 4 – Paraplegia and Quadriplegia	Category 6 – Degenerative Neurological Disease
Category 2 – Cerebral Palsy	Category 5 – Acquired Neurological Conditions	<ul style="list-style-type: none"> <li>• Huntington Chorea/Disease</li> <li>• Motor Neurone Disease</li> <li>• Muscular Dystrophy</li> <li>• Multiple Sclerosis</li> <li>• Parkinson's Disease</li> </ul>
Category 3 – Intellectual Disability	<ul style="list-style-type: none"> <li>• Acquired brain injury</li> <li>• Alzheimer's Disease</li> <li>• Epilepsy</li> <li>• Encephalitis</li> <li>• Lewi Body Disease</li> <li>• Pick's Disease</li> <li>• Poliomyelitis</li> <li>• Stroke/Cerebrovascular Accident (CVA)</li> </ul>	Category 7 – Bladder Innervation Disorders
<ul style="list-style-type: none"> <li>• Congenital neurological infections</li> <li>• Developmental Delay associated with;</li> <li>• Aspergers Syndrome</li> <li>• Autism</li> <li>• Autism Spectrum Disorder</li> <li>• Down Syndrome</li> <li>• Rare congenital neurological syndromes and conditions</li> </ul>		<ul style="list-style-type: none"> <li>• Ectopia Vesica</li> <li>• Neurogenic Bladder</li> <li>• Neuropathic Bladder</li> </ul>

**CAPS - Eligible Other Conditions (Category 8: Other)**

<ul style="list-style-type: none"> <li>• Anal Carcinoma</li> <li>• Anal Fistula</li> <li>• Anorectal Malformation</li> <li>• Anterior Prolapse</li> <li>• Bilateral Nephrostomy Tubes</li> <li>• Bladder Cancer</li> <li>• Bladder Instability</li> <li>• Bladder Muscle Dysfunction</li> <li>• Bladder Neck Dysfunction</li> <li>• Bladder Neck Fibrosis</li> <li>• Bladder Prolapse</li> <li>• Bowel Cancer</li> <li>• Bowel Prolapse</li> <li>• Cervical Cancer</li> </ul>	<ul style="list-style-type: none"> <li>• Chronic Urinary Retention</li> <li>• Congenital Epispadias</li> <li>• Detrusor Instability</li> <li>• Detrusor Overactivity</li> <li>• Enterocutaneous Fistula</li> <li>• Faecal Incontinence Post-Colectomy</li> <li>• Hypertonic Bladder</li> <li>• Imperforate Anus</li> <li>• Irradiated Rectum/Radiation Proctitis</li> <li>• Metastatic Ovarian Carcinoma</li> <li>• Post Ileorectal Anastomosis</li> <li>• Post Ileal J Pouch Anastomosis</li> <li>• Posterior Urethral Valve Syndrome</li> <li>• Prostate Cancer</li> </ul>	<ul style="list-style-type: none"> <li>• Prostate Disease</li> <li>• Rectal Prolapse</li> <li>• Rectal Ulcer Syndrome</li> <li>• Severe Ulcerative Proctitis</li> <li>• Spastic Bladder</li> <li>• Transurethral Resection of the Prostate (TURP)</li> <li>• Urethral Stenosis</li> <li>• Urinary Fistula</li> <li>• Uterine Cancer</li> <li>• Uterine Prolapse</li> <li>• Vaginal Prolapse</li> <li>• Vesico-Vaginal Fistula</li> <li>• Vulva Cancer</li> </ul>
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Source: [50]



### 5.4.3 Reimbursement method

Table 45 gives an overview of the reimbursement methods used in Belgium and the analysed countries, distinguishing between (1) reimbursement by a periodical grant paid to the patient, (2) day price paid to the pharmacist, (3) reimbursement per item, and (4) provision free-of-charge by the national health services.

#### 1. Fixed periodical grant

In case of a grant, the patient periodically receives a fixed lump sum to compensate for the expenses made for pads. The patient can buy the products from a supplier or retailer they choose, the purchases are not registered by the health insurer.

- a. The grant can be accorded independently of the real expenditures by the patient, like is the case for RIZIV – INAMI, VAPH and Australia-CAPS. (See Table 46)
- b. Alternatively, the grant can be accorded conditionally to justification of expenditures. The grant can consist of a single payment or, like in the case of PHARE, can be split into a base payment, which is granted without justification of expenditures, and additional fractionated payments, that are only granted when expenditures exceeding the base payment are declared by the patient.

#### 2. Fixed day price per patient

This system has recently been introduced in the Netherlands. In this new system, patients are categorised into profiles. For each profile, guidelines are made for consumption (volumes and type of products). The pharmacist gets a day price per patient, which varies in function of the patient profile. With this payment the pharmacist has to deliver the materials to the patient. The patient is not allowed to pay extra for more material compared to what is written in the guidelines.

#### 3. Reimbursement per piece

In case of a reimbursement per item, the patient receives (partial or total) reimbursement for each of the products he or she buys. In this case, the reimbursed amount increases in function of the amount and type of products bought. The patient has to buy the products in a community pharmacy and the purchases are registered by the health insurer.

- a. Reimbursement can be capped by a maximum periodical amount. (See Table 47.) In this case, the patient receives a reimbursement per item up to a certain amount. Once the maximum amount for reimbursement has been reached, the patient pays for the extra purchases him/herself.
- b. Reimbursement can be capped by a maximum number of pads. In this case, above a certain amount, the patient needs to pay the pads him/herself.
- c. In some countries, reimbursement is “floored”. Like in the Netherlands, for instance, under the old system, the patient first has to pay the amount of the “own risk” him/herself and the insurer only intervenes for costs above the own risk level. The own risk level applies to nearly all health services, so not just incontinence products. (On top of the “own risk”, there can be an “own contribution” in the Netherlands, which is health service-specific. However, there is no such own contribution for incontinence products.)

In Germany and Switzerland, absorbent materials are reimbursed per item. In Switzerland, reimbursement is capped up to a maximum amount, depending on severity of incontinence. In Germany, insurers may impose volume restrictions, like max. 5 per day.

Previously, in the Netherlands, insurers reimbursed absorbent materials per piece (at 100% for contracted suppliers and at a reduced rate of e.g. 75% for non contracted suppliers), without limitations on volume. However, in order to curb costs, the largest insurers have now switched to a new system of “day prices”.



#### 4. Pads provided free of charge

Typically in national health service systems, pads can be provided free-of-charge to some patient groups. The free provision of pads can be restricted by volume measures (maximum number of pads supplied per person), as in Italy (see illustration below), and actions can be taken to reduce costs by organising central public procurement.

Another possibility would be a voucher system. This system however is not observed in any of the analysed countries. Under a voucher system, the patient gets a voucher that permits him/her to buy products up to a maximum amount. If the patient does not need the maximum amount, he/she does not necessarily need to valorise the voucher. If the patient requires more than the maximum amount of the voucher, he/she pays the costs on top. The system is similar to a system where the patient can get full reimbursement for products upon prescription.

**Table 45 – Reimbursement methods (periodical grant; reimbursement per item; free provision by the national health service)**

	Periodical grant	Day price per patient	Reimbursement per item	Provision by national health service
<b>BE</b>	RIZIV – INAMI	X		
	VAPH	X		
	AVIQ-Handicap	X		
	PHARE	X		
	German community	(No reimbursement)		
<b>NL</b>		X (new system)	X (old system)	
<b>DE</b>			X	
<b>CH</b>			X	
<b>IT</b>				X
<b>UK</b>				X
<b>AU</b>	X			
<b>CA</b>				

**Table 46 – Reimbursement by periodical grant: with or without justification of expenditures**

	Periodical grant; no justification of expenditures	Periodical grant; upon justification of expenditures
BE – RIZIV – INAMI	X	
BE – VAPH	X	
BE – AVIQ-Handicap		X
BE – PHARE	X (base grant level)	X (additional grant levels)
AU	X	

**Table 47 – Reimbursement per item: with a cap or a floor**

	Reimbursement per item – with a cap	Reimbursement per item – with a floor
NL (old system)	X <ul style="list-style-type: none"> <li>• Max. n° disposable pads: 455 / 3 months (~ 5 / day)</li> <li>• Max. n° re-usable pads: 3 / yr</li> </ul>	X “own risk” contribution for patients 18 yrs+
DE	X Insurance funds can impose volume restrictions, e.g. max. 5 per day	
CH	X Max. amount / year for medium / severe / total incontinence	

In Italy, pads are listed in a national benefit catalogue. The Italian list (see Table 48) comprises the types of pads and the maximum number of pads provided per patient.

**Table 48 – Urinary incontinence pads in the Italian national benefit catalogue (Decree 332/99)**

Description	ISO classification code	Maximum number provided per patient per month
<b>INCONTINENCE PADS</b>	09.30.04	
<b>Under pads</b>		
• Big size (waist measure between 100 and 150 cm)	09.30.04.003	120
• Medium size (waist measure between 70 and 110 cm)	09.30.04.006	120
• Small size (waist measure between 50 and 80 cm)	09.30.04.009	120
<b>Anatomic shaped pads</b>		
• Big size	09.30.04.012	120
• Medium size	09.30.04.015	120
• Small size	09.30.04.018	120
<b>Rectangular pads</b>		
• Unique size	09.30.04.021	150
<b>SUPPORTS AND CLAMPS FOR INCONTINENCE</b>		
<b>Paint elasticized reusable</b>		
• Big size	09.30.09.003	3
• Medium size	09.30.09.006	3
• Small size	09.30.09.009	3

*Source:[51]*



**Germany and Switzerland reimburse incontinence pads per item up to a certain volume/budget.**

**The main insurers in the Netherlands have switched from a reimbursement per item (in combination with maximum number of products) to a system with patient profiling and a day price per patient adapted in function of the profile (in combination with an indicative number of products per type to be provided to the patient).**

**A periodical grant without justification of expenditures is used by the Australian CAPS system and in Belgium (RIZIV – INAMI; VAPH; PHARE for the base grant).**

**A periodical grant upon justification of expenditures is used by AVIQ-Handicap and PHARE (for the 2nd and 3rd grant level).**

#### *5.4.4 Strengths and weaknesses of different reimbursement methods*

In what follows, we discuss the advantages and disadvantages of reimbursement by a periodical grant versus reimbursement per item.

##### **Periodical grant**

###### Advantages:

- Leaves high flexibility to patients to choose for the products they prefer. Patients are empowered to make their own product choice.
- Limited administrative burden, for the health insurance as well as for the patients.
- May stimulate price competition on the market and product innovation, as patients will choose for the product with the best value for money.
- A possible way to contain or (more or less) control costs for the health insurance. Individual patient expenditures are capped at the amount of the lump sum.

###### Disadvantages:

- In reality patients' costs vary widely. Inevitably, for some patients, the lump sums will be too small, and for other, they will be too generous.

##### **Reimbursement per item**

###### Advantages:

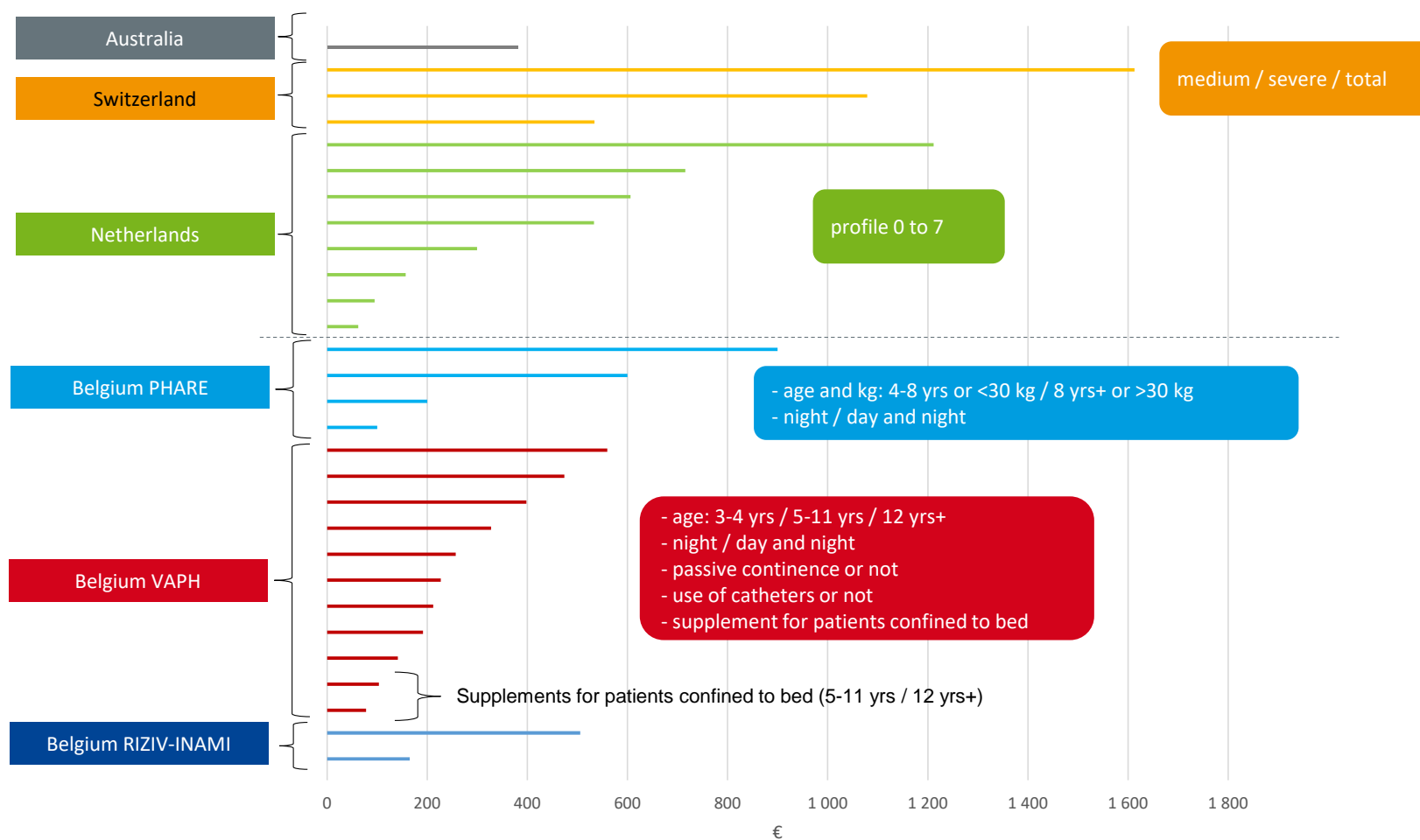
- Patients are reimbursed in line with their real expenditures.
- If the patient has to pay a co-payment for the absorbent materials, there is a financial incentive for the patient to minimise the volume and to search treatment.
- The reimbursement budget can be controlled by price, volume or spending measures:
  - Co-payment
  - Price-quality agreements through public procurement
  - Volume cap, i.e. a maximum number of items reimbursed
  - Fee cap, i.e. a maximum fee reimbursed
  - Spending floor, i.e. reimbursement only occurs when a certain level of expenditures is exceeded
- Furthermore, reimbursement could be restricted to heavier pads. However this holds the risk that prescribers may prescribe towards heavier (reimbursed) pads.

Disadvantages:

- Takes more administrative effort than a periodical grant. A list must be made with reimbursed incontinence pads, their price and reimbursement level. Reimbursed incontinence pads are only available in the medical distribution channels of community pharmacies and medical equipment shops and the purchases must be registered.
- The pads (size, type, number, ...) have to be prescribed, this also takes more effort for physicians.
- There is no uniform, internationally recognised classification of incontinence materials (with regard to e.g. absorption capacity), so each country has to work out its own categorisation of materials for reimbursement. The Italian reimbursement and classification system has been criticised for favouring products with high amounts of absorbent material, hampering product improvement such as development of thinner products with weight reduction.
- As the patient only pays the co-payment, normal price competition on the market may be hampered. This is even more so the case when there is full reimbursement, which also entails a risk of stocking behavior or reselling.

#### 5.4.5 Patient classification and reimbursement amounts

Figure 33 shows an overview of patient categorisation and reimbursement amounts for the set of countries where reimbursement is a fixed amount or capped at a maximum amount, i.e. the Netherlands, Switzerland, Australia and Belgium (both the federal and federated level). Note that the grants by AVIQ Handicap are not shown in this graph as the amounts vary and depend on the RIZIV – INAMI grant the patient receives. Table 49 presents the details behind the graph for the examples from abroad.

**Figure 33 – Overview of reimbursement categories and yearly amounts in countries with a fixed or maximum reimbursement amount**




**Table 49 – Patient categories and payment amounts**

Categories	Amount
<b>NL</b> The largest health insurers now work with a system of day prices for incontinence. Patients are categorised into 7/8 profiles, taking into account: <ul style="list-style-type: none"> <li>• fluid intake</li> <li>• incontinence form and pattern</li> <li>• personal situation</li> </ul> An example protocol is given in Table 50.	Achmea day price per patient, according to profile: Profile 0: €0.17/day → €62.05/yr Profile 1: €0.26/day → €94.90/yr Profile 2: €0.43/day → €156.95/yr Profile 3: €0.82/day → €299.30/yr Profile 4: €1.46/day → €532.90/yr Profile 5: €1.66/day → €605.90/yr Profile 6: €1.96/day → €715.40/yr Profile 7: €3.32/day → €1 211.80/yr
<b>CH</b> <ul style="list-style-type: none"> <li>• Medium incontinence: Urine loss 100-200 ml/4h</li> <li>• Severe incontinence: Urine loss &gt;200 ml/4h</li> <li>• Total incontinence: Incontrollable and continuous loss of urine or faeces</li> </ul>	Max. 624 CHF (~ € 534) Max. 1 260 CHF (~ € 1 079) Max. 1 884 CHF (~ € 1 613) <sup>h</sup>
<b>AU</b> Single tariff	583.20 (~ € 380.84)

In the Netherlands, under the new system of day prices, the pharmacist or medical shop (or a nurse or other health professional at work at the pharmacy or medical shop) categorises patients into categories defined by the health insurers. Achmea, VGZ and Menzis (three amongst the four largest health insurers in the Netherlands), divide patients into 7/8 profiles. The profiles range from 0 (light incontinent) to 6/7 (heavy incontinent).

Table 50 gives an example of how patients are categorised, in function of incontinence form, pattern of loss and personal situation of the patient. The higher the profile, the higher the day tariff the pharmacist or medical shop receives to provide materials to the patient. The health insurers give instructions on the maximum number of products per type that can be provided to the patient. An example of the volume details for a specific brand can be found in Table 51. As such the financial responsibility is shifted away from the health insurer to the pharmacists and medical shops, who must find a way to provide the products to the patients in a financially profitable way and to buy the products as cheap as possible.

<sup>h</sup> Live average exchange rates per 2017.12.14 14:05:00 UTC ([www.xe.com](http://www.xe.com))

**Table 50 – Example of a Dutch health insurer protocol to categorise patients into profiles**

Profile	Incontinence form and pattern	Personal situation
0/1	UI: - loss of a single drop or - loss of multiple drops (a small dash or a thimble) FI (alone or in combination with UI): Track of faecal incontinence or wet flatulence	Patient is independent for changing the incontinence material
2	UI: - loss of multiple drops (a small dash or a thimble) - small dashes/layer in a glass FI (alone or in combination with UI): Track of faecal incontinence or wet flatulence	Patient is independent for changing the incontinence material
3	UI: - small dashes/layer in a glass - loss of considerable dashes/half glass up to full glass FI (alone or in combination with UI): Track of faecal incontinence or wet flatulence	Patient is independent for changing the incontinence material
4	UI: - loss of considerable dashes/half glass up to full glass - almost complete bladder content/full glass to more FI (alone or in combination with UI): One or multiple portions per day	Patient is independent for changing the incontinence material; OR patient is sometimes dependent on care for changing the material; OR patient is nearly totally dependent on care for changing the material
5	UI - almost complete bladder content/full glass to more - entire bladder content/half a measuring cup or more (> 2000cc) FI (alone or in combination with UI) One or multiple portions per day	Terminal care; OR Patient is independent for changing the incontinence material; OR patient is sometimes dependent on care for changing the material; OR patient is nearly totally dependent on care for changing the material OR patient is totally dependent on care for changing the material
6	UI: - almost complete bladder content/full glass to more - entire bladder content/half a measuring cup or more (> 2000cc) Or if patient drinks more than 2500 cc per day FI (alone or in combination with UI):	Patient is nearly totally dependent on care for changing the material; OR patient is totally dependent on care for changing the material



One or multiple portions per day		
7	UI: - almost complete bladder content/full glass to more - entire bladder content/half a measuring cup or more (> 2000cc) FI (alone or in combination with UI): One or multiple portions per day	Patient is totally dependent on care for changing the material; OR multiple handicap (physical and mental); OR mental handicap; OR severe physical handicap; OR advanced dementia (code 4 or 5 on nursing care need (code 4 = sheltered accommodation with intensive guidance and comprehensive care; code 5 = protected living with intensive dementia care)

Source: based on <sup>[52]</sup>

**Table 51 – Patient profiling example from a Dutch health insurer**

Profile	Day price	Iso absorption	Extra protection	Panty liners and pads	Slip Classic	Pants	Anatomic	Flex	Slip
0	0.12	0		≤1 panty liner ultra mini ≤1 pad mini					
1	0.22	Max. 100		≤2 panty liner ultra mini ≤2 pad mini ≤1 inlay classic normal ≤1 shields (for male)					
2	0.40	101-300		≤3 pad mini ≤3 pad normal ≤2 pad normal plus ≤2 inlay classic normal ≤1 guards (for male)					
3	0.82	301-900	≤2 inlay	slip	≤4 pad normal plus ≤3 pad extra ≤3 pad super ≤2 pad super plus ≤2 guards (for male)	≤2 slip extra plus classic	≤1 pants female normal S/M or L ≤1 pants female super XS ≤1 pants male super S/M or L/XL	≤3 anatomic normal ≤3 anatomic extra ≤2 anatomic super plus	



4	1.46	901-1500	≤2 inlay	slip	≤5 pad super plus ≤4 pad maximum ≤4 guards (for male)	≤3 slip classic extra plus	≤2 pants female super XS or S/M ≤1 pants female super L or XL ≤2 pants male super S/M ≤1 pants male super L/XL ≤2 pants super easy-fit S/M ≤1 pants super easy-fit L/XL	≤6 anatomic normal ≤5 anatomic extra ≤3 anatomic super plus		≤3 slip normal S or M ≤2 slip normal L or XL
5	1.65	1501-2000	≤2 inlay	slip	≤4 pad maximum		≤2 pants female super XS or S/M or L ≤1 pants female super L ≤2 pants male super S/M or L/XL ≤2 pants super easy-fit S/M ≤1 pants super easy-fit L/XL	≤6 anatomic extra ≤4 anatomic super plus	≤2 flex super plus M or L	≤3 slip normal S or M ≤2 slip normal L or XL ≤3 slip super S or M ≤2 slip super L or XL ≤2 slip super plus S or M or L ≤1 slip super plus XL
6	1.86	>2000	≤ 2 inlay	slip				≤4 anatomic super plus	≤3 flex super plus M ≤2 flex super plus L	≤3 slip super S or M or L ≤2 slip super XL ≤3 slip super plus S ≤2 slip super plus M or L or XL
7	3.30	N.A.	> 2 inlay	slip	>6 pad maximum	≤8 slip classic extra plus	≤5 pants female super XS ≤4 pants female super S/M or L ≤3 pants female super XL ≤4 pants male super S/M or L/XL ≤4 pants super easy-fit S/M ≤3 pants super easy-fit L/XL	>6 anatomic normal >6 anatomic extra >6 anatomic super plus	≤5 flex super plus M ≤4 flex super plus L	≤7 slip normal S or M ≤5 slip normal L ≤4 slip normal XL ≤6 slip super S or M ≤5 slip super L ≤4 slip super XL ≤5 slip super plus S ≤4 slip super plus M or L ≤3 slip super plus XL

Source: [53]

**Patient classification**

- The largest health insurers in the Netherlands categorise patients into 8 profiles, ranging from 0 (light incontinent) to 6 (heavy incontinent) and 7 (for fully dependent or handicapped persons or persons with advanced dementia). The daily tariff, the type of reimbursed products and quantities are differentiated according to the profile.
- In Switzerland, patients are categorised into 3 levels (medium; severe; total incontinence). The maximum reimbursement amount is adapted to the level.
- In Belgium, at the RIZIV – INAMI level, 2 categories are distinguished for reimbursement (incontinence with high care dependency; untreatable incontinence).
- VAPH currently applies 9 categories and a supplement for bedridden patients. It distinguishes patients in function of age, night-only versus day and night, passive continent versus not, use of catheters or not, bedridden or not.
- PHARE distinguishes 4 categories of patients in function of age/weight, night-only versus day and night.

**Level of the reimbursement amounts**

- When comparing the highest-level reimbursement amounts amongst the different countries, then we can make the following ranking:
  - Switzerland ranks on top with the highest (maximum) amount of €1 613, followed by

- The French community and French-speaking community in Brussels (AVIQ-Handicap and PHARE, including RIZIV – INAMI large lump sum) with €1 406,
- The Netherlands (“new system”) with €1 212,
- Flanders (including RIZIV – INAMI large lump sum) with €1 168,
- German-speaking community (which has no reimbursement on top of the RIZIV – INAMI lump sum) with €506,
- Australia CAPS with €381.
- When comparing the lowest-level reimbursement amounts, then we see the following ranking:
  - Switzerland with an amount of up to €34 for medium incontinence,
  - Australia CAPS with €381 (single tariff regardless type and severity of incontinence),
  - Belgium (regardless the community) with €165 for untreatable incontinence (small lump sum tariff),
  - The Netherlands with €62 for patient profile 0.

***5.4.6 Involved professionals for assessing incontinence***

Table 52 gives an overview of professionals involved to diagnose or assess the patient's condition and to fulfil the formalities for reimbursement of incontinence aids.

**Table 52 – Involved professionals**

Involved professionals	
<b>BE</b>	<p>Who fills out the request form:</p> <ul style="list-style-type: none"><li>For the large lump sum: <b>home nurse</b>; any <b>physician</b> (GP, urologist, geriatrician,...).</li><li>For the small lump sum: <b>GP</b> (the possibility to fill out the form will possibly be expanded to urologists, paediatricians, geriatricians and gynaecologists. However, this proposal has not yet been formally accepted.)</li></ul>
<b>NL</b>	<p>Under the new “day price” system for incontinence material, insurers let the <b>provider (pharmacist or medical shop)</b> do the patient profiling.</p> <ul style="list-style-type: none"><li>An intake session takes place between the patient and the provider, to determine the degree of incontinence, the pattern of loss over the day, the degree of independent functioning, fluid intake ... On the basis of this intake session,<ul style="list-style-type: none"><li>An assessment is made of whether the patient can use ‘stepped care’, pelvic therapy or “pipo poli” to remedy or reduce the incontinence complaints</li><li>The patient is categorised in a profile. In the start phase, it is not always possible to determine a definite profile as treatment may have been started.</li></ul></li><li>The provider gets a day payment per patient from the health insurer and has to advise the patient what and how many products the patient can get on day basis.</li><li>The health insurers propose providers to contract with the health insurer. The contract determines the day price paid per patient and the coverage per patient. As such, the patient-client from the health insurer can then purchase from the contracted provider.</li></ul> <p>Under the old system, the insurer requires a referral from a physician, specialised stoma or continence nurse or pelvic floor physiotherapist.</p>
<b>DE</b>	<p>A <b>physician</b> has to diagnose incontinence and prescribe appropriate remedies and aids.</p>
<b>CH</b>	<p>A <b>physician</b> has to diagnose incontinence (urine loss of <math>\geq 100\text{ml/4h}</math>) and the severity (medium, severe, total) on a prescription form.</p>
<b>UK</b>	<p>Patients in the UK can get advice about their condition from:</p> <ul style="list-style-type: none"><li>A NHS continence service</li><li>A <b>GP</b> who may refer to a continence adviser or a local district nurse.</li></ul> <p>NHS <b>continence services</b>, staffed by <b>specialist nurses (continence advisers)</b> and <b>physiotherapists</b>, play an important role in the management of incontinence. They provide clinical advice, support and information to patients and healthcare professionals/carers on incontinence. They may offer confidential advice by telephone and at the continence service/clinic. Before the patient goes to the appointment, he/she gets the necessary charts to complete and to bring to the appointment. This enables the nurses or physiotherapists to perform a more thorough assessment of the patient's condition immediately on the first consultation.</p> <p>Support/treatment can include lifestyle advice, bladder retraining, pelvic floor exercises, electrical stimulation and bladder scanning.</p> <p>The continence services work with <b>GPs</b> for the prescription of medication, where necessary, and can link in with other healthcare professionals when more specialised treatment is required. They also provide support to families and carers, and advice for other health and social care professionals.</p> <p>There are also over 260 NHS <b>continence clinics</b> in the UK, staffed by specialist teams. The clinics can be based in a hospital or in the community, such as in a health centre. Some clinics may be directly accessible, other require a referral from a GP.</p> <p>Once the patient has been assessed, the treating professionals (GP, continence service or continence clinic) inform the patient about the incontinence products available on the NHS.</p>



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**IT** A **physician** prescribes the type and number of incontinence pads needed.

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**AU** CAPS applicants are required to obtain a continence assessment from an appropriate Health Professional. A Health Professional should only complete the Health Report of the CAPS application if they are in a position to make an accurate assessment of the applicant in relation to their incontinence and the cause of their incontinence. The Health Professional's assessment must be based on evidence that the applicant has been diagnosed with an eligible neurological condition or an eligible other condition. Appropriate Health Professionals, include but are not limited to a

- **continence nurse,**
- **GP,**
- **medical specialist,**
- **community nurse,**
- **physiotherapist,**
- **aboriginal health worker or**
- **occupational therapist.**

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- In the Netherlands, under the “new system” it is the pharmacist (or other professional in the pharmacy or medical shop) that links the patient to a patient profile, which details the number and type of products the patient is entitled to. For this, the pharmacist takes an “intake meeting” with the patient. Under the “old system” not only a treating physician can make a referral for reimbursement, but also a specialised nurse or pelvic floor physiotherapist.
- In the NHS England, both GPs and continence services play an important role in the first-line management of incontinence. Continence services are staffed by continence advisors (specialist nurses) and physiotherapists.
- In the Australian CAPS schedule, a variety of health professionals can fill out the assessment of the patient and fill out the application form: continence nurses, GPs, medical specialists, physiotherapists, ...
- In Germany, Switzerland and Italy, it is a physician that has to prescribe incontinence materials, including absorbent materials.



## 6 COST OF ABSORBENT MATERIALS

### 6.1 Introduction

Patient expenditures for absorbent materials for incontinence can vary widely as both the product choice and used amounts may vary largely from one patient to another. The product choice of patients may not only depend on the quantity and severity of urine and/or faecal loss, but also on the body size, mobility and activity degree, skin condition, cognitive capabilities, comfort needs, ease of use, day or night use and not to forget the price that comes at charge of the patient.<sup>[54]</sup> Also the number of pads used per day can vary largely, depending on needs, product choice (heavier products may require less renewal) and personal preferences.

In what follows we bring together a number of data from cost estimates or cost studies that previously have been performed in a Belgian context.

### 6.2 Urobel cost estimates

Table 53 shows a number of cost estimates made by Urobel. A distinction is made between the type of material used and the severity of incontinence (light versus severe).



**Table 53 – Cost estimates Urobel**

	Unit cost (€/piece)	N° used/day	Year cost
<b>Light urine loss</b> (Prices are based on name-brand (not store brand) products sold in a supermarket.)			
Panty liner (for various use, including light incontinence)	0.07 €	3	77 €
Incontinence material (thin pad)	0.14 €	3	153 €
Incontinence material (pad)	0.28 €	3	307 €
Incontinence adult napkin or pull up pant	0.80 €	3	876 €
<b>Heavy urine loss</b> (Prices are based on products sold in a home care shop.)			
Pad (without net pant)	0.43 €	4	628 €
Adult napkin	0.69 €	4	1 007 €
Pull up pant	1.34 €	4	1 956 €

Source: [55]

### 6.3 VAPH data

In 2010 VAPH made a number of cost estimates on patient's costs for absorbent materials for incontinence. The old VAPH lump sums for incontinence were based on these estimates, as shown in Table 54. The costs were differentiated for:

- Patients < 12 yrs versus ≥ 12 yrs
- Night versus day and night incontinence
- UI versus FI
- Passive incontinence or not
- Use of catheters or not
- Need for bed protection (permanently bedridden patient or else).<sup>[56]</sup>

Note that these assumptions were made for patients who are recognised to have a handicap. However, costs are not expected to be very different from other patients.



Table 54 – Cost assumptions for previous VAPH lump sums

&lt; 12 years

	N° of pieces Day (1)	Price/piece Day (2)	N° of pieces Night (3)	Price/piece Night (4)	Year cost (5)	→ Lump sum *
Night incontinence			1	0,35 €	128 €	125 €
UI day and night; use of catheters	1	0,30 €	1	0,35 €	237 €	225 €
UI day and night; no catheters used	2,5	0,30 €	1	0,35 €	402 €	400 €
UI day and night; passive continence	1	0,30 €	1	0,30 €	237 €	225 €
FI or FI+UI day and night	4	0,37 €	1	0,37 €	675 €	675 €
FI or FI+UI day and night; passive continence	1	0,30 €	1	0,30 €	237 €	225 €
Permanently bedridden – supplement for bed protection					75 €	75 €

&gt;= 12 years

	N° of pieces Day (1)	Price/piece Day (2)	N° of pieces Night (3)	Price/piece Night (4)	Year cost (5)	→ Lump sum *
Night incontinence			1	0,40 €	146 €	150 €
UI day and night; use of catheters	1	0,35 €	1	0,40 €	274 €	275 €
UI day and night; no catheters used	2,5	0,35 €	1	0,40 €	465 €	475 €
UI day and night; passive continence	1	0,35 €	1	0,40 €	274 €	275 €
FI or FI+UI day and night	4	0,42 €	1	0,42 €	767 €	775 €
FI or FI+UI day and night; passive continence	1	0,35 €	1	0,40 €	274 €	275 €
Permanently bedridden – supplement for bed protection					100 €	100 €

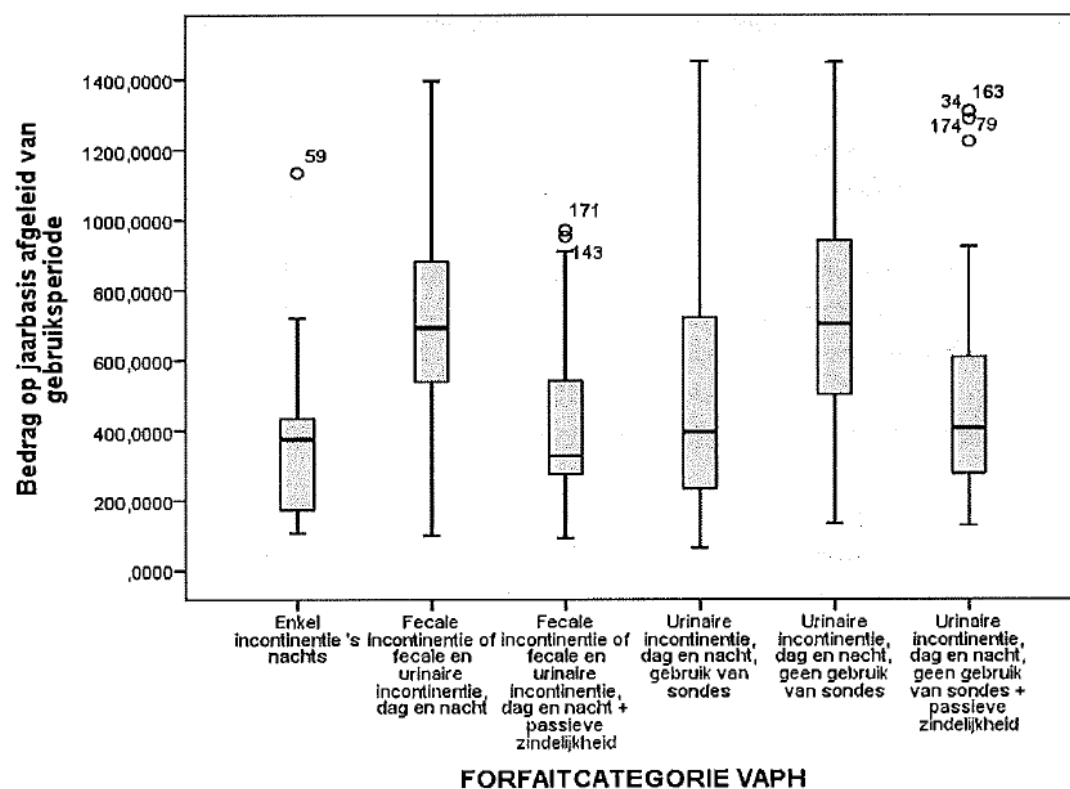
$$*(5) = ((1) \times (2)) + ((3) + (4))$$



In 2011-12 a new cost study was performed for VAPH. Invoices were collected from 274 patients. As in the previous VAPH study, the focus was on expenditures for absorbent and protecting material. Expenditures for Figure 34. The data show large variation in yearly costs per patient, both within and between the lump sum categories applied by VAPH.

catheters, medication, care products as well as unspecified expenditures were excluded. The cost results are depicted in

**Figure 34 – Results of cost study commissioned by VAPH (2011-12)**



Source: [57]

**Table 55 – Results of cost study commissioned by VAPH (2011-12)**

			v.	Median cost	n.	n
<b>Night incontinence</b>				374 €		32
<b>Day and night incontinence</b>	FI or FI + UI	No passive continence		693 €		46
	FI or FI + UI	Passive continence		327 €		19
	UI	No use of catheters		704 €		70
	UI	Use of catheters		395 €		44
	UI	Passive continence ; no use of catheters		406 €		39

Source: <sup>[57]</sup>Based on this study the VAPH lump sums for patients 12+ were adapted as follows:

- The lump sums for night incontinence were reviewed upwards from 150 € to 225 € for 12+; this is based on the median cost of 374 € minus the RIZIV – INAMI lump sum of 150 €.
- The study showed similar median costs for “UI day + night; no use of catheters” and “FI (in combination or not with UI)”. Therefore the revised lump sums no longer distinguish between UI and FI. The new lump sum for these indications was set at 555 €, based on the median costs of 704 € and 693 € minus the RIZIV – INAMI lump sum of 150 €.
- The study showed similar median costs for “UI day + night; passive continence” and “FI (in combination or not with UI); passive continence”. The new lump sum was set at 255 €. This is more or less based on the median costs of 406 € and 327 € minus the RIZIV – INAMI lump sum of 150 €.

It was assumed for these patient groups that they receive the RIZIV – INAMI “small lump sum”; however, in reality some patients may receive or be entitled to the “large lump sum”.

- For “UI day + night; use of catheters”, the new lump sum was set at 395 €. This is based on the median cost of 395 €. This patient group is not eligible for the RIZIV – INAMI lump sum of 150 €.

The lump sums for patients under 12 and under 5 were adapted in a similar way.<sup>[57]</sup>



## 6.4 Data estimates from Dutch College Voor Zorgverzekeringen

According to health insurance data from the Netherlands, 70% of the patients who declared costs for absorbing material for incontinence, had costs below €250. 30% of patients declared more than 250€ per year. The patient population concerns persons who stay at home, not in a nursing home. The more detailed data are presented in Table 56.

**Table 56 – Estimated cost per user for incontinence absorbent material in the Netherlands (2009), based on macro data**

Estimated cost per user 2009	% of users
0 to 75 euro	28%
75 to 150 euro	24%
150 to 250 euro	17%
250 to 500 euro	16%
500 euro or more	15%

Source: GIP / College voor Zorgverzekeringen

In the Netherlands, under the new system of day prices for incontinence pads, a pharmacist, a nurse or other health professional at work at the pharmacy or medical shop, categorises patients into profiles defined by the health insurers. Achmea, VGZ and Menzis (three amongst the four largest health insurers in the Netherlands), divide patients into 7/8 profiles. The profiles range from 0 (light incontinent) to 6/7 (heavy incontinent).

## 7 BELRAI

### 7.1 Introduction

Currently a multitude of scales are used by the federal and federated instances in Belgium to measure the care needs of a person (Katz scale, *BEL profiel*, *zorgzwaarte instrument*, ...). As using different scales creates inefficiencies (a person needs to be assessed several times and the assessments cannot be re-used by other instances), a new scale, BelRAI, is being developed with the aim to become the unique scale.

BelRAI is an instrument that enables to collect high-quality data about the patient, in a longitudinal way, and to share these data between healthcare professionals. The data are collected online through a website. The general goal of BelRAI is to improve care for vulnerable persons. BelRAI is the Belgian version of InterRAI which was initially developed for elderly in residential setting (RAI: Resident Assessment Instrument). Over time, RAI has developed to InterRAI to be used in a wider range of settings.<sup>[58]</sup>

BELRAI is currently rolled out, used and or investigated in the following settings:

- Home care
- LT care facilities
- Acute care
- Palliative care
- Mental health
- Community mental health.

The question in this report arises, “Could the BelRAI also be used for granting the lump sums for incontinence?” As we explore possible alternatives to the Katz scale for scoring incontinence, we will briefly examine in this chapter how incontinence is scored in the BelRAI, by whom and for which patients.



## 7.2 BelRAI items on (in)continence

InterRAI and BelRAI have a dedicated section on continence as part of the module on home care, with five subheadings H1 to H5. The section N on treatments and procedures comprises a subheading N4 which covers incontinence materials.

### BelRAI components on incontinence

(For French version we refer the reader to <http://wiki.belrai.org/fr/>)

#### H. CONTINENTIE

##### H1. Urinecontinentie

Het gaat om continentiepatronen van de periode over de laatste 3 dagen, 24 uur per dag.

0. Continent — Volledige beheersing (ook door mictietraining, ...). GEBRUIKT GEEN katheter of een ander urineopvangsysteem.

1. Volledige beheersing met om het even welke katheter of stoma — Volledige beheersing met gebruik van om het even welke katheter of om het even welk urineopvangsysteem in de laatste 3 dagen (ook intermitterend gebruik of autosondage).

2. Accidenteel incontinent — Continent in de laatste 3 dagen, maar accidenteel incontinent.

3. Minder vaak dan dagelijks incontinent — Incontinentievoorvallen minder vaak dan dagelijks.

4. Dagelijks incontinent — Dagelijks incontinent, maar nog enige beheersing (bijv., gedurende een bepaald deel van de dag).

5. Incontinent — Geen beheersing (d.w.z. elke dag voortdurend incontinent).

8. Kwam niet voor — Geen urineoutput in de laatste 3 dagen.

##### H2. Urineopvangsysteem

0. Geen

1. Condoomkatheter

2. Verblijfkatheter

3. Cystostoma, nefrostoma, ureterostoma, ...

##### H3. Stoelgangcontinentie

Het gaat om continentiepatronen van de periode over de laatste 3 dagen gaat, 24 uur per dag.

0. Continent — Volledige beheersing. GEEN stoma aanwezig.

1. Beheersing met een stoma in de laatste 3 dagen.

2. Accidenteel incontinent — Continent in de laatste 3 dagen, maar accidenteel incontinent.

3. Minder vaak dan dagelijks incontinent — Incontinentievoorvallen minder vaak dan dagelijks.

4. Dagelijks incontinent — Dagelijks incontinent, maar nog enige beheersing (bijv., gedurende een bepaald deel van de dag).

5. Incontinent — Geen beheersing (d.w.z. elke dag voortdurend incontinent).

8. Kwam niet voor — Geen stoelgang in de laatste 3 dagen.

##### H4. Incontinentiemateriaal

Het gaat om ieder absorberend, wegwerp of herbruikbaar, incontinentiemateriaal dat door de cliënt gedragen wordt of bijvoorbeeld in bed wordt gelegd. Beschermingsmaterialen (matras- en zetelbeschermers) die routinematig bij cliënten die nooit of bijna nooit incontinent zijn worden gebruikt, vallen hier niet onder.

0. Nee



1. Ja

#### **H5. Stoma**

Aanwezigheid van stoma:

0. Nee

1. Ja

### **N. BEHANDELINGEN EN PROCEDURES**

#### **N2. Ontvangen of geplande behandelingen en programma's in de laatste 3 dagen**

n. Mictie- of blaastraining – Een schema waarbij zorgverleners of familie elke dag, op geplande tijdstippen de cliënt naar het toilet begeleiden, of de cliënt bijvoorbeeld een urinaal geven, of de cliënt er aan herinneren naar het toilet te gaan.

##### **Codering:**

- 0. Niet opgedragen EN kwam niet voor
- 1. Opgedragen, niet uitgevoerd
- 2. Op 1-2 van de laatste 3 dagen
- 3. Dagelijks in de laatste 3 dagen

#### **N4. beperkende maatregelen en noodzakelijke hulpmiddelen**

Voor elk van volgende materialen wordt een score gegeven:

- 1. Inlegluiers
- 2. Stretchbroekjes en inlegluiers
- 3. Luiers (pleistersysteem)
- 4. Pants (luier en slip in één)

5. Bedbeschermers

6. Stoel- en/of zetelbeschermers

Scores:

- 0. Niet gebruikt
- 1. Minder dan dagelijks gebruikt
- 2. Dagelijks gebruikt, maar alleen 's nachts
- 3. Dagelijks gebruikt, maar alleen overdag
- 4. 's Nachts en overdag gebruikt, maar niet constant
- 5. Constant 24 uur gebruikt (omvat ook periodiek losmaken)

Source: <sup>[58]</sup>

### **7.3 Clinical assessment protocols (CAPs)**

On the basis of the BelRAI scores, clinical assessment protocols (CAPs) are automatically calculated. CAPs send an alerting signal in case there are potential or actual problems for which professional follow-up is required. There are CAPs for urinary incontinence and bowel conditions.

#### **7.3.1 CAP for urinary incontinence**

The CAP algorithm for UI results in four groups of patients:

- 3 = CAP triggered to Facilitate Improvement in Bladder Function
- 2 = CAP triggered to Prevent Decline-Higher Rate of Decline Expected
- 1 = CAP not Triggered-Continent
- 0 = CAP not Triggered-Poor Decision-Making



When a CAP for urinary incontinence is activated, the general care goals are:

- To recognise UI and to determine the causes
- If possible, to improve the bladder function by starting up adequate diagnostic and therapeutic interventions (code 3)
- If improvement is difficult, to prevent worsening of the condition in people who could possibly benefit from a treatment programme (code 2)

#### 7.3.1.1 UI CAP code 3: Facilitate improvement in bladder function

The UI CAP code 3 is for persons with all of the below characteristics:

- Recurring episodes of incontinence (also if less than weekly) or of lack of urine production
- A minimum of cognitive capabilities (independent or to limited extent independent in terms of cognitive skills in the daily decision-making)
- Can move to limited extent independently (so not fully dependent or requiring considerable help to move)
- Fulfills at least one of the following acute criteria:
  - Does **not** follow miction training or
  - Has at least one of the following characteristics pointing to a variable status which implies that UI is recent and for which improvement is possible:
    - Hip fracture
    - Recent ADL-decline

- Use of permanent catheter
- Has a pneumonia
- Has diarrhea <sup>i</sup>

In other words, if a person is on miction training, he/she cannot be assigned to group 3 (“to facilitate improvement”), but will be assigned to group 2 (“to prevent decline”), unless he/she has had a hip fracture, recent ADL-decline, ... .

- In the US, about 5% of elderly in residential care setting belongs to this group, 10% of elderly with home care and 2% of elderly who live independently. About 22% of elderly in residential care setting will show improvement of the condition. About 16% of elderly with home care will show improvement. About 15% of elderly in residential setting will show deterioration. About 10% of elderly with home care will show deterioration.

#### 7.3.1.2 UI CAP code 2: Prevent decline

The UI CAP code 2 is for persons with:

- Recurring episodes of incontinence (also if less than weekly) or of lack of urine production
- ‘Independent’ to ‘medium limitation’ in terms of cognitive skills in the daily decision-making (so not severely limited)
- Can move independently to limited extent (so not fully dependent or receiving a lot of help to move)
- Does **not** fulfil any of the below two criteria:
  - Does **not** follow “miction training” or

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<sup>i</sup> Note that according to experts participating to the expert meetings also urinary tract infection should be added to this list.





- Has at least one of the following characteristics pointing to a variable status which implies that UI is recent and for which improvement is possible:
  - Hip fracture
  - Recent ADL-decline
  - Use of permanent catheter
  - Has a pneumonia
  - Has diarrhea <sup>j</sup>

In other words, if a patient is on miction training, he/she is assigned code 2 ("to prevent decline"), unless in case of hip fracture, recent ADL-decline, ... , in which case he/she will be assigned code 3 ("to facilitate improvement").

In the US, 40% of elderly living in residential care setting, 24% of elderly with home care and 5% of elderly living independently belong to this group with code 2. In a period of 90 days, about 20% of the elderly staying in residential care will deteriorate, whilst 10% will show improvement. 10% of elderly with home care will deteriorate, whilst 10% will improve.

#### 7.3.1.3 UI CAP code 1: Continent

- The UI cap is not activated for people with CAP code 1. CAP code 1 is assigned to people who are continent for urine or who use a catheter or stoma.
- In the U.S. about 35% of elderly in residential setting belong to this group. In elderly with home care this percentage is 55%. In elderly living independently this is 92%.
- UI CAP code 0: Poor decision-making
- The UI cap is not activated for people with CAP code 0. CAP code 0 is assigned to people who have no observable consciousness or who

have very limited cognitive skills for daily decision-making (severely disturbed).

In the U.S. about 15% of elderly living in residential setting belong to this group. In elderly with home care, this percentage is at 11%, whilst in elderly living independently the percentage is lower than 1%. <sup>[58]</sup>

#### 7.3.1.4 Rest group

Note that the above CAP codes do not cover the full patient population, as there is a rest group of patients who are fully dependent or require a lot of help to move, for which a CAP should not be triggered.

#### 7.3.2 CAP for bowel conditions

The CAP for bowel conditions deals with constipation, diarrhea and faecal incontinence.

The CAP algorithm for bowel conditions results in three groups of patients:

- 2 = Triggered With Potential for Improvement
- 1 = Triggered to Prevent Decline
- 0 = Not Triggered

To identify the groups, first the sum must be made of chance-for-deterioration items:

- Cognitive skills for daily decision-making (severely impaired)
- Eating ('needs supervision' to 'total dependency')
- Mobility in bed (total dependency, did not occur)
- Urine continence (incontinent)
- Easily distracted (changed behavior)

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<sup>j</sup> Idem previous footnote



- Periods of changed perception or changed consciousness (changed behavior)
- Periods of confused speech (changed behavior)
- Mental situation changes over the course of the day (changed behavior)

Then secondly, the sum must be made of chance-for-improvement items:

- Use of toilet ('independent' to 'requires help to limited extent')
- Formal caregivers believe the patient can be more independent
- Pneumonia
- Deteriorated
- Urine continence ('continent' and 'usually continent')
- Hip fracture in the last 180 days

#### 7.3.2.1 *Bowel condition CAP code 2: Potential for improvement*

A CAP is activated for potential for improvement, when the person meets the following three conditions:

- The SUM of the chance-for-deterioration items is 0 or 1, AND
- The SUM of the chance-for-improvement items is 2 or more AND
- Score of faecal continence is higher than 0 ('usually continent' to 'incontinent')

This group covers about 5% of elderly in residential care setting, 7% of elderly with home care and less than 1% of the independently living elderly.

About 33% of the elderly in residential care will improve over a period of 90 days, whilst 19% will deteriorate. In elderly with home care, the percentages are respectively 20% and 6%.

#### 7.3.2.2 *Bowel condition CAP code 1: Prevent decline*

The person must meet the following two conditions:

- SUM of the chance-for-deterioration is 2 or more AND
- Faecal continence is not coded as incontinent (so a score below 4)

This group comprises about 15% of elderly in residential care setting, 6% of elderly with home care and less than 1% of independently living elderly. About 30% of elderly in residential care will deteriorate in a period of 90 days, whilst 11% will improve. In elderly with home care, these percentages are respectively 14% and 13%.

#### 7.3.2.3 *Bowel condition CAP code 0: Not triggered*

All other persons are categorised under code 0 for which a CAP is not activated. Some persons in this group have bowel problems and should, if necessary, get a normal treatment for it.<sup>[58]</sup>

## 7.4 *Assessment of the possible use of BelRAI for the incontinence lump sums*

### 7.4.1 *Sensitivity of the BelRAI scale for incontinence*

In order to evaluate whether BelRAI could be a useful tool for selecting patients that should be eligible for a lump sum for incontinence, first question to be addressed is whether BelRAI provides a scale that is **sensitive** enough to

- A. distinguish those patients who are in need of a lump sum for incontinence, and
- B. divide these patients into groups with more or less homogeneous expenditures, e.g. following the criteria currently set for the large and the small lump sum, and
- C. distinguish those patients who have followed first-line treatment (for whom this can reasonably be expected) as a condition for obtaining a



lump sum. This distinction is particularly of relevance for the patient group currently eligible for the small lump sum.

On the basis of the BelRAI instrument the following types of incontinence can be distinguished:

- Urinary versus faecal versus combined incontinence
- Day versus night versus day-and-night incontinence
- Severity degree: accidentally incontinent – less than daily incontinent – daily incontinent but with some control – fully incontinent
- Furthermore it is known whether the patient is heavy care-dependent, has advanced dementia, is on 'miction training', ...

On the basis of these characteristics, BelRAI could possibly be used for assessing the eligibility of a patient for the lump sums for incontinence (A.), and for distinguishing a limited number of patient groups to adapt the level of the lump sum (B.). However, BelRAI does not allow to distinguish patients who have gone through a care trajectory or not.

So in conclusion, the BelRAI could possibly replace the KATZ scale for the large lump sum. If the BelRAI would be used for the small lump sum, it would need to be complemented with a form filled out by a GP/physician to attest that the patient has gone through a care trajectory.

Note that the instrument cannot be changed, as it is based on the InterRAI which has been internationally validated. The only option to change is to add a new item, but given that BelRAI is already very exhaustive, this is not a desirable option.

#### 7.4.2 For which patients can the BelRAI be filled out?

BelRAI can be filled out for all persons in need of care from the age of 16 years. First a person is assessed on the BelRAI screener. If the person appears in need of care, he or she gets a full BelRAI assessment.

For patients suffering from incontinence who have not undergone a BelRAI assessment for another reason, it would be possible to only fill out the

sections required for incontinence. As long as each section that has been started is complete, the assessment is accepted.

#### 7.4.3 Who fills out the BelRAI?

All health professionals as recognised by the coordinated law of May 10<sup>th</sup> 2015 regarding the execution of health professions (replacing the so-called Royal Decree n° 78) are allowed to fill out the BelRAI. If the BelRAI would be used to identify patients eligible for an incontinence lump sum, RIZIV – INAMI could impose that all required sections are filled out by a certain sub-selection of health professions, like nurses, physiotherapists or physicians.

A health professional can also fill out part of it, but each started section has to be completed. It is possible that multiple assessments are done by several health professionals, over time or at the same time. In this case, each file stands on its own, there is no calculation of mean score and the latest assessment does not cancel previous assessments.

- **The incontinence questions in BelRAI could potentially be used for the incontinence lump sums. However, the feasibility and appropriateness should be further tested when BelRAI becomes more operational.**
  - **BelRAI could be used as tool to detect incontinent patients for whom treatment is difficult (i.e. patients with no mobility or advanced dementia; this group largely overlaps with the patients currently eligible for the large lump sum) and to whom a lump sum could be automatically granted.**
  - **If BelRAI would be used to detect incontinent patients eligible for the small lump sum or any new lump sum, it would need to be complemented with a form filled out by a GP/physician to attest that the patient has gone through a care trajectory.**
  - **With BelRAI the the lump sums could potentially be refined on the basis of type and severity of incontinence.**



## 8 POLICY ANALYSIS: ASSESSMENT OF THE CURRENT SITUATION AND PROPOSALS FOR IMPROVEMENT

### 8.1 Introduction

Up to this point, we have provided facts and data about incontinence. We examined the clinical literature to get an overview of guidelines on management of incontinence. We examined how patients are currently treated and reimbursed for incontinence. In parallel, we looked at other countries to get a view on possible alternatives for the Belgian approach and we presented existing data on costs incurred by patients in Flanders. In this chapter we put the different elements together and make an appraisal of the current situation. We look at possible alternatives and propose suggestions for improvement.

We have split up the appraisal in a number of subtopics:

- Reimbursement method: periodical grants versus alternatives
- Accessibility to the lump sums
- Eligible indications
- Accessibility to diagnosis, treatment and support aids
- Possible patient typologies
- Which scale to use
- Patient information on support aids
- Patient awareness and health literacy
- Focus on the setting of home care
- Focus on the setting of continence clinics
- Involvement of both the federal and federated levels

### 8.2 Methods

This chapter combines and triangulates the input from the previous chapters with elements from interviews with stakeholders and two expert meetings. The following stakeholders were separately interviewed:

- General Practitioners (n=8)
- Specialist physicians: gynaecologist, urologist (n=2)
- Incontinence nurses: representative of Urobel and incontinence nurse at specialised incontinence clinic (n=2)
- Nurse coordinator of home care nursing organisation (n=1)
- Physiotherapists: representatives of Pelvired and ABCIG BICAP ([www.pelvired.be](http://www.pelvired.be); [www.AXXON.be](http://www.AXXON.be) and [www.BICAP.be](http://www.BICAP.be)) (physiotherapists specialised in pelvic floor rehabilitation and perinatal physiotherapy) and physiotherapists at specialised incontinence clinics (n=3)
- Representative of a patient organisation (n=1)
- Controlling nurse from RIZIV – INAMI (n=1)
- Collaborators of sickness funds (n=2)
- Representatives of the section Incontinence of the federation of the medical technologies industry, beMedTech (n=3)

For a detailed overview of the experts and stakeholders that participated to the expert meetings, we refer the reader to the colophon.



### 8.3 Reimbursement method: lump sum versus reimbursement per item

#### 8.3.1 Assessment of the current situation

**In general, stakeholders see lump sums (periodical grants) as a viable way to reimburse absorbent materials**

Compared to reimbursement upon prescription, an approach with lump sums has a number of strengths:

- It poses limited administrative burden, for the physicians and the patients, as no repeated prescriptions are required.
- It empowers patients to choose for the products they prefer. In a system of reimbursement upon prescription, patients can only choose for products which are part of a reimbursement list.
- Price competition and product innovation may be stimulated, as patients will choose for the product with the best value for money.
- Patients can purchase the products in any shop, not just pharmacies.
- It is a possible way to (more or less) contain and control costs from the health insurance perspective. Expenditures per patient are fixed to the amount of the lump sums.

Still, the method of lump sums also poses some specific challenges. As in reality patients' costs vary widely, inevitably for some patients the lump sums will be too small, and for other, they will be too generous. One can also never be 100% certain that the patient effectively uses the lump sum for absorbent materials. This makes that the conditions for the lump sum have to be well-thought and that the patients have to be categorised in groups in such way that their costs are expected to be homogenous. These are some of the challenges that will be discussed in further sections.

### 8.4 Access to the incontinence lump sums

#### 8.4.1 Evaluation of the current situation

**Accessibility of the lump sums: some patients fall through the cracks**

##### Small lump sum

As long as the form for the small lump sum is complete and the patient meets the administrative conditions, requests are approved by the sickness funds. In this sense, the small lump sum is relatively accessible. However a critique is that still many patients may fall through the cracks, as

- often patients do not know of the existence of the small lump sum
- even if patients do know the small lump sum, they may think the initiative should come from the GP. If the GP does not propose the form, the patient may think he/she is not eligible. The patient may also be hesitant to ask the GP for the form as it may feel like begging for money. The patient may also be embarrassed to talk about his/her incontinence and may not bring up the problem simply to avoid the administration.
- many GPs do not know of the existence of the small lump sum and often do not take the initiative to propose the lump sum (though exceptions exist - we encountered a GP practice that started a project to detect incontinence in frail elderly at home with the aim to optimise care and access to the lump sum).
- urologists and other specialists are often not aware of the lump sum and are not allowed to fill out the form. There are patients however who prefer to skip the GP and go directly to the specialist to discuss their incontinence problem. According to a patient organisation, some patients have gone through a complete care trajectory and have never been informed by any physician about the lump sum.



### Large lump sum

Given that the large lump sum is granted automatically on the basis of the Katz scale as filled out by a home nurse, the lump sum is also relatively accessible, especially to persons who get visited by a home nurse.

An alternative access track to the lump sum has been created for patients who do not call upon the services of a home nurse. These patients can obtain the large lump sum on the basis of a written statement by a physician. Data show that 9% of patients who benefit from the large lump sum get access through this alternative track. As this statement can be written by any physician (GPs as well as specialists), the chances that the problem is picked up by any of the treating physicians are increased. However, similar critiques hold as for the small lump sum:

- a group of heavy dependent patients stays at risk of being left out, notably those who do not get Katz scoring by a home care nurse, as they may be unaware of consulting a physician for it.
- sometimes physicians are unaware of its existence and they may find the administrative burden high, especially when extra documentation is required by the sickness fund.

### **There is an underuse of the lump sums in Wallonia and Brussels compared to Flanders**

Furthermore, data show that almost 9 patients out of 10 receiving a small lump sum live in Flanders (86.5%) against 12.5% in Wallonia and only 1% in Brussels. The geographic distribution of beneficiaries of a large lump sum is better: respectively 61%, 33% and 6% of patients living in Flanders, Wallonia and Brussels, respectively.

### *8.4.2 Proposals for improvement*

**Strengthen communication and information towards both health professionals and patients** about the existence of the lump sums.

**Make the small lump sum (or any future lump sum) prescribable not only by GPs but also by other involved physicians:** urologists, gynaecologists, geriatricians, paediatricians, colorectal surgeons, gastroenterologists and neurologists.

**Provide clear guidance as to who is expected to take the initiative to propose the form for the small lump sum (or any future lump sum):** both the prescribing health professionals and the patient. This is currently not clear and leads to assumptions being made by both GPs and patients: GPs assume the patient will ask for it if they need it, and patients assume the GP will propose it to them if it is applicable to them. These assumptions cause misunderstandings and could be avoided by clearly stating on the form that both the prescribing health professional and the patient should raise the form whenever they think it is applicable.

## **8.5 Eligible indications**

### *8.5.1 Assessment of the current situation*

#### **Some indications are currently not covered**

The small lump sum covers urinary incontinence, but excludes faecal incontinence. This means that there are patients with faecal incontinence who are not eligible for the small lump sum, nor the large lump sum (this is notably the case for patients with faecal incontinence who are not heavy care-dependent).

#### **Some patients miss out on a lump sum because of too strict exclusion criteria**

The small lump sum cannot be combined with reimbursements for sheaths or CIC, whilst some patients prefer to combine the use of a sheath at night with the use of absorbent material during the day, e.g. to protect against skin





irritation, or patients performing CIC may wear pads to protect against daytime accidents or for overnight protection.

**The form for the small lump sum is too vague and the interpretation of “untreatable” varies**

Through the form for the small lump sum, the GP has to provide information on

1. the patient,
2. the evaluation of the patient: anamnestic factors, clinical information, technical investigations and referrals, and therapy (medication, physiotherapy, and surgery); and
3. a conclusion statement that treatable factors have been excluded, the patient has received all available treatment and continues to suffer with incontinence.

The small lump sum is meant for “untreatable incontinence”, but this is an ambiguous term. *Sensu stricto* it can mean that a patient has gone through a complete care trajectory, up to the specialist (including surgery) and despite all possible interventions could not be cured. However, the term can also be interpreted less strictly and in practice it is left to the individual judgement of the GP. Although it is considered perfectly normal to call upon the clinical judgement of the GP to evaluate the treatment possibilities for each individual patient (and for instance to evaluate up to which point a patient can be expected to follow physiotherapy, taking into account the guidelines), the form lacks clarity on where to draw a line on certain aspects. It is for instance not clear if a patient who was proposed (non-reimbursed) medication but who finds it too expensive to continue, should be considered “untreatable”.

In reality some GPs judge that patients should be entitled to the lump sum, even when they have not tried treatment. GPs state they aim to maximise the quality-of-life of their patients, and if the patient prefers to wear absorbent pads instead of taking treatment, they fully support the patient in his/her preference. Many of their patients do not see incontinence as their

main concern, as they often have co-morbidities. Therefore the GPs do not want to put extra burden on the patient with medication or physiotherapy.

Furthermore the form is vague and too open for interpretation on certain indications. It is not clear whether the indications of night incontinence, light incontinence, stress incontinence, urge incontinence, overflow incontinence, ... are included or not. The interviews with the GPs demonstrated that the understanding of whether these indications are included or not varies.

**The indications for the large lump sum also require further specification**

In order to grant a patient the large lump sum for incontinence, the home care nurse has to fill out the form which primarily serves to determine the home nursing lump sum. The Katz scale on this form has the following four scores for incontinence:

- Score 1: continent
- Score 2: occasionally incontinent
- Score 3: incontinent for urine or faeces
- Score 4: incontinent for urine and faeces.

Instructions are given by RIZIV – INAMI on how to categorise certain patients on incontinence:

- Score 2:
  - Occasionally incontinent, e.g. stress incontinence or dribbling
  - Artificial anus
  - Urostomy
  - Indwelling catheter
  - Self-catheterisation
- Score 3:



- Continuously suffering from undeliberate urine OR faeces loss
- On miction training (get support from caregiver to go to toilet min. 4 times a day)
- Catheterisation by a third person
- Permanent inappropriate behaviour when going to toilet, for urine OR faeces
- Score 4:
  - Continuously suffering from undeliberate urine AND faeces loss
  - Permanent inappropriate behaviour when going to toilet, for urine AND faeces

Thanks to these instructions the eligible indications for the large lump sum are relatively clear. However, also here some vagueness remains on e.g. night incontinence and urge incontinence.

#### **A number of countries and regions explicitly exclude light incontinence forms**

From what we see abroad and at federated level, a number of countries and regions explicitly exclude short term incontinence, light incontinence, night incontinence, stress incontinence, urge incontinence, and or encopresis. The exclusion of light forms of incontinence can be supported on the basis of several arguments:

- Patients with light incontinence face lower costs than patients with moderate, heavy or total incontinence. In the Netherlands, it has been shown that 30% of incontinent patients declare less than €75 for incontinence pads on yearly basis. This is a cost that most patients can pay for themselves.
- Incontinence with lower symptom severity and lower frequency is associated with a lower degree of bothersomeness. Not all incontinent persons declare to be bothered by the condition.
- In its widest definition, urinary incontinence has a very high prevalence. If all urinary incontinence is included, it may become too expensive for

the health insurer to cover. If light forms of incontinence are excluded, more means may be available to reimburse patients with moderate, heavy and total incontinence.

Some countries do not exclude but adapt the grant level for light incontinence. We refer to e.g. profile 0 and 1 in the Netherlands with a respective coverage level of €60 and €95 per year.

#### **There are no clear rules as to how to deal with short term incontinence**

In reality it is often not known ex ante whether incontinence will be short or long term.

- E.g. The duration of UI after radical prostatectomy varies widely. On average it may take about 30 to 40 days, but it can take up to 5 months or can eventually remain permanent.<sup>[59]</sup>
- Another example is in case of major pelvic surgery. Most commonly, patients will spontaneously recover within 6 months, however, for others recovery may take longer, or incontinence may eventually be irreversible.

For the large lump sum there is a minimum incontinence duration of four months (four months of the last twelve months preceding the award). For the small lump sum, however, it is currently not clear from what point onwards a patient is eligible for it. The possible uncertainty around the duration of incontinence points to the need for a workable definition of short term incontinence, e.g. by defining a minimum duration of incontinence applied looking backward, ex post. In the Netherlands, short term incontinence is defined as shorter than 2 months for UI and shorter than 2 weeks for FI; e.g. short term incontinence that occurs after an operation or during and after pregnancy or incontinence that is expected to be temporarily, e.g. in period of urinary infection or flu.

Note that also people with short term incontinence may benefit from a care trajectory, especially for prevention in the longer run. These patients should follow the same care pathway as other patients, however they do not necessarily have to follow the same lump sum pathway.





### 8.5.2 *Proposals for improvement*

**Expand the lump sums to include faecal incontinent patients that are not care-dependent.**

**Reimbursement for the use of sheaths or CIC should not be an absolute exclusion criteria for the small lump sum as some patients require absorbent material in combination with it.**

- The amount of the lump sum for these patients should be lower than for patients who do not use sheaths or CIC.

**Clearly define the indications for coverage of the lump sums**

- As the term “incontinence” covers a wide continuum ranging from very light, for some patients unbothering, symptoms to more severe symptoms, up to total incontinence, it is necessary to clearly define the conditions for the lump sums. The indications which are meant to be covered should be sufficiently detailed and refined so that health professionals apply the same rules.

**Light forms of incontinence: lower the grant level?**

- Considering the above mentioned arguments, it should be considered to adapt the grant level for light forms of incontinence:
  - **Night incontinence:** Costs for absorbent products are lower in case of night incontinence than in case of day-and-night incontinence. We refer to the cost studies performed for VAPH.
  - **Stress and urge incontinence:** Stress and urge incontinence can be considered light incontinence. Costs in case of light incontinence are lower than in case of heavy or total incontinence.
  - Experts participating to the meeting however did not find using a threshold like in Germany and Switzerland of “< 100 ml loss in 4 hrs” a feasible way to exclude light incontinence as it is difficult to precisely measure the loss. They also share the opinion that this threshold is very high (they do not consider a loss of up to 100 ml/4hrs to be light).

**Clarify interpretation rules for short term incontinence**

- As the small lump sum is currently meant for “untreatable incontinence”, short term incontinence is currently excluded, but it would be worth explicitly stating and detailing it, so that the definition is clear for both physicians and patients. The definition of short term incontinence should take into account the validity period of the lump sums (which is currently one year for the large lump sum and three years for the small lump sum).
- Making the amount revisable for incontinence that has stopped before the lump sum period has expired is another possibility, but involves practical difficulties (how to check how long the incontinence lasts?).

**It is currently not clear whether patients who take non-reimbursed medication are eligible for the small lump sum. The incoherency in the reimbursement system (incontinence materials versus drugs) should be tackled**

- Whilst there is a lump sum for incontinence materials, many incontinence drugs are not reimbursed. This gives patients and health professionals the impression that the reimbursement system favours absorbent materials over drugs. Cost-effectiveness and budget impact analyses should be undertaken to decide on the usefulness and the possibility to reimburse more incontinence drugs in second line. In theory, expenditures for incontinence drugs and incontinence materials should to a certain extent be communicating vessels (if more incontinence drugs are reimbursed, less patients need a lump sum for material). However, as cure rates are not very high (see medical chapter), it remains to be seen if this would hold in real world.

**Explicitly include patients who take non-reimbursed medication?**

- As long as many incontinence drugs are not reimbursed, it should be clarified:
  - Whether patients who take non-reimbursed medication are eligible for a lump sum, a. in case they are still suffering from some leakage and b. in case they are completely continent with the medication. In theory, if patients are successfully treated with medication, they are not “untreatable” and therefore currently not eligible for the small lump sum, however they have to pay for the relatively expensive medication. It is currently not clear for physicians how to deal with such cases.
  - Whether patients who stopped taking medication, either because they experienced intolerable side effects from the reimbursed medication or the non-reimbursed medication was unaffordable, and who preferred or were forced to switch to absorbent materials, are eligible for a lump sum.
- Some experts raised the idea to redefine the “lump sum for materials” to a lump sum that leaves the choice to the patient to spend the money either on materials or on non-reimbursed drugs. Although the idea makes sense, in practice it may be difficult to implement this proposal. A first difficulty is that the lump sum finds its legal basis in the coordinated law of 14 July 1994, Art. 34, 14° on the compulsory insurance, which mentions coverage of “materials and care products” (so drugs are not included) for patients, taken care of at home, who suffer from a severe condition or who get palliative care. A further counter-argument is that it would be a very unconventional way to reimburse drugs. If the non-reimbursed drugs appear to be cost-effective, they should simply be reimbursed following the conventional pathway to reimburse drugs.
- Note that some patients who are treated with medication continue to suffer from some (though reduced) leakage. In the current situation, it seems justifiable to grant a lump sum to these patients, especially when they do not get any reimbursement for the medication. However, should

in the future more medication be reimbursed, then the use of reimbursed medication could be an exclusion criteria for a lump sum, so that the patient would have to choose either between reimbursement of medication or a lump sum for absorbent material.

## 8.6 Patient categorisation

### 8.6.1 Assessment of the current situation

**A criticism is that there are only two levels of lump sums**

Patients dealing with incontinence currently fall in one of three categories: either they receive the small lump sum, or the large lump sum, or they receive no lump sum at all. This categorisation is rather rough taking into account the large variation in costs actually borne by the patients. The large lump sum is three times as high as the small lump sum, but this is not always in proportion to the real costs patients are confronted with. E.g. Persons who are not heavy care dependent can also suffer from total urinary incontinence, e.g. after total prostatectomy with complication, but they only receive the small lump sum.

**For some indications, the grant level is too low**

Indeed, while being incontinent and being care-dependent may go hand in hand, this need not necessarily be the case. According to the specialists interviewed, patients who are totally incontinent, yet still mobile (and e.g. at work) do exist. In the current situation, these particular patients are only entitled to the small lump sum, not the large lump sum, even if they are totally incontinent and require up to 7 pads a day. (In some but certainly not all cases these patients can be eligible for a grant by the federated instances, but only on the condition that they are recognised as being handicapped. A recognition for being handicapped needs to be obtained before the age of 65 and in Flanders, for instance, the recognition process requires the patient to present in front of a jury. This lengthy process is perceived as particularly cumbersome by the patients and therefore not commonly started.)

**The use of the Katz scale for the large lump sum is problematic**

Although it is difficult to measure and categorise incontinence in a precise way, interviewed stakeholders agree that the Katz scale is not a good tool for this. The problem with the use of the Katz scale for the incontinence lump sum works in different ways.

**First of all, the Katz scale is not a very sensitive scale to measure continence**

Katz has four scores with only three grades for incontinence (score 2: occasionally incontinent; score 3: incontinent for urine or faeces; score 4: incontinent for urine and faeces). The sensitivity of the scale is furthermore not fully exploited as the scoring translates into a dichotomous result of whether 'yes' or 'no' the patient can be entitled to the large lump sum for incontinence (depending on whether the patient gets 'score 3 or 4' versus '1 or 2'). The scoring has been refined with instructions from RIZIV – INAMI on where to categorise specific types of patients (see two left columns of Table 57). However, the scoring does not necessarily match the estimated real costs of the patients (see own estimates in right column of Table 57).

**Also there is a lack of connection between the Katz-scoring for the large lump sum and the examination for the small lump sum**

Patients who are scored on the Katz scale but not entitled to the lump sum can possibly be eligible for the small lump sum. However, in such cases, the patient must find his way to the GP on his own initiative, and the GP has to make a new evaluation of the patient's situation.

**Finally, nurses have an incentive to give a higher score**

This is because a score of 3 or 4 for incontinence is a pivot towards a higher lump sum for home care (lump sum B or C) for the nurses themselves, on the one hand, and towards the large lump sum for incontinence for the patient, on the other hand.

**Table 57 – Eligibility criteria for the lump sums and estimated costs for different indications**

	Currently eligible for large lump sum ?	Currently eligible for small lump sum ?	Estimated costs for incontinence material (not elsewhere covered by RIZIV – INAMI)
Continent	No (score 1)	No	0
Occasionally incontinent (e.g. stress incontinence or dribbling)	No (score 2)	Unclear	+
Artificial anus	No (score 2)	No	0; +
Urostomy	No (score 2)	No	0; +
Indwelling catheter	No (score 2)	No (reimbursement for indwelling catheter cannot be combined with small lump sum)	0; +
Self-catheterisation	No (score 2)	No (reimbursement for self-catheterisation cannot be combined with small lump sum)	0; +
Continuously suffering from undeliberate urine loss, but no faeces loss	Yes (score 3) If also heavy care dependent	Yes On the condition that the patient has not received the large lump sum	+++
Continuously suffering from undeliberate faeces loss, but no urine loss	Yes (score 3) If also heavy care dependent	No	+++
On miction training (get support from caregiver to go to toilet minimum 4 times a day)	Yes (score 3) If also heavy care dependent	No (as patients on miction training are care dependent and will normally receive the large lump sum)	+ ; ++ ; +++ (depends on effectiveness of the miction training, but also takes caregiver support)
Catheterisation by a third person	Yes (score 3) If also heavy care dependent	No (reimbursement for catheter cannot be combined with small lump sum)	+ (similar costs as for self-catheterisation, but also takes caregiver support)
Permanent inappropriate behaviour when going to toilet, for urine but not for faeces	Yes (score 3) If also heavy care dependent	Yes On the condition that the patient has not received the large lump sum	+ ; ++ (depends on situation)
Permanent inappropriate behaviour when going to toilet, for faeces but not for urine	Yes (score 3) If also heavy care dependent	No	+ ; ++ (depends on situation)



Continuously suffering from undeliberate urine AND faeces loss	Yes (score 4) If also heavy care dependent	Yes On the condition that the patient has not received the large lump sum	+++ ; ++++ (depends on situation)
Permanent inappropriate behaviour when going to toilet, for urine AND faeces	Yes (score 4) If also heavy care dependent	Yes On the condition that the patient has not received the large lump sum	+ ; ++ (depends on situation)
Use of penile sheaths	Yes	No (reimbursement for sheath cannot be combined with small lump sum)	+
Short term incontinence	No (but definition of short term not clear)	No (but definition of short term not clear)	+
Night incontinence only	No (score 2)	Unclear	+

+: minor costs; ++: medium costs; +++: high costs; ++++: highest costs

### 8.6.2 Possible typologies of patients

In this section we examine alternatives on how patients could be classified, to underpin a possible fine-tuning of the lump sums, more specifically to

- adapt the level of the lump sums, and or
- adapt the validity duration of the lump sums, and or
- adapt who is allowed to prescribe the lump sum.

First of all, what are determinant factors that could be used to classify patients into groups with homogeneous costs? A classification of patients ideally should be

- reliable: same person gets same score, regardless of timing of test or testing health professional; and persons in same situation get same score;
- valid: persons get scores as expected; the classification should effectively reflect one's expenditures on absorbent materials; and

- practical: it should be feasible, not posing too heavy administrative or diagnostic 'burden'.

The following classification possibilities are briefly examined in this section:

- Neurogenic versus non-neurogenic UI/FI.
- On the basis of treatment possibilities. This categorisation is currently reflected in the two lump sums of RIZIV – INAMI: the large lump sum mainly targets patients who have limited first-line treatment possibilities (given their high care-dependency), whereas the small lump sum targets patients who are still mobile but "untreatable".
- On the basis of type of incontinence (day/night ; UI/FI) and a combination of other elements like age or size of the patient and other materials used. This categorisation is used by the regional instances in Belgium.



Note that abroad we observe still other possibilities to classify patients:

- On the basis of severity of incontinence, measured by loss in ml per 4 hours. This categorisation is used in Germany and Switzerland. However, this method is criticised as the amount of loss is not easy to measure and results can be influenced (e.g. by drinking behavior before the test).
- On the basis of quantity and type of needed products, as is one of the multiple factors considered by Dutch insurers. With this approach, persons are classified very practically into groups with homogeneous material use. This system is especially well-suited for the Netherlands as Dutch patients receive products rather than a lump sum.

#### **Type of incontinence: neurogenic UI/FI versus non-neurogenic UI/FI**

- **Group of neurogenic UI/FI**
  - Different management options are possible for this patient group (see clinical chapter). Patients may require continence products for temporary support during treatment. Some patients will also require continence products in the long run.
  - The quantity of continence products used will a.o. depend on whether it is combined with other management options (catheters, drugs, ...). Therefore the costs for continence products vary largely from one patient to the other.
  - These patients are currently eligible for the small lump sum or the large lump sum (if heavy dependent). In many cases they are also eligible for a lump sum by a regional instance, as these patients may be recognised as handicapped.
  - For most patients the condition is irreversible, however it often cannot be excluded that the condition and the need for materials evolves with a change in management and treatment.

- **Group of non-neurogenic UI or FI**

- Also for these patients, different management options are possible, but the options are different than for neurogenic UI/FI, e.g. physiotherapy plays a more important role.
  - These patients are currently typically eligible for the small lump sum. They are typically not eligible for a lump sum for incontinence by a regional instance in Belgium, as these patients may not be recognised as handicapped.
  - The quantity and type of continence products used varies largely, in function of severity of condition and combination with other management options like drugs, penile sheaths, ...
  - Urgency and mixed types tend to suffer from higher volume leakage, but there are exceptions.
  - The condition can be short-term, long-standing or irreversible. Note that not necessarily long-standing means irreversible.
- In conclusion we see that this categorisation renders two groups with still very heterogeneous costs, heterogeneous treatment possibilities and uncertainty on the long-term outlook of their expenditures on absorbent material. It therefore appears not useful to use this classification for adapting the lump sums.

#### **Patients for whom containment is the only option versus patients for whom treatment is possible.**

- **Group of patients for whom containment is the only option.** According to the ICS criteria, these include elderly suffering from incontinence with advanced dementia, OR with minimal mobility i.e. require assistance of > 2 people to transfer, OR with nocturnal urinary and faecal incontinence
  - This patient group largely overlaps with the patient group currently eligible for the large lump sum. This patient group is typically not eligible for a lump sum for incontinence by a regional instance, as



these patients are not recognised as handicapped (recognition has to be obtained before the age of 65).

- The incontinence in this patient group is generally severe and so are the patient's associated costs. Nevertheless costs may vary widely depending on whether the patient is on miction training, whether it concerns only UI or also FI.
- The incontinence status of this group is irreversible and treatment is not indicated; the condition hampers participation in physiotherapy treatment. As treatment is not indicated, a lump sum can be granted by another health professional than a physician to reduce the administrative burden for the physicians. This is currently the case as the home care nurse fills out the Katz scale.
- As the condition is irreversible, the validity period of the lump sum can be extended until the patient moves out of his/her home (cfr. the current conditions for living at home) or deceases.
- **Group of patients for whom treatment is possible.**
  - Part of the patients who have undertaken or started treatment will still need continence products. Patients for which treatment options exist can be both patients with neurogenic or non-neurogenic incontinence.
  - These can be patients with lighter, medium, severe or total incontinence. The patient's costs may vary largely between patients.
  - The need for products may vary over time. Once the patient has undertaken treatment, the condition will in many cases be more or less stabilised, however, initial treatment may be followed by further treatment after time and this makes that the continence status (and the need for continence products) may still evolve over time. For patients who have not completed treatment yet, the need for continence products in the medium and long run is even more uncertain.

**A combination of type of incontinence (UI/FI, night/day), patient age/size, other materials/methods used (catheters, sheaths, miction training) and severity of incontinence (light incontinence versus severe incontinence)**

As opposed to the two above mentioned typologies, this third typology appears to reflect rather well the actual costs borne by the patient for the use of continence materials, yet also with this classification still large variation in costs remains within the groups (cfr. cost analysis performed for VAPH).

***8.6.3 Proposals for improvement***

**Using more than two categories allows to attain higher fairness in the reimbursement and allows to better distribute the financial means to those who actually need it most**

Examples abroad and inland show various alternatives to categorise patients into groups with more or less homogeneous expenditures:

- Switzerland uses three levels (medium-severe-total),
- the largest insurers in the Netherlands work with 7 to 8 profiles, differentiating on the basis of incontinence type, pattern of loss and personal situation of the patient,
- VAPH uses 9 categories (and an optional supplement), differentiating on the basis of age, night versus day-and-night and use of catheters or not
- PHARE uses 4 categories, differentiating on the basis of night versus day-and-night and age/size of the patient.
- AVIQ-Handicap uses 8 categories, differentiating on the basis of night versus day-and-night, the use of catheters, urinary versus faecal incontinence.





**Create a higher lump sum for severely/total incontinent patients who are not care-dependent (this holds for UI as well as FI)**

**Consider reducing the lump sum for the indication of light incontinence, so that more means can be distributed to patients with medium/heavy incontinence.**

**Consider slightly reducing the large lump sum for patients on miction training** and who require a minimal amount of pads, yet keeping the level high enough to give an incentive for miction training.

## 8.7 The validity period of the lump sums

### 8.7.1 Assessment of the current situation

Currently the **large lump sum** is valid for one year, after which it can be renewed (either automatically via the home care nurse Katz evaluation or upon a statement of a physician). The patient population eligible for the large lump sum is not typically expected to improve or heal from incontinence, so a longer validity period until the patient moves to nursing or care home or deceases, would be possible.

The approval for the **small lump sum** is valid for three years (once approval is obtained, the small lump sum is paid yearly, so there are three payments). As the small lump sum is for “untreatable incontinence”, in theory the lump sum could be approved for a longer period (until the patient no longer stays at home or deceases). However, as mentioned above, for many patients the long-term outlook is uncertain and in practice it is very hard for a healthcare professional to predict whether a patient will for certain stay incontinent for the rest of his or her life. The condition of some patients can still improve after a certain time, as he/she may take further steps in treatment by e.g. putting a neurostimulator, undergoing surgery after a period of containment, trying new medication, losing weight etc. Generally renewal after a 3-year period is not considered a significant burden, nor for patients, nor for GPs.

In conclusion, the validity period of three years for the small lump sum is defensible, as on the one hand, the lump sum does not target short-term incontinence (including short-term incontinence would call for a shorter

validity period), and on the other hand, for many patients the long-term outlook remains uncertain.

### 8.7.2 Proposals for improvement

The validity period of the large lump sum (of one year) could be extended as this patient population is typically not expected to return continent (and considering that short-term incontinence is excluded). This would reduce administration which would be particularly relevant when a physician introduces the demand. (In case the lump sum is granted automatically via the Katz scoring by the home care nurse, this is of less relevance as the Katz scoring has to be renewed after a year anyway to determine the home care lump sum).

## 8.8 Access to diagnosis, treatment and toileting aids

### 8.8.1 Assessment of the current situation

**There are effective first-line treatments for incontinence, but too few patients seek or receive care**

First-line treatments consist of conservative treatments, such as lifestyle interventions, pelvic floor muscle training with or without biofeedback, vaginal cone therapy and use of pessaries, sacral neuromuscular electrical stimulation, stimulation of the tibial nerve, scheduled voiding regimens (bladder training, timed voiding, habit training, prompted voiding), and acupuncture. These treatments have relatively high success rates if they are initiated at an early stage of the incontinence symptoms. They have fewer risks and adverse effects compared with pharmacologic or surgical treatments, and are less expensive, making them well-suited for all patients including older women.

A study in GP practice however showed that UI is underdiagnosed.<sup>[60]</sup> This point was also confirmed by stakeholders in the interviews. As a direct consequence of underdiagnosis, there is undertreatment. Instead of seeking professional help, many patients cope with their symptoms by using absorbent materials. GPs admit that often incontinence is not given the time





it deserves. Not only is there a lack of diagnosis and treatment, there is also a lack of access to information about other containment possibilities or toileting aids, i.e. support aids other than pads.

*“Naar schatting 70% van de mensen die nu een [klein] forfait krijgen, kunnen in eerste instantie bij de huisarts behandeld worden.”*

*“As patient organisation we see many patients who did not follow and did not get recommended physiotherapy.”*

The suspected underdiagnosis and undertreatment may find its cause in a combination of factors.

Firstly, only few patients seek professional help for incontinence problems. Studies have shown that incontinence is still considered a taboo by many patients and is a source of shame and embarrassment.<sup>[61]</sup> Some patients prefer not to be treated for incontinence, especially female and elderly patients.<sup>[62]</sup> Other patients are embarrassed to raise the problem with their GP and prefer to go directly to the urologist. At the same time, some patients may not want a referral to the urologist or gynaecologist as they fear the specialist physician will propose them to undergo surgery. However, many other options exist, before undergoing surgery.

On the other side, also many GPs acknowledge to give incontinence little attention. Research on treatment of UI in GP setting pointed to problems of lack of time and lack of knowledge of GPs, and even to “therapeutic nihilism”.<sup>[63]</sup>

Further, the home care nurse has limited time to discuss the problem with the patient. Even though the home care nurse has to fill out the Katz form and thus has to evaluate the patient’s condition with regard to continence, this does not imply that the problem is clinically discussed between the nurse and the patient. Also, the large lump sum is granted automatically, without any dedicated intervention by a GP, physiotherapist or nurse.

In summary, all interviewed stakeholders agree that incontinence is a rather “ignored” condition, not only by the patient but also by many health professionals.

### **The procedures to obtain the small or the large lump sum do not support the GP, the home care nurse nor the patient to initiate a care trajectory**

Generally the impression exists among stakeholders that also the way how the small lump sum has been conceived does not optimally incentivise patients to seek treatment for their incontinence. GPs experience the form for the small lump sum merely as an administrative task and burden as opposed to a tool helping them to link the patient into care.

*“Probleem met de forfaits is dat je de mensen luiers verkoopt, je krijgt de mensen niet in de zorg.”*

The condition of “untreatable incontinence” is not explicit and as in practice all requests are accepted, treatment currently remains voluntary.

Furthermore, although all patients seen by a home care nurse get a Katz scoring, and thus a large number of patients are “screened” for incontinence, the information from the scoring does not trigger the initiation of a care trajectory in those patients where it could be of use, which is a missed opportunity.

In fact many of the patients who get scored by a home care nurse could benefit from incontinence treatment: also many of those who are not eligible for the large lump sum for incontinence, e.g. patients who get a score 2 for stress incontinence or dribbling, or patients who get a score 3 for incontinence but who are not entitled to home care lump sum B or C. According to the ICS guidelines, even some of the patients who are entitled to the large lump sum, could still benefit from treatment.

### **GPs play a central role to make a diagnosis and start with a treatment plan**

GPs have the tools to deal with uncomplicated cases of incontinence. We refer to the clinical chapter which outlines the pathways for initial management of incontinence in different patient populations. Note that recently an innovative tool (Minze Health tool) has been launched to measure the urinary flow and volumes at home with a link to a digital application providing the information directly and in real time to the GP’s



computer or smart phone. This allows for GPs to plan the follow up of their patients more easily without having to wait for the results of a pre- and post-treatment urinary flow investigations at the urology clinic. Previously these investigations were only possible at the urology clinic where the patient had to be seated on a special chair. The Minze Health tool can be used on any toilet, including toilets for children.

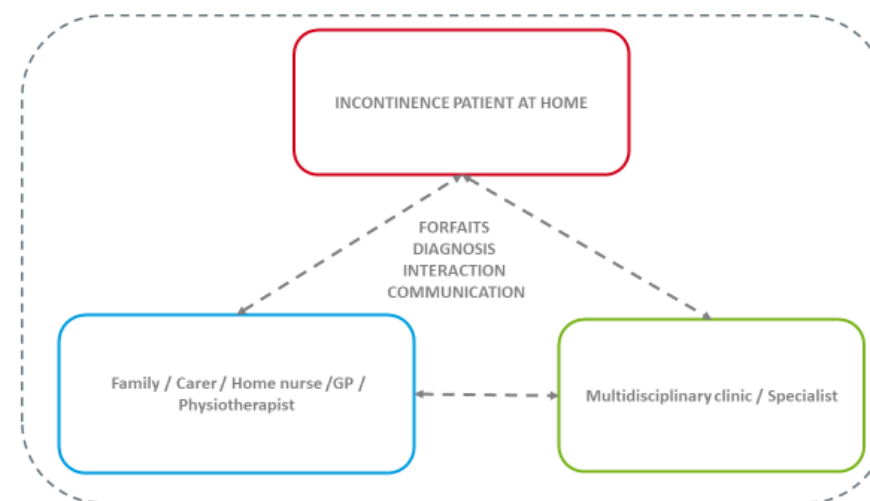
### 8.8.2 *Proposals for improvement*

**The form content for the small lump sum should be reworked to become a check-up tool rather than an administrative burden**

The form can be conceptualised as a catalyst of communication between different settings (Figure 35):

- Home care / patient living conditions
- Practitioners / Carers / Family / home care nurse / Physiotherapist
- Continence clinics / Multidisciplinary teams / Specialists

**Figure 35 – The lump sum form as a catalyst of communication**



**In order to increase the number of patients accessing diagnosis and treatment, the lump sums should be more explicitly linked to first-line care.**

In the Netherlands all patients of whom it can be reasonably expected have to start a care trajectory as a condition for reimbursement. Making grants conditional to care should effectively and at an early stage increase access into care and improve cure rates. Therefore, for all patients where treatment is of potential benefit, it should be considered to make lump sum coverage explicitly dependent on a primary care conservative care trajectory as described in the international guidelines, with - if considered useful by the GP –

- a functional assessment by a physiotherapist followed by physiotherapy for all patients of whom it can be reasonably expected, and



- an assessment of the usefulness of toileting aids and patient education on continence management by a nurse.

**Attention should be paid so that patients are not forced to any treatment and that accessibility of the lump sums is not compromised.**

At the same time, if the social security intervenes with grants for incontinence pads, a minimum of effort to comply with safe and effective treatments can be expected in advance from the patient.

As the wording “untreatable incontinence” is ambiguous, it is recommended to precise it as “a condition of incontinence that persists after having gone through at least a first-line treatment (according to the guidelines), when this can be reasonably expected from the patient”.

**Especially physiotherapy should be more generally proposed as important and first step in the treatment of incontinence.**

**In the initial phase of incontinence treatment, reimbursement should focus on making treatments maximally financially accessible.**

In order to get a more treatment-oriented trajectory for incontinence care financed in a cost-neutral way for the healthcare payer, it could be considered to re-allocate part of the first lump sum towards this trajectory. In other words, part of the first lump sum currently granted to a patient could be rechanneled towards a number of reimbursed consultations by a nurse and or physiotherapist. By doing so, patients may be more supported to effectively undertake treatment, in a way that is cost-neutral to the healthcare payer.

When considering more pro-active pathways that are more expensive to the healthcare payer in the long run, cost-effectiveness analyses are needed to investigate to what extent and under what conditions they can be cost-effective in a Belgian context (see for example an analysis performed for the Netherlands <sup>[63]</sup>).

**For all patients who have been identified of suffering from incontinence** (at least score 2 on Katz for incontinence) and who have not yet undertaken a care trajectory, **a signal or flag should be sent to the GP.**

**Public information campaigns and education of physicians should help to inform the public and physicians to engage more actively in the treatment of incontinence.**

**Consider adapting the tariffs for interventions by health professionals accordingly.**

E.g. by creating a fee for (specialised) home care nurse visits dedicated to educate the patient to manage incontinence problems.

**Consider a more detailed registration of physiotherapy acts.**

E.g. through use of pseudocodes. This will enable RIZIV – INAMI to have a clearer view on how many patients get physiotherapy treatment for incontinence.



## 8.9 Optimising the pathways to the lump sums

### 8.9.1 *Assessment of the current situation*

**Currently there are three distinct pathways to obtain a lump sum for incontinence.**

There are currently two pathways to obtain a large lump sum and one pathway to obtain a small lump sum:

- Katz scoring for home care done by a home care nurse for a large lump sum
- request statement by a physician for a large lump sum
- request form by a GP for a small lump sum.

Working with these parallel tracks has a number of advantages. First of all, the Katz scoring takes no extra administration for the home care nurse, as the nurse fills out the Katz scale anyway to determine the home care lump sum. Using the Katz scale makes that a large group of patients, for which there are limited treatment possibilities, is reached relatively easily and that GPs are not bothered by administrative formalities.

However, points of critic are that some persons who match the heavy-dependency criteria still have some treatment possibilities. Furthermore, the parallel tracks are perceived as rather confusing for physicians as they have to work with two distinct request procedures: a statement for the large lump sum, on the one hand, and a form for the small lump sum, on the other hand.

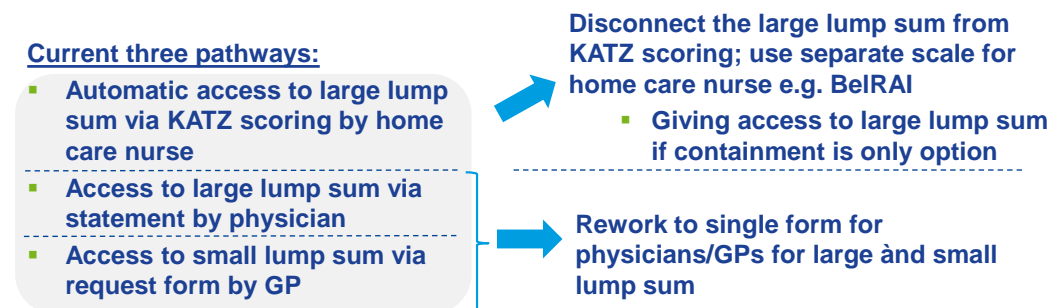
### 8.9.2 *Proposals for improvement*

#### **Switch to a single form for the physicians/GPs**

Instead of working with two distinct procedures for the physician/GP to request the large or the small lump sum, it would be recommended to melt the two into a single form (see Figure 36).



Figure 36 – Recommended switch to a single form for physicians/GPs



## 8.10 Financial accessibility of treatments and support aids

### 8.10.1 Assessment of the current situation

**Some treatments, like physiotherapy, incontinence nurse consultation and newer medication, are financially not always accessible for the patient**

Once a patient starts a care trajectory, he or she may encounter financial barriers. Physiotherapy involves considerable out-of-pocket expenses for the patient, which are even higher when the physiotherapist does not adhere to the RIZIV – INAMI tariffs. (15.19 % of the physiotherapists refused to adhere to the convention 2018-2019.) For interventions by (specialised) incontinence nurses, there is currently no reimbursement.

Furthermore many patients will not continue medication treatment as many medicinal products are not reimbursed. Except for patients with urgency incontinence as a result of neurological disorder (cerebral lesion or spinal cord lesion), the only medication reimbursed for UI is oxybutynin, which is

an immediate release preparation and unfortunately has the most side effects. (Remind that cure rate of oxybutynin at 3 months (20-25%) is much lower as compared to the newer anticholinergica and mirabegron (40-50%)). The newer drugs, which have less side effects, are not reimbursed for non-neurological disorders and cost the patient about €30 to €50 per month. Stakeholders agree that the more recent UI drugs with fewer side effects are expensive for patients and that for this reason compliance is also relatively low.

Support aids like urinals on the other hand are considered rather accessible as, even though they are not reimbursed, they are not very expensive. A simple urinal costs about €5, a more advanced one may cost up to €45, but they have a long lifespan. A vaginal pessary ring costs about €60 and can be used for many years.



### 8.10.2 *Proposals for improvement*

Based on further analysis of cost-effectiveness and budget impact, **examine whether newer drugs for incontinence**, which have fewer side effects, should be reimbursed in second line to non-neurologic incontinence patients.

**Consider reimbursement for (specialised) nurse interventions dedicated to incontinence (cfr. further).**

## 8.11 Patient information on support aids

### 8.11.1 *Assessment of the current situation*

**Patients are often not well informed about possible aids and types of products**

A small advice to use a bedpan can make a considerable difference for a patient and can even make the difference between staying at home or moving to a residential care home. (E.g. For a bedridden patient, the caregiver can use a bedpan). Interviews with continence nurses in hospital setting show however that often patients are not aware of the different possibilities. Many patients also appear not well informed about the range of available absorbent materials, going from relatively cheap to very expensive.

*“Bij de 65+ die ik zie, ze dragen allemaal van die optrekbroekjes, dat zijn de duurste broekjes, die kosten meer dan het dubbele dan de grote inleggers. Die dure optrekbroekjes krijgen ze aanbevolen in de winkel. Nadeel van de optrekbroekjes is ook nog dat ze zich volledig moeten uitkleden om er een nieuwe aan te doen.”*

In the current situation, patients do not have easy access to neutral information on support aids.

- The patient does not get adequate advice on treatment possibilities nor on support materials from the home nurse as he/she lacks time (and is not specifically rewarded for this task).

- (Home care) shops provide information to patients, but (according to some interviewees) are not always advising products that provide the best value for money for the patients.
- Informing the patient about all different options involves taking more time than feasible within a normal consultation for a GP.
- Specialised nursing staff are at work in continence clinics, but they are not very accessible. As the hospital does not get paid for consultations performed by the nursing staff, access to the nursing staff of a continence clinic is only assured through seeing a specialist first.

### 8.11.2 *Proposals for improvement*

- Even in absence of a possible healing treatment, behavioral methods and assistive materials exist and the patient should be informed about them. Patients will benefit from better information in terms of quality of life and self esteem, and also home care nurses or informal carers will benefit from it as it will ease their tasks. Costs can also be reduced as the functional decline of patients can be slowed down. It should be clarified to patients where they can obtain adequate and neutral information about the various possible aids and materials. Possible options to improve access to information are:
  - to improve the accessibility to (specialised) nursing staff, in continence clinics as well as at home, to inform the patient on support aids. For patients receiving home care, it could be considered that besides the regular home care nurse, another (specialised) nurse performs one or two separate visits to patients at home, to educate the patients on the management of incontinence.
  - to improve the accessibility to (specialised) physiotherapists for treatment and management of the condition.



- It could be considered whether the social services of the sickness funds (“Dienst Maatschappelijk Werk”, “Service Social”) could play a role in providing information to the patients regarding management of incontinence.

## 8.12 Patient awareness and health literacy

### 8.12.1 Appraisal of the current situation

#### Ageing is not a cause of incontinence

Even though physiologic ageing processes do affect the urinary and anorectal tract, ageing as such is not a cause of incontinence. Yet marketing campaigns present incontinence as a normal phenomenon that comes with higher age. This vision impedes patients to search help for care and treatment. Wearing absorbent materials becomes the default option for patients. Stakeholders agree that marketing campaigns do not give the right message.

*“Mensen worden bijna gestimuleerd om luiers te dragen. De reclame stuit ons enorm tegen de borst.”*

### 8.12.2 Proposals for improvement

- Create patient awareness on the fact that in many cases incontinence can be improved or healed and that preferably it is dealt with at an early stage, e.g. by a public information campaign.
- Collaborate with the industry to agree on a code of conduct to get a label on absorbent materials for incontinence, indicating “Have you already taken the step to discuss your continence problem with a health professional?” or “Continence problems can be cured when taken care of sooner rather than later! Contact your doctor.”, following the example of the label on formula feeding products “Breastfeeding is the best nutrition for babies.”

## 8.13 Focus on the setting: nurses

### 8.13.1 Appraisal of the current situation

As mentioned previously, the general impression exists that home care nurses lack time and incentives to individually educate the patient about incontinence, to give preventive advice and to propose first-line care. Often they also do not have the complete knowledge to educate the patient. Training for continence nurses exists, but no recognition exists for it.

### 8.13.2 Proposals for improvement

- Cfr. above, create a fee for a (specialised continence) nurse visit to the patient at home or nurse consultation, dedicated to incontinence management.
  - In these nurse interventions an initial assessment can take place, to explain the patient and caregiver how to make a voiding diary, to prepare a ‘continence file’ for the GP, which includes a voiding diary and a urine sample. In this phase, the nurse can start to educate the patient and propose lifestyle interventions. As some patients may have difficulties in making a voiding diary, even after explanation, more simple alternatives could be considered, like the ICIQ-SF (International Consultation on Incontinence Questionnaire – Short Form), which also provides a good basis for the GP to make a diagnosis.
  - Consecutively, on the basis of the voiding diary and urine sample, the GP can make an initial diagnosis. For those patients where applicable (behavioral treatments are not effective for all and patient selection is required), the GP should stimulate the patient to first-line treatment, by prescribing e.g. pelvic floor training, or an extra nurse intervention to give the patient and caregiver advice on support aids, like condom catheters for male, urinals or other materials. In function of the diagnosis and treatment outcomes, the GP or another physician can then fill out a form for a lump sum for incontinence, if still applicable.





- In the base education of nurses, more attention should be paid to incontinence.

## 8.14 Focus on the setting: physiotherapists

### 8.14.1 Appraisal of the current situation

As noted above, the general impression exists that too few patients with incontinence are referred to the physiotherapist, keeping in mind that pelvic re-education can also be done by elder patients (>80 years). In the patient selection for physiotherapy age does not matter, the indication does. Ideally, all incontinence patients should have been referred by the GP for physiotherapy before a referral is made to a second line clinic. A physiotherapist also plays a role to educate the patient on behavioural therapy and improvement of the physical condition more in general, as pelvic re-education is most effective in combination with these. (There is a partial overlap with the tasks of a nurse.)

There is recognition by law for physiotherapists specialised in pelvic re-education. Hospitals with an incontinence or perineology clinic work with pelvic re-education physiotherapists. In this setting, the physiotherapist will work on related problems of urology, gynaecology and proctology and is part of a multidisciplinary team dealing with more complex issues. The physiotherapist in the first-line can also be specialised in pelvic re-education or have a less specific expertise but can still teach and guide patients on the pelvic floor functioning or other exercises.

### 8.14.2 Proposals for improvement

- Although the out-of-pocket expenses for physiotherapy sessions are not particularly high, they may nevertheless pose a barrier to some patients. For this reason and to stimulate patients at maximum to follow physiotherapy, it could be considered to reimburse a limited number of sessions at a 100% for patients with incontinence. However, the feasibility of this proposal is rather low as lowering out-of-pocket expenses would be interesting for many other indications and for many other health professionals.
- Physiotherapists interviewed propose to make the payment of a lump sum conditional to a functional evaluation by a specialised physiotherapist. However, not all patients require a functional evaluation, therefore it should remain upon the judgement of the GP whether this is useful. Furthermore, the proposal of restricting access to specialised physiotherapists raises a number of concerns: 'Are there sufficient specialised physiotherapists?' and 'Are they geographically sufficiently well spread not to compromise accessibility?'
- Provide tools for physiotherapists and patients to stimulate knowledge and improve compliance with exercises.





## 8.15 Focus on the setting: continence clinics

### 8.15.1 Appraisal of the current situation

#### Financing of continence clinics

According to continence clinics, current financing through nomenclature does not support the running of a continence clinic. Continence clinics appear to be loss-making in some cases and this makes it hard to continue their existence. Furthermore nomenclature does not support multidisciplinary collaboration between physician, physiotherapist, nurse, psychologist and sexologist.

Also from the interviews it appears that some treatments are financially uninteresting for specialists. The nomenclature appears outdated and has left the opportunity for specialists

- to prefer well remunerated interventions over those that are less well paid but more or equally effective
- to avoid interventions that are taking up too much time e.g. during a clinic visit

Example 1: At some hospitals, vaginal pessary rings are increasingly used for stress incontinence for women not wanting to undergo surgery. However, fitting a pessary to define the right size is financially not very interesting from a gynaecologist point of view. It is a time consuming activity for which only a normal consultation is remunerated. Operating, on the other hand, is financially more favourable for the gynaecologist.

Example 2: the injection of botox takes 5 minutes of work and can be remunerated 3 times a year (about 3x110€) and is not very effective whereas neurostimulation is performed over several sessions, is rewarded only once (about 75€) and can help the patient for a time span of 5 years.

#### Referring the patient to second and third-line

According to specialist physicians, issues with accessing the second line and referrals (from GPs to specialists and from specialists to specialised continence clinics) are the following:

- The patient is referred too early
  - GPs are not always confident managing their incontinence patients and this leads to early referral of patients to the second line who can be treated in the first-line.
  - Patients can also refer themselves to a specialist without seeing their GP.
- The patient is not always consulting the best specialism for her/his problem
  - Complex incontinence cases should be seen by a multidisciplinary team/ perineology clinic e.g. combined urinary and faecal incontinence pathology needs a different approach from early on to have success.
  - Not all specialists have access to physical therapies (electrical stimulation) that are more time intensive and cheaper but have a better long term outcome compared to e.g. surgery.
  - Patients with complex pathology in need of a multidisciplinary approach at a larger specialised centre are not always referred by the local hospitals for fear of losing the patient and income.
- The patient is referred too late. The outcome will be less favourable the longer the patient waits with treatment.

#### Complications

- A considerable part of the patients who underwent TVT and TVTO transvaginal sling-procedures get moderate to severe chronic pain. Patients with this complication of chronic pain get permanently invalidated, disappear from the labour market and need help from pain



centres. Despite the complication risk, the patient organisation perceives little reticence in the performance of these procedures.

### 8.15.2 *Proposals for improvement*

- Ensure adequate payment of the different health professionals at work in continence clinics. E.g. physiotherapists are only financed for pelvic floor exercise sessions, but they are not financed for participating to meetings with the physician to discuss the diagnosis.
- For some interventions the remuneration should be reviewed so that specialists' fees are proportional to real costs and so that the treatment choice is not influenced by it.
- To the example of the mandatory registration of mesh, patient organisations plead for registering smaller polypropylene slings in an implant register with complications in order that complication rates can be monitored in Belgium.

## 8.16 Intervention by the federal and federated levels

### 8.16.1 *Appraisal of the current situation*

Currently both the federal and the federated level intervene for incontinence. The federal level intervenes for incontinence in all patients (handicapped or not), the intervention at federated level is restricted to handicapped patients. This double intervention poses a number of difficulties:

- For handicapped patients, it takes double administration as they need to request a grant from both the federal level and the federated level. As different forms are used for the lump sums at federal and at federated level, patients have to undergo more than one assessment.
- For the federated government instances it is particularly difficult to adjust the lump sum to what the patient already has received from the federal level, as there is no data sharing across the different government levels.

- Some patients may fall between the cracks. In the German community for instance, there is no financial intervention from the federated level based on the argument that it is the responsibility of the federal level.

### 8.16.2 *Proposals for improvement*

**Working with a single scale for incontinence, e.g. BelRAI, by both the federal and federated levels would increase efficiency (no double assessments) and would enable to share the scoring results.** Sharing the scoring results between the federal and federated level would make it more easy for the federated instances to attune the grant of the (handicapped) patients to the grants they already received at federal level.

BelRAI could potentially be used for the incontinence lump sums, but one should keep in mind that the primary reason of the creation of BelRAI was not specifically to support reimbursement purposes but rather to improve care.

**The patient population currently eligible for the large lump sum could be detected on the basis of BelRAI.** So for these patients BelRAI could replace the Katz scale for incontinence. Note however, that as BelRAI can be filled out by any recognised health professional. RIZIV – INAMI could however impose that the required sections on incontinence are filled out by a subselection of health professions. Note further that multiple BelRAI assessments can be done by multiple health professionals, and currently there are no rules about what to do in case of conflicting assessments.

**For patients currently eligible for the small lump sum, a BelRAI assessment would not be sufficient, as BelRAI does not distinguish between patients who have tried (first-line) treatment.** For these patients, an intervention by the GP or another physician is required, to attest that the patient still requires continence products after treatment. This attestation is not possible in BelRAI, but would have to be done on a separate form.



## ■ APPENDIX TO CHAPTER 2

### APPENDIX 1. SELECTION OF REFERENCES

#### Appendix 1.1. Medline and Cochrane

From the retrieved references for Medline and Cochrane the following were selected on the basis of the title on February 26<sup>th</sup> 2018 by one researcher (VIJ).

16	Maturitas	Almoussa S, et al. 2018 Maturitas 107(78-83 - The prevalence of urinary incontinence in nulliparous adolescent and middle-aged women and the associated risk factors: A systematic review
100	Neurourology & Urodynamics	Averbeck MA, et al. 2017 Neurourology & Urodynamics 36(2):245-252 - Management of LUTS in patients with dementia and associated disorders
51	Clinical Gastroenterology & Hepatology	Bharucha AE, et al. 2017 Clinical Gastroenterology & Hepatology 15(12):1844-1854 - Surgical Interventions and the Use of Device-Aided Therapy for the Treatment of Fecal Incontinence and Defecatory Disorders
106	International Urogynecology Journal	Bo K, et al. 2017 International Urogynecology Journal 28(2):191-213 - An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction
29	Neurourology & Urodynamics	Booth J, et al. 2017 Neurourology & Urodynamics 21(21 - The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: A systematic review
93	Neurourology & Urodynamics	Chang SJ, et al. 2017 Neurourology & Urodynamics 36(1):43-50 - Treatment of daytime urinary incontinence: A standardization document from the International Children's Continence Society
66	European Urology	Chapple CR, et al. 2017 European Urology 72(3):424-431 - Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence
147	Cochrane Database of Systematic Reviews	Dean N, et al. 2017 Cochrane Database of Systematic Reviews 7):- Laparoscopic colposuspension for urinary incontinence in women
11	Neurourology & Urodynamics	Deegan EG, et al. 2018 Neurourology & Urodynamics 37(1):33-45 - Quantification of pelvic floor muscle strength in female urinary incontinence: A systematic review and comparison of contemporary methodologies
109	Cochrane Database of Systematic Reviews	Ford AA, et al. 2017 Cochrane Database of Systematic Reviews 7(CD006375 - Mid-urethral sling operations for stress urinary incontinence in women
148	Cochrane Database of Systematic Reviews	Glazener CMA, et al. 2017 Cochrane Database of Systematic Reviews 7):- Bladder neck needle suspension for urinary incontinence in women



149	Cochrane Database of Systematic Reviews	Glazener CMA, et al. 2017 Cochrane Database of Systematic Reviews 7):- Anterior vaginal repair for urinary incontinence in women
98	Neurourology & Urodynamics	Hascoet J, et al. 2017 Neurourology & Urodynamics 36(3):557-564 - Outcomes of intra-detrusor injections of botulinum toxin in patients with spina bifida: A systematic review
124	Neurogastroenterology & Motility	Heymen S, et al. 2017 Neurogastroenterology & Motility 29(5):05 - Patient preferences for endpoints in fecal incontinence treatment studies
128	Techniques in Coloproctology	Hong KD, et al. 2017 Techniques in Coloproctology 21(3):203-210 - Midterm outcomes of injectable bulking agents for fecal incontinence: a systematic review and meta-analysis
146	Cochrane Database of Systematic Reviews	Kirchin V, et al. 2017 Cochrane Database of Systematic Reviews 7):- Urethral injection therapy for urinary incontinence in women
73	International Urogynecology Journal	Leone Roberti Maggiore U, et al. 2017 International Urogynecology Journal 28(8):1119-1130 - Long-term outcomes of TOT and TVT procedures for the treatment of female stress urinary incontinence: a systematic review and meta-analysis
76	Urology	Lopez Ramos H, et al. 2017 Urology 100(53-58 - Management of Overactive Bladder With OnabotulinumtoxinA: Systematic Review and Meta-analysis
130	CMAJ Canadian Medical Association Journal	Maund E, et al. 2017 CMAJ Canadian Medical Association Journal 189(5):E194-E203 - Considering benefits and harms of duloxetine for treatment of stress urinary incontinence: a meta-analysis of clinical study reports
61	JBIC Database Of Systematic Reviews And Implementation Reports	Mendes A, et al. 2017 JBIC Database Of Systematic Reviews And Implementation Reports 15(5):1350-1408 - Adult women's experiences of urinary incontinence: a systematic review of qualitative evidence
2	European Urology	Nambiar AK, et al. 2018 European Urology 02(02 - EAU Guidelines on Assessment and Nonsurgical Management of Urinary Incontinence
83	European Urology	Nambiar AK, et al. 2017 European Urology 71(4):501-503 - The Role of Urodynamics in the Evaluation of Urinary Incontinence: The European Association of Urology Recommendations in 2016
90	International Journal of Gynaecology & Obstetrics	Nie XF, et al. 2017 International Journal of Gynaecology & Obstetrics 138(3):250-255 - A meta-analysis of pelvic floor muscle training for the treatment of urinary incontinence
144	International Urogynecology Journal	Paiva LL, et al. 2017 International Urogynecology Journal 28(3):351-359 - Pelvic floor muscle training in groups versus individual or home treatment of women with urinary incontinence: systematic review and meta-analysis
4	Neurourology & Urodynamics	Powell LC, et al. 2018 Neurourology & Urodynamics 13(13 - The economic burden of overactive bladder in the United States: A systematic literature review
102	BMC Medicine	Riemsma R, et al. 2017 BMC Medicine 15(1):63 - Can incontinence be cured? A systematic review of cure rates
26	International Urogynecology Journal	Rodrigues MP, et al. 2017 International Urogynecology Journal 15(15 - Vibratory perineal stimulation for the treatment of female stress urinary incontinence: a systematic review



23	European Child & Adolescent Psychiatry	Schafer SK, et al. 2017 European Child & Adolescent Psychiatry 25(25 - Standard urotherapy as first-line intervention for daytime incontinence: a meta-analysis
36	International Urogynecology Journal	Siddiqui ZA, et al. 2017 International Urogynecology Journal 28(9):1275-1284 - Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review
5	Neurourology & Urodynamics	Song P, et al. 2018 Neurourology & Urodynamics 13(13 - The efficacy and safety comparison of surgical treatments for stress urinary incontinence: A network meta-analysis
87	Cochrane Database of Systematic Reviews	Stewart F, et al. 2017 Cochrane Database of Systematic Reviews 12(CD012390 - Electrical stimulation with non-implanted devices for stress urinary incontinence in women

## Appendix 1.2. Embase

From the 183 abstracts retrieved and reviewed on February 26<sup>th</sup> and 27<sup>th</sup> by one researcher (VIJ), the following 27 in the table below are selected on the basis of the title.

Embase number	
3	Ferdinando Fusco, Mohamed Abdel-Fattah, Christopher R. Chapple, et al. Updated Systematic Review and Meta-analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence. Eur Urol 2017;72:567–91
4	<a href="#">Management of female stress urinary incontinence: A care pathway and update</a> <a href="#">Capobianco G.</a> , <a href="#">Madonia M.</a> , <a href="#">Morelli S.</a> , <a href="#">Dessole F.</a> , <a href="#">De Vita D.</a> , <a href="#">Cherchi P.L.</a> , <a href="#">Dessole S.</a> Maturitas 2018 109 (32-38)
11	<a href="#">EAU Guidelines on Assessment and Nonsurgical Management of Urinary Incontinence</a> <a href="#">Nambiar A.K.</a> , <a href="#">Bosch R.</a> , <a href="#">Cruz F.</a> , <a href="#">Lemack G.E.</a> , <a href="#">Thiruchelvam N.</a> , <a href="#">Tubaro A.</a> , <a href="#">Bedretidnova D.A.</a> , <a href="#">Ambühl D.</a> , <a href="#">Farak F.</a> , <a href="#">Lombardo R.</a> , <a href="#">Schneider M.P.</a> , <a href="#">Burkhard F.C.</a> [Article in Press] European Urology 2018
13	<a href="#">The prevalence of urinary incontinence in nulliparous adolescent and middle-aged women and the associated risk factors: A systematic review</a> <a href="#">Almoussa S.</a> , <a href="#">Bandin van Loon A.</a> Maturitas 2018 107 (78-83)
16	<a href="#">Quantification of pelvic floor muscle strength in female urinary incontinence: A systematic review and comparison of contemporary methodologies</a> <a href="#">Deegan E.G.</a> , <a href="#">Stothers L.</a> , <a href="#">Kavanagh A.</a> , <a href="#">Macnab A.J.</a> Neurourology and Urodynamics 2018 37:1 (33-45)
23	<a href="#">Diagnostic scores, questionnaires, quality of life, and outcome measures in pediatric continence: A review of available tools from the International Children's Continence Society</a>



	<a href="#">Chase J., Bower W., Gibb S., Schaeffer A., von Gontard A.</a> [Article in Press] Journal of Pediatric Urology 2018
24	<a href="#">No. 283-Treatments for Overactive Bladder: Focus on Pharmacotherapy</a> <a href="#">Geoffrion R.</a> Journal of Obstetrics and Gynaecology Canada 2018 40:1 (e22-e32)
25	<a href="#">Brain Over Bladder: A Systematic Review of Dual Cholinesterase Inhibitor and Urinary Anticholinergic Use</a> <a href="#">Triantafylidis L.K., Clemons J.S., Peron E.P., Roefaro J., Zimmerman K.M.</a> Drugs and Aging 2018 35:1 (27-41)
27	<a href="#">Incontinence-Associated Dermatitis: Pathogenesis, Contributing Factors, Prevention and Management Options</a> <a href="#">Beele H., Smet S., Van Damme N., Beeckman D.</a> Drugs and Aging 2018 35:1
28	<a href="#">The efficacy of botulinum toxin A and sacral neuromodulation in the management of interstitial cystitis (IC)/bladder pain syndrome (BPS), what do we know? ICI-RS 2017 think thank, Bristol</a> <a href="#">Rahnama'i M.S., Marcelissen T., Apostolidis A., Veit-Rubin N., Schurch B., Cardozo L., Dmochowski R.</a> [Article in Press] Neurourology and Urodynamics 2018
37	<a href="#">Neurostimulation Therapy for Non-neurogenic Overactive Bladder in Children: A Meta-analysis</a> <a href="#">Fernandez N., Chua M.E., Ming J.M., Silangcruz J.M., Zu'bi F., Dos Santos J., Lorenzo A.J., Braga L.H., Lopes R.I.</a> Urology 2017 110 (201-207)
62	<a href="#">Desmopressin plus anticholinergic agent in the treatment of nocturnal enuresis: A meta-analysis</a> <a href="#">Yu J., Yan Z., Zhou S., Han F., Xiao F., Han J., Sun C.</a> Experimental and Therapeutic Medicine 2017 14:4 (2875-2884)
68	<a href="#">Standard urotherapy as first-line intervention for daytime incontinence: a meta-analysis</a> <a href="#">Schäfer S.K., Niemczyk J., von Gontard A., Pospeschill M., Becker N., Equit M.</a> [Article in Press] European Child and Adolescent Psychiatry 2017 (1-16)
70	<a href="#">Single-centre experience with intradetrusor injection of onabotulinumtoxinA: a retrospective study of the years 2003–2012 in a Danish population</a> <a href="#">Christiansen F.E., Pedersen T.B., Juel J., Kirkeby H.J.</a> Scandinavian Journal of Urology 2017 51:5 (392-396)
71	<a href="#">Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review</a> <a href="#">Siddiqui Z.A., Abboudi H., Crawford R., Shah S.</a> International Urogynecology Journal 2017 28:9 (1275-1284)
72	<a href="#">What Works to Improve and Manage Fecal Incontinence in Care Home Residents Living With Dementia? A Realist Synthesis of the Evidence</a> <a href="#">Buswell M., Goodman C., Roe B., Russell B., Norton C., Harwood R., Fader M., Harari D., Drennan V.M., Malone J.R., Madden M., Bunn F.</a> Journal of the American Medical Directors Association 2017 18:9 (752-760.e1)



73	<a href="#">Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence</a> <a href="#">Chapple C.R.</a> , <a href="#">Cruz F.</a> , <a href="#">Deffieux X.</a> , <a href="#">Milani A.L.</a> , <a href="#">Arlandis S.</a> , <a href="#">Artibani W.</a> , <a href="#">Bauer R.M.</a> , <a href="#">Burkhard F.</a> , <a href="#">Cardozo L.</a> , <a href="#">Castro-Diaz D.</a> , <a href="#">Cornu J.N.</a> , <a href="#">Deprest J.</a> , <a href="#">Gunnemann A.</a> , <a href="#">Gyhagen M.</a> , <a href="#">Heesakkers J.</a> , <a href="#">Koelbl H.</a> , <a href="#">MacNeil S.</a> , <a href="#">Naumann G.</a> , <a href="#">Roovers J.-P.W.R.</a> , <a href="#">Salvatore S.</a> , <a href="#">Sievert K.-D.</a> , <a href="#">Tarcn T.</a> , <a href="#">Van der Aa F.</a> , <a href="#">Montorsi F.</a> , <a href="#">Wirth M.</a> , <a href="#">Abdel-Fattah M.</a> European Urology 2017 72:3 (424-431)
88	<a href="#">Vibratory perineal stimulation for the treatment of female stress urinary incontinence: a systematic review</a> <a href="#">Rodrigues M.P.</a> , <a href="#">Paiva L.L.</a> , <a href="#">Ramos J.G.L.</a> , <a href="#">Ferla L.</a> [Article in Press] International Urogynecology Journal 2017 (1-8)
89	<a href="#">Long-term outcomes of TOT and TVT procedures for the treatment of female stress urinary incontinence: a systematic review and meta-analysis</a> <a href="#">Leone Roberti Maggiore U.</a> , <a href="#">Finazzi Agrò E.</a> , <a href="#">Soligo M.</a> , <a href="#">Li Marzi V.</a> , <a href="#">Digesu A.</a> , <a href="#">Serati M.</a> International Urogynecology Journal 2017 28:8 (1119-1130)
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## APPENDIX 2. SELECTION GUIDELINE – AGREE ICS 2017

	expert 1
<b>Domain 1. Scope and Purpose</b>	
1. overall objective	7
2. health question(s)	7
3. population	7
<i>Domain score</i>	100,0
<b>Domain 2. Stakeholder Involvement</b>	
4. all relevant professional groups	5
5. target population views and preferences	5
6. target users	5
<i>Domain score</i>	66,7
<b>Domain 3. Rigour of Development</b>	
7. systematic search	7
8. selection criteria	7
9. strengths and limitations of evidence	7
10. formulation of recommendations	7
11. benefits, side effects and risks	7
12. explicit link	7





13. external review	6
14. update procedure	6
<i>Domain score</i>	95,8
<b>Domain 4. Clarity of Presentation</b>	
15. specific and unambiguous	7
16. different options for management	7
17. key recommendations	7
<i>Domain score</i>	100,0
<b>Domain 5. Applicability</b>	
18. facilitators and barriers	7
19. advice and tools	5
20. possible resource implications	4
21. monitoring and/or auditing criteria	4
<i>Domain score</i>	66,7
<b>Domain 6. Editorial Independence</b>	
22. editorially independent	7
23. conflicts of interest	6
<i>Domain score</i>	91,7
<b>Overall quality</b>	<b>8,7</b>
<b>Recommend?</b>	
<b>Number of items scoring <sup>3</sup> 5</b>	<b>21</b>
<b>Number of domains scoring &gt; 60%</b>	<b>6</b>



## APPENDIX 3. INCONTINENCE IMPACT QUESTIONNAIRES: IIQ7 AND IIQ LONG VERSION

### IIQ-7

-----

Sommige vrouwen vinden dat ongewenst hun activiteiten, relaties en gevoelens kunnen beïnvloeden. De vragen in onderstaande lijst gaan over aspecten van uw leven die door uw probleem beïnvloed of veranderd kunnen zijn. Geef voor iedere vraag het antwoord aan dat het beste beschrijft hoe zeer uw activiteiten, relaties en gevoelens beïnvloed worden door uw urineverlies . Omcirkel het juiste antwoord.

-----

*Hoeveel invloed heeft ongewenst urineverlies gehad op:*

1. Uw vermogen om huishoudelijk werk te doen (koken, schoonmaken, wassen) 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
2. Actieve ontspanning zoals wandelen, zwemmen of andere activiteiten 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
3. Activiteiten zoals naar de film, theater of concert gaan 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
4. Reizen met auto of openbaar vervoer over een afstand van meer dan 20 minuten 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
5. Deelnemen aan sociale activiteiten buitenshuis 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
6. Geestelijke / emotionele gezondheid (nervositeit, depressie) 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg

*Veroorzaakt uw probleem gevoelens van:*

7. Frustratie? 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg

### IIQ-long version

-----

Sommige vrouwen vinden dat ongewenst urineverlies en/of een verzakking en/of problemen met de ontlasting hun activiteiten, relaties en gevoelens kunnen beïnvloeden. De vragen in onderstaande lijst gaan over aspecten van uw leven die door uw probleem beïnvloed of veranderd kunnen zijn. Geef voor iedere vraag het antwoord aan dat het beste beschrijft hoe zeer uw activiteiten, relaties en gevoelens beïnvloed worden door uw urineverlies en/of verzakking en/of problemen met de ontlasting. Omcirkel het juiste antwoord.

-----



*Hoeveel invloed heeft ongewenst urineverlies en/of verzakking en/of problemen met de ontlasting gehad op:*

1. Uw vermogen om huishoudelijk werk te doen (koken, schoonmaken, wassen) 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
2. Uw vermogen om klein onderhoud of reparaties te verrichten in en om het huis 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
3. Boodschappen doen en winkelen 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
4. Hobby's en vrijetijdsbesteding 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
5. Actieve ontspanning zoals wandelen, zwemmen of andere activiteiten 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
6. Activiteiten zoals naar de film, theater of concert gaan 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
7. Reizen met auto of openbaar vervoer over een afstand van minder dan 20 minuten 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
8. Reizen met auto of openbaar vervoer over een afstand van meer dan 20 minuten 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
9. Ergens naar toe gaan als u niet helemaal zeker weet of er daar toiletten zijn 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
10. Op vakantie gaan 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
11. Naar de kerk, moskee of synagoge gaan 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
12. Vrijwilligerswerk 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
13. Betaald werk buitenshuis 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
14. Bezoek krijgen van vrienden en kennissen 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
15. Deelnemen aan sociale activiteiten buitenshuis 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
16. Relaties met vrienden en kennissen 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
17. Relaties met familie en gezin behalve uw partner / echtgenoot 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
18. Vermogen om een seksuele relatie te hebben 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
19. Keuze van kleding 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
20. Geestelijke / emotionele gezondheid 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
21. Lichamelijke gezondheid 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
22. Slapen 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg
23. Wordt u in uw activiteiten beperkt door angst dat anderen u ruiken? 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg



24. Beperkt de angst om in verlegenheid gebracht te worden u in uw activiteiten? 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg

*Heeft u als gevolg van uw probleem de volgende gevoelens ?*

25. Nervositeit of ongerustheid 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg

26. Angst 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg

27. Frustratie 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg

28. Boosheid 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg

29. Depressie 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg

30. Zich gegeneerd voelen 0. Helemaal niet 1. Een beetje 2. Nogal 3. Heel erg



# ■ APPENDIX TO CHAPTER 3

## APPENDIX 1. HOME NURSE FORM WITH KATZ SCALE

**Annexe 3**  
*A envoyer sous enveloppe fermée au médecin-conseil*  
Soins infirmiers- Echelle d'évaluation  
- justifiant la demande d'honoraires forfaitaires par journée de soins (1)  
- notifiant des soins de toilette (1)  
Données d'identification du bénéficiaire

Nom et prénom: .....  
Adresse (résidence principale): .....  
Date de naissance: .....  
N° de sécurité sociale (NISS): .....  
N° d'inscription O.A. (uniquement pour les patients sans NISS): .....  
N° d'identification de l'O.A.: [ ] [ ] [ ] [ ] [ ] [ ]  
Adresse de lieu de soins (si différente de la résidence principale): .....  
Je soussigné(e) ..... inscrit(e)  
sur la liste des praticiens de l'I.N.A.M.I. sous le n° [ ] [ ] [ ] [ ] [ ] [ ] déclare que:  
- conformément à la nomenclature des soins infirmiers, la dépendance physique du bénéficiaire peut être décrite comme suit:  
Echelle d'évaluation

Critère	Score	1	2	3	4
Se laver		est capable de se laver complètement sans aucune aide	a besoin d'une aide partielle pour se laver au dessus ou en dessous de la ceinture	a besoin d'une aide partielle pour se laver tant au-dessus qu'en-dessous de la ceinture	doit être entièrement aidé pour se laver tant au-dessus qu'en-dessous de la ceinture
S'habiller		est capable de s'habiller et se déshabiller complètement sans aucune aide	a besoin d'une aide partielle pour s'habiller au dessus ou en dessous de la ceinture (sans tenir compte des lacets)	a besoin d'une aide partielle pour s'habiller tant au-dessus qu'en-dessous de la ceinture	doit être entièrement aidé pour s'habiller tant au-dessus qu'en-dessous de la ceinture
Transfert et déplacement		est autonome pour le transfert et se déplace de façon entièrement indépendante, sans aide mécanique(s), ni aide de tiers	est autonome pour le transfert et ses déplacements moyennant l'utilisation d'aides mécaniques (déroulées, chaise roulante, ...)	a absolument besoin de l'aide de tiers pour au moins un des transferts et/ou ses déplacements	est grabataire ou en chaise roulante et dépend entièrement des autres pour se déplacer
Aller à la toilette		est capable d'aller seul à la toilette, de s'habiller ou de s'essuyer	a besoin d'aide pour un des trois items: se déplacer ou s'habiller ou s'essuyer	a besoin d'aide pour deux des trois items: se déplacer et/ou s'habiller et/ou s'essuyer	a besoin d'aide pour les trois items: se déplacer et s'habiller et s'essuyer
Continence		est continent pour les urines et les selles	est accidentellement incontinent pour les urines ou les selles (sorde vésicale ou anus artificiel compris)	Est incontinent pour les urines (y compris exercices de miction) ou les selles	est incontinent pour les urines et les selles
Manger		est capable de manger et de boire seul	a besoin d'une aide préalable pour manger ou boire	a besoin d'une aide partielle pendant qu'il mange ou boit	le patient est totalement dépendant pour manger et boire

- en cas de score 2 pour le critère de continence: une combinaison de l'incontinence d'urine nocturne et de l'incontinence d'urine occasionnelle durant la journée a été constatée chez le bénéficiaire  
et donne connaissance au médecin-conseil qu'elle commence les soins chez le bénéficiaire:  
en date du .....  
pendant une période qui se termine: .....  
Si des soins ont été prescrits, identification du médecin prescripteur:  
nom: ..... n° I.N.A.M.I.: [ ] [ ] [ ] [ ] [ ] [ ]  
Sur base de l'échelle d'évaluation reprise ci-dessus, le forfait A / forfait B / forfait C (2) est demandé, des soins de toilette sont notifiés (2).

Le certificat médical établi par le médecin traitant, conformément au modèle fixé par le Comité de l'assurance des soins de santé, permettant de considérer le bénéficiaire comme désorienté dans le temps et l'espace est / n'est pas (2) joint (article 8, § 0, de la nomenclature).  
identification du médecin prescripteur de ce certificat médical:  
nom: ..... n° I.N.A.M.I.: [ ] [ ] [ ] [ ] [ ] [ ]  
Le praticien de l'art infirmier,  
(date, nom et signature)

(1) Biffer la mention inutile  
(2) Biffer ce qui ne convient pas

**Bijlage 3**  
*Onder gesloten omslag toe te sturen naar de adviserend geneesheer*  
Verpleegkundige verzorging - Evaluatieschaal  
- tot staving van de aanvraag tot forfaitair honorarium per verzorgingsdag (1)  
- tot kennisgeving van toiletverzorging (1)  
Identificatiegegevens van de rechthebbende

Naam en voornaam: .....  
Adres (hoofdverblijfplaats): .....  
Geboortedatum: .....  
Inschrijvingsnummer sociale zekerheid (INSZ): .....  
Inschrijvingsnr. V.I. (alleen voor patiënten zonder INSZ): .....  
Identificatienr. V.I.: [ ] [ ] [ ] [ ] [ ] [ ]  
Adres verzorgingsplaats (indien anders dan de hoofdverblijfplaats): ..... ingeschreven  
Ondergetekende ..... op de lijst der verpleegkundigen van het R.I.Z.V., onder het nummer [ ] [ ] [ ] [ ] [ ] [ ] verklaart dat:  
- de fysieke afhankelijkheid van de rechthebbende, conform met de nomenclatuur van de verpleegkundige verzorging, als volgt kan worden omschreven:  
Evaluatieschaal

Criterium	Score	1	2	3	4
Zich wassen		kan zichzelf helemaal wassen zonder enige hulp	heeft gedeeltelijke hulp nodig om zich te wassen boven of onder de gordel	heeft gedeeltelijke hulp nodig om zich te wassen zowel boven als onder de gordel	moet volledig worden geholpen om zich te wassen zowel boven als onder de gordel
Zich kleden		kan zich helemaal aan- en uittrekken zonder enige hulp	heeft gedeeltelijke hulp nodig om zich te kleden boven of onder de gordel (zonder rekening te houden met de veters)	heeft gedeeltelijke hulp nodig om zich te kleden zowel boven als onder de gordel	moet volledig worden geholpen om zich te kleden zowel boven als onder de gordel
Transfer en verplaatsingen		is zelfstandig voor de transfer en kan zich volledig zelfstandig verplaatsen zonder mechanische hulpmiddel(en) of hulp van derden	is zelfstandig voor de transfer en voor zijn verplaatsingen, mits het gebruik van mechanische hulpmiddel(en) (trankken, rolstoel, ...)	heeft volledige hulp van derden nodig voor minstens één van de transfers en/of zijn verplaatsingen	is bedlegerig of zit in een rolstoel en is volledig afhankelijk van anderen om zich te verplaatsen
Toiletbezoek		kan alleen naar het toilet gaan, zich kleden en zich reinigen	heeft hulp nodig voor één van de drie items: zich verplaatsen of zich kleden of zich reinigen	heeft hulp nodig voor twee van de drie items: zich verplaatsen en/of zich kleden en/of zich reinigen	heeft hulp nodig voor de drie items: zich verplaatsen en zich kleden en zich reinigen
Continente		is continent voor urine en faeces	is accidenteel incontinent voor urine of faeces (inclusief blaascondit of kunststam)	is incontinent voor urine (inclusief mictietraining) of voor faeces	is incontinent voor urine en faeces
Eten		kan alleen eten en drinken	heeft vooraf hulp nodig om te eten of te drinken	heeft gedeeltelijke hulp nodig tijdens het eten of drinken	de patiënt is volledig afhankelijk om te eten of te drinken

- in geval van een score 2 voor het criterium 'continentie': bij de rechthebbende een combinatie van nachtelijke urine-incontinentie en occasionele urine-incontinentie overdag werd vastgesteld: ..... JA ☐ NEE ☐ (1)  
en stelt de adviserend geneesheer ervan in kennis dat hij zij bij de rechthebbende begint met de verzorging:  
op datum van .....  
gedurende een periode die eindigt op: .....  
Indien verzorging werd voorgeschreven, identificatie van de voorschrijvende geneesheer:  
naam: ..... RIZIV-nummer: [ ] [ ] [ ] [ ] [ ] [ ]  
Op basis van bovenstaande evaluatieschaal wordt forfait A / forfait B / forfait C (2) aangevraagd, wordt toiletverzorging ter kennis gegeven (2).  
Het geneeskundig getuigschrift opgemaakt door de behandelend geneesheer, overeenkomstig het model vastgelegd door het Verzekeringscomité voor geneeskundige verzorging, waaruit blijkt dat de rechthebbende gedesorienteerd is in tijd en ruimte, is/is niet (2) bijgevoegd (Artikel 8, § 0 van de nomenclatuur).  
identificatie van de voorschrijvende geneesheer van dit geneeskundig getuigschrift:  
naam: ..... RIZIV-nummer: [ ] [ ] [ ] [ ] [ ] [ ]  
De verpleegkundige,  
(datum, naam en handtekening)

(1) Aankruisen vast past  
(2) Schrapen wat niet past



## APPENDIX 2. REQUEST FORM FOR “SMALL LUMP SUM” FOR INCONTINENCE

MONITEUR BELGE — 18.11.2011 — Ed. 2 — BELGISCH STAATSBAD 68661

Bijlage bij het koninklijk besluit tot wijziging van het koninklijk besluit van 2 juni 1998 tot vaststelling van de tegemoetkoming van de verplichte verzekering voor geneeskundige verzorging voor het incontinentiemateriaal, bedoeld in artikel 34, 14°, van de wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen, gecoördineerd op 14 juli 1994

Bijlage bij het koninklijk besluit van 2 juni 1998 tot vaststelling van de tegemoetkoming van de verplichte verzekering voor geneeskundige verzorging voor het incontinentiemateriaal, bedoeld in artikel 34, 14°, van de wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen, gecoördineerd op 14 juli 1994

### FORMULIER AANVRAAG « ONBEHANDELBARE INCONTINENTIE-FORFAIT »

Voor thuiszorg door de huisarts in te vullen  
Naar de adviserend geneesheer te sturen

#### 1. Identificatie van de patiënt

##### 2. Evaluatie

- Anamnese
  - Incontinentie is continu ☐
  - Incontinentie is intermitterend ☐
  - Stress incontinentie ☐
  - Urge incontinentie ☐
  - Urinaire incontinentie en ook feces incontinentie ☐

##### • Objectieve gegevens

##### > Klinisch onderzoek ter opzoeken van

- 1. fecaloma ☐
- 2. globe vesicalis ☐
- 3. prostatiche hypertrofie ☐
- 4. gynecologische prolaps ☐
- 5. anale hypotonus ☐

##### > Technische onderzoeken :

- Urine ☐

##### Eventuele specialistische onderzoeken :

- (tam, gynaec, gynaec) ☐

##### > Eventuele intercurrente factoren :

- sommige geneesmiddelen ☐
- omgevingsfactoren ☐
- gevorderde dementie ☐

##### > Therapie :

- Medicatie ☐
- Kine ☐
- Heelkunde ☐

3. Na uitsluiting van behandelbare oorzaken van incontinentie en poging tot therapie toch blijvende incontinentie. Daarom vraag ik voor De heer/Mevr. .... de tekenening van het forfait aan de adviserend geneesheer.

Stempel en handtekening van de huisarts

Datum

Gezien om gevraagd te worden bij Ons besluit van 7 oktober 2011 tot wijziging van het besluit van 2 juni 1998 tot vaststelling van de tegemoetkoming van de verplichte verzekering voor geneeskundige verzorging voor het incontinentiemateriaal, bedoeld in artikel 34, 14°, van de wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen, gecoördineerd op 14 juli 1994.

ALBERT

Van Koningswege :

De Minister van Sociale Zaken en Volksgezondheid,  
beast met Maatschappelijke Integratie  
Mevr. L. ONKELINX

68660 MONITEUR BELGE — 18.11.2011 — Ed. 2 — BELGISCH STAATSBAD

Annexe à l'arrêté royal modifiant l'arrêté royal du 2 juin 1998 déterminant l'intervention de l'assurance soins de santé obligatoire pour le matériel d'incontinence visé à l'article 34, 14°, de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994

Annexe à l'arrêté royal du 2 juin 1998 déterminant l'intervention de l'assurance soins de santé obligatoire pour le matériel d'incontinence visé à l'article 34, 14°, de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994

### FORMULAIRE DE DEMANDE DE FORFAIT POUR INCONTINENCE URINAIRE INCURABLE

Pour les patients soignés, à remplir par le médecin généraliste  
À envoyer au médecin conseil

#### 1. Identification du patient

#### 2. Evaluation de l'incontinence

##### • Anamnèse

- l'incontinence est continue ☐
- l'incontinence est intermittente ☐
- incontinence de stress ☐
- incontinence d'urgence ☐
- incontinence urinaire et fécale ☐

##### • Eléments objectifs :

##### > Examen clinique à la recherche de :

- 1. fécalome ☐
- 2. globe vésical ☐
- 3. hypertrophie prostatique ☐
- 4. prolapsus gynécologique ☐
- 5. hypotonie anale ☐

##### > Examen(s) technique(s) :

- Urines ☐

##### > Examens spécialisés éventuels :

- avis urologique / gynécologique / gériatrique ☐

##### > Facteurs intercurrents éventuels :

- certains médicaments ☐
- facteurs environnementaux ☐
- démenie avancée ☐

##### > Traitements :

- Médicament(s) ☐
- Kinésithérapie ☐
- Chirurgie ☐

3. Après exclusion des causes traitables d'incontinence et essai de traitement, l'incontinence s'est avérée incurable. C'est pourquoi, je demande au médecin-conseil pour M./Mme ..... l'octroi du forfait « matériel d'incontinence incurable ».

Signature et cachet du médecin généraliste

Date

Vu pour être annexé à Notre arrêté du 7 octobre 2011 modifiant l'arrêté du 2 juin 1998 déterminant l'intervention de l'assurance soins de santé obligatoire pour le matériel d'incontinence visé à l'article 34, 14°, de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994.

ALBERT

Par le Roi :

La Ministre des Affaires sociales et de la Santé publique,  
chargée de l'Intégration sociale,  
Mme L. ONKELINX



## ■ APPENDIX TO CHAPTER 4

### APPENDIX 1. NUMBER AND TYPE OF ADMISSIONS, AGE AND SEX PER APR-DRG (2014)

MDC	APR-DRG	Number stays	% Day care	Age								% Female
				mean	SD	min	p25	p50	p75	max		
13 Female reproductive system	514 Female Reproductive System Reconstructive Procedures	5 174	24.3%	56.9	13.1	16	47	55	67	93	100%	
	532 Menstrual & Other Female Reproductive System Disorders	126	76.2%	61.6	14.6	10	51	61.5	75	86	100%	
	513 Uterine & Adnexa Procedures For Non-Malignancy Except Leiomyoma	72	23.6%	53.4	11.7	29	44	52	63	78	100%	
	518 Other Female Reproductive System & Related Procedures	18	44.4%	59.1	14.7	29	47	62	72	80	100%	
	510 Pelvic Evisceration, Radical Hysterectomy & Other Radical Gynaecological Procedures	1	100%	74	.	74	74	74	74	74	100%	
11 Kidney & urinary tract	468 Other Kidney & Urinary Tract Diagnoses, Signs & Symptoms	1 015	81.3%	60.7	23.2	4	51	68	77	94	35.0%	
	445 Other Bladder Procedures	616	23.1%	60.6	16.4	3	52	64	72	95	65.1%	
	446 Urethral & Transurethral Procedures	22	81.8%	21.9	23.7	4	7	10	24	72	50.0%	
	441 Major Bladder Procedures	13	0%	57.1	20.5	5	48	59	75	79	53.8%	
	447 Other Kidney, Urinary Tract & Related Procedures	5	40%	62.2	12.5	46	53	67	68	77	60.0%	
	443 Kidney & Urinary Tract Procedures For Nonmalignancy	4	0%	64.3	16.1	45	51	66.5	77.5	79	75.0%	
06 Digestive system	254 Other Digestive System Diagnoses	296	65.2%	53.8	25.7	0.5	42.5	59	74	98	59.8%	
	221 Major Small & Large Bowel Procedures	34	0%	62.9	17.3	29	52	68	78	93	76.5%	
	226 Anal Procedures	21	38.1%	57.4	15.9	24	45	62	67	82	90.5%	
	229 Other Digestive System & Abdominal procedures	4	0%	56.3	5.9	50	52	55.5	60.5	64	100%	
	220 Major Stomach, Esophageal & Duodenal Procedures	1	0%	57	.	57	57	57	57	57	100%	
00 Remaining group	951 Moderately Extensive Procedure Unrelated To Principal Diagnosis	118	45.8%	57.9	15.4	13	49	59	70	90	83.9%	
	950 Extensive Procedure Unrelated To Principal Diagnosis	11	9.1%	57.1	19	8	49	63	69	76	81.8%	
	952 Nonextensive Procedure Unrelated To Principal Diagnosis	8	37.5%	56.5	17.5	20	49	62	66.5	77	62.5%	
19 Mental diseases & disorders	760 Other Mental Health Disorders	36	8.3%	9.5	9.7	3	5.5	8	10	63	33.3%	
	740 Mental Illness Diagnoses With Operating Room Procedure	1	0%	28	.	28	28	28	28	28	100%	



## APPENDIX 2. TEN MOST FREQUENT PROCEDURE PERFORMED PER MDC (2014)

MDC (total number of stays and procedures)	Procedure	Number admissions concerned	% total procedures	Cumulative % total procedures
13 Female reproductive system (5391 stays – 6738 procedures)	5979 other repair of urinary stress incontinence	4 828	71.7	71.7
	5732 other cystoscopy	181	2.7	74.3
	595 retropubic urethral suspension	154	2.3	76.6
	596 paraurethral suspension	149	2.3	78.8
	5794 insertion of indwelling urinary catheter	116	1.7	80.6
	594 suprapubic sling operation	114	1.7	82.3
	9921 injection of antibiotic	91	1.4	83.6
	9919 injection of anticoagulant	71	1.1	84.7
	3893 venous catheterization, not elsewhere classified	52	0.8	85.4
	6909 other dilation and curettage	52	0.8	86.2
11 Kidney & urinary tract (1675 stays -	5732 other cystoscopy	658	31.3	31.3
	5979 other repair of urinary stress incontinence	422	20.1	51.3
	9929 injection or infusion of other therapeutic or prophylactic substance	102	4.9	56.2
	5893 implantation of artificial urinary sphincter [AUS]	86	4.1	60.3
	8924 uroflowmetry [UFR]	65	3.1	63.4
	5794 insertion of indwelling urinary catheter	49	2.3	65.7
	8777 other cystogram	43	2.	67.7
	594 suprapubic sling operation	38	1.8	69.5
	5717 percutaneous cystostomy	37	1.8	71.3
	8929 other nonoperative genitourinary system measurements	30	1.43	72.7
06 Digestive system (356 stays -	4523 colonoscopy	89	17.9	17.9
	4525 closed [endoscopic] biopsy of large intestine	64	12.9	30.8
	4513 other endoscopy of small intestine	34	6.8	37.6
	4514 closed [endoscopic] biopsy of small intestine	34	6.8	44.5
	4542 endoscopic polypectomy of large intestine	20	4	48.5
	4516 esophagogastroduodenoscopy [EGD] with closed biopsy	18	3.6	52.1





MDC (total number of stays and procedures)	Procedure	Number admissions concerned	% total procedures	Cumulative % total procedures
	8939 other nonoperative measurements and examinations	17	3.4	55.5
	4613 permanent colostomy	12	2.4	58
	4992 insertion of subcutaneous electrical anal stimulator	10	2	60
	9638 removal of impacted feces	10	2	62
00 Remaining group (137 stays -	0492 implantation or replacement of peripheral neurostimulator	92	47.7	47.7
	8696 insertion or replacement of other neurostimulator pulse generator	36	18.7	66.3
	8694 insertion or replacement of single array neurostimulator pulse generator	9	4.7	71
	0393 implantation or replacement of spinal neurostimulator	6	3.1	74.1
	4613 permanent colostomy	2	1	75.1
	5749 other transurethral excision or destruction of lesion or tissue of bladder	2	1	76.2
	5893 implantation of artificial urinary sphincter [AUS]	2	1	77.2
	598 ureteral catheterization	2	1	78.2
	5994 replacement of cystostomy tube	2	1	79.3
	6029 other transurethral prostatectomy	2	1	80.3
19 Mental diseases & disorders (37 stays -	4525 closed [endoscopic] biopsy of large intestine	2	8.70	8.70
	8875 diagnostic ultrasound of urinary system	2	8.70	17.39
	8876 diagnostic ultrasound of abdomen and retroperitoneum	2	8.70	26.09
	0331 spinal tap	1	4.35	30.43
	4311 percutaneous [endoscopic] gastrostomy [peg]	1	4.35	34.78
	4879 other repair of rectum	1	4.35	39.13
	5732 other cystoscopy	1	4.35	43.48
	8674 attachment of pedicle or flap graft to other sites	1	4.35	47.83
	8764 lower GI series	1	4.35	52.17
	8777 other cystogram	1	4.35	56.52



## APPENDIX 3. SELECTION CRITERIA TO EXTRACT EPS DATA 2008-2015

Code (ATC or RIZIV – INAMI)	Label	Incontinence: urinary (U), faecal (F)
Drugs (ATC codes)		
G04BD	Drugs for urinary frequency and incontinence	U
Large and small incontinence lump sums (RIZIV – INAMI codes)		
740191	Forfait incontinentiemateriaal - Forfait matériel d'incontinence	U/F
740515	Forfait incontinentiemateriaal ; onbehandelbare incontinentie - Forfait matériel d'incontinence; incontinence non traitable	U
Self-catheterisation material (RIZIV – INAMI codes) <sup>k</sup>		
754375	Tegemoetkoming in de kosten van autosondage bij de patiënt thuis, forfait per kalendermaand - Intervention dans le coût de l'autosondage au domicile du patient, forfait par mois calendrier	U
Incontinence material: article 27 (RIZIV – INAMI codes)		
640010_640021	Kegelvormige penishuls met inbegrip der kleefstrips of lijmsysteem (tweedelig systeem) - Dotatie : 90 stuks/3 maanden - Lijst 0010 - Etui pénien conique avec bandes adhésives ou système collant (système en deux parties) - Dotation : 90 pièces/3 mois - Liste 0010	U
640032_640043	Zelfklevende penishuls (ééndelig systeem) - Dotatie : 90 stuks/3 maanden - Lijst 0032 - Etui pénien auto-adhésif (système en une partie) - Dotation : 90 pièces/3 mois - Liste 0032	U
640054_640065	Zelfklevende penishuls, voorzien van een kraagje dat het terugvloeien belet, al dan niet voorzien van een afneembare tip - Dotatie : 90 stuks/3 maanden - Lijst 0054 - Etui pénien auto-adhésif, muni d'une collerette anti-reflux, muni ou non d'un embout amovible - Dotation : 90 pièces/3 mois - Liste 0054	U

<sup>k</sup> This lump sum was valid until 1 November 2017. From this date, it was replaced by two lump sums (743396 and 743411), applied according to the type of catheter (see 3.1.5.4.)



640076	Ledigbaar urinezakje voor overdag met antirefluxklep, inclusief koppelstukken, leidingen en volledig bevestigingssysteem nodig voor 3 maanden, ongeacht de overige produktattributen - Dotatie : 20 stuks/3 maanden - Lijst 0076 - Poche urinaire de jour à vider, avec valve anti-reflux, y compris raccords, conduits et système de fixation complet nécessaire pour 3 mois, quels que soient les autres accessoires - Dotation : 20 pièces/3 mois - Liste 0076	U
640091	Ledigbare urinezak (min. 1,5 liter) voor 's nachts met antirefluxsysteem, inclusief koppelstukken, leidingen en bedbevestigingssysteem, nodig voor 3 maanden, ongeacht de overige bijhorende produktattributen - Dotatie : 20 stuks/3 maanden - Lijst 0091 - Poche urinaire de nuit à vider (min. 1,5 litre) avec valve anti-reflux, y compris raccords, conduits et système de fixation au lit, nécessaire pour 3 mois, quels soient les autres accessoires - Dotation : 20 pièces/3 mois - Liste 0091	U
640113_640124	Ambulant urinaal met gordel, ringen en penishouder en zakjes om te ledigen : Gordel met ringen en penishouder - Dotatie : 1 stuk/6 maanden - Lijst 0113 - Urinal ambulatoire avec ceinture, anneaux et porte-pénis et poche à vider : Ceinture avec anneaux et porte-pénis - Dotation : 1 pièce/6 mois - Liste 0113	U
640135	Ambulant urinaal met gordel, ringen en penishouder en zakjes om te ledigen : Gedubbeld zakje met afvloeiing en systeem dat het terugvloeien belet - Dotatie : 35 stuks/3 maanden - Lijst 0135 - Urinal ambulatoire avec ceinture, anneaux et porte-pénis et poche à vider : Poche doublée avec écoulement et système anit-reflux - Dotation : 35 pièces/3 mois - Liste 0135	U
640150_640161	Ambulant urinaal met gordel, ringen en penishouder en zakjes om te ledigen : Penishouder - Dotatie : 25 stuks/3 maanden - Lijst 0150 - Urinal ambulatoire avec ceinture, anneaux et porte-pénis et poches à vider : Porte-pénis - Dotation : 25 pièces/3 mois - Liste 0150	U
640172	Container voor 's nachts, inclusief stop, 3 tubes met roterende connectoren, 3 universele adaptoren en beschermhoes - Dotatie : 1 set/3 maanden - LIJST 0172 - Conteneur de nuit, y compris bouchon, 3 tubes avec connecteurs rotatifs, 3 adaptateurs universels et housse protectrice - Dotation : 1 set/3 mois - LISTE 0172	U
640194	Beschermfilm in flacon per 40 ml - Dotatie : 1 flacon/3 maanden - Lijst 0194 - Film protecteur en flacon de 40 ml - Dotation : 1 flacon/3 mois - Liste 0194	U
640216	Forfaitaire tegemoetkoming voor beschermfilm voor een behandelingsperiode van minimum 3 maanden - Intervention forfaitaire pour film protecteur pour une période de traitement de minimum 3 mois	U
640231	Set bevattende 5 ledigbare urine opvangzakken voor 's nachts (min 1.5 liter) met antirefluxklep, inclusief koppelstukken, leidingen en bedbevestigingssysteem, eveneens 5 ledigbare urinezakjes voor overdag met antirefluxklep, inclusief koppelstukken, leidingen en volledig bevestigingssysteem - Dotatie: 1set/maand - LIJST 0231 - Set comprenant 5 poches urinaires de nuit à vider (min 1,5 litre) avec valve anti-reflux, y compris raccords, conduits et système de fixation au lit ainsi que 5 poches urinaires de jour à vider, avec valve anti-reflux, y compris raccords, conduits et système de fixation complet - Dotation : 1 set/mois - LISTE 0231	U
641535	Condoombevestigingsplaat uit silicone - Dotatie : 1 stuk / 6 maanden - LIJST 1535 - Système de fixation du préservatif en silicone - Dotation : 1 pièce / 6 mois - LISTE 1535	U
641550	Bevestigingssysteem voor ambulant urinaal - Dotatie : 1) 3 stuks/3 maanden bij de eerste aflevering 2) 1 stuk/3 maanden vanaf de tweede aflevering - LIJST 1550 - Système de fixation pour urinal ambulatoire - Dotation 1) 3 pièces/3 mois lors de la première fourniture 2) 1 pièce/3 mois à partir de la deuxième fourniture - LISTE 1550	U



641572	Condoomcatheter - Dotatie : 6 stuks/3 maanden - LIJST 1572 - Etui pénien - Dotation : 6 pièces/3 mois - LIJST 1572	U
641594	Beenzak - Dotatie : 20 stuks/3 maanden - LIJST 1594 - Poche de jambe - Dotation : 20 pièces/3 mois - LISTE 1594	U
641524	Forfaitair dagbedrag in geval van incontinentie voor de produkten bedoeld door de verstrekkingen 640010, 640032, 640054, 640113 of 640150 - Forfait journalier en cas d'incontinence pour les produits visés par les prestations 640010, 640032, 640054, 640113 ou 640150	U
Incontinence material: implantable or not, outside article 27 (RIZIV – INAMI codes)		
154792_154803	Set voor percutaan plaatsen of vervangen van een suprapubische blaaskatheter - Set pour le placement percutané ou le remplacement d'un cathéter urinaire suspubien	U
154976_154980	Geïmplanteerde urinaire kunstsfincter, samengesteld uit een opblaasbare manchet, een pomp met controlesysteem en een reservoir dat de druk regelt - Sphincter urinaire artificiel implanté composé d'une manchette gonflable, d'une pompe avec système de contrôle et d'un réservoir régulateur de pression	U
154991_155002	Toestel bestaande uit ingeplante lumbosacrale elektroden en een uitwendige stimulator, geplaatst ter behandeling van spastisch neurogeen blaaslijden als gevolg van een onomkeerbaar ruggemergletstel - Appareil composé d'électrodes lombo-sacrées implantées et d'un stimulateur externe, placé pour le traitement d'affections vésicales neurogènes spastiques consécutives à une lésion irréversible de la moelle épinière	U
155013_155024	Eerste ingeplante neurostimulator bij dysfunctie van de lage urinewegen - Premier neurostimulateur implanté en cas de dysfonction des voies urinaires inférieures	U
155035_155046	Ingeplante vervangingsneurostimulator bij dysfunctie van de lage urinewegen - Neurostimulateur de remplacement implanté en cas de dysfonction des voies urinaires inférieures	U
155050_155061	Ingeplante elektrode voor neurostimulator bij dysfunctie van de lage urinewegen - Electrode implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	U
155072_155083	Vervanging van de ingeplante elektrode voor neurostimulator bij dysfunctie van de lage urinewegen - Remplacement de l'électrode implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	U
155094_155105	Elektrode in geval van negatieve proefstimulatie bij dysfunctie van de lage urinewegen - Electrode en cas de stimulation d'essai négative en cas de dysfonction des voies urinaires inférieures	U
155116_155120	Ingeplante extensie voor neurostimulator bij dysfunctie van de lage urinewegen - Extension implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	U



155131_155142	Vervanging van de ingeplante extensie voor neurostimulator bij dysfunctie van de lage urinewegen - Remplacement de l'extension implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	U
155153_155164	Patiëntcontroleapparaat voor neurostimulatie bij dysfunctie van de lage urinewegen - Appareil de contrôle par le patient pour neurostimulation en cas de dysfonction des voies urinaires inférieures	U
156634_156645	Geheel van gebruiksmateriaal en implanteerbaar materiaal gebruikt tijdens de verstrekking 244156 - 244160 van de nomenclatuur, via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 244156 - 244160 de la nomenclature, par voie endoscopique	F
156656_156660	Geheel van gebruiksmateriaal en implanteerbaar materiaal gebruikt tijdens de verstrekking 244156 - 244160 van de nomenclatuur, bij open chirurgie - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 244156 - 244160 de la nomenclature, en chirurgie ouverte	F
156671_156682	Geheel van gebruiksmateriaal en van implanteerbaar materiaal gebruikt tijdens de verstrekking 244193 - 244204 van de nomenclatuur, via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 244193 - 244204 de la nomenclature, par voie endoscopique	F
157511_157522	Artificiële anale sfincter ter behandeling van fecale incontinentie, inclusief het bijgaande toebehoren - Sphincter anal artificiel pour le traitement de l'incontinence fécale, y compris les accessoires	F
157533_157544	Eerste ingeplante stimulator voor behandeling van fecale incontinentie door middel van dynamische graciloplastie - Premier stimulateur implanté pour le traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	F
157555_157566	Vervangingsstimulator voor behandeling van fecale incontinentie door middel van dynamische graciloplastie - Stimulateur de remplacement pour le traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	F
157570_157581	Ingeplante elektrode voor de verstrekking 157533-157544 of 157555-157566 - Electrode implantée pour la prestation 157533-157544 ou 157555-157566	F
157592_157603	Vervanging van de ingeplante elektrode voor de verstrekking 157533-157544 of 157555-157566 - Remplacement de l'électrode implantée pour la prestation 157533-157544 ou 157555-157566	F
157614_157625	Patiëntcontroleapparaat voor neurostimulatie bij behandeling van fecale incontinentie door middel van dynamische graciloplastie - Appareil de contrôle par le patient pour neurostimulation en cas de traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	F
157636_157640	Eerste ingeplante stimulator voor behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Premier stimulateur implanté pour le traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
157651_157662	Vervangingsstimulator voor behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Stimulateur de remplacement pour le traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F



157673_157684	Ingeplante elektrode voor de verstrekking 157636-157640 of 157651-157662 - Electrode implantée pour la prestation 157636-157640 ou 157651-157662	F
157695_157706	Vervanging van de ingeplante elektrode voor de verstrekking 157636-157640 of 157651-157662 - Remplacement de l'électrode implantée pour la prestation 157636-157640 ou 157651-157662	F
157710_157721	Elektrode in geval van negatieve proefstimulatie bij behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Electrode en cas de stimulation d'essai négative en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
157732_157743	Ingeplante extensie voor neurostimulator bij de behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Extension implantée pour neurostimulateur en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
157754_157765	Vervanging van de ingeplante extensie voor neurostimulator bij de behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Remplacement de l'extension implantée pour neurostimulateur en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
157776_157780	Patiëntcontroleapparaat voor neurostimulatie bij behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Appareil de contrôle par le patient pour neurostimulation en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
162256_162260	Volledig synthetisch netje voor herstel van prolaps, per cm <sup>2</sup> - Filet entièrement synthétique pour la réparation d'un prolapsus, par cm <sup>2</sup>	U
162271_162282	Volledig biologisch netje voor herstel van prolaps, per cm <sup>2</sup> - Filet entièrement biologique pour réparation d'un prolapsus, par cm <sup>2</sup>	U
162293_162304	Hybride biosynthetisch netje voor herstel van prolaps, per cm <sup>2</sup> - Filet hybride biosynthétique pour la réparation d'un prolapsus, par cm <sup>2</sup>	U
162315_162326	Volledig synthetisch speciaal netje voor herstel van prolaps, per cm <sup>2</sup> - Filet spécial entièrement synthétique pour la réparation d'un prolapsus, par cm <sup>2</sup>	U
162330_162341	Volledig biologisch speciaal netje voor herstel van prolaps, per cm <sup>2</sup> - Filet spécial entièrement biologique pour réparation d'un prolapsus, par cm <sup>2</sup>	U
162352_162363	Hybride biosynthetisch speciaal netje voor herstel van prolaps, per cm <sup>2</sup> - Filet spécial hybride biosynthétique pour la réparation d'un prolapsus, par cm <sup>2</sup>	U
162374_162385	Geheel van gebruiksmateriaal en van implanteerbaar materiaal gebruikt tijdens de verstrekking 431373 - 431384 van de nomenclatuur, via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 431373 - 431384 de la nomenclature, par voie endoscopique	U
162396_162400	Transvaginaal aangebrachte suburethrale band ter behandeling van stress-incontinentie naar aanleiding van de verstrekking 432751-432762 van de nomenclatuur - Treillis suburétral placé par voie transvaginale pour le traitement de l'incontinence de stress lors de la prestation 432751-432762 de la nomenclature	U



162411_162422	Geheel van gebruiksmateriaal en implanteerbaar materiaal gebruikt tijdens de verstrekking 432073 - 432084 van de nomenclatuur, via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 432073 - 432084 de la nomenclature, par voie endoscopique	U
172476_172480	Geheel van netjes voor herstel van prolaps, voor plaatsing langs abdominale weg - Ensemble des filets pour la réparation d'un prolapsus, pour un placement par voie abdominale	U
613056_613060	Toestel bestaande uit ingeplante lumbosacrale elektroden en een uitwendige stimulator, geplaatst ter behandeling van spastisch neurogeen blaaslijden als gevolg van een onomkeerbaar ruggemergletstel - Appareil composé d'électrodes lombo-sacrées implantées et d'un stimulateur externe, placé pour le traitement d'affections vésicales neurogènes spastiques consécutives à une lésion irréversible de la moelle épinière	U
613071_613082	Patiënt controleapparaat voor neurostimulatie bij dysfunctie van de lage urinewegen - Appareil de contrôle par le patient pour neurostimulation en cas de dysfonction des voies urinaires inférieures	U
613093_613104	Patiënt controleapparaat voor neurostimulatie bij behandeling van fecale incontinentie door middel van dynamische graciloplastie - Appareil de contrôle par le patient pour neurostimulation en cas de traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	F
613115_613126	Patiënt controleapparaat voor neurostimulatie bij behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Appareil de contrôle par le patient pour neurostimulation en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
613130_613141	Elektrode in geval van negatieve proefstimulatie bij dysfunctie van de lage urinewegen - Electrode en cas de stimulation d'essai négative en cas de dysfonction des voies urinaires inférieures	U
613152_613163	Elektrode in geval van negatieve proefstimulatie bij behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Electrode en cas de stimulation d'essai négative en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
613174_613185	Ingeplante elektrode en toebehoren voor de verstrekking 613056 - 613060 of 613071 - 613082 - Electrode implantée et accessoires pour la prestation 613056 - 613060 ou 613071 - 613082	U
614493_614504	Ingeplante elektrode en toebehoren voor de verstrekking 613093 - 613104 of 613115 - 613126 - Electrode implantée et accessoires pour la prestation 613093 - 613104 ou 613115 - 613126	F
614515_614526	Ingeplante elektrode voor de verstrekking 613056-613060 of 613071-613082 - Electrode implantée pour la prestation 613056-613060 ou 613071-613082	U
614530_614541	Ingeplante elektrode voor de verstrekking 613093-613104 of 613115-613126 - Electrode implantée pour la prestation 613093-613104 ou 613115-613126	F
614552_614563	Ingeplante elektrode voor neurostimulator bij dysfunctie van de lage urinewegen - Electrode implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	U



614574_614585	Geheel van gebruiksmateriaal en van implanteerbaar materiaal gebruikt tijdens de verstrekking 431373 - 431384 via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 431373 - 431384, par voie endoscopique	U
614596_614600	Geheel van gebruiksmateriaal en implanteerbaar materiaal gebruikt tijdens de verstrekking 432073 - 432084 via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 432073 - 432084, par voie endoscopique	U
614611_614622	Ingeplante extensie voor neurostimulator bij dysfunctie van de lage urinewegen - Extension implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	U
614633_614644	Ingeplante extensie voor neurostimulator bij de behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Extension implantée pour neurostimulateur en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
614655_614666	Volledig biologisch netje voor herstel van prolaps, per cm2 - Filet entièrement biologique pour réparation d'un prolapsus, par cm2	U
680956_680960	Volledig synthetisch netje voor herstel van prolaps, per cm2 - Filet entièrement synthétique pour la réparation d'un prolapsus, par cm2	U
680971_680982	Hybride biosynthetisch netje voor herstel van prolaps, per cm2 - Filet hybride biosynthétique pour la réparation d'un prolapsus, par cm2	U
684036_684040	Volledig biologisch speciaal netje voor herstel van prolaps, per cm2 - Filet spécial entièrement biologique pour réparation d'un prolapsus, par cm2	U
684154_684165	Volledig synthetisch speciaal netje voor herstel van prolaps, per cm2 - Filet spécial entièrement synthétique pour la réparation d'un prolapsus, par cm2	U
684235_684246	Hybride biosynthetisch speciaal netje voor herstel van prolaps, per cm2 - Filet spécial hybride biosynthétique pour la réparation d'un prolapsus, par cm2	U
697675_697686	Ingeplante vervangingsneurostimulator bij dysfunctie van de lage urinewegen - Neurostimulateur de remplacement implanté en cas de dysfonction des voies urinaires inférieures	U
697690_697701	Eerste ingeplante neurostimulator bij dysfunctie van de lage urinewegen - Premier neurostimulateur implanté en cas de dysfonction des voies urinaires inférieures	U
697712_697723	Eerste ingeplante stimulator voor behandeling van fecale incontinentie door middel van dynamische graciloplastie - Premier stimulateur implanté pour le traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	F
697734_697745	Eerste ingeplante stimulator voor behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Premier stimulateur implanté pour le traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
697793_697804	Vervanging van de ingeplante elektrode voor de verstrekking 613056-613060 of 613071-613082 - Remplacement de l'électrode implantée pour la prestation 613056-613060 ou 613071-613082	U





697815_697826	Vervanging van de ingeplante elektrode voor de verstrekking 613093-613104 of 613115-613126 - Remplacement de l'électrode implantée pour la prestation 613093-613104 ou 613115-613126	F
699834_699845	Vervanging van de ingeplante elektrode voor neurostimulator bij dysfunctie van de lage urinewegen - Remplacement de l'électrode implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	U
702752_702763	Vervanging van de ingeplante extensie voor neurostimulator bij dysfunctie van de lage urinewegen - Remplacement de l'extension implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	U
702774_702785	Vervanging van de ingeplante extensie voor neurostimulator bij de behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Remplacement de l'extension implantée pour neurostimulateur en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
702796_702800	Set voor percutaan plaatsen of vervangen van een suprapubische blaaskatheter - Set pour le placement percutané ou le remplacement d'un cathéter urinaire suspubien	U
702811_702822	Artificiële anale sfincter ter behandeling van fecale incontinentie, inclusief het bijgaande toebehoren - Sphincter anal artificiel pour le traitement de l'incontinence fécale, y compris les accessoires	F
702833_702844	Geïmplanteerde urinaire kunstsfincter, samengesteld uit een opblaasbare manchet, een pomp met controlesysteem en een reservoir dat de druk regelt - Sphincter urinaire artificiel implanté composé d'une manchette gonflable, d'une pompe avec système de contrôle et d'un réservoir régulateur de pression	U
702855_702866	Vervangingsstimulator voor behandeling van fecale incontinentie door middel van dynamische graciloplastie - Stimulateur de remplacement pour le traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	F
730634_730645	Vervangingsstimulator voor behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Stimulateur de remplacement pour le traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	F
733596_733600	Transvaginaal aangebrachte suburethrale band ter behandeling van stress-incontinentie - Treillis suburétral placé par voie transvaginale pour le traitement de l'incontinence de stress	U
Interventions (RIZIV – INAMI codes)		
244156_244160	Operatieve behandeling van rectumprolaps langs abdomino-perineale weg of langs abdominale weg volgens Loygues - Cure opératoire du prolapsus rectal par voie abdomino-périnéale ou par voie abdominale selon Loygues	F
244171_244182	Hechten van de hefspieren wegens rectumprolaps - Suture des releveurs pour prolapsus rectal	F
244193_244204	Resectie van een rectumprolaps - Résection d'un prolapsus rectal	F



244215_244226	Aarscerclage wegens rectumprolaps - Cerclage de l'anus pour prolapsus rectal	F
244392_244403	Refectie van de sfincter ani wegens incontinentie (oude scheur of heringreep), buiten de verlossing - Réfection du sphincter anal pour incontinence (déchirure ancienne ou réintervention) en dehors de l'accouchement	F
260455_260466	Herstellen van blaashals bij de vrouw, wegens urine-incontinentie - Réfection du col vésical féminin pour incontinence urinaire	U
260610_260621	Heelkundige behandeling van vesico-vaginale fistel - Cure chirurgicale de fistule vésico-vaginale	U
262150_262161	Endoscopische behandeling van urine-incontinentie - Traitement endoscopique d'incontinence urinaire	U
262415_262426 <sup>1</sup>	Plaatsen of vervangen van een suprapubische katheter - Placement ou remplacement d'un cathéter supra-pubien	U
262430_262441	Plaatsen van een suprapubische katheter - Placement d'un cathéter sus-pubien	U
262452_262463	Vervangen van een suprapubische katheter - Remplacement d'un cathéter sus-pubien	U
262474_262485	Plaatsing van een definitieve epidurale elektrode voor stimulatie van de sacrale zenuw, inclusief werkingscontrole - Mise en place d'une électrode épidurale définitive pour la stimulation du nerf sacré, y compris le contrôle du fonctionnement	U
262496_262500	Plaatsing van een tijdelijke epidurale elektrode als proeftherapie voor stimulatie van de sacrale zenuw, verbonden aan een externe stimulator, inclusief werkingscontrole - Mise en place d'une électrode épidurale temporaire reliée à un stimulateur externe, à titre de thérapie d'essai en vue de la stimulation du nerf sacré, y compris le contrôle du fonctionnement	U
262511_262522	Verwijderen van de tijdelijke extensie gebruikt bij de proeftherapie voor stimulatie van de sacrale zenuw - Enlèvement de l'extension temporaire utilisée pour la thérapie d'essai en vue de la stimulation du nerf sacré	U
262533_262544	Vervangen van een definitieve elektrode voor stimulatie van de sacrale zenuw - Remplacement d'une électrode définitive pour la stimulation du nerf sacré	U
262555_262566	Controle van de werking van de neurostimulator voor stimulatie van de sacrale zenuw - Contrôle du fonctionnement du neurostimulateur pour la stimulation du nerf sacré	U
431373_431384	Heelkundige bewerking wegens genitale prolaps met abdominale en vaginale bewerking tijdens een zelfde ingreep - Intervention chirurgicale pour prolapsus génital avec temps abdominal et vaginal au cours d'une même intervention	U

<sup>1</sup> Replaced by 262430\_262441 and 262452\_262463 on 4 January 2010.



431491_431502	Amputatie van baarmoederhals en plastiek met vaginale lappen (Sturmdorf) - Amputation du col utérin et plastie par lambeaux vaginaux (Sturmdorf)	U
431852_431863	Colporrafie vooraan of colpoperineorrafie achteraan met hechten van de hefspieren - Colporraphie antérieure ou colpopérinéorraphie postérieure avec sutures des releveurs	U
431896_431900	Colporrafie vooraan en colporineorrafie achteraan met hechten van de hefspieren - Colporraphie antérieure et colporinéorraphie postérieure avec sutures des releveurs	U
431911_431922	Bewerking wegens uterusprolapsus langs vaginale weg met supravaginale amputatie van de hals, hechten van de cardinale ligamenten aan de isthmus uteri en colporrafie vooraan, inclusief de eventuele colpoperineorrafie achteraan (operatie van Manchester-Fothergill of variante) - Intervention pour prolapsus utérin par voie vaginale avec amputation supravaginale du col, suture des ligaments cardinaux à l'isthme utérin et colporraphie antérieure, y compris la colpopérinéorraphie postérieure éventuelle (opération de Manchester Fothergill ou variante)	U
432073_432084	Heelkundige bewerking wegens urine-incontinentie, één weg, hetzij abdominale, hetzij vaginale - Intervention chirurgicale pour incontinence urinaire, une voie, soit abdominale, soit vaginale	U
432095_432106	Heelkundige bewerking wegens urine-incontinentie, langs abdominale en vaginale wegen (Steckel en afgeleide) - Intervention chirurgicale pour incontinence urinaire, par voies abdominale et vaginale (Steckel et dérivés)	U
432751_432762	Heelkundige behandeling van urine-incontinentie door het transvaginaal aanbrengen van een suburethrale band in synthetisch materiaal - Traitement chirurgical de l'incontinence urinaire par l'apposition transvaginale d'un treillis sous-urétral en matériel synthétique	U
558132_558143	Complexe monodisciplinaire bekkenbodembrevalidatie voor acuut ontstane urinaire of faecale incontinentie, op verwijzing van de behandelend geneesheer-specialist - Rééducation du plancher pelvien monodisciplinaire complexe pour incontinence urinaire ou fécale apparue de manière aiguë, sur prescription du médecin spécialiste traitant	U/F



## APPENDIX 4. VARIABLES DERIVED FROM EPS VARIABLES (2015)

User defined variable	Label	EPS source variables	Definition
<b>FORF_BC</b>	Entitlement to a B or C nursing care lump sum	PP2001, PP2002	if PP2001=1 or PP2002=1 then Forf_BC=YES else Forf_BC=NO
<b>STATUT_PREF</b>	Entitlement to preferential reimbursement	PP1010	if PP1010=0 then statut_pref=NO else statut_pref=YES
<b>RECON_HANDICAP</b>	Handicap recognition	PP1009	if PP1009 <> 0 then recon_handicap=YES else recon_handicap=0
<b>STATUT_CHRON</b>	Chronic illness status	PP3015, PP3016, PP3017	if PP3015 <> 0 or PP3016 <> 0 or PP3017 <> 0 then statut_chron=YES else statut_chron=NO
<b>GMF</b>	Global medical file (GMF)	SS00020	Patient has at least one of the following code billed during the year: 102395, 102771, 102793, 103272, 103294, 103574, 103596 (see next table).

GMF Code (RIZIV – INAMI)	Label
102395	Supplement voor de realisatie van de preventiemodule in het kader van het GMD ter gelegenheid van een raadpleging (101032, 101076) of van een bezoek (103132, 103412, 103434) - Supplément pour la réalisation du module de prévention dans le cadre du DMG à l'occasion d'une consultation (101032, 101076) ou d'une visite 103132, 103412, 103434)
102771	Supplement voor het beheer van het globaal medisch dossier (GMD) door een huisarts, ter gelegenheid van een raadpleging (101032, 101076) of van een bezoek (103132, 103412, 103434), met het schriftelijk akkoord van de patiënt - Supplément pour la gestion du dossier médical global (DMG) par un médecin généraliste, à l'occasion d'une consultation (101032, 101076) ou d'une visite (103132, 103412, 103434) avec l'accord écrit du patient
102793	Honorarium voor het beheer van het globaal medisch dossier zonder gebruik van de functionaliteiten van de MyCareNet-diensten: verlenging van het globaal medisch dossier - Honoraire pour la gestion du dossier médical global sans utilisation des fonctionnalités des services MyCareNet : prolongation du dossier médical
103272	Preventiemodule GMD medische huizen : facturatie aan 70% - Module de prévention DMG maisons médicales : facturation à 70%
103294	Preventiemodule GMD medische huizen : facturatie aan 30% - Module de prévention DMG maisons médicales : facturation à 30%
103574	Honorarium voor het beheer van het globaal medisch dossier met gebruik van de functionaliteiten van de MyCareNet-diensten: opening van het globaal medisch dossier - Honoraires pour la gestion du dossier médical global avec utilisation des fonctionnalités des services MyCareNet : ouverture du dossier médical



103596	Honorarium voor het beheer van het globaal medisch dossier met gebruik van de functionaliteiten van de MyCareNet-diensten: verlenging van het globaal medisch dossier - Honoraires pour la gestion du dossier médical global avec utilisation des fonctionnalités des services MyCareNet : prolongation du dossier médical
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Home care (RIZIV – INAMI)	Label
421072	Verwijdering van een verblijfskatheter of van specifiek materiaal dat de toediening van een geneeskundige oplossing in een implanteerbare kamer toelaat - Retrait d'un cathéter à demeure ou d'un matériel spécifique permettant l'administration d'une solution médicamenteuse dans une chambre implantable
421094	Verwijdering van een verblijfskatheter of van specifiek materiaal dat de toediening van een geneeskundige oplossing in een implanteerbare kamer toelaat - Retrait d'un cathéter à demeure ou d'un matériel spécifique permettant l'administration d'une solution médicamenteuse dans une chambre implantable
423054	Toedienen van geneesmiddelen, waaronder de vervanging van het heparineslot, via een directe intraveneuze toedieningsweg of via een eerder geplaatste intraveneuze katheter - Administration de médicaments, y compris le remplacement de l'héparjet, par voie intraveineuse directe ou via un cathéter intraveineux préalablement installé
423076	Toedienen van geneesmiddelen langs intramusculaire, subcutane of hypodermale toedieningsweg - Administration de médicaments par voie intramusculaire, sous-cutanée ou hypodermique
423091	Toedienen van geneesmiddelen langs intramusculaire, subcutane, hypodermale of intraveneuze toedieningsweg in verschillende injectieplaatsen - Administration de médicaments par voie intramusculaire, sous-cutanée, hypodermique ou intraveineuse, en plusieurs sites d'injection
423113	Plaatsing van een verblijfskatheter of van specifiek materiaal dat de toediening van een geneeskundige oplossing in een implanteerbare kamer toelaat - Mise en place d'un cathéter à demeure ou d'un matériel spécifique permettant l'administration d'une solution médicamenteuse dans une chambre implantable
423135	Forfaitair honorarium voor de opmaak van een specifiek verpleegdossier van de diabetische patiënt en overleg met de behandelende arts - Honoraire forfaitaire pour la constitution du dossier infirmier spécifique au patient diabétique et la concertation avec le médecin traitant
423150	Forfaitair honorarium voor individuele educatie tot zelfzorg van een diabetespatiënt door een referentieverpleegkundige inzake diabetes - Honoraire forfaitaire pour l'éducation individuelle aux soins autonomes d'un patient diabétique par un infirmier relais en diabétologie
423172	Forfaitair honorarium voor de aanwezigheid van een vaste verpleegkundige bij individuele educatie tot zelfzorg - Honoraire forfaitaire pour la présence d'un infirmier référent lors de l'éducation individuelle aux soins autonomes
423194	Forfaitair honorarium voor individuele educatie tot inzicht, waarbij een vaste verpleegkundige of een referentieverpleegkundige inzake diabetes een diabetespatiënt inzicht verschafft in de pathologie - Honoraire forfaitaire pour l'éducation individuelle à la compréhension, dans laquelle un infirmier référent ou un infirmier relais en diabétologie fournit au patient diabétique des explications sur la pathologie
423216	Forfait voor de opvolging van een diabetespatiënt na de educatie tot zelfzorg - Forfait pour le suivi d'un patient diabétique après l'éducation aux soins autonomes



423231	Opvolgingshonorarium voor begeleiding van een diabetespatiënt die niet overschakelt op zelfzorg door een vaste verpleegkundige - Honoraire de suivi pour l'accompagnement, par un infirmier référent, d'un patient diabétique qui ne passe pas aux soins autonomes
423253	Toedienen van geneesmiddelen, waaronder de vervanging van het heparineslot, via een directe intraveneuze toedieningsweg of via een eerder geplaatste intraveneuze katheter - Administration de médicaments, y compris le remplacement de l'héparjet, par voie intraveineuse directe ou via un cathéter intraveineux préalablement installé
423275	Toedienen van geneesmiddelen langs intramusculaire, subcutane of hypodermale toedieningsweg - Administration de médicaments par voie intramusculaire, sous-cutanée ou hypodermique
423290	Toedienen van geneesmiddelen langs intramusculaire, subcutane, hypodermale of intraveneuze toedieningsweg in verschillende injectieplaatsen - Administration de médicaments par voie intramusculaire, sous-cutanée, hypodermique ou intraveineuse, en plusieurs sites d'injection
423312	Plaatsing van een verblijfskatheter of van specifiek materiaal dat de toediening van een geneeskundige oplossing in een inplanteerbare kamer toelaat - Mise en place d'un cathéter à demeure ou d'un matériel spécifique permettant l'administration d'une solution médicamenteuse dans une chambre implantable
423334	Opvolgingshonorarium voor begeleiding van een diabetespatiënt die niet overschakelt op zelfzorg door een vaste verpleegkundige - Honoraire de suivi pour l'accompagnement, par un infirmier référent, d'un patient diabétique qui ne passe pas aux soins autonomes
424255	Toezicht op wonde met bioactief verband - Surveillance de plaie avec pansement bioactif
424270	Aanbrengen van zalf of van een geneeskrachtig product - Application de pommades ou d'un produit médicamenteux
424292	Aanbrengen van oogdruppels en/of oogzalf in de postoperatieve fase - Application de collyre et/ou de pommade ophtalmique en phase postopératoire
424314	In het kader van compressietherapie: aanbrengen van bandage(s), compressieverband(en) - Dans le cadre d'une thérapie de compression : application de bandage(s), pansement(s) de compression
424336	Eenvoudige wondzorg met uitzondering van de verstrekkingen die vallen onder de codenummers 424255, 424270, 424292, 424314 en 424933 - Soins de plaie(s) simples à l'exception des prestations 424255, 424270, 424292, 424314 et 424933
424351	Complexe wondzorg - Soins de plaie(s) complexes
424373	Specifieke wondzorg - Soins de plaie(s) spécifiques
424395	Bezoek van een referentieverpleegkundige bij specifieke wondzorg - Visite d'un infirmier relais pour des soins de plaie(s) spécifiques
424410	Toezicht op wonde met bioactief verband - Surveillance de plaie avec pansement bioactif



424432	Aanbrengen van zalf of van een geneeskrachtig product - Application de pommades ou d'un produit médicamenteux
424454	Aanbrengen van oogdruppels en/of oogzalf in de postoperatieve fase - Application de collyre et/ou de pommade ophtalmique en phase postopérative
424476	In het kader van compressietherapie: aanbrengen van bandage(s), compressieverband(en) - Dans le cadre d'une thérapie de compression : application de bandage(s), pansement(s) de compression
424491	Eenvoudige wondzorg met uitzondering van de verstrekkingen die vallen onder de codenummers 424410, 424432, 424454, 424476 en 424955 - Soins de plaie(s) simples à l'exception des prestations 424410, 424432, 424454, 424476 et 424955
424513	Complexe wondzorg - Soins de plaie(s) complexes
424535	Specifieke wondzorg - Soins de plaie(s) spécifiques
424874	Wekelijkse voorbereiding van de geneesmiddelen per os - Préparation hebdomadaire de médicaments administrés par voie orale
424896	Verpleegkundig advies en overleg in functie van de wekelijkse voorbereiding van de geneesmiddelen per os met akkoord van de behandelend arts - Avis infirmier et concertation en vue de la préparation hebdomadaire de médicaments administrés par voie orale, suivi d'un accord du médecin traitant
424933	In het kader van compressietherapie: aandoen en/of uittrekken van kous(en) - Dans le cadre d'une thérapie de compression : application et/ou enlèvement de bas
424955	In het kader van compressietherapie: aandoen en/of uittrekken van kous(en) - Dans le cadre d'une thérapie de compression : application et/ou enlèvement de bas
425014	Eerste basisverstrekking van de verzorgingsdag - Première prestation de base de la journée de soins
425036	Tweede basisverstrekking van de verzorgingsdag - Deuxième prestation de base de la journée de soins
425051	Derde of latere basisverstrekking van de verzorgingsdag - Troisième prestation de base ou plus de la journée de soins
425110	Hygiënische verzorging (toiletten) - Soins d'hygiène (toilettes)
425176	Blaassondage , blaasinstillatie , blaasspoeling - Sondage vésical , Instillation vésicale, Lavage de vessie
425191	Aseptische vulvazorgen , vagina-irrigatie , aspiratie luchtwegen - Soins aseptiques de vulve , Irrigation vaginale , Aspiration des voies respiratoires



425213	Manueel verwijderen van faecalomen , lavement en/of toediening van medicamenteuze oplossingen via rectale sonde , gastro-intestinale tubage en drainage , darmspoeling , enterale voeding via maagsonde, gastro- of enterostomiesonde - Evacuation manuelle de fécalome , lavement et/ou administration de solution médicamenteuse par une sonde rectale , tubage et drainage gastro-intestinal , lavage intestinal , nutrition entérale via une sonde gastrique, une sonde de gastrostomie ou d'entérostomie
425272	Forfaitair honorarium, forfait A genoemd, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan de rechthebbende wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijk wegens het criterium zich wassen en het criterium zich kleden (score 3 of 4), en - afhankelijk wegens het criterium transfer en verplaatsingen en/of het criterium toiletbezoek (score 3 of 4) - Honoraires forfaitaires, dits forfait A, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire dont l'état de dépendance physique répond aux critères suivants: - dépendance pour le critère se laver et le critère s'habiller (score 3 ou 4), et - dépendance pour le critère transfert et déplacements et/ou le critère aller à la toilette (score 3 ou 4)
425294	Forfaitair honorarium, forfait B genoemd, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan de rechthebbende wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijk wegens het criterium zich wassen en het criterium zich kleden (score 3 of 4), en - afhankelijk wegens het criterium transfer en verplaatsingen en het criterium toiletbezoek (score 3 of 4), en - afhankelijkheid wegens het criterium continentie en/of het criterium eten (score 3 of 4) - Honoraires forfaitaires, dits forfait B, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire dont l'état de dépendance physique répond aux critères suivants: - dépendance pour le critère se laver et le critère s'habiller (score 3 ou 4), et - dépendance pour le critère transfert et déplacements et le critère aller à la toilette (score 3 ou 4), et - dépendance pour le critère continence et/ou pour le critère manger (score 3 ou 4)
425316	Forfaitair honorarium, forfait C genoemd, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan de rechthebbende wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijk wegens het criterium zich wassen (score 4) en het criterium zich kleden (score 4) en - afhankelijk wegens het criterium transfer en verplaatsingen (score 4) en om het criterium toiletbezoek (score 4) en - afhankelijkheid wegens het criterium continentie en het criterium eten (waarvoor één van de twee criteria een score 4 heeft en het andere criterium een score van minimum 3) - Honoraires forfaitaires, dits forfait C, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire dont l'état de dépendance physique répond aux critères suivants: - dépendance pour le critère se laver (score 4) et le critère s'habiller (score 4), et - dépendance pour le critère transfert et déplacements (score 4) et le critère aller à la toilette (score 4), et - dépendance pour le critère continence et pour le critère manger (pour laquelle un des deux critères obtient un score de 4, et l'autre un score de minimum 3)
425375	Forfaitair honorarium per verzorgingsdag voor patiënten die verzorging met één of meerdere van de volgende specifieke technische verpleegkundige verstrekkingen vereisen : - plaatsen van en/of toezicht op (intraveneuze of subcutane) perfusie; - toediening van en/of toezicht op parenterale voeding; - Honoraires forfaitaires par journée de soins comprenant un ou plusieurs des actes techniques spécifiques suivants : - mise en place et/ou surveillance des perfusions (intraveineuses ou sous-cutanées); - administration et/ou surveillance de l'alimentation parentérale;
425412	Eerste basisverstrekking van de verzorgingsdag - Première prestation de base de la journée de soins
425434	Tweede basisverstrekking van de verzorgingsdag - Deuxième prestation de base de la journée de soins
425456	Derde of latere basisverstrekking van de verzorgingsdag - Troisième prestation de base ou plus de la journée de soins
425515	Hygiënische verzorging (toiletten) - Soins d'hygiène (toilettes)





425574	- Blaassondage; - blaasinstillatie; - blaasspoeling - - Sondage vésicale; - instillation vésicale; - lavage de vessie
425596	- Aseptische vulvazorgen; - vagina-irrigatie; - aspiratie luchtwegen - - Soins aseptiques de vulve; - irrigation vaginale; aspiration des voies respiratoires
425611	- Manueel verwijderen van faecalomen; - lavement en/of toediening van medicamenteuze oplossingen via rectale sonde; - gastro-intestinale tubage en drainage; - darmspoeling; - enterale voeding via maagsonde, gastro- of enterostomiesonde - - Evacuation manuelle de fécalome; - lavement et/ou administration de solution médicamenteuse par une sonde rectale; - tubage et drainage gastro-intestina; -, llavage intestinal; - nutrition entérale via une sonde gastrique, une sonde de gastrostomie ou d
425670	Forfaitair honorarium, forfait A genoemd, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan de rechthebbende wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijk wegens het criterium zich wassen en het criterium zich kleden (score 3 of 4), en - afhankelijk wegens het criterium transfer en verplaatsingen en/of het criterium toiletbezoek (score 3 of 4) - Honoraires forfaitaires, dits forfait A, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire dont l'état de dépendance physique répond aux critères suivants: - dépendance pour le critère se laver et le critère s'habiller (score 3 ou 4), et - dépendance pour le critère transfert et déplacements et/ou le critère aller à la toilette (score 3 ou 4)
425692	Forfaitair honorarium, forfait B genoemd, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan de rechthebbende wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijk wegens het criterium zich wassen en het criterium zich kleden (score 3 of 4), en - afhankelijk wegens het criterium transfer en verplaatsingen en het criterium toiletbezoek (score 3 of 4), en - afhankelijkheid wegens het criterium continentie en/of het criterium eten (score 3 of 4) - Honoraires forfaitaires, dits forfait B, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire dont l'état de dépendance physique répond aux critères suivants: - dépendance pour le critère se laver et le critère s'habiller (score 3 ou 4), et - dépendance pour le critère transfert et déplacements et le critère aller à la toilette (score 3 ou 4), et - dépendance pour le critère continence et/ou pour le critère manger (score 3 ou 4)
425714	Forfaitair honorarium, forfait C genoemd, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan de rechthebbende wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijk wegens het criterium zich wassen (score 4) en het criterium zich kleden (score 4) en - afhankelijk wegens het criterium transfer en verplaatsingen (score 4) en om het criterium toiletbezoek (score 4) en - afhankelijkheid wegens het criterium continentie en het criterium eten (waarvoor één van de twee criteria een score 4 heeft en het andere criterium een score van minimum 3) - Honoraires forfaitaires, dits forfait C, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire dont l'état de dépendance physique répond aux critères suivants: - dépendance pour le critère se laver (score 4) et le critère s'habiller (score 4), et - dépendance pour le critère transfert et déplacements (score 4) et le critère aller à la toilette (score 4), et - dépendance pour le critère continence et pour le critère manger (pour laquelle un des deux critères obtient un score de 4, et l'autre un score de minimum 3)
425736	Vorbereiding en toediening van medicatie bij chronische psychiatrische patiënten - Préparation et administration de médicaments pour patients psychiatriques chroniques
425751	Vorbereiding en toediening van medicatie bij chronische psychiatrische patiënten - Préparation et administration de médicaments pour patients psychiatriques chroniques
425773	Forfaitair honorarium per verzorgingsdag voor patiënten die verzorging met één of meerdere van de volgende specifieke technische verpleegkundige verstrekkingen vereisen : - plaatsen van en/of toezicht op (intraveneuze of subcutane) perfusie; - toediening van en/of toezicht op parenterale voeding; - Honoraires forfaitaires par journée de soins comprenant un ou plusieurs des actes techniques spécifiques suivants : - mise en place et/ou surveillance des perfusions (intraveineuses ou sous-cutanées); - administration et/ou surveillance de l'alimentation parentérale;



427011	Forfaitair honorarium PC, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan een rechthebbende : • wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijkheid wegens het criterium zich wassen (score 4) en het criterium zich kleden (score 4), en - afhankelijk wegens het criterium transfer en verplaatsingen (score 4) en om het criterium toiletbezoek (score 4), en - afhankelijkheid wegens het criterium continentie en het criterium eten (waarvoor één van de twee criteria een score 4 heeft en het andere criterium een score van minimum 3) • en die beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires forfaitaires PC, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire : • dont l'état de dépendance physique répond aux critères suivants : - dépendance pour le critère se laver (score 4) et le critère s'habiller (score 4), et - dépendance pour le critère transfert et déplacements (score 4) et le critère aller à la toilette (score 4), et - dépendance pour le critère continence et pour le critère manger (pour laquelle un des deux critères obtient un score de 4, et l'autre un score de minimum 3) • et qui répond à la définition du patient palliatif reprise au § 5bis, 1°
427033	Forfaitair honorarium PB, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan een rechthebbende : • wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijkheid wegens het criterium zich wassen en het criterium zich kleden (score 3 of 4), en - afhankelijk wegens het criterium transfer en verplaatsingen en het criterium toiletbezoek (score 3 of 4), en - afhankelijkheid wegens het criterium continentie en/of het criterium eten (score 3 of 4) • en die beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires forfaitaires PB, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire : • dont l'état de dépendance physique répond aux critères suivants : - dépendance pour le critère se laver et le critère s'habiller (score 3 ou 4), et - dépendance pour le critère transfert et déplacements (score 3 ou 4), et - dépendance pour le critère continence et/ou pour le critère manger (score 3 ou 4). • et qui répond à la définition du patient palliatif reprise au § 5bis, 1°
427055	Forfaitair honorarium PA, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend : • aan een rechthebbende wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijk wegens het criterium zich wassen en het criterium zich kleden (score 3 of 4), en - afhankelijk wegens het criterium transfer en verplaatsingen en/of het criterium toiletbezoek (score 3 of 4) • op voorwaarde dat deze rechthebbende beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires forfaitaires PA, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués : • au bénéficiaire dont l'état de dépendance physique répond aux critères suivants : - dépendance pour le critère se laver et le critère s'habiller (score 3 ou 4), et - dépendance pour le critère transfert et déplacements et/ou le critère aller à la toilette (score 3 ou 4) • sous la condition que le bénéficiaire répond à la définition de patient palliatif reprise au § 5bis, 1°
427070	Supplémentair honorarium, forfait PN, genoemd, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan een rechthebbende : . in wiens hoofde één of meer verstrekkingen bedoeld sub I of sub III van deze rubriek worden aangerekend, zonder dat het dagplafond bedoeld in § 4, 6° wordt bereikt ; . en die beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires supplémentaires, dits forfaits PN, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire : . pour lequel une ou plusieurs prestations visées sous I ou sous III de la présente rubrique ont été attestées, sans que le plafond journalier visé au § 4, 6° n'ait été atteint ; . et qui répond à la définition de patient palliatif reprise au § 5bis 1°
427092	Forfaitair honorarium PC, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan een rechthebbende : • wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijkheid wegens het criterium zich wassen (score 4) en het criterium zich kleden (score 4), en - afhankelijk wegens het criterium transfer en verplaatsingen (score 4) en om het criterium toiletbezoek (score 4), en - afhankelijkheid wegens het criterium continentie en het criterium eten (waarvoor één van de twee criteria een score 4 heeft en het andere criterium een score van minimum 3) • en die beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires forfaitaires PC, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire : • dont l'état de dépendance physique répond aux critères suivants : - dépendance pour le critère se laver (score 4) et le critère s'habiller (score 4), et - dépendance pour le critère transfert et déplacements (score 4) et le critère aller à la toilette (score 4), et - dépendance pour le critère continence et pour le critère manger (pour laquelle un des deux critères obtient un score de 4, et l'autre un score de minimum 3) • et qui répond à la définition du patient palliatif reprise au § 5bis, 1°
427114	Forfaitair honorarium PB, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan een rechthebbende : • wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijkheid wegens het criterium zich wassen en het criterium zich kleden (score 3 of 4), en -



	afhankelijk wegens het criterium transfer en verplaatsingen en het criterium toiletbezoek (score 3 of 4), en - afhankelijkheid wegens het criterium continentie en/of het criterium eten (score 3 of 4) • en die beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires forfaitaires PB, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire : • dont l'état de dépendance physique répond aux critères suivants : - dépendance pour le critère se laver et le critère s'habiller (score 3 ou 4), et - dépendance pour le critère transfert et déplacements et le critère aller à la toilette (score 3 ou 4) et - dépendance pour le critère continence et/ou pour le critère manger (score 3 ou 4). • et qui répond à la définition du patient palliatif reprise au § 5bis, 1°
427136	Forfaitair honorarium PA, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend • aan een rechthebbende wiens fysieke afhankelijkheidstoestand beantwoordt aan de volgende criteria : - afhankelijk wegens het criterium zich wassen en het criterium zich kleden (score 3 of 4), en - afhankelijk wegens het criterium transfer en verplaatsingen en/of het criterium toiletbezoek (score 3 of 4) • op voorwaarde dat deze rechthebbende beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires forfaitaires PA, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués : • au bénéficiaire dont l'état de dépendance physique répond aux critères suivants : - dépendance pour le critère se laver et le critère s'habiller (score 3 ou 4), et - dépendance pour le critère transfert et déplacements et/ou le critère aller à la toilette (score 3 ou 4) • sous la condition que le bénéficiaire répond à la définition de patient palliatif reprise au § 5bis, 1°
427151	Supplémentair honorarium forfait PN genoemd, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend aan een rechthebbende : . in wiens hoofde één of meer verstrekkingen bedoeld sub I of sub III van deze rubriek worden aangerekend, zonder dat het dagplafond bedoeld in § 4, 6° wordt bereikt ; . en die beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires supplémentaires, dits forfaits PN, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués au bénéficiaire : . pour lequel une ou plusieurs prestations visées sous I ou sous III de la présente rubrique ont été attestées, sans que le plafond journalier visé au § 4, 6° n'ait été atteint ; . et qui répond à la définition de patient palliatif reprise au § 5bis, 1°
427173	Forfaitair honorarium PP, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend: • aan een rechthebbende in wiens hoofde de bepalingen in § 4, 6° van toepassing zijn; • op voorwaarde dat deze rechthebbende beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires forfaitaires PP, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués : • au bénéficiaire pour qui s'appliquent les dispositions du § 4, 6°; sous la condition que le bénéficiaire répond à la définition de patient palliatif reprise au § 5bis, 1°
427195	Forfaitair honorarium PP, dat één keer per verzorgingsdag wordt toegekend voor het geheel van de verpleegkundige verzorging, verleend : • aan een rechthebbende in wiens hoofde de bepalingen in § 4, 6° van toepassing zijn; • op voorwaarde dat deze rechthebbende beantwoordt aan de definitie van palliatieve patiënt, zoals bedoeld in § 5bis, 1° - Honoraires forfaitaires PP, accordés une seule fois par journée de soins pour l'ensemble des soins infirmiers effectués : • au bénéficiaire pour qui s'appliquent les dispositions du § 4, 6°. • sous la condition que le bénéficiaire répond à la définition de patient palliatif reprise au § 5bis, 1°
427416	Vervangen van een suprapubische sonde met ballon - Remplacement d'une sonde vésicale sus-pubienne à ballonnet
427431	Vervangen van een suprapubische sonde met ballon - Remplacement d'une sonde vésicale sus-pubienne à ballonnet
427475	Vervangen van een gastrostomiesonde met ballon - Remplacement d'une sonde de gastrostomie à ballonnet
427490	Vervangen van een gastrostomiesonde met ballon - Remplacement d'une sonde de gastrostomie à ballonnet
427534	Toezichts- en opvolgingshonorarium bij het gebruik van pompsystemen voor het toedienen van chronische analgesie via epidurale of intrathecale catheter - Honoraire pour la surveillance et le suivi lors de l'utilisation d'un système de pompe pour l'administration d'une analgésie chronique via un cathéter épidural ou intrathécal



427556	Toezihts- en opvolgingshonorarium bij het gebruik van pompsystemen voor het toedienen van chronische analgesie via epidurale of intrathecale catheter - Honoraire pour la surveillance et le suivi lors de l'utilisation d'un système de pompe pour l'administration d'une analgésie chronique via un cathéter épidural ou intrathécal
428035	vergoeding voor de herhaaldelijke noodzakelijke verstrekkingen bij zeer afhankelijke patiënten - valorisation des prestations multiples et contraignantes chez les patients très dépendants
428050	vergoeding voor de herhaaldelijke noodzakelijke verstrekkingen bij zeer afhankelijke patiënten - valorisation des prestations multiples et contraignantes chez les patients très dépendants
429015	Verpleegkundig consult in de thuisverpleging - Consultation infirmière dans le cadre des soins à domicile



## APPENDIX 5. VOLUME (DDD), REIMBURSEMENTS (€) AND NUMBER OF PATIENTS FOR URINARY FREQUENCY AND INCONTINENCE DRUGS (RIZIV – INAMI 2008-2017)

ATC = G04BD	Year									
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
<b>Volume (DDDs)</b>										
G04BD02 Flavoxate	509 200	487 130	448 068	410 095	375 845	344 705	318 025	314 716	290 820	48 925
G04BD04 Oxybutynin	6 204 907	6 241 640	6 163 066	5 863 970	5 682 073	5 514 582	5 398 002	5 141 441	4 895 934	4 613 358
G04BD07 Tolterodine	775 495	721 126	609 204	515 032	440 076	379 176	332 836	385 545	454 857	309 538
G04BD08 Solifenacin	495 180	900 630	1 313 320	1 554 391	1 713 150	1 882 531	2 049 480	2 264 804	2 382 916	2 391 289
G04BD10 Darifenacin	129 248	178 733	155 251	129 290	106 120	90 944	95 648	132 542	217 962	273 294
G04BD11 Fesoterodine		209 538	695 783	1 225 252	1 593 315	1 795 357	1 809 285	1 855 930	1 867 898	1 883 709
<b>TOTAL</b>	<b>8 114 030</b>	<b>8 738 797</b>	<b>9 384 691</b>	<b>9 698 030</b>	<b>9 910 579</b>	<b>10 007 295</b>	<b>10 003 276</b>	<b>10 094 978</b>	<b>10 110 386</b>	<b>9 520 113</b>
<b>Reimbursements (€)</b>										
G04BD02 Flavoxate	63 312	60 472	69 482	69 148	64 875	61 269	57 757	44 539	38 934	6 736
G04BD04 Oxybutynin	401 403	392 575	726 952	826 219	826 257	820 291	822 973	781 680	701 538	667 143
G04BD07 Tolterodine	1 119 352	988 489	808 736	667 290	559 945	476 744	363 175	209 700	163 420	110 553
G04BD08 Solifenacin	473 537	880 607	1 309 783	1 534 604	1 659 532	1 802 930	1 952 151	2 172 547	2 261 251	2 239 720
G04BD10 Darifenacin	124 919	174 593	149 447	122 373	91 601	76 244	78 447	112 935	135 878	163 809



G04BD11 Fesoterodine	190 231	593 681	1 014 430	1 289 862	1 425 605	1 421 699	1 465 341	1 458 056	1 449 401	
TOTAL	2 182 524	2 686 967	3 658 080	4 234 064	4 492 073	4 663 085	4 696 201	4 786 741	4 759 079	4 637 362
Number of patients (€)										
G04BD02 Flavoxate	10 941	10 344	9 313	8 593	7 923	7 552	6 964	5 980	5 392	1 583
G04BD04 Oxybutynin	77 759	78 025	75 948	71 674	70 034	68 175	66 744	64 758	61 731	59 464
G04BD07 Tolterodine	3 073	2 553	2 066	1 691	1 400	1 171	1 158	1 762	2 340	1 591
G04BD08 Solifenacin	1 689	2 698	3 651	3 926	4 259	4 650	5 070	5 486	5 635	5 646
G04BD10 Darifenacin	459	491	372	283	228	195	245	353	684	771
G04BD11 Fesoterodine	0	886	1 984	3 202	3 628	3 797	3 857	3 915	3 855	3 946
TOTAL	91 437	92 441	91 001	87 358	85 705	83 994	82 468	80 588	78 063	71 586

Source: Farmanet – Pharmanet (RIZIV – INAMI)



## APPENDIX 6. – NUMBER OF IMPLANTS AND REIMBURSEMENTS FOR INCONTINENCE (DOC N 2016)

RIZIV – INAMI codes	Label	Number	Reimbursed amount (€)
<b>Urinary incontinence</b>			
154792_154803	Set voor percutaan plaatsen of vervangen van een suprapubische blaaskatheter - Set pour le placement percutané ou le remplacement d'un cathéter urinaire suspubien	15 910	223 461
162256_162260	Volledig synthetisch netje voor herstel van prolaps, per cm² - Filet entièrement synthétique pour la réparation d'un prolapsus, par cm²	11 150	8 301
162396_162400	Transvaginaal aangebrachte suburethrale band ter behandeling van stress-incontinentie naar aanleiding van de verstrekking 432751-432762 van de nomenclatuur - Treillis suburétrhal placé par voie transvaginale pour le traitement de l'incontinence de stress lors de la prestation 432751-432762 de la nomenclature	6 402	2 305 585
162315_162326	Volledig synthetisch speciaal netje voor herstel van prolaps, per cm² - Filet spécial entièrement synthétique pour la réparation d'un prolapsus, par cm²	2 437	1 935
172476_172480	Geheel van netjes voor herstel van prolaps, voor plaatsing langs abdominale weg - Ensemble des filets pour la réparation d'un prolapsus, pour un placement par voie abdominale	1 357	407 628
162374_162385	Geheel van gebruiksmateriaal en van implanteerbaar materiaal gebruikt tijdens de verstrekking 431373 - 431384 van de nomenclatuur, via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 431373 - 431384 de la nomenclature, par voie endoscopique	351	155 844
155050_155061	Ingeplante elektrode voor neurostimulator bij dysfunctie van de lage urinewegen - Electrode implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	183	253 631
154976_154980	Geïmplanteerde urinaire kunstsfincter, samengesteld uit een opblaasbare manchet, een pomp met controlesysteem en een reservoir dat de druk regelt - Sphincter urinaire artificiel implanté composé d'une manchette gonflable, d'une pompe avec système de contrôle et d'un réservoir régulateur de pression	177	863 605
155013_155024	Eerste ingeplante neurostimulator bij dysfunctie van de lage urinewegen - Premier neurostimulateur implanté en cas de dysfonction des voies urinaires inférieures	142	961 685
162411_162422	Geheel van gebruiksmateriaal en implanteerbaar materiaal gebruikt tijdens de verstrekking 432073 - 432084 van de nomenclatuur, via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 432073 - 432084 de la nomenclature, par voie endoscopique	98	17 255
155153_155164	Patiëntcontroleapparaat voor neurostimulatie bij dysfunctie van de lage urinewegen - Appareil de contrôle par le patient pour neurostimulation en cas de dysfonction des voies urinaires inférieures	88	53 882



155035_155046	Ingeplante vervangingsneurostimulator bij dysfunctie van de lage urinewegen - Neurostimulateur de remplacement implanté en cas de dysfonction des voies urinaires inférieures	71	455 007
155072_155083	Vervanging van de ingeplante elektrode voor neurostimulator bij dysfunctie van de lage urinewegen - Remplacement de l'électrode implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	39	54 052
155094_155105	Elektrode in geval van negatieve proefstimulatie bij dysfunctie van de lage urinewegen - Electrode en cas de stimulation d'essai négative en cas de dysfonction des voies urinaires inférieures	18	24 947
155116_155120	Ingeplante extensie voor neurostimulator bij dysfunctie van de lage urinewegen - Extension implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	1	267
155131_155142	Vervanging van de ingeplante extensie voor neurostimulator bij dysfunctie van de lage urinewegen - Remplacement de l'extension implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	1	267
614552_614563	Ingeplante elektrode voor neurostimulator bij dysfunctie van de lage urinewegen - Electrode implantée pour neurostimulateur en cas de dysfonction des voies urinaires inférieures	1	1 386
614655_614666	Volledig biologisch netje voor herstel van prolaps, per cm2 - Filet entièrement biologique pour réparation d'un prolapsus, par cm2	1	612
684235_684246	Hybride biosynthetisch speciaal netje voor herstel van prolaps, per cm2 - Filet spécial hybride biosynthétique pour la réparation d'un prolapsus, par cm2	1	372
<b>TOTAL</b>			<b>5 789 723</b>
<b>Faecal incontinence</b>			
156634_156645	Geheel van gebruiksmateriaal en implanteerbaar materiaal gebruikt tijdens de verstrekking 244156 - 244160 van de nomenclatuur, via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 244156 - 244160 de la nomenclature, par voie endoscopique	1 643	1 017 598
156656_156660	Geheel van gebruiksmateriaal en implanteerbaar materiaal gebruikt tijdens de verstrekking 244156 - 244160 van de nomenclatuur, bij open chirurgie - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 244156 - 244160 de la nomenclature, en chirurgie ouverte	102	63 072
156671_156682	Geheel van gebruiksmateriaal en van implanteerbaar materiaal gebruikt tijdens de verstrekking 244193 - 244204 van de nomenclatuur, via endoscopische weg - Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 244193 - 244204 de la nomenclature, par voie endoscopique	53	23 532
155153_155164	Patiëntcontroleapparaat voor neurostimulatie bij dysfunctie van de lage urinewegen - Appareil de contrôle par le patient pour neurostimulation en cas de dysfonction des voies urinaires inférieures	50	30 615
157673_157684	Ingeplante elektrode voor de verstrekking 157636-157640 of 157651-157662 - Electrode implantée pour la prestation 157636-157640 ou 157651-157662	41	56 797
157776_157780	Patiëntcontroleapparaat voor neurostimulatie bij behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Appareil de contrôle par le patient pour neurostimulation en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	39	23 880





157636_157640	Eerste ingeplante stimulator voor behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Premier stimulateur implanté pour le traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	38	258 609
157651_157662	Vervangingsstimulator voor behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Stimulateur de remplacement pour le traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	19	119 910
157695_157706	Vervanging van de ingeplante elektrode voor de verstrekking 157636-157640 of 157651-157662 - Remplacement de l'électrode implantée pour la prestation 157636-157640 ou 157651-157662	11	15 246
157570_157581	Ingeplante elektrode voor de verstrekking 157533-157544 of 157555-157566 - Electrode implantée pour la prestation 157533-157544 ou 157555-157566	10	11 460
157614_157625	Patiëntcontroleapparaat voor neurostimulatie bij behandeling van fecale incontinentie door middel van dynamische graciloplastie - Appareil de contrôle par le patient pour neurostimulation en cas de traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	9	5 511
157533_157544	Eerste ingeplante stimulator voor behandeling van fecale incontinentie door middel van dynamische graciloplastie - Premier stimulateur implanté pour le traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	5	22 284
157710_157721	Elektrode in geval van negatieve proefstimulatie bij behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Electrode en cas de stimulation d'essai négative en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	4	5 544
157555_157566	Vervangingsstimulator voor behandeling van fecale incontinentie door middel van dynamische graciloplastie - Stimulateur de remplacement pour le traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	3	13 370
157754_157765	Vervanging van de ingeplante extensie voor neurostimulator bij de behandeling van fecale incontinentie door middel van sacrale zenuwstimulatie - Remplacement de l'extension implantée pour neurostimulateur en cas de traitement de l'incontinence fécale au moyen de la stimulation du nerf sacré	1	267
613093_613104	Patiënt controleapparaat voor neurostimulatie bij behandeling van fecale incontinentie door middel van dynamische graciloplastie - Appareil de contrôle par le patient pour neurostimulation en cas de traitement de l'incontinence fécale au moyen de la graciloplastie dynamique	1	6 806
<b>TOTAL</b>			<b>1 674 501</b>



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