



Market Access for Medical Technologies in Belgium



Prepared for



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Reimbursement Is the Key Market Access Barrier for Medical Technologies in Belgium

Reimbursement

Mechanism to pay for medical technology or procedure

- Fee for procedure (INAMI/RIZIV Nomenclature code or APR-DRG)
- Fee for implants and invasive devices (INAMI/RIZIV Lists of reimbursable devices)
- Introduction of the procedure or material code involves an in-depth review of clinical and economic evidence by INAMI/RIZIV, the key reimbursement decision-maker

Acceptance by payers

Independent acceptance by payers or national decision-makers

- Not relevant in Belgium

Stand-alone HTA

Stand-alone health technology assessment

- Health technology assessments by the Belgian Health Care Knowledge Center (KCE) play a limited indirect role in the acceptance of medical technologies by INAMI/RIZIV and payers



INAMI/RIZIV Is the Central Reimbursement Decision-Maker in Belgium

Policy-makers



Federal Public Service for Health (SPF)

The highest healthcare entity in Belgium. In charge of organization, funding, quality and planning of healthcare



National Institute for Health and Disability Insurance (INAMI/RIZIV)

Responsible for overall organization and financing of compulsory healthcare and benefits. The key reimbursement organization in Belgium. Provides funds, pooled by the National Social Security Office (NSSO), to the sickness funds

Payers



Sickness funds

Private, not-for-profit companies that are the main payers in the Belgian system. Six national sickness funds exist, which cover the majority of Belgian citizens. Sickness funds are organized according to religious or political affiliations into five national alliances, plus the sickness fund of national railway employees



Auxiliary Sickness & Invalidity Insurance Fund

Secondary sickness fund that covers a <1% of Belgian citizens (those not affiliated with one of the large six sickness funds)

Decision influencers



Health Care Knowledge Centre (KCE)

Performs health technology assessment and develops clinical practice guidelines for physicians. An important stakeholder in the system



Sciensano

Institution, which incorporates the ex-Scientific Institute of Public Health (WIV-ISP). Provides scientific advice to the stakeholders in the system, including the introduction of novel procedure codes



Hospital Payment Combines Procedure Fees, Device and Medicine Fees, Ward Funding



The same fee-for-service payment mechanism is applicable to outpatient specialist (ambulatory) settings




Specialist Services Are Funded Through a Multi-Component Payment Model

- Belgium has a complex and unique (in Europe) reimbursement system. It consists of the sum of payments for hospital beds and hospital management (Budget of Financial Means), procedures performed by physicians (using INAMI/RIZIV physician fees or DRGs substituting INAMI/RIZIV fees), materials (implants and invasive medical devices), pharmaceuticals, laboratory services and imaging procedures
- At the center of reimbursement of individual procedures / device is [INAMI/RIZIV reimbursement nomenclature](#) (for procedures) and [INAMI/RIZIV Lists of reimbursable devices](#) (for implants and invasive devices)
- INAMI/RIZIV codes are always available for ambulatory (first code) and hospital use (second code)
 - For example, in the code 258635 – 258646 “Subperichondral correction of the nasal septum”, the code 258635 is for the use of the procedure in ambulatory, and the code 258646 – for the use in hospital settings
- The payment model is, in general, the same for hospital, hospital day case, and ambulatory care (same codes, same tariffs)
- For day case surgeries, hospitals also receive Budget of Financial Means payment for the ward stay, and other maintenance of the hospital. For day case non-surgical procedures, several additional lump-sum payments to cover hospital cost (not covered by INAMI/RIZIV fees, material fees) are available as well
- For a limited number of low-variable procedures, DRG payment (using APR-DRG system) replaces the sum of individual INAMI/RIZIV fees. Also, for a limited number of procedures, reimbursement works on the basis of the direct contacts (conventions) between INAMI/RIZIV and hospitals with tariffs defined in the contract



Hospital Payment Combines Procedure Fees, Device and Medicine Fees, Ward Funding

- Example of calculation of reimbursement tariff for total nephrectomy:
 - Procedure code: 261634 - 261645 “Total nephrectomy” +
 - Material code: 154335 -154346 “All consumable equipment and implantable equipment used during the procedure 261634 - 261645 of the nomenclature, by endoscopic approach” +
 - Hospital admission fee (cost/day) depends on the hospital + Physician honorarium + Other medical products + Co-payments
- 
- Reimbursement tariff fee to the physician of €607 +
 - Fee for the material of €849 +
 - Only 75% of the fee for consumable and implantable equipment for the delivery of the procedure is reimbursed, 25% left is paid by the patient as personal share (“Intervention personnelle”)
 - Budget for the ward stay (paid via Budget of Financial Means)
 - Fees for pharmaceuticals
 - INAMI/RIZIV fees for other examinations and activities (lab tests, imaging etc.)



Device Reimbursement Depends on Inclusion in the List of Reimbursable Devices

- Reimbursement for implantable or invasive non-implantable medical devices is determined by the presence of the device on the [List of reimbursable devices](#)
- The List itself can define a reimbursement category but never mentions brands. However, for some devices (under certain reimbursement categories), reimbursable devices are listed by brands in additional lists, which are called “nominative lists”
- National Institute for Health and Disability Insurance (INAMI/RIZIV) is responsible for managing reimbursement for implantable medical devices
- The Commission of Reimbursement of Implants and Invasive Medical Devices (CRIDMI/CTIIM) at INAMI/RIZIV is responsible for managing and reviewing applications for reimbursement
- Applications can only be made by distributors or manufacturers, registered within Belgian Federal Agency for Medicines and Health Products (AFMPS/FAGG) (more information about the registration process can be found [here](#)), scientific or professional associations, the Minister, the INAMI/RIZIV
- Types of modifications of the List include registration of a new device, modification of existing registration, abolishment of the code
- Reimbursement for a new device (or new indication) comes into force according to the date indicated in the Decree. The exception is for the new device: reimbursement comes into force the 1st day of the month following the publication on the INAMI/RIZIV website
- Reimbursement for a new device on the Nominative list comes into force the 1st day of the month following the publication at the INAMI/RIZIV website
- Applications are made in the electronic format via the IRREQ platform



Device Category Determines Generic Tariff, Brand-Specific Listing, or Contract-Based Funding

- When included into the List of reimbursable devices, implantable and invasive devices will receive one of the designated categories
- Reimbursement category is important in order to determine whether the device has brand-specific or generic reimbursement level, and whether inclusion into the Nominative list is required or not

Category of medical devices	Explanation
Category A	Implants and invasive medical devices, reimbursed on the basis of individual price (tariff determined individually for each brand name) when registered on the nominative list
Category B	Implants and invasive medical devices, which are not reimbursed with a generic tariff (the same tariff irrespective of the brand name) and no registration on the nominative list is required
Category C	Implants and invasive medical devices, which are not reimbursed with a generic tariff, but reimbursed when registered on the nominative list
Category D	Implants and invasive medical devices, reimbursed with a generic tariff, without registration on the nominative list
Category E	Implants and invasive medical devices, reimbursed with a generic tariff, but reimbursed when registered on the nominative list
Category F	Implants and invasive medical devices, reimbursed on the basis of selling price, VAT included
Category G	Implants and invasive medical devices, reimbursed through an ACL (Restricted Clinical Application) – coverage with evidence development program
Category H	Implants and invasive medical devices, reimbursed under a contract with the INAMI/RIZIV

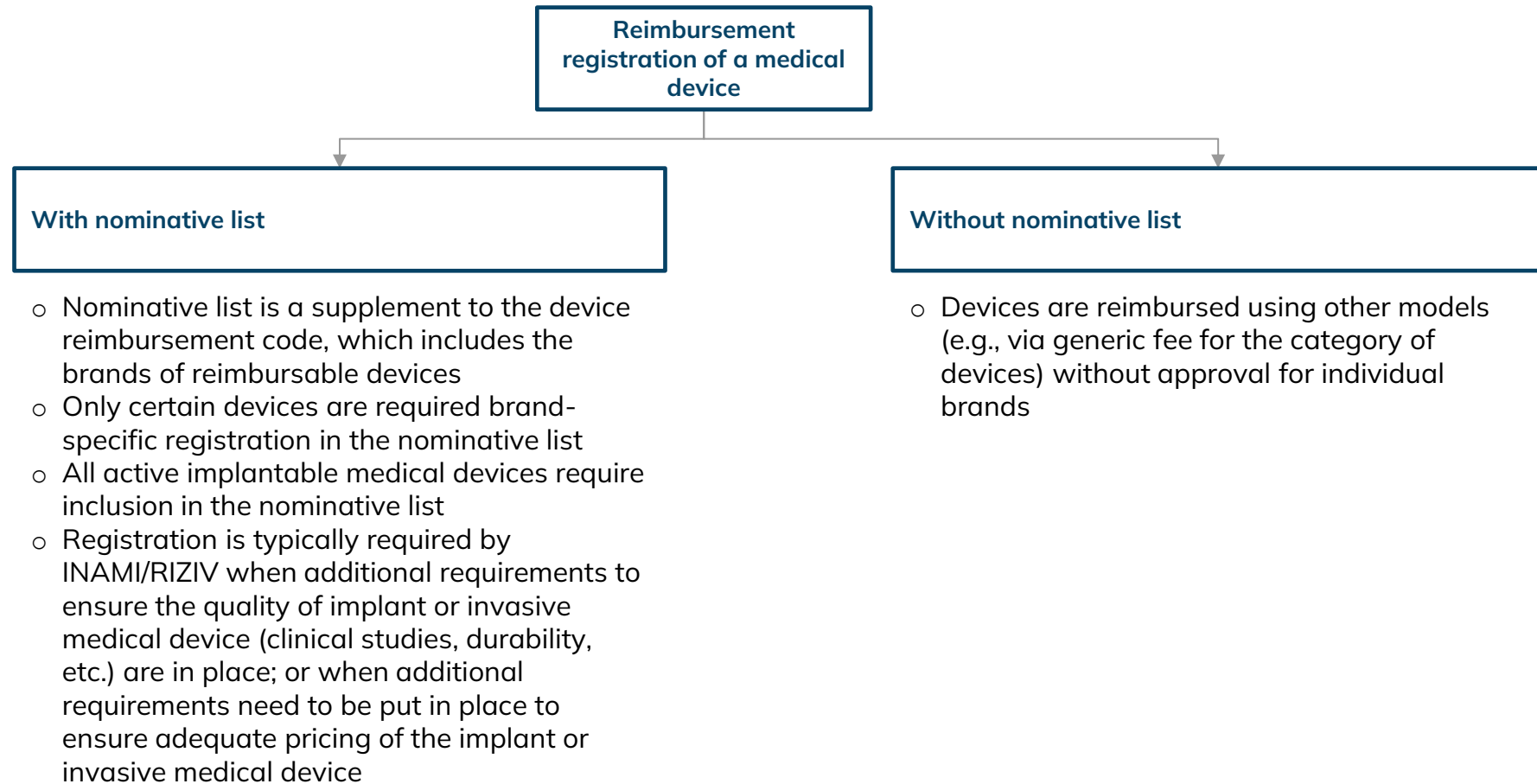
Chapters of the List of reimbursable devices chapters

- A: Ophthalmology
- B: Neurosurgery
- C: ENT
- D: Urology and nephrology
- E: Abdominal and digestive surgery
- F: Thoracic and cardiac surgery
- G: Vascular surgery
- H: Gynaecology
- I: Pulmonology and respiratory system
- J: Plastic and reconstructive surgery
- K: General surgery
- L: Orthopaedics and traumatology
- M: Other

Group I are implants or invasive medical devices for long-term use, while Group II are invasive medical devices other than for long-term use. Typically, the categories are named I.A, I.B, II.C, II.D, or similar to distinguish between implants and invasive devices. Orthopedic devices mostly belong to categories C and D, rarely to other categories (B, E, F)



Nominative Lists Create Brand-Specific Access Only for Selected Device Categories





Nominative Lists Are Relevant Only for Selected Medical Devices

301	Lentilles toriques
302	Pompes implantables à débit réglable
303	Pompes implantables à débit constant
304	Accessoires pour pompes
305	Neurostimulateurs douleur
306	Neurostimulateurs rechargeable douleur
307	Electrodes et accessoires neurostimulateurs douleur
308	Neurostimulateurs en cas de maladie Parkinson ou de tremblements essentiels
309	Tissus de dure-mère d'origine animale
310	Valves d'hydrocéphalie
311	Implants cochléaires
312	Implants cochléaires contralatéraux
313	Implants de l'oreille moyenne
314	Sphincters urinaire artificiel
315	Stimulateurs vésical implantable
316	Neurostimulateurs des voies urinaires
317	Sphincters anal artificiel
318	Stimulateurs et électrodes pour graciloplastie dynamique
319	Stimulateurs et électrodes pour stimulation du nerf sacré
320	Filets en chirurgie abdominale
321	Filets en chirurgie abdominale – forfait
323	Stimulateurs de resynchronisation cardiaque
324	Tuteurs coronaires
325	Valves cardiaques
326	Cathéters de thermodilution
327	Endoprothèses
328	Ischemie
329	Colles
330	Produits hémostatiques
331	Anti-adhésifs
332	Prothèses de disque

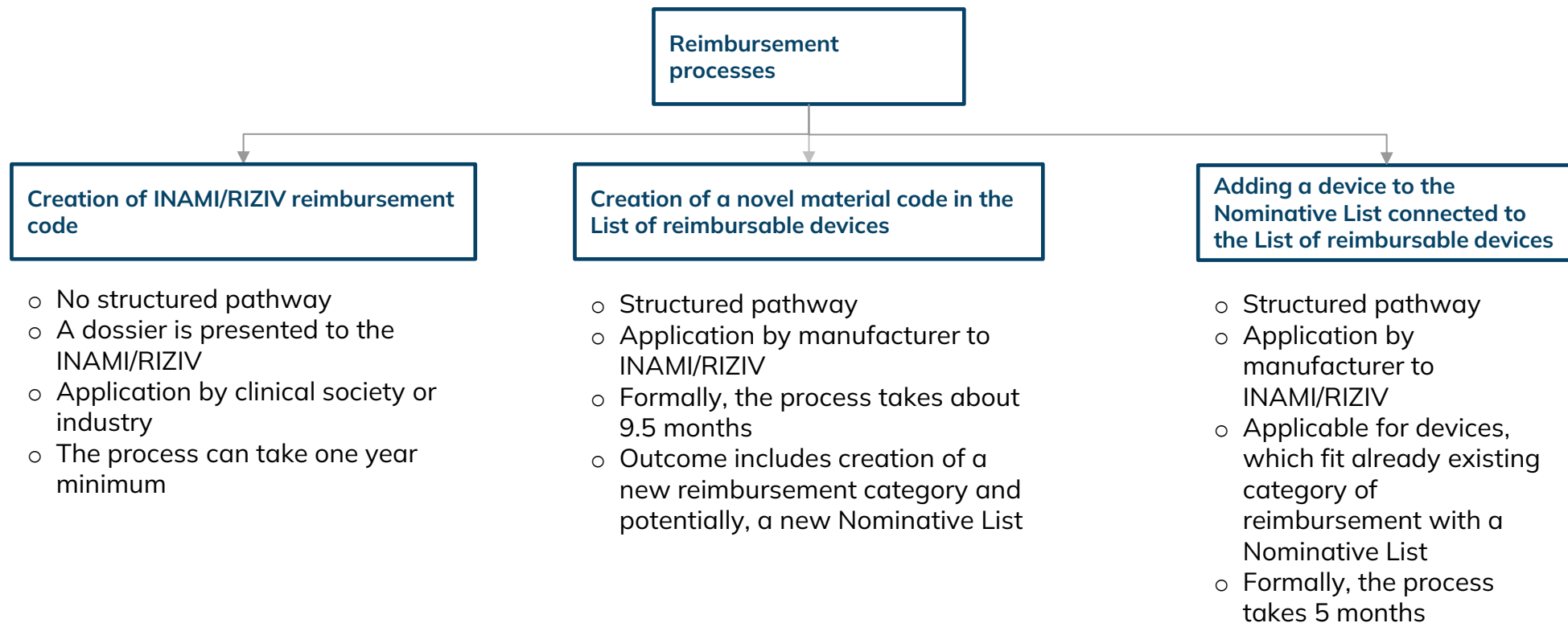
334	Implants de la colonne vertébrale – forfait
335	Implants pour la stabilisation dynamique
336	Prothèses d'épaule
337	Prothèses d'extrémités
340	Prothèses de genou
341	Prothèses de cheville
342	Clous
343	Plaques d'ostéosynthèse
344	Implants de l'arthroscopie
345	Fixateurs externs
346	Substituts osseux ostéoconducteur
347	Stimulateur du nerf vague
348	Neurostimulateurs DBS Epilepsie, Electrodes et accessoires
349	Stimulateurs cardiaques
350	Implants de l'oreille moyenne – processeur vocal
351	Filets pour prolapses
352	Implants pour rétablissement percutané des feuillets des valves mitrales
353	Prothèses de hanche forfait
354	Moniteur cardiaque

356	TAVI
357	TOC
358	Stent valvulaire pulmonaire
359	Dystonie
360	DES
361	Drug Eluting Ballon
362	Fermeture percutanée de l'auricule gauche
363	Prothèses externe
364	Filets vaginaux
365	Matériel Foam
366	Tiges magnétiques allongeables
367	Clou télescopique
368	Cœur artificiel
369	Prothèses de hanche
370	Lames non-hélicoidales pour DHS
371	Prothèses de la parole en cas de fuites prématurées

Belgium Has Three Main Reimbursement Change Routes With Different Evidence and Process Burdens



- There are two primary reimbursement sources in Belgium: INAMI/RIZIV Nomenclature (which includes the list of reimbursed procedures and IVD tests) and the List of reimbursable devices (which includes reimbursed material codes and Nominative lists – the lists of reimbursed brand names)
- The Belgian INAMI/RIZIV Nomenclature defines both inpatient and outpatient procedures
- There are three principally different types of reimbursement processes in Belgium:



Belgium Uses DRGs Narrowly for Low-Variable Care Rather Than as the Dominant Payment Model



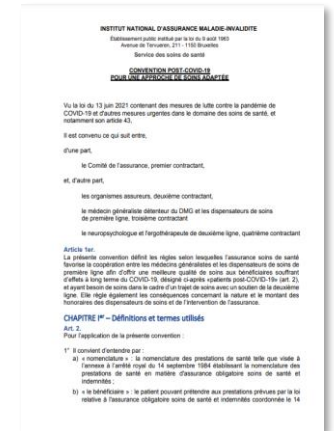
- Historically, the fee-for-service model was the only one for coverage of services. Under this model, the total reimbursement is composed of fees for individual procedures and another payment for the ward stay. The procedure needs to be specifically coded to obtain reimbursement. Materials also require a specific reimbursement
- Since 2019, Belgian authorities introduced DRG reimbursement for a number of low-variable care procedures, such as tonsillectomy, laparoscopic cholecystectomy, prostatectomy, coronarography
- Allocation to DRGs is still driven by INAMI/RIZIV codes (each DRG has a number of INAMI/RIZIV codes that lead to this DRG), and DRG tariff (unlike the standard DRG system, where DRG tariff covers the entire stay) covers only fees to physicians (instead of the sum of INAMI/RIZIV physician fee tariffs)
- As of January 2023, there are 61 DRG groups (using the APR-DRG system) available for reimbursement instead of individual INAMI/RIZIV fees. Their tariffs can be found [here](#)

numéro groupe de patients/ nummer patiëntengroep	APRDRG	type*	Pseudo-codes Ambu	Pseudo-codes Hospi	montant global / globaal bedrag	groupe ticket modérateur / remgeldgroep	bénéficiaire / rechthebbende	
							ticket modérateur/ remgeld	montant oa / vergoeding verzekeringsinstelling
001	120_121	H12		798022	3 962.52	9	74.00	3 888.52
002	163	H12		798044	6 891.97	6	48.00	6 843.97
003	166	H12		798066	6 937.12	6	48.00	6 889.12
004	171	H12		798081	731.36	4	34.00	697.36
005	171	H12		798103	926.14	4	34.00	892.14

Hospital Conventions Allow Reimbursement for Complex or Piloted Procedures or Technologies Outside Regular Nomenclature Mechanisms



- Certain types of care in Belgium are not reimbursed via INAMI/RIZIV Nomenclature and List of implantable and invasive medical devices, but via specific agreements (called Conventions) between healthcare providers and INAMI/RIZIV
- This framework is more flexible than the Nomenclature and allows the INAMI/RIZIV to pay for a range of health care services, for example, multidisciplinary follow-up in a specialized center for certain chronic diseases (rehabilitation Conventions), complex treatment by specialized centers, or piloting novel services
- The payment mechanism and conditions are defined in each Convention
 - Typically, a Convention sets lump-sum payments for certain services (procedures/technologies) via so-called pseudo-nomenclature codes
 - Such pseudo-nomenclature codes are not included in regular Nomenclature articles
 - Tariffs for pseudo-nomenclature codes are set in the initial Convention, but then regularly revised by INAMI/RIZIV in the so-called Circulars
- At least several dozen Conventions were established for reimbursement of different types of care. There is no specific webpage or document that lists all the Conventions. Instead, information is presented at multiple INAMI/RIZIV webpages in an unstructured way
- Some examples of Conventions are provided below:
 - Diabetes: using advanced or expensive technologies in a specialized center
 - Complex pancreatic surgery in the specialized center
 - Next Generation Sequencing (NGS) in oncology or hemato-oncology
 - Remote monitoring and therapeutic guidance in chronic heart failure (reimbursement for health apps)





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