


REIMBURSEMENT OF IMPLANTS

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A focus on reimbursement of orthopaedic implants in Belgium


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Overview

- Legal Framework
- Reimbursement procedure
- News
- Spine
- Orthopride
- Other current projects


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Legal Framework

- 25 JUNI 2014. — Koninklijk besluit tot vaststelling van de procedures, termijnen en voorwaarden inzake de tegemoetkoming van de verplichte verzekering voor geneeskundige verzorging en uitkeringen **in de kosten van implantaten en invasieve medische hulpmiddelen**
- 25 JUNI 2014. — Arrêté royal fixant les procédures, délais et conditions en matière d'intervention de l'assurance obligatoire soins de santé et indemnités dans **le coût des implants et des dispositifs médicaux invasifs**


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Procedure: notification

- Registration of all implantable devices on the Belgian market
- Distributor registers through an online application
- Notification is required for a reimbursement
- If not notified, not billable to the patient
- Exceptions:
 - Tooth implants
 - Custom-made implants
 - Device for clinical research
 - Stitching and ligation
- Currently managed by RIZIV/INAMI
 - To be transferred to FAGG / AFMPS


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Procedure: the List

- **ENG: « The List »: the list of reimbursement codes for implants and invasive medical devices**
 - NL: "de lijst": de lijst van verstrekkingen van vergoedbare implantaten en invasieve medische hulpmiddelen
 - FR: "la liste": la liste des prestations des implants et des dispositifs médicaux invasifs remboursables
- Reimbursement codes available on our website:
 - On-line application "sIMPL"
 - Dutch: <http://ondpanon.riziv.fgov.be/IRREQPublic/nl/>
 - French: <http://ondpanon.riziv.fgov.be/IRREQPublic/fr/>

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Procedure: the List



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Procedure: the List

Verzekeringnummer Ziekteblij 16229 - 16228 Winkel 2018

Omschrijving
 Beschrijving van de wettelijk geïmputeerde vergoedingscode van het heupbeen op te plaatsen met correct occaust de eventuele ontlasting
 L.2.2.1.1. Fysische prothesen

Nominatieve lijst details
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Vergoedingsvoorwaarden
 06.01 - L.617 - L.69

Details

Categorie	1124	Vergoeding	€ 1.317,34
Vergoedingsbasis	€ 1.317,34	Vergoedingsgrens	€ 131,73
Vergoedingsgrens %	10,00%	Maximumvergoeding	€ 1.185,61
Partiële vergoeding	2	Personlijk aandeel	0,00%
Gezondheidsaanpak	€ 0,00	Gezondheidsaanpak	7
Gezondheidsaanpak	1110216	Medicatiecode systeem 05	8
Register	2 (Zijn naar de registratie)	Info aanpak	Wijziging vergoedingsvoorwaarden
Formuletoelichting	L. Formuletoelichting		

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Procedure: nominative lists

- **What?**
 - List of specific models that are reimbursed
- **When?**
 - All active implants
 - Need for additional guarantees as to quality of the device (clinical studies, warranty, ...)
 - Need for additional guarantees as to a correct / appropriate tariffication of the device

Procedure: nominative lists

Zoeken in nominatieve lijst

Identificatiecode: Naam hulpmiddel: Verzekering:

Gezondheidsaanpak: Kwaliteitsniveau: Verzekeringnummer:

Identificatiecode	Categorie	Verzekering	Verzekeringnummer
10000000179	Orthopedie - 32422 Base Type + 32422 Base Ontlasting	Winkel	061001
16229-16228	32422 Base Type + 32422 Base	Winkel	10.10.00 + 10.10.00
16229-16228	32422 Base Type + 32422 Base	Winkel	10.10.00 + 10.10.00
€ 1.317,34	€ 1.317,34	€ 1.317,34	€ 1.317,34
€ 1.317,34	€ 1.317,34	€ 1.317,34	€ 1.317,34
€ 1.317,34	€ 1.317,34	€ 1.317,34	€ 1.317,34

Procedure: who pays?

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    graph TD
      A[CE-mark?] -- No --> B[Not on the market!]
      A -- Yes --> C[Reimbursement code? & Nominative List?]
      C -- No --> D[Implant?]
      C -- Yes --> E[RIZIV / INAMI <br/> (part hospital or patient)]
      D -- No --> F[Hospital budget *]
      D -- Yes --> G[Notified by distributor?]
      G -- No --> F
      G -- Yes* --> H[patient]
      H -.-> I[Distributor can demand reimbursement code]
  
```

* See Art.102 of Coordinated Act on Hospitals and Other Care Facilities (Décret/Réglemeent wet op de Ziekenhuizen en andere verzorgingsinstellingen / Loi coordonnée sur les hôpitaux et autres établissements de soins) for exceptions

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Creating a reimbursement for an implant or invasive medical device

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    graph TD
      A[The distributor Submits a request] --> B[The Commission Evaluates* & proposes reimbursement conditions]
      B --> C[The Minister of Public Health Decides]
      D[The Minister or the Commission Submits a request] --> B
      E[Administered by RIZIV/INAMI <br/> (prepare documents; contact experts,...)] --> B
  
```

* evaluation based on evidence (literature), therapeutic (added) value, health-economical value, social needs, contacts with experts, budgetary impact

Who submits?

- **Distributor:** mainly related to new devices
- **Commission:** mainly modifying existing codes or reimbursement conditions
- **Minister:** mainly budgetary aspects
- + in the future: **Scientific associations**
 - Non-profit professional organization of caregivers (with in their objectives the promotion of scientific information and quality of care), will be allowed to submit reimbursement dossiers to RIZIV/INAMI.
 - In consultation with the distributor(s)
 - For example: modification of reimbursement category, extension of target population, change in indications, new technique,...


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News

- Saving measures 2018
 - 0.95 % decrease of implants reimbursement, except implantable cardiac defibrillators, hip and spinal cord implants. Effective 1st of April 2018.
 - Hip implants: revision of all implants acts (to be implemented later this year, probably 1st of June). Few nominative lists preserved/created for acts with added value.


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Spine Units

- For a uniform approach to spinal cord pathology by introducing a standard diagnostic triage and a multidisciplinary organization mode
- Mandatory multidisciplinary consultation for critical spine procedures and other complex treatments (including neuromodulation)
- Mandatory data registration for some interventions (e.g. Spine Tango)
- A new nomenclature for spinal surgery


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Spine Tango Registry

- Spinal conservative therapy and surgery registry
- is being created with HealthData, to be launched Q4 2018
- Belgian Spine Tango data will be pooled with the Spine Tango European Registry.
- Under the supervision of SSBc / Eurospine
- Goals:
 - Monitor outcome. Data analysis, Overall quality, Comparative effectiveness
 - Objective view with great amount of quality data
 - Improve practice (local or general), establish guidelines


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Orthopride

- ORTHOpedic Prosthesis Identification Data
- Belgian Hip and Knee Arthroplasty Registry
- Main goals:
 - collect data to study the quality of care
 - to know which prosthesis has been implanted in one patient coming to a consultation (possibly order material accordingly)
 - to measure lifespan of prosthesis


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Orthopride

- Created in 2008. Compulsory data completion to get reimbursement started in July 2014.
- BVOT/SORBCOT evaluates recorded data and reports annually to the CRIDMI/CTIIMH
- Will be transferred to HealthData in 2019. Opportunity to improve the registry. System-to-System in some hospitals will need adjustments
- Possible addition of other joints in the future (ankle, shoulder)


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What's coming next...


- Custom-made / 3D printing devices challenge: currently not notified, not CE-marked, change in legislation (Medical Device Regulation Vs Medical Device Directive), KCE report Jan 2018.
 - Currently no consensus, different approaches for different custom-made devices
 - Effort will be made to align reimbursement with new regulations and new evidences

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 **What's coming next...**


- TMJ Temporo mandibular joint prothesis: currently no reimbursement via regular procedure, but reimbursement possible for custom-made devices through a custom-made implant code with agreement of Collège des médecins directeurs/College van artsen-directeurs.
 - The Commission is working on a proposal to streamline as regular procedure (target Q42018)
 - New reimbursement codes foreseen next year


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 **To contact us**

- General questions:
 - implant@riziv.fgov.be / implant@inami.fgov.be
- Management of the "nominative list":
 - dimplist@riziv.fgov.be / dimplist@inami.fgov.be
- Management of the "List":
 - evalimp@riziv.fgov.be / evalimp@inami.fgov.be

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 **Thank you for your attention.**



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