



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 JUIN 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

NIHDI **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

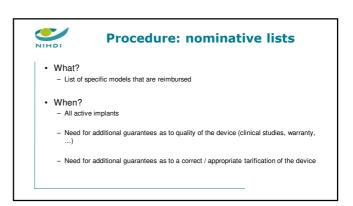


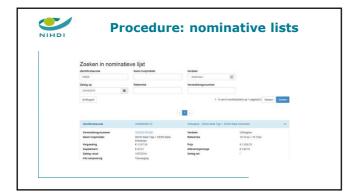
Procedure: the List

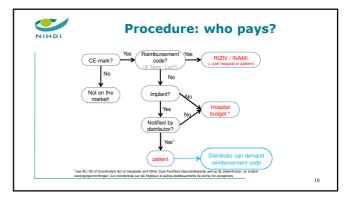
- ENG: « The List »: the list of reimbursement codes for implants and invasive medical devices
- · Reimbursement codes available on our website:
 - On-line application "sIMPL"
 - Dutch: http://ondpanon.riziv.fgov.be/IRREQPublic/nl/
 - French: http://ondpanon.riziv.fgov.be/IRREQPublic/fr/

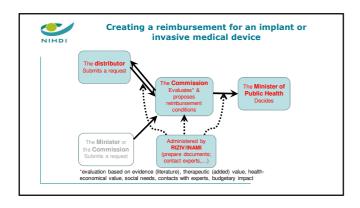
Procedure: the List

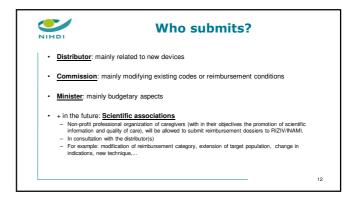














News

- · Saving measures 2018
 - 0.95 % decrease of implants reimbursement, except implantable cardiac defibrillators, hip and spinal cord implants. Effective 1st of April
 - 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.



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
- · A new nomenclature for spinal surgery



Spine Tango Registry

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

NIHDI

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



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)

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 concensus, different approaches for different custom-
 - →Effort will be made to align reimbursment with new regulations and new evidences

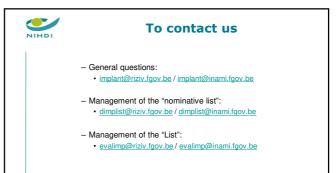


What's coming next...

- TMJ Temporo mandibular joint prothesis: currently no reimbursment via reimporo intarioliouar joint protnesis: currently no reimbursment via regular procedure, but reimbursment 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





4