

beMedTech - Sections 2019



ExeCo Implants

Section Overview 2019



Implants - ANGIO-PERI :

IMPROVE

Alle perifere stents, abdominale en thoracale vasculaire (endo)protheses, epidurale en intratecale implantpoorten en alle materiaal specifiek voor de vaatheelkunde.
Tous les tuteurs périphériques, (endo)prothèses vasculaires, chambres implantables épidurales ou intratécales et tout le matériel spécifique pour la chirurgie vasculaire.

	Description
General Objective	Improving collaboration with scientific organisations (vasc. Surg. & radiol.)
Funding Objective	Higher reimbursement for peripheral embolization Higher reimbursement for venous procedures
Regulatory Objective	
Market Intelligence & Data Objective and activities	Contact MTEU for Statistics
Specific Goal(s) 2018-19 ?	MEAT Tender E17 hospital network
Internal financial resources Needed in 2018-19 ?	To be evaluate if needed for funding objectives
Owner	Koen Bruylant

Implants - CIC :

CONSOLIDATE

Chirurgische instrumentatie: Alle chirurgische instrumenten en toebehoren.
Instrumentation chirurgicale: *Tous les instruments chirurgicaux et accessoires.*

	Description
General Objective	Inform members correctly about (future) legislation and regulatory issues for MD in general and for surgical instruments more specific.
Funding Objective	
Regulatory Objective	
Market Intelligence & Data Objective and activities	
Specific Goal(s) 2018-19 ?	
Internal financial resources Needed in 2018-19 ?	/
Owner	Wim Vandenberghe

Implants - COH :

CONSOLIDATE

Oogheelkunde: Visco-elastische stoffen voor oogheelkunde, irrigatievloeistoffen (met CE), intra-oculaire lenzen, synthetische orbitavloervervanging, glaucoomkleppen, enz.

Chirurgie oculaire: Tissus viscoélastiques pour chirurgie oculaire, liquides d'irrigation (avec CE), lentilles intraoculaires, remplacement synthétique de la surface orbitale, valves en cas de glaucome etc.

	Description
General Objective	Logistic synergy with Contactology Solve issue with distribution Extra Muros (allowed to delivered to HCP) by prescription needed with “addendum 14” (former Y-Form)
Funding Objective	Get reimbursement for 3-D diagnostic imaging
Regulatory Objective	Distribution implants extra-muros Follow up on Traceability register, avoid additional burden, once-only
Market Intelligence & Data Objective and activities	NIHDI data unreliable. Objective to find source of problem and solve it
Specific Goal(s) 2018-19 ?	Push new distribution framework short term (EU MDR). If not possible consider writing execution decree and work with FAGG. Royal Decree has been published, but Execution Decree hasn't.
Internal financial resources Needed in 2018-19 ?	3-4 meetings/year Legal support needed to follow up (and write if necessary) on general framework distribution channels
Owner	Koen Bruylant

Implants - CORO :

CONSOLIDATE

Coronair : alle invasief materiaal, zoals drug eluting stents, ballonnen,,voor interventionele cardiologie.

Coronaire: tout matériel invasif, tel que les drug eluting stents, ballons,...., pour la cardiologie interventionnelle.

	Description
General Objective	Improving relation with BWGIC
Funding Objective	Monitor changes in reimbursement. (project Prof. Taeymans)
Regulatory Objective	
Market Intelligence & Data Objective and activities	Copy of Qermid long term data presentation
Specific Goal(s) 2018-19 ?	Could become 'Change' depending on changes in point 2.
Internal financial resources Needed in 2018-19 ?	
Owner	Koen Bruylant

Implants - CRM :

IMPROVE

Cardiac Rhythm Management

Pacemakers en implanteerbare hartdefibrillatoren en bijhorende elektroden.

Stimulateurs cardiaques et défibrillateurs implantables et électrodes.

	Description
General Objective	Get funding for telemonitoring Enhance collaboration with BeHRA/young cardiologists
Funding Objective	Pacemaker exchange in day-clinic Telemonitoring New technologies (cf. leadless PM)
Regulatory Objective	
Market Intelligence & Data Objective and activities	Date PM/ICD OK Start with collection statistics heart monitor
Specific Goal(s) 2018-19 ?	Redefine strategy for telemonitoring + Project KCE
Internal financial resources Needed in 2018-19 ?	
Owner	Koen Bruylant

Implants - CT :

IMPROVE

Cardio-Thorax:

Implantaten en toebehoren gebruikt in cardiale en thoracale heelkunde, zoals hartkleppen en annuloplastieringen, cabg, chirurgische ablatiesystemen, systemen voor myocardstabilisatie, cardiotoemiesets (materiaal voor extracorporele circulatie), enz.

Implants et accessoires utilisés en chirurgie cardiaque et thoracique, tels que valves cardiaques, anneaux d'angioplastie, cabg, systèmes d'ablation chirurgicale, systèmes pour stabilisation du myocarde, sets de cardiologie (matériel pour circulation extracorporelle) etc.

	Description
General Objective	Facilitate reimbursement new technologies
Funding Objective	Most new reimbursement in this section accepted: mitra/tavi/laa, lvad (actually only bridge to transplant and bridge to decision ongoing).
Regulatory Objective)	Follow up on traceability register, avoid additional burden, once-only
Market Intelligence & Data Objective and activities	Own statistics: ok
Specific Goal(s) 2018-19 ?	Lvad destination therapy: get reimbursement for indication extension. File is submitted Section horizon scanning: what's coming?
Internal financial resources Needed in 2018-19 ?	Valves = 1/year Other group meet only with specific action items
Owner	Koen Bruylant

Implants - DID :

IMPROVE

Dentale implantaten
Implants dentaires

	Description
General Objective	Act and communicate as a clustered and united group of professional and ethical compliant dental implant industry towards other stakeholders (users - scientific organisations - government) Discuss regulatory issues and create a level playing
Funding Objective	Reimbursement is controlled by users (in NIHDI/INAMI) No change wanted
Regulatory Objective	Defend direct delivery to the users as the most safe, reliable and qualitative solution FAGG should make it mandatory for users (Private & Hospitals) only to work with officially “notified” distributors
Market Intelligence & Data Objective and activities	Strengthen current data analysis system : timely follow-up
Specific Goal(s) 2018-19 ?	Sales Data must be entered no longer than 1 month after Q
Internal financial resources Needed in 2018-19 ?	-
Owner	Wim Vandenberghe

Implants - ENDO :

CONSOLIDATE

Endoscopie & viscerosynthese:

Alle invasieve MH die niet sorteren onder één van de andere omschrijvingen, zoals bvb voor uro-, nefro- en gastrologische toepassingen.

Tous les DM invasifs qui ne sont pas classés sous un des autres descriptifs, comme p.ex. pour les interventions en urologie, néphrologie ou gastrologie.

	Description
General Objective	New name and new recruitment
Funding Objective	
Regulatory Objective	
Market Intelligence & Data Objective and activities	
Specific Goal(s) 2018-19 ?	Brainstorming on new activities
Internal financial resources Needed in 2018-19 ?	No common activities actually - case by case action Cfr vaginal mesh 2016
Owner	Koen Bruylant

Implants - GITA (Ortho & Trauma):

CHANGE

Implantaten voor gewrichtsreconstructie voor de ledematen alsook alle implantaten voor botreconstructie na trauma (behalve van de wervelkolom) en alle implantaten voor de cranio-maxillo-faciale heelkunde en arthro.

Implants pour reconstruction articulaire des membres ainsi que tous les implants pour la reconstruction osseuse après un traumatisme. (excepté la colonne vertébrale) et tous les implants pour la chirurgie cranio-maxillo-faciale et arthro.

	Description
General Objective	Gain insights and share all relevant information for the orthopaedic implants business Create a stronger involvement with authorities & other stakeholders Monitor and try to influence the evolutions in healthcare financing with special attention for Low Variable Care & move towards forfeits
Funding Objective	Keep or make the reimbursement system value-based Keep or re-install differentiated patient co-payment (low for basic care - higher for sophisticated and innovative technologies) Improve the decision-making process within the CTIIMH-CRIDMI (conflicts of interest - budget transferability - etc.)
Regulatory Objective	Create level playing field within bMT based on art.10 Be involved with FAGG-AFMPS in implementing the MDR
Market Intelligence & Data Objective and activities	Make Big Data available to all : Try to gain access to data from other stakeholders (Registries - Claim Data from Sickness Funds - Anonymised Patient Data - Anonymised Hospitals Records ...)
Specific Goal(s) 2018-19 ?	Suppress pricing procedure at F.P.S Economy where it doesn't bring any value Try to establish a possibility for reimbursement for implant-related technologies : PSI-MIC-3Dsolutions
Internal financial resources Needed in 2018-19 ?	-
Owner	Wim Vandenberghe

Implants - IERI :

IMPROVE

Esthetische en reconstructie implantaten: onderhuidse borstimplantaten voor esthetische en reconstructieve chirurgie, weefselexpanders, inspuitbare implantaten voor rimpelbehandeling, enz...
Implants esthétiques et réconstructifs: implants mammaires sous-cutanés pour la chirurgie esthétique et reconstructive, épanseurs tissulaires, implants injectables, traitement des rides, etc...

	Description
General Objective	Move towards direct distribution to the users, at least for “fillers”. Monitor and take part in discussions on “publicity” issues.
Funding Objective	Not a priority but reimbursement for reconstruction has decreased and should not be cut “again”
Regulatory Objective	Changes in “distribution chain” (cf. general objective) + FAGG should make it mandatory <u>for users</u> (Drs & Clinics) only to work with “notified” distributors
Market Intelligence & Data Objective and activities	Now : Only NIHDI data on reconstruction Future : Start in 2019 with sales stats on breast implants , expanders & ADM’s
Specific Goal(s) 2018-19 ?	Start Data collection in 2019
Internal financial resources Needed in 2018-19 ?	-
Owner	Wim Vandenberghe

Implants - NKO - ORL :

IMPROVE

Neus-Keel-Oor: cochleaire implantaten, protheses bij doofheid, botverankerde hoorapparaten, spraakprothesen en toebehoren, enz.

Oto-Rhino-Laryngologie: implants cochléaires, prothèses en cas de surdit , appareils auditifs ancr s au niveau osseux, prothèses de la parole et accessoires, etc.

	Description
General Objective	Monitor and actively be involved in improved reimbursement for implantable hearing solutions
Funding Objective	<ul style="list-style-type: none">- Push approval for extended CI Criteria- Push approval for improved reimbursement for Bone Conduction Devices (surgical/non-surgical) including a new reimbursement for children < 7y in collaboration with "HAA section" within beMedTech
Regulatory Objective	None
Market Intelligence & Data Objective and activities	Initiate Standard of Care: <ul style="list-style-type: none">- insights in treatment pathway for implantable hearing solutions (number of visits, fitting, rehabilitation)- Insights in reimbursement for care and service activities for Implantable hearing solutions
Specific Goal(s) 2018-19 ?	<ul style="list-style-type: none">- Align stakeholders to receive approval for new CI criteria- Alignment with WHO workgroup in Belgium- Quality standards for implantable hearing solution treatments
Internal financial resources Needed in 2018-19 ?	No specific financial resources needed. Minimal 2-3 meetings needed / year
Owner	Wim Vandenberghe

Implants - NEURO :

IMPROVE

Implanteerbare neurostimulatoren en intratecale toedieningspompen, aneurysmaclips, synthetische dura mater substituten, externe ventrikeldrainage , hydrocefaluskleppen en alle toebehoren.
Neurostimulateurs implantables, réservoirs avec cathéters implantables intra-thécaux, clips d'anévrisme, substituts synthétiques de dure-mère, drainage ventriculaire externe , valves hydro céphaliques et tous les accessoires.

	Description
General Objective	Create awareness about added value of our therapies (existing & new)
Funding Objective	Tabling reimbursement files for new stimulation in common approach, followed by individual company files after expert advise which data are required (optimizing Bewell innovations app) Facilitate market access also for 'non-pain therapy related' neurologic procedures
Regulatory Objective	
Market Intelligence & Data Objective and activities	Investigate possibility to make BELGIAN statistics by beMedTech (cfr. ICD,PM,..)
Specific Goal(s) 2018-19 ? (Inspanning en/of Resultaat)	<ul style="list-style-type: none">- Start initiative reimbursement CRPS- Evaluate collaboration with patient group(s)
Internal financial resources Needed in 2018-19 ?	Eventually if initiatives specific goals become concrete and update of existing figures is required
Owner	Koen Bruylant

Implants - SPINE :

IMPROVE

Alle implantaten en toebehoren gebruikt bij rug- en nekchirurgie: zoals osteosynthesemateriaal, dynamische stabilisatie, kypho- en vertebroplastie, discusprothesen, enz.

Tous les implants et accessoires utilisés en cas de chirurgie du dos ou du cou tels que le matériel d'ostéosynthèse, la stabilisation dynamique, la kypho- et la vertébroplastie, les prothèses discales

	Description
General Objective	To be informed on trends and intentions of other stakeholders in the field of SPINE (NIHDI,FAGG, HCP's...) and to defend the interests of the members by ensuring acces to innovation and high quality evidence based SPINE-devices
Funding Objective	Optimize funding in line with latest scientific evidence and innovations in order to ensure the best care for patients (e.g. Kypho- & vertebroplasty, TDR , ...)
Regulatory Objective	Avoid local hurdels for market acces. Monitor and ensure correct application of legislation on Ethics. The industry needs to be consulted priorly on new initiatives considered by the regulatory authorities to avoid conflicts with internal procedures.
Market Intelligence & Data Objective and activities	Exchange relevant sales data to document the spine market and its evolution
Specific Goal(s) 2018-19 ?	Start the preparations for the roll-out of the Medical Device Regulation from the EU in 2020. Lobby for the 20% proposed price increase after the reimbursement impact of 1/04/2015. If volume decreased
Internal financial resources Needed in 2018-19 ?	Three meetings per year of the members - regular updates by medtech on contacts & evolutions with other stakeholders in the field of spine
Owner	Wim Vandenberghe

Implants - VISCO :

CONSOLIDATE

Visco-elastische stoffen voor gewrichten.
Produits viscoélastiques pour les articulations

	Description
General Objective	The members want to be correctly informed about (future) legislation and regulatory issues for MD in general and (V.E.-) implants more specific. Direct distribution to end-users should be allowed
Funding Objective	No need to strive for reimbursement (free market)
Regulatory Objective	V.E. direct distribution to end-user (cf general objective)
Market Intelligence & Data Objective and activities	No (to specific - not enough players)
Specific Goal(s) 2018-19 ?	Monitor evolution in “depots”-legislation
Internal financial resources Needed in 2018-19 ?	No
Owner	Wim Vandenberghe