hereco clinical evidence for the real world Prostheses List Reforms

Guide to the proposed structure for Part A

This guide describes the rationale used for the regrouping of the Prostheses List (Part A) undertaken by hereco. It does not represent any work being undertaken by the department to address the issue of mixed benefits. The structures outlined in this guide represent the starting point for the mixed benefits activity.

December 2022

All information in this document is correct as at December 2022 however is subject to change. This document should not be used to inform applications to the Prostheses List until stakeholders are informed by the Department of Health and Aged Care that the document is finalised.

CONTENTS

1 Overview

1.1 Organising Principles

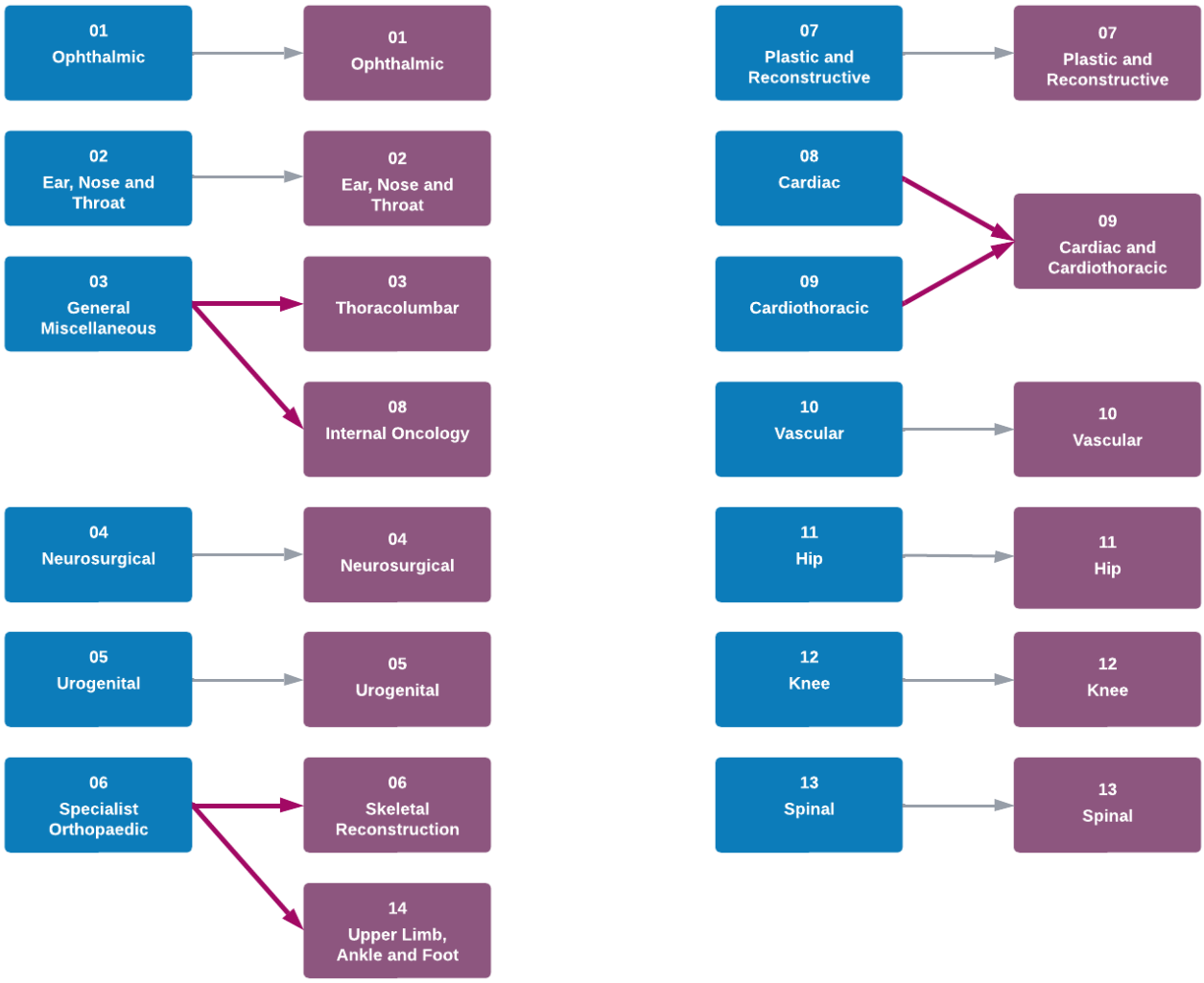
- Hierarchical classification structure
- Consistent approach across product categories
- Patient-centred: groups based on clinical care not product features
- Like-for-like products grouped together
- Individual components of products not listed separately, unless clinically warranted

1.2 Objective

- A reduced number of groupings
- Each item has a single billing code
- Supports the ability for data to be collected at a granular level and easily aggregated and linked for data analysis
- Aligns with the potential use of HTA methods to set PL benefits (i.e., differences in health or economic outcomes underpin differences in PL benefits)
- Is forward-looking and able to accommodate emerging technologies (including hybrid technologies) within existing or new groups
- No unintended clinical consequences (e.g., use of a clinically inappropriate product)
- No unintended economic consequences (e.g., cost-shifting to consumers)
- No reduction in choice for clinicians or consumers
- Clear, mutually exclusive definitions of groups and subgroups to facilitate allocation of new products to an appropriate group
- Alignment with other potential changes to PHI

1.3 Category level organisation

Figure 1 **Current and Proposed Prostheses List Categories: current categories are shown in blue and proposed categories are in maroon, with red arrows showing where categories have been changed**



The proposed reorganisation of the Prostheses List (PL) largely retains the existing category structure however there are some changes at the category level which are shown in Figure 1. Where new categories have been created, they have been numbered with the next available number however categories could be renumbered in a more clinically logical order.

The General Miscellaneous Category of the PL consists of the remainder of devices approved for inclusion by the Clinical Implementation Reference Group (CIRG) in the early stages of the PL Reforms. As General devices are not eligible for PL listing, this category has been renamed and split into two new Categories called Thoracoabdominal, and Internal Oncology. Devices that do not fit into one these two Categories have been regrouped into appropriate existing Categories. For example, nerve repair stents have been regrouped in the Neurosurgical Category.

The Specialist Orthopaedic Category has the most billing codes of any Prostheses List category and additionally has some of the highest benefits on the List, second only to the cardiothoracic category. It is currently split into three Subcategories: Ankle and Foot, Upper Limb, and Skeletal Reconstruction. It has been proposed that the Upper Limb Subcategory and the Ankle and Foot Subcategory are taken out and placed in a new category. It is proposed that Skeletal Reconstruction is elevated to Category level on the PL.

It is proposed to merge the Cardiac and Cardiothoracic categories. This allows devices to be grouped based on clinical purpose rather than clinical specialty; devices with the same clinical purpose to be placed in the same group regardless of whether they are delivered surgically or percutaneously. For example, surgical and percutaneous left atrial appendage devices are no longer split across two categories.

Where possible, sub-category labels have been altered to reflect clinical purpose rather than the characteristics or types of devices.

1.4 Billing codes flagged for rolling up

Consultation Paper Number one on the Purpose, Definitions and Scope of the PL stated that "Accessories, the devices designed and intended by the manufacturer to always be used together with another implantable or surgically invasive device for therapy, to enable that device to be used as the manufacturer intended. Some of these devices (accessories) will no longer be separately funded through the PL, but instead **it is anticipated that their cost will be bundled into the cost of the device** they are intended to be used with or funded under a different funding mechanism. [These issues will further be considered as part of the revision of the current grouping scheme and the associated future consultation]."

On the basis of this, there are a range of billing codes which are proposed to be 'rolled up' in the proposed structure, however these may need to be revisited when benefits are set as the groups have been proposed based on clinical logic but there may be challenges in billing which have not been foreseen.

In general, devices have been rolled up where they are used in the same clinical episode, are part of the same device system and have the same sponsor/manufacturer. This may include components which are only used when required, and in these cases benefit setting is more complex again.

Some groups are proposed for rolling up in part because they are very low-cost components of a device system, the extent to which these are 'removed' vs 'rolled up' also needs consideration with respect to benefits.

1.5 Products of varying size

All products of varying size, whether this is by volume, weight, area or length have been grouped together as a general principle. These may need to be split when benefits are set but it is clinically sensible to group them together. Exceptions to this are due to clinical differences, for example femoral stems.

2 Rationale and structure of the PL Categories

2.1 Ophthalmology Category

Intraocular lenses (IOL) are used in cataract surgery to replace the natural lens. Intraocular lenses can also be used for vision correction as an alternative to laser eye surgery (or wearing glasses or contact lenses). This type of surgery is **not** covered by the Medicare benefits Schedule. IOLs are low-cost, high utilisation items on the PL.

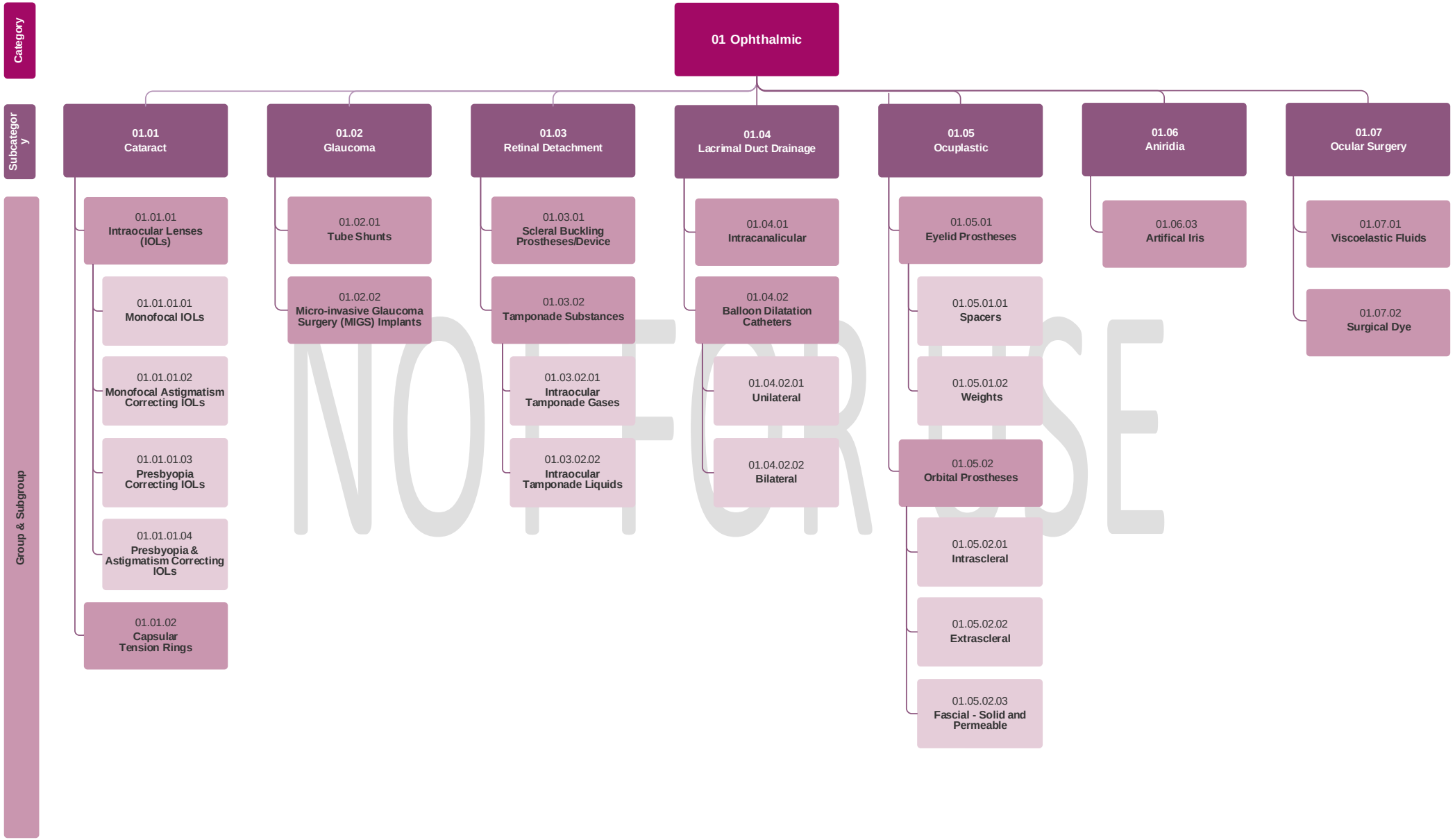
Four subgroups have been created for IOLs based on their clinical role:

- Monofocal
- Monofocal Astigmatism correcting
- Presbyopia correcting, and
- Astigmatism and presbyopia correcting.

Product features have not been used to categorise these devices.

The remainder of the ophthalmic category underwent minor changes.

Figure 2 **Proposed Structure of the Ophthalmology Category**



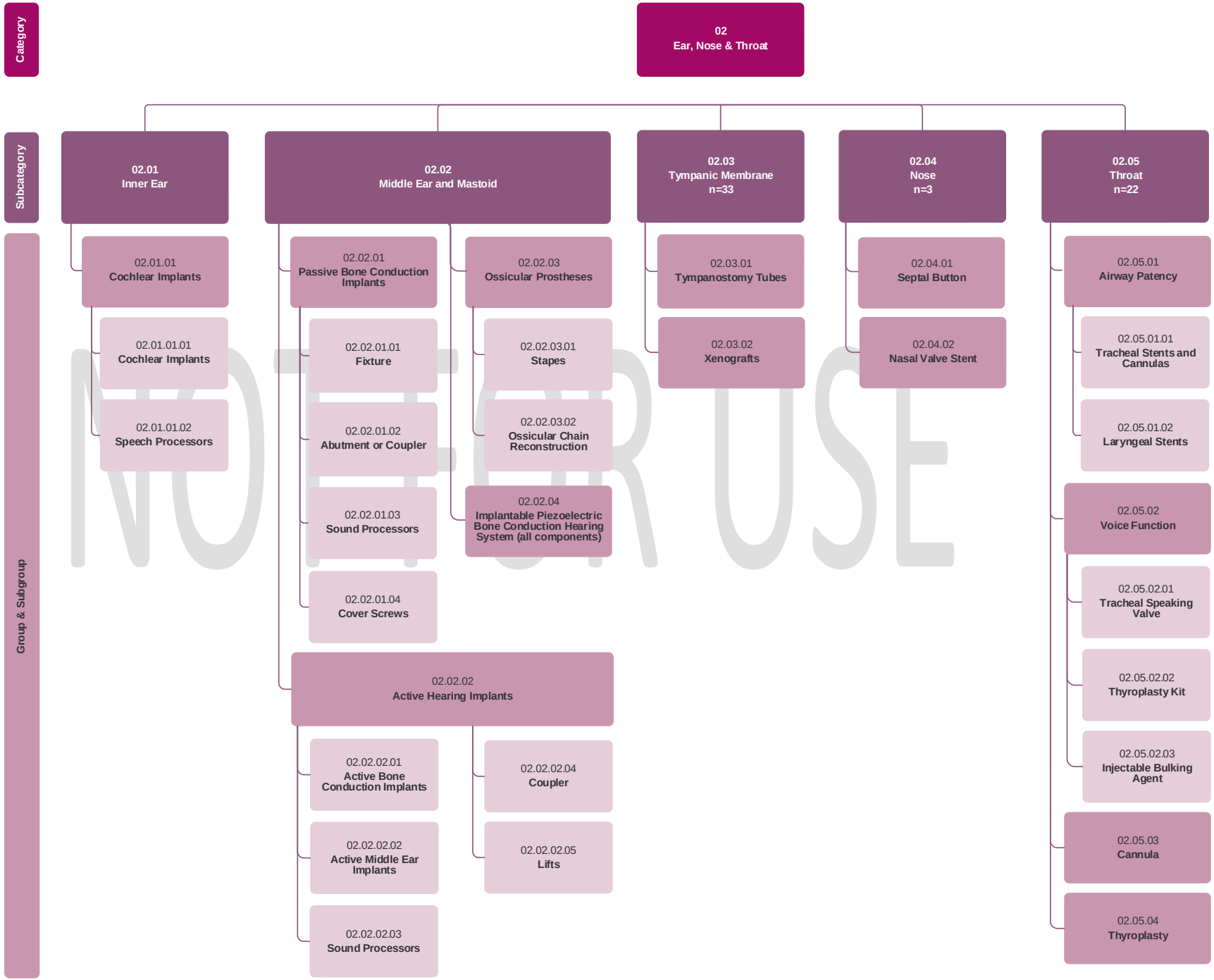
2.2 Ear, Nose and Throat Category

The Ear, Nose and Throat (ENT) Category of the November 2021 Prosthesis List (PL) currently includes three subcategories; Ear, Nose and Throat. The proposed regrouping splits the Ear Subcategory into three new subcategories: Inner Ear, Middle Ear and Mastoid, and Tympanic Membrane, as this frees up lower levels of categorisation for new groupings.

The biggest change in the Ear Subcategory is the separation of passive and active bone conduction devices into separate groups (currently allocated to the osseointegration subgroup). Passive and active bone conduction devices are multicomponent systems, and each component has a separate Billing Code. This allows for claims where only one component is replaced, and this approach is being retained in the proposed restructure. Billing Codes for these components are now allocated to component-specific subgroups. There are five Billing Codes in the Passive Bone Conduction Group that include both an abutment and a fixture component. As the individual components are also listed separately, these additional multi-component Billing Codes are redundant, and have been marked for removal from the PL.

Malleus, partial ossicle replacement and total ossicle replacement devices have been combined into a single Ossicular Chain Reconstruction Subgroup. The Throat Subcategory has been regrouped into Airway Patency and Voice and Laryngeal Patency Groups.

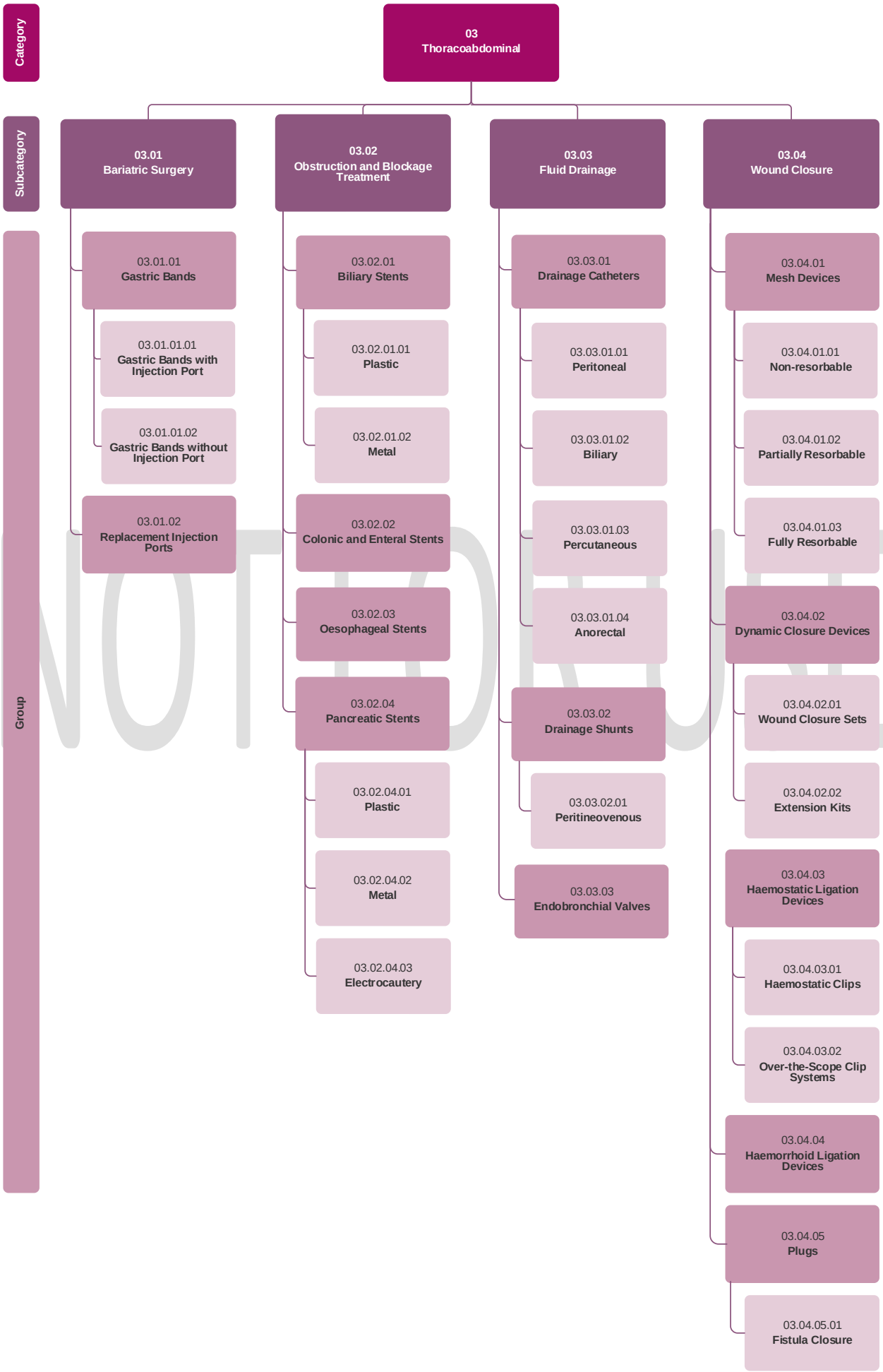
Figure 3 **Proposed Structure for Ear, Nose and Throat Category**


Category
02
Ear, Nose & Throat
Subcategory
Group & Subgroup
02.01
Inner Ear
02.01.01
Cochlear Implants
02.01.01.01
Cochlear Implants
02.01.01.02
Speech Processors
02.02
Middle Ear and Mastoid
02.02.01
Passive Bone Conduction Implants
02.02.01.01
Fixture
02.02.01.02
Abutment or Coupler
02.02.01.03
Sound Processors
02.02.01.04
Cover Screws
02.02.02
Active Hearing Implants
02.02.02.01
Active Bone Conduction Implants
02.02.02.02
Active Middle Ear Implants
02.02.02.03
Sound Processors
02.02.02.04
Coupler
02.02.02.05
Lifts
02.02.03
Ossicular Prostheses
02.02.03.01
Stapes
02.02.03.02
Ossicular Chain Reconstruction
02.02.04
Implantable Piezoelectric Bone Conduction Hearing System (all components)
02.03
Tympanic Membrane
n=33
02.03.01
Tympanostomy Tubes
02.03.02
Xenografts
02.04
Nose
n=3
02.04.01
Septal Button
02.04.02
Nasal Valve Stent
02.05
Throat
n=22
02.05.01
Airway Patency
02.05.01.01
Tracheal Stents and Cannulas
02.05.01.02
Laryngeal Stents
02.05.02
Voice Function
02.05.02.01
Tracheal Speaking Valve
02.05.02.02
Thyroplasty Kit
02.05.02.03
Injectable Bulking Agent
02.05.03
Cannula
02.05.04
Thyroplasty

2.3 Thoracoabdominal Category

The Thoracoabdominal Category is proposed to include gastric bands, luminal stents, drainage catheters and shunts, mesh devices, and dynamic wound closure devices from the current General Miscellaneous Category. The large majority of the devices have retained the same grouping structure as in the current General Miscellaneous Category, except for the mesh devices where a distinction by material has not been retained and they are instead separated by absorbability. A number of ligation devices have been retained on the PL and these have been allocated to the Thoracoabdominal Category. The devices consist of haemostatic clips and haemorrhoid bands

Figure 4 Proposed Structure of Thoracoabdominal Category


Category
03
Thoracoabdominal
Subcategory
03.01
Bariatric Surgery
03.02
Obstruction and Blockage Treatment
03.03
Fluid Drainage
03.04
Wound Closure
Group
03.01.01
Gastric Bands
03.01.01.01
Gastric Bands with Injection Port
03.01.01.02
Gastric Bands without Injection Port
03.01.02
Replacement Injection Ports
03.02.01
Biliary Stents
03.02.01.01
Plastic
03.02.01.02
Metal
03.02.02
Colonic and Enteral Stents
03.02.03
Oesophageal Stents
03.02.04
Pancreatic Stents
03.02.04.01
Plastic
03.02.04.02
Metal
03.02.04.03
Electrocautery
03.03.01
Drainage Catheters
03.03.01.01
Peritoneal
03.03.01.02
Biliary
03.03.01.03
Percutaneous
03.03.01.04
Anorectal
03.03.02
Drainage Shunts
03.03.02.01
Peritineovenous
03.03.03
Endobronchial Valves
03.04.01
Mesh Devices
03.04.01.01
Non-resorbable
03.04.01.02
Partially Resorbable
03.04.01.03
Fully Resorbable
03.04.02
Dynamic Closure Devices
03.04.02.01
Wound Closure Sets
03.04.02.02
Extension Kits
03.04.03
Haemostatic Ligation Devices
03.04.03.01
Haemostatic Clips
03.04.03.02
Over-the-Scope Clip Systems
03.04.04
Haemorrhoid Ligation Devices
03.04.05
Plugs
03.04.05.01
Fistula Closure

2.4 Neurosurgical Category

An organising principle for the reorganisation of the Prostheses List (PL) is that individual components of products are not listed separately unless clinically warranted. The Neurosurgical Category consists of a number of device systems which are currently listed as individual components and where 'rolling up' of some of these components is proposed. These systems are:

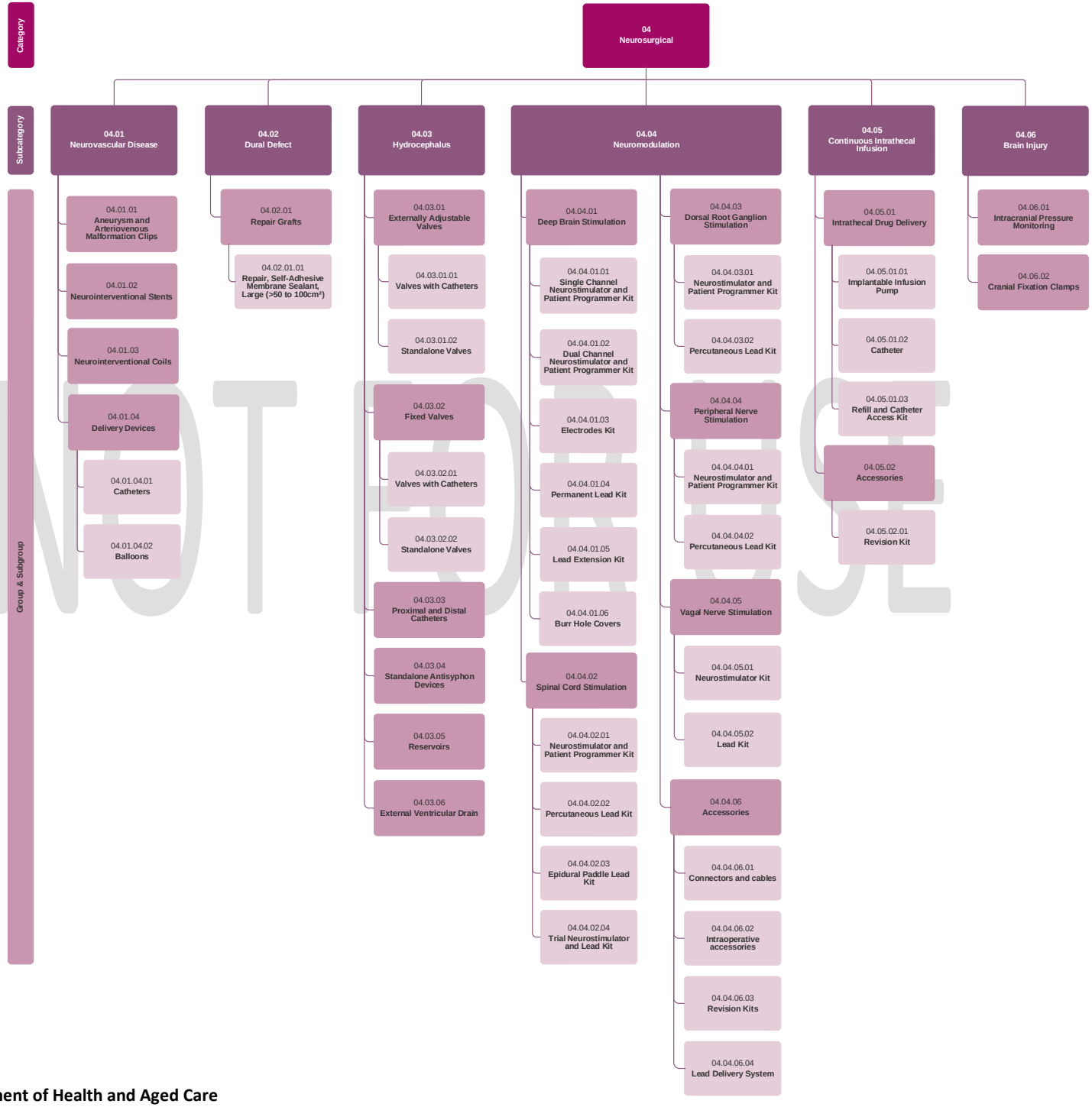
- Deep Brain Stimulation (DBS) systems,
- Spinal Cord Stimulation (SCS) systems,
- Dorsal Root Ganglion (DRG) Stimulation systems,
- Peripheral Nerve Stimulation (PNS) systems,
- Vagal Nerve Stimulation (VNS) systems, and
- continuous intrathecal infusion.

Neurotransmitters and patient programmers are components of neuromodulation systems (DBS, SCS, DRG, PNS, and VNS) that are largely used together within a single episode of care based on available utilisation data. Similarly, the permanent leads from SCS systems are also almost always used with lead extensions when needed within a single episode of care. This, however, is not seen in DBS systems where the lead extension is a necessary component of the system and can either be implanted in the same episode as the permanent lead or in a follow up episode. It is therefore proposed that the various components of these neuromodulation systems be 'rolled-up' based on whether they are used in the same episode of care.

The remainder of the Neurosurgical Category underwent minor changes. Membrane and liquid sealants have been removed consistent with Consultation Paper 1[1]. In contrast to regrouping in previous categories, the Catheters and Balloons from the Delivery Devices Group in the Neurovascular Disease Subcategory has been retained because they are used with coils and stents across various sponsors.

[1] Available at https://consultations.health.gov.au/technology-assessment-access-division/prostheses-list- -purpose-scope-and-definitions/

Figure 5 Proposed Structure of Neurosurgical Category


Category
04
Neurosurgical
Subcategory
04.01
Neurovascular Disease
04.02
Dural Defect
04.03
Hydrocephalus
04.04
Neuromodulation
04.05
Continuous Intrathecal Infusion
04.06
Brain Injury
Group & Subgroup
04.01.01
Aneurysm and Arteriovenous Malformation Clips
04.01.02
Neurointerventional Stents
04.01.03
Neurointerventional Coils
04.01.04
Delivery Devices
04.01.04.01
Catheters
04.01.04.02
Balloons
04.02.01
Repair Grafts
04.02.01.01
Repair, Self-Adhesive Membrane Sealant, Large (>50 to 100cm²)
04.03.01
Externally Adjustable Valves
04.03.01.01
Valves with Catheters
04.03.01.02
Standalone Valves
04.03.02
Fixed Valves
04.03.02.01
Valves with Catheters
04.03.02.02
Standalone Valves
04.03.03
Proximal and Distal Catheters
04.03.04
Standalone Antisyphon Devices
04.03.05
Reservoirs
04.03.06
External Ventricular Drain
04.04.01
Deep Brain Stimulation
04.04.01.01
Single Channel Neurostimulator and Patient Programmer Kit
04.04.01.02
Dual Channel Neurostimulator and Patient Programmer Kit
04.04.01.03
Electrodes Kit
04.04.01.04
Permanent Lead Kit
04.04.01.05
Lead Extension Kit
04.04.01.06
Burr Hole Covers
04.04.02
Spinal Cord Stimulation
04.04.02.01
Neurostimulator and Patient Programmer Kit
04.04.02.02
Percutaneous Lead Kit
04.04.02.03
Epidural Paddle Lead Kit
04.04.02.04
Trial Neurostimulator and Lead Kit
04.04.03
Dorsal Root Ganglion Stimulation
04.04.03.01
Neurostimulator and Patient Programmer Kit
04.04.03.02
Percutaneous Lead Kit
04.04.04
Peripheral Nerve Stimulation
04.04.04.01
Neurostimulator and Patient Programmer Kit
04.04.04.02
Percutaneous Lead Kit
04.04.05
Vagal Nerve Stimulation
04.04.05.01
Neurostimulator Kit
04.04.05.02
Lead Kit
04.04.06
Accessories
04.04.06.01
Connectors and cables
04.04.06.02
Intraoperative accessories
04.04.06.03
Revision Kits
04.04.06.04
Lead Delivery System
04.05.01
Intrathecal Drug Delivery
04.05.01.01
Implantable Infusion Pump
04.05.01.02
Catheter
04.05.01.03
Refill and Catheter Access Kit
04.05.02
Accessories
04.05.02.01
Revision Kit
04.06.01
Intracranial Pressure Monitoring
04.06.02
Cranial Fixation Clamps

2.5 Urogenital Category

The urogenital category consists of a number of device systems which are currently listed as individual components. The systems are:

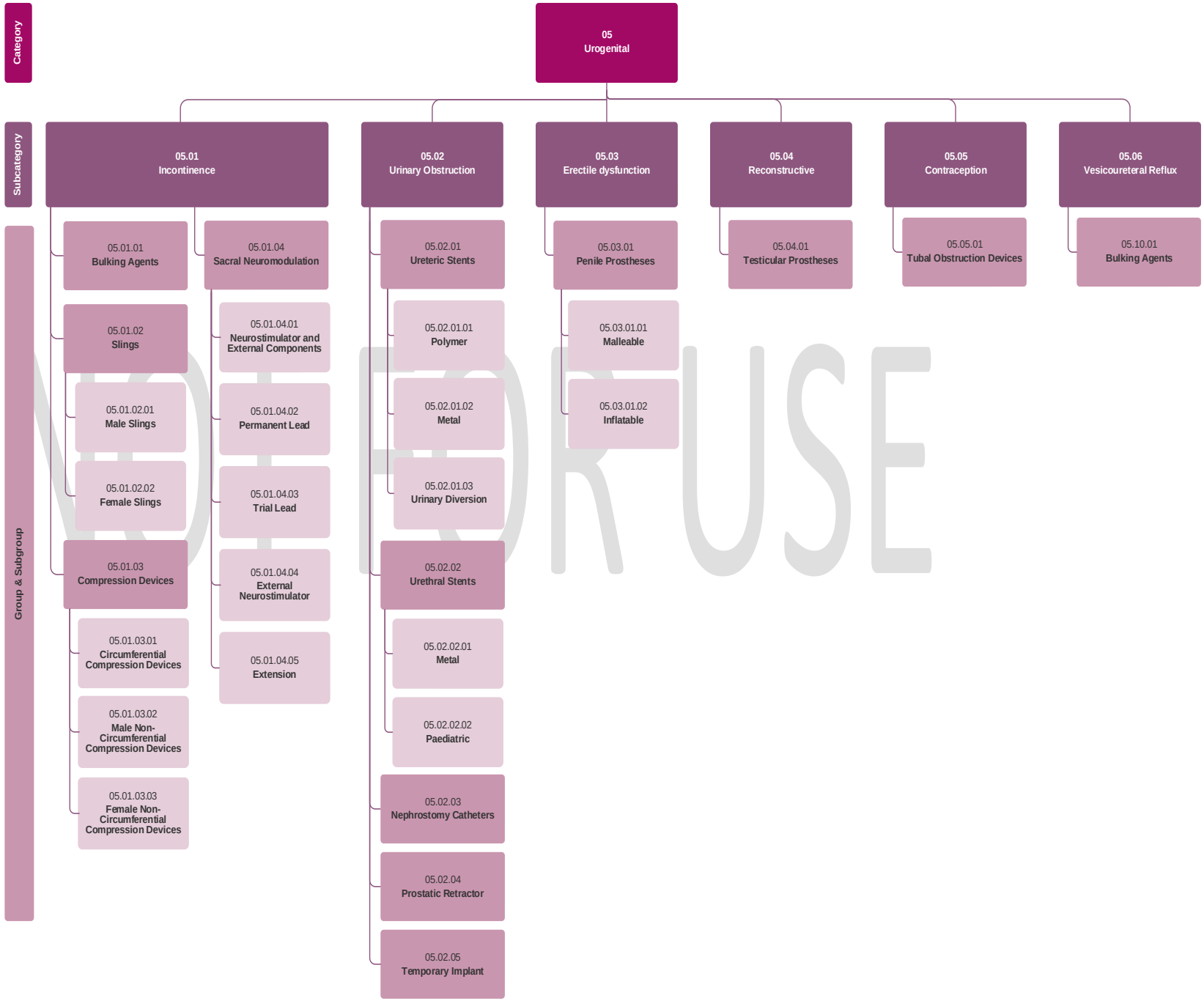
- Circumferential compression devices (artificial urinary sphincters)
- Three component inflatable penile prostheses, and
- Sacral neurostimulators.

Circumferential compression devices also include a grouping for the system. Both circumferential compression devices and penile prostheses are low utilisation devices and based on available data, components are largely used at a one-to-one ratio and within a single episode. For these reasons, these devices have been listed as a single group containing all parts of the system.

In contrast, neurostimulators and their leads are often inserted and/or replaced in different episodes of care and at different rates. Furthermore, trial systems can be used before permanent implantation. For this reason, sacral neurostimulator systems are proposed to be grouped into four groups. Associated accessories (external components, lead adaptors, recharger) have been included within these groups.

The remainder of the urogenital category underwent minor changes.

Figure 6 **Proposed Structure of Urogenital Category**



2.6 Skeletal Reconstruction Category

It is proposed that Skeletal Reconstruction Subcategory of the current Specialist Orthopaedic Category is elevated to Category level on the PL.

Plates

There are approximately 1,000 plates listed in the Specialist Orthopaedic category, currently grouped into 51 subgroups. The subgroups are defined on the basis of:

- Size – both screw size and number of holes
- Periarticular – these are plates designed to reconstruct a joint surface.

The suffix complex is problematic with respect to definition and implementation and therefore is proposed to be removed. Therefore, the plates are proposed to be grouped anatomically.

Screws

Screws have been simplified into three groups based on clinical role of the screw; standalone bone screws and those that fix either a plate or another type of orthopaedic device. The same approach is applied for spinal screws enabling a comparison of benefits across the two categories.

Intramedullary Nails and Nail Accessories

The intramedullary nail accessories Subcategory has not been retained and the devices have either been reallocated to the screws Subcategory or they have been rolled up with their intramedullary parent device. Arthrodesis nails have been reallocated to the Ankle and Foot and Knee Categories.

Soft Tissue Substitutes

The current group 'Soft Tissue Substitute – Non-biological' has been renamed 'Artificial Tendons or Ligaments.' Two products in the group have been reallocated as Button Kits. Artificial tendons currently have a condition on the PL which states 'an Artificial Ligament should only be funded for intra-articular cases where no non-synthetic graft sources (allografts and autografts) are available.' These products are very high cost both in comparison to auto and allo grafts and to international prices and there is a risk that products are listed in this group which are simple suture/tape/mesh devices.

Bone Cement

Currently in Skeletal Reconstruction, bone cement devices have been separated based on whether they contain antibiotics and whether they come with a complex delivery system. Neither of these distinctions have been retained in the current proposal.

Bone Graft Substitute

Bone graft substitutes have been regrouped according to material and include bone graft substitute devices from the Plastic and Reconstructive Category. The distinction of ceramic and demineralised bone matrix (DBM) graft substitutes has been retained, while devices under the composite have been reallocated to ceramic or DBM.

External Fixateurs

The current External Fixateurs Group in the Skeletal Reconstruction Subcategory includes 19 subgroups, with five suffices applied in various combinations to create 40 unique subgroup-suffix combinations. Three suffices are related to size (small, mini and standard), but these are inconsistently attributed to Billing Codes. One suffix – 3D – is defined as "Multiaxial – device features multi axis of rotational and or

translational movement", and the last is CDD, for "Compression / Distraction / Dynamisation". These last two suffices are also inconsistently attributed.

Many components are allocated to a variety of subgroups, creating a substantial degree of device-type heterogeneity across many of the current subgroups. A number of Billing Codes include catalogue numbers for an array of component types, which will necessitate the splitting of Billing Codes to allow allocation of each of the listed component types to appropriate subgroups. These Billing Codes have been flagged, noting the appropriate subgroups for the additional Billing Codes.

In light of the high degree of classification irregularities in the External Fixatuers Group, the rationale table (Table 6) is restricted to the suffices. The current subgroups have been rationalised and renamed. The following points provide a high-level summary of the changes:

- The three subgroups for circular frames, which are currently split between full circle, partial circle and footplates, have been collapsed into a single subgroup.
- The three monoplanar subgroups have been removed as it is unclear what they were intended to capture, and they currently include a wide range of components, all of which have been re-allocated.
- The Billing Codes for pins have been moved to the Pins and Wires Group in the Skeletal Reconstruction Subcategory.
- The Billing Codes for nuts and bolts for circular frames have been flagged for rolling up with circular frames (specific circular frame Billing Codes have not been indicated).
- Coupling devices and pin clamps are no longer distinguished, and are all considered couplers, regardless of the components they join together. However, as couplers, they are distinguished by the characteristics described in the following point.
- All couplers have been allocated to one of four subgroups according to:
    - whether they join a part to one other part, or to multiple other parts, and
    - whether the relative angle of those parts will be fixed, or there is a plane of rotation within the component that allows that angle to be adjusted (the proposed structure does not distinguish between components with a single plane of rotation and those with multiplanar, or polyaxial, rotation).

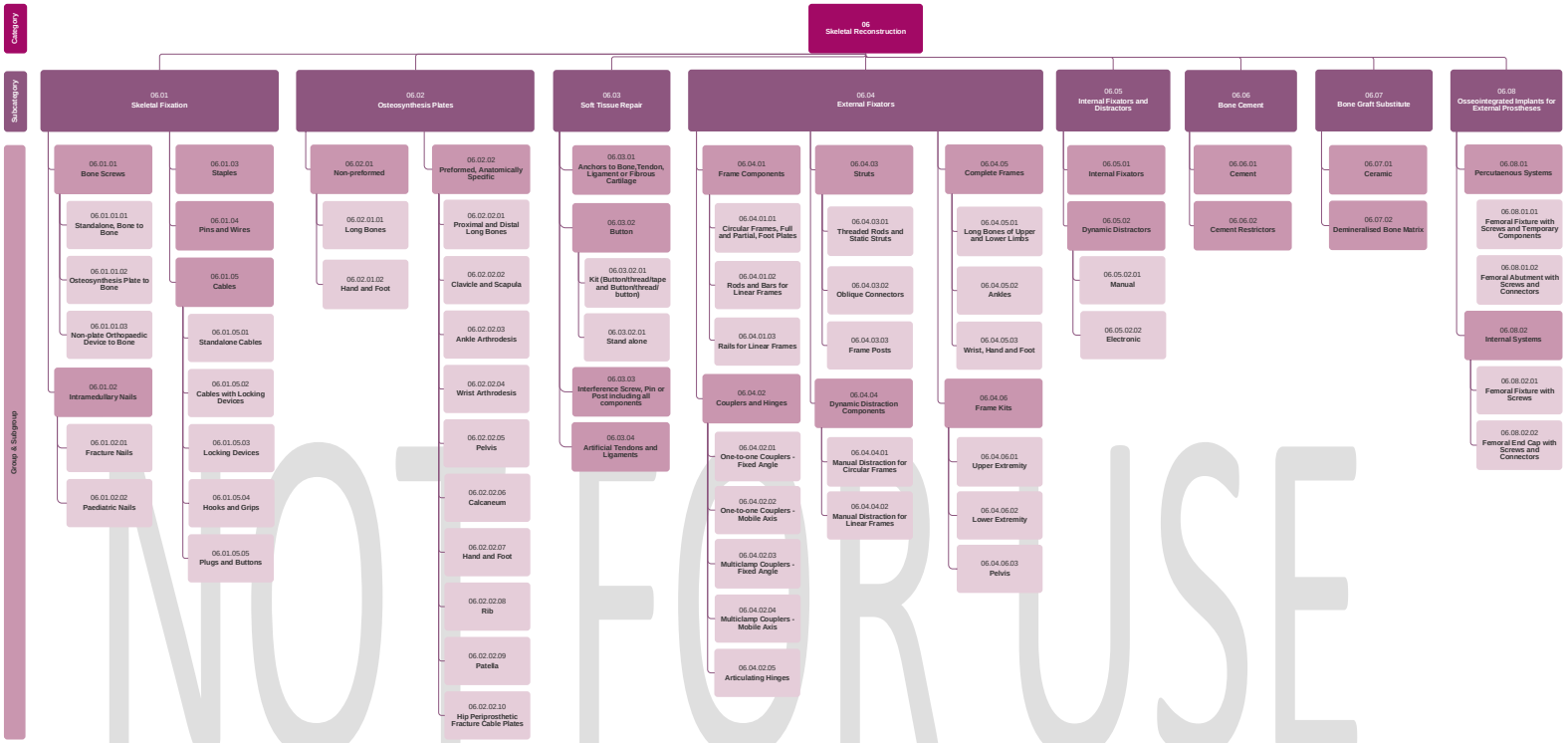
Tumour/Limb Deficiency

The current Tumour / Limb Deficiency Group of the Skeletal Reconstruction Subcategory includes two types of devices: megaprostheses and osseointegrated implants for external prostheses. The 21 Billing Codes for this latter type of device will remain in Skeletal Reconstruction, and will be moved to a new subcategory called Osseointegrated Implants for External Prostheses. After bringing in three Billing Codes from the Intramedullary Nail Accessories Subcategory, there are 24 Billing Codes for osseointegration devices. Of these, 11 are marked for rolling up, leaving 13 Billing Codes in total.

These 13 Billing Codes have been organised into two groups – percutaneous systems and internal systems. Each of these has two subgroups – a fixtures subgroup for osseointegrated stems and all associated permanent screws or connectors and any necessary temporary components, and a subgroup for the non-osseointegrated components. In the case of percutaneous systems, this is the abutments and any required screws or connectors; in the case of internal systems, this is the femoral end cap, and any required screws or connectors. This structure allows for the addition of humeral systems in the future.

The current Tumour / Limb Deficiency Group consists of 34 subgroups. The proposed structure consists of 2 groups.

Figure 7 Proposed Structure of Skeletal Reconstruction Category



2.7 Plastic and Reconstructive Category

The Plastic and Reconstructive Category of the Prostheses List (PL) consists of a relatively large number of billing codes, however with a low total value of claims in comparison to other Categories of similar size. The devices in the Plastic and Reconstructive Category are proposed to be regrouped into six major Subcategories based on their clinical purpose:

- Craniomaxillofacial Reconstruction
- Osseointegration
- Distraction Osteogenesis
- Soft Tissue Reconstruction
- Breast Reconstruction and Deformity Correction, and
- Microsurgery.

The devices regrouped under the Craniomaxillofacial Reconstruction Subcategory are currently in either the Craniomaxillofacial Reconstruction and Fixation Subcategory or the Craniomaxillofacial Implants Subcategory. Given the large overlap in clinical purpose and use of the devices in both Subcategories, they have been merged to create a single Subcategory to encompass all implant and reconstructive devices. In particular, the devices found in the Craniomaxillofacial Implants Subcategory are a combination of standard implants for various areas of the craniomaxillofacial region and patient matched implants to tailor for individual patients' craniomaxillofacial anatomy. Merging of the two Subcategories has allowed for the reallocation of the standard implants to either plates, meshes or non-meshes where similar devices are grouped, while the patient matched implants have been regrouped into a separate group. The surgical guides in this Category are currently subject to a post-market review which will advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.

The current organisation of the Category also includes a Soft Tissue and Tissue Expanders Subcategory that consists of muscular implants, tissue expanders, artificial skin, and anastomosis couplers. Given the heterogeneity, the Subcategory has been split into three new Subcategories - Soft Tissue Reconstruction, Skin Substitution, and Microvascular Surgery. Artificial skin is currently the only device in the Skin Substitution Subcategory as its clinical indication differs from devices in the Soft Tissue Reconstruction and Microvascular Surgery Subcategories. The Microvascular Surgery Subcategory includes anastomotic clips and nerve repair stents from the General Miscellaneous Category, and anastomotic couplers.

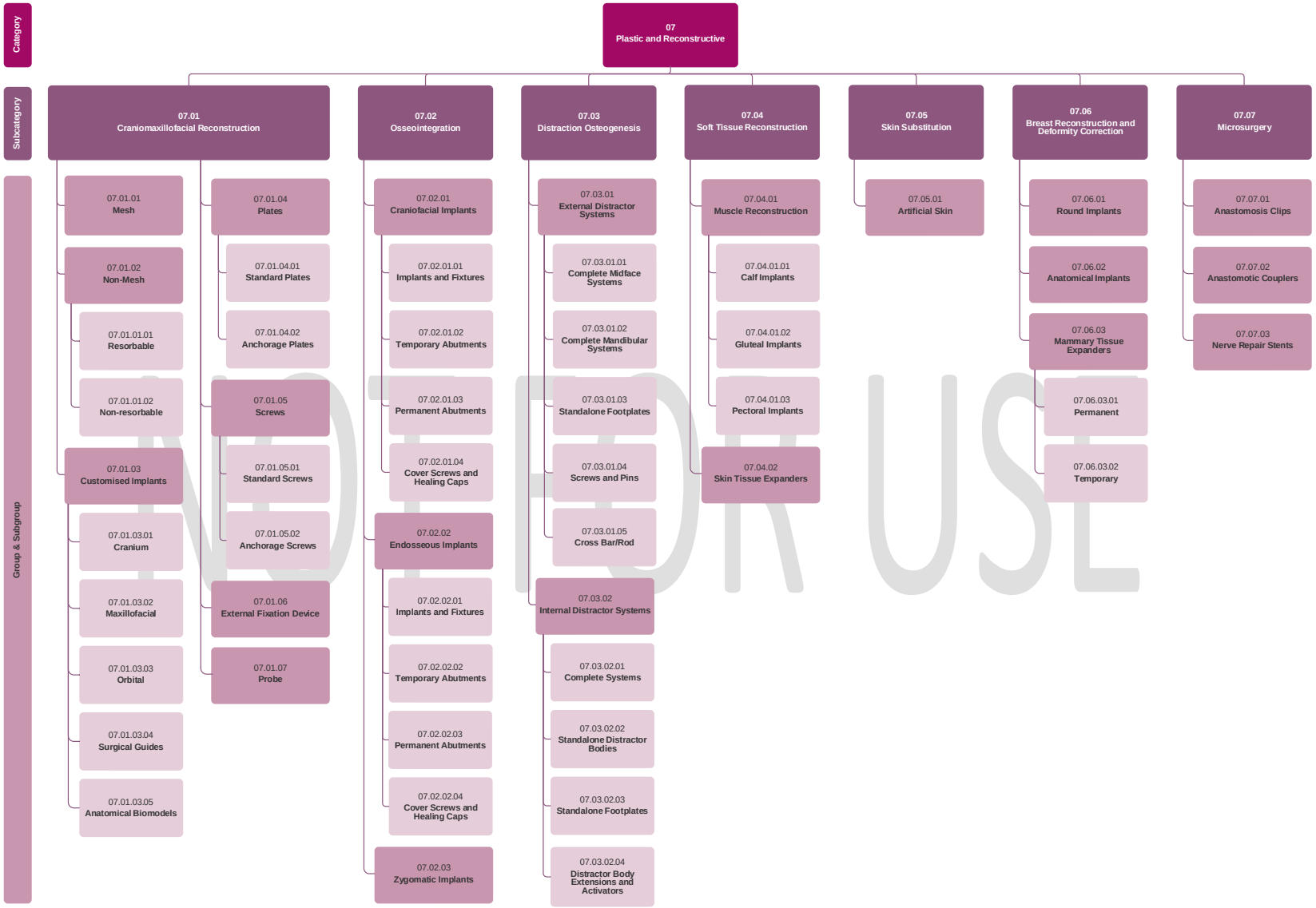
The remaining Subcategory is Breast Reconstruction and Deformity Correction. Mammary tissue expanders have been moved here rather than with skin tissue expanders which are in the Soft Tissue Reconstruction Category.

The listing of smooth versus textured mammary implants was considered by the Medical Services Advisory Committee (MSAC) in 2019[2] with MSAC not supporting a higher benefit for textured devices. Therefore, this distinction has not been reinstated. The distinction between saline and gel filled implants has been removed due to limited, and declining, utilisation of saline filled implants with only a single device listed on the PL. A distinction has been retained for anatomic compared to round implants.

The remainder of the Plastic and Reconstructive Category underwent minor changes. Bone graft substitutes have been moved to the Skeletal Reconstruction Category to be grouped with bone graft substitutes in that category.

[2] http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1626-public

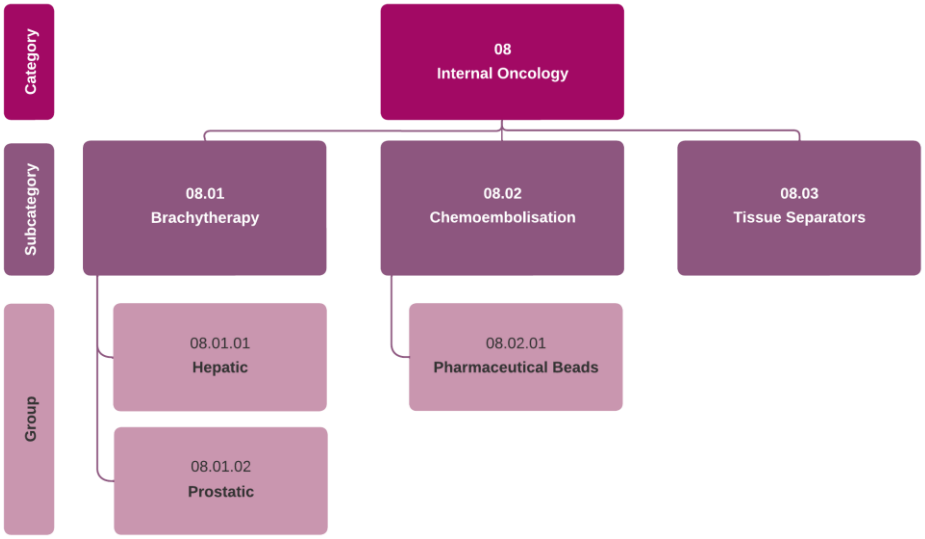
Figure 8 **Proposed Structure of Plastic and Reconstructive Category**



2.8 Internal Oncology Category

The Internal Oncology Category consists of brachytherapy devices, pharmaceutical beads, and tissue separators.

Figure 9 Proposed Structure for Internal Oncology Category



2.9 Cardiac and Cardiothoracic Category

Remote monitoring products and cardiac event recorders are included in the current proposal regardless of whether they are currently listed on Part A or Part C, but any final decision on the inclusion of these products in the CIED subcategory will need to align with the yet-to-be-agreed purpose and scope of the PL.

CIEDs are comprised of one or two active electrode(s) called leads and a generator known as a can. Leads can be replaced earlier than cans and are therefore grouped separately to the cans.

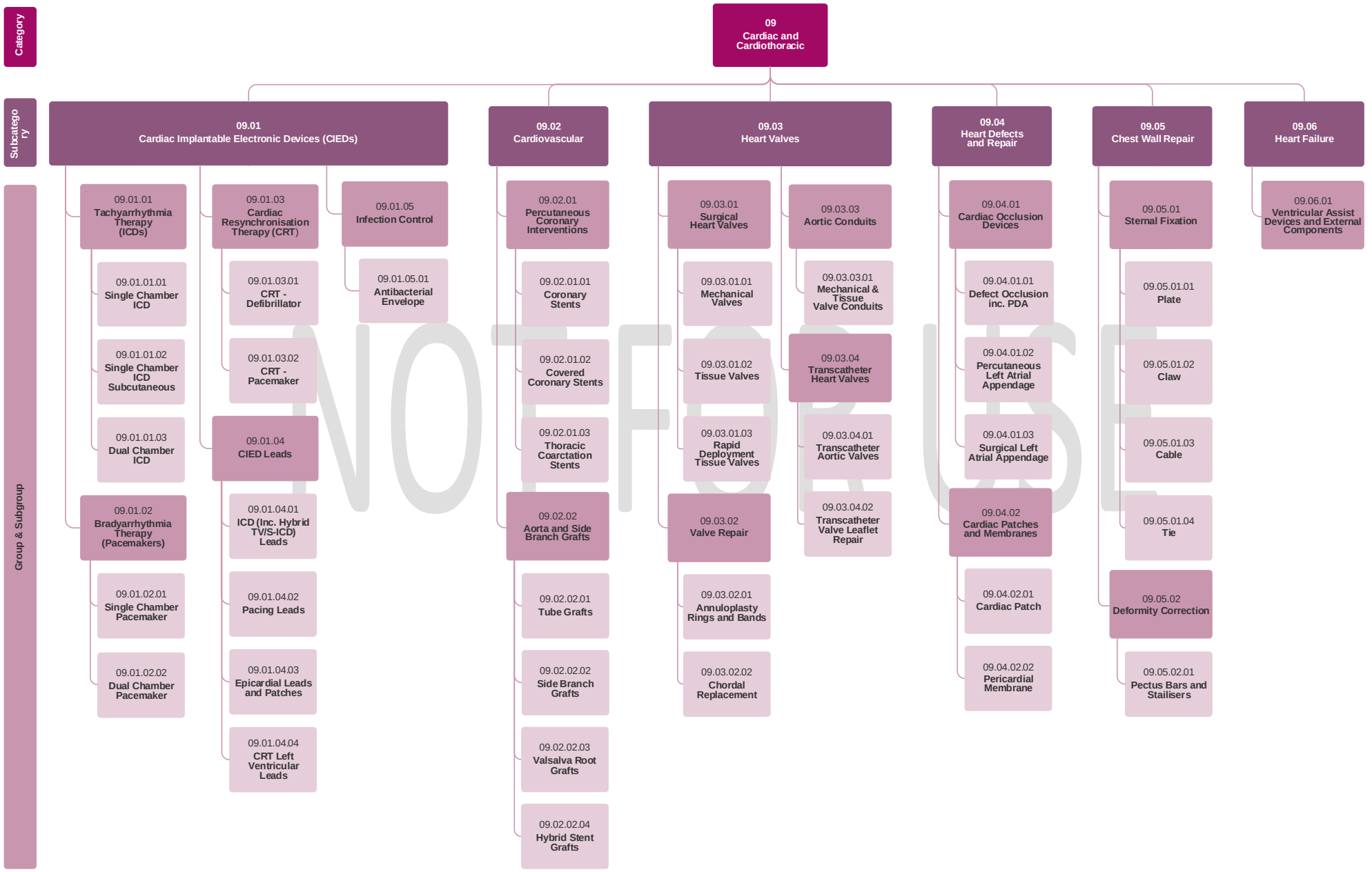
Accessories associated with CIEDs are proposed to be rolled up with either the can (ICD adaptors and extenders) or the leads (Lead accessories).

One of the most widely used devices in the category are coronary stents. Due to the limited and declining use of bare metal stents, a single group is proposed to include both bare metal and drug eluting stents, however a separate group is retained for covered coronary stents.

The proposed Category includes a subcategory 'Chest Wall Repair.' Within this subcategory, sternal fixation devices have been reconciled from across the PL. This includes orthopaedic plates designed to close the chest wall but excludes rib plates which remain in the Skeletal Reconstruction Category.

The external components and patient mobility accessories of Left Ventricular Assist Devices (LVADs) have been proposed to be rolled up with the LVAD as a single device.

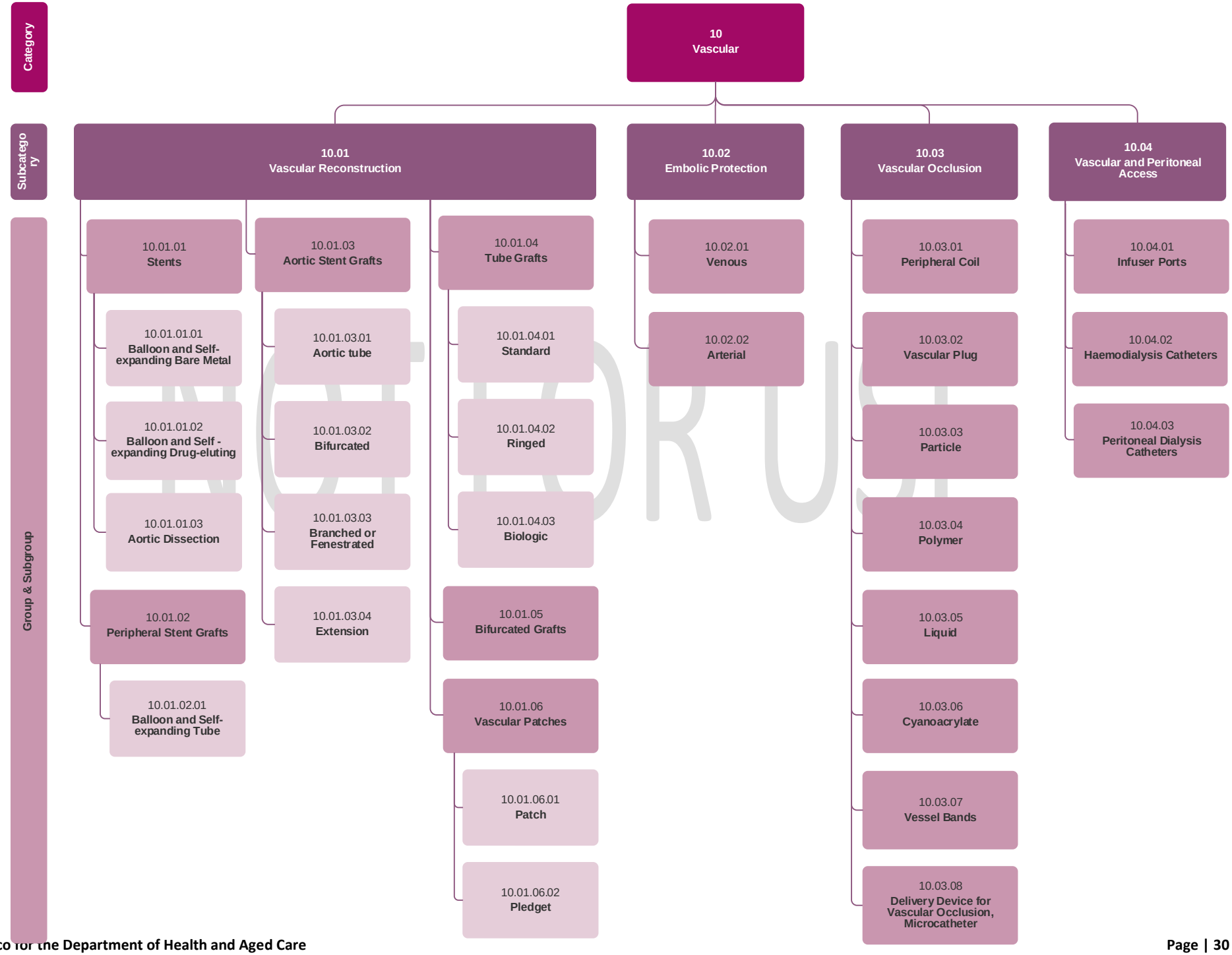
Figure 10 Proposed structure of the Cardiac and Cardiothoracic Category



2.10 Vascular Category

Unlike in the Structural Heart Category, separate groups for Bare Metal and Drug Eluting stents have been retained in the Vascular Category. However, no distinction is made throughout the category on the basis of balloon or self-expanding.

Figure 11 Proposed Structure of Vascular Category


Category
Subcategory
Group & Subgroup
10
Vascular
10.01
Vascular Reconstruction
10.02
Embolic Protection
10.03
Vascular Occlusion
10.04
Vascular and Peritoneal Access
10.01.01
Stents
10.01.01.01
Balloon and Self-expanding Bare Metal
10.01.01.02
Balloon and Self - expanding Drug-eluting
10.01.01.03
Aortic Dissection
10.01.02
Peripheral Stent Grafts
10.01.02.01
Balloon and Self-expanding Tube
10.01.03
Aortic Stent Grafts
10.01.03.01
Aortic tube
10.01.03.02
Bifurcated
10.01.03.03
Branched or Fenestrated
10.01.03.04
Extension
10.01.04
Tube Grafts
10.01.04.01
Standard
10.01.04.02
Ringed
10.01.04.03
Biologic
10.01.05
Bifurcated Grafts
10.01.06
Vascular Patches
10.01.06.01
Patch
10.01.06.02
Pledget
10.02.01
Venous
10.02.02
Arterial
10.03.01
Peripheral Coil
10.03.02
Vascular Plug
10.03.03
Particle
10.03.04
Polymer
10.03.05
Liquid
10.03.06
Cyanoacrylate
10.03.07
Vessel Bands
10.03.08
Delivery Device for Vascular Occlusion, Microcatheter
10.04.01
Infuser Ports
10.04.02
Haemodialysis Catheters
10.04.03
Peritoneal Dialysis Catheters

2.11 Hip Category

The prostheses in this category are all used for hip replacements (full or hemi, primary or revision). In the proposed structure, prostheses used to replace sections of the femoral shaft or pelvis (often due to trauma or tumours) have been separated from standard hip replacement Billing Codes and placed in a new subcategory 'Hip Megaprostheses,' reflecting the organisation of such devices in the Knee Category.

In the proposed structure, femoral stems remain separated by fixation method and length. There are fewer subgroups in the proposed structure as finish is no longer recognised, neither at the subgroup nor suffix level. Separate groups have been created for single-piece stems and stems for modular systems. Two subgroups have been created for modular system stems, based on fixation methods.

The proposed Modular Proximal Components Subgroup includes only components that include metaphyseal sections. These typically also include a neck but sometimes are a sleeve that slips over the stem with a metaphysis.

Billing Codes for necks without a metaphysis have been flagged for rolling up with their respective modular stems, which include the metaphysis. Despite being part of a two-piece system, the stems used with exchangeable necks have been moved from the modular stems subgroup to the relevant standard stem subgroup. After findings of high failure rates at the neck/metaphysis junction, diminishing use has been observed for these systems.

Femoral heads have been separated according to whether they are conventional (distinction between large and small has not been retained), resurfacing, or for bipolar systems. The LFIT suffix for low-friction ion treated metal heads has not been retained, and they are grouped with other metal heads. Ceramic heads and heads with a ceramicised surface have been grouped together.

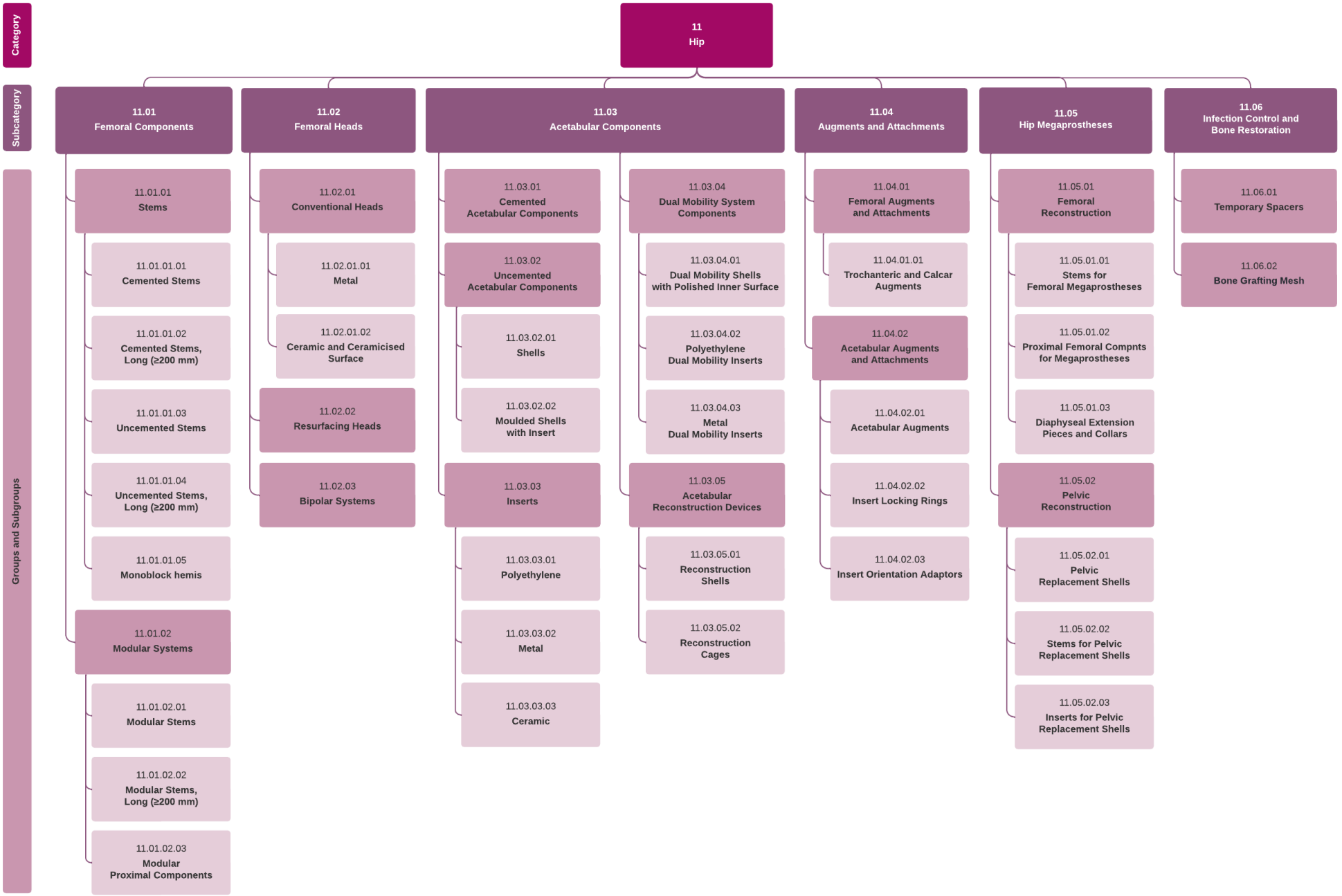
In the Acetabular Components Subcategory, the distinction between finishes on metal shells has not been retained. Constrained and unconstrained liners are now grouped together – while being functionally different, they are not sufficiently different in form to warrant separate grouping. The distinction between modified and unmodified polyethylene inserts has also been removed as use of the latter is diminishing, and it is expected the modified polyethylene will become standard over time.

A higher level of organisation was introduced to the current Accessories Subcategory, which has been renamed Augments and Attachments. Devices have been moved from this Subcategory into Skeletal Reconstruction (e.g., bone screws, cement restrictors), or marked for rolling up with the components they are used with (e.g., centralisers are to be rolled up with femoral stem; acetabular screw hole plugs are to be rolled up with the acetabular shell, taper adaptor/sleeves are to be rolled up with femoral heads etc.).

The components remaining in the Augments and Attachments Subgroup have been separated into Femoral Augments and Attachments and Acetabular Augment and Attachments. They include trochanteric and calcar augments, augments for acetabular shells, attachments for polyethylene liners (e.g., rings for constraint), and adaptor cups that sit between an acetabular shell and liner to re-orient the articulating axis.

A new subcategory was created for devices that are not part of a permanent hip replacement construct. These include the temporary spacer devices, typically used to treat infection prior to revision procedures, and metal meshes used for impaction bone grafting to build up missing bone stock in conjunction with hip replacement.

Figure 12 Proposed Structure for Hip Category



2.12 Knee Category

Similar to the proposed structure for the Hip Category, the re-organised Knee Category retains the current approach of grouping by the types of components used to build the implant construct (e.g., femoral vs tibial components vs tibial inserts etc). Separate groupings for different procedures – total knee arthroplasty (TKA) vs uni-compartmental knee arthroplasty – is also retained.

Much of the remaining criteria have not been retained in the proposed structure, most notably the revision suffix, which is currently attributed to Billing Codes for femoral components and tibial components. However, in the proposed structure, components appropriate for revision procedures are distinguished from standard components for femoral components only. The following definition of a revision device was developed:

A femoral component that has been modified to accept stem attachments and/or augments.

Note, that these devices can also be used for complex primary procedures and that this definition includes hinged devices, which all accept stems.

The approach of making a distinction between standard and revision devices for femoral components only avoids the complexity of identifying revision versus standard components for all components currently listed, and for new components when listed. An appropriate premium can be applied to revision femoral components only, which is the component most adapted for revision procedures, with standard Benefits applied to all other components of revision systems. This will simplify ongoing administration of the Prostheses List.

Other grouping criteria not retained include fixation method and level of constraint. The latter differentiates between articulating mechanisms – minimally stabilised, posterior stabilised and totally constrained. Minimally stabilised and posterior stabilised devices are used in largely overlapping populations, and both the femoral and tibial components have a high degree of similarity, so they are not distinguished in the proposed structure. The tibial components for totally constrained constructs are also not substantially different to those for minimally stabilized or posterior stabilised constructs, so they are all grouped together. However, the femoral components for totally constrained constructs are grouped separately – these are the revision components mentioned above.

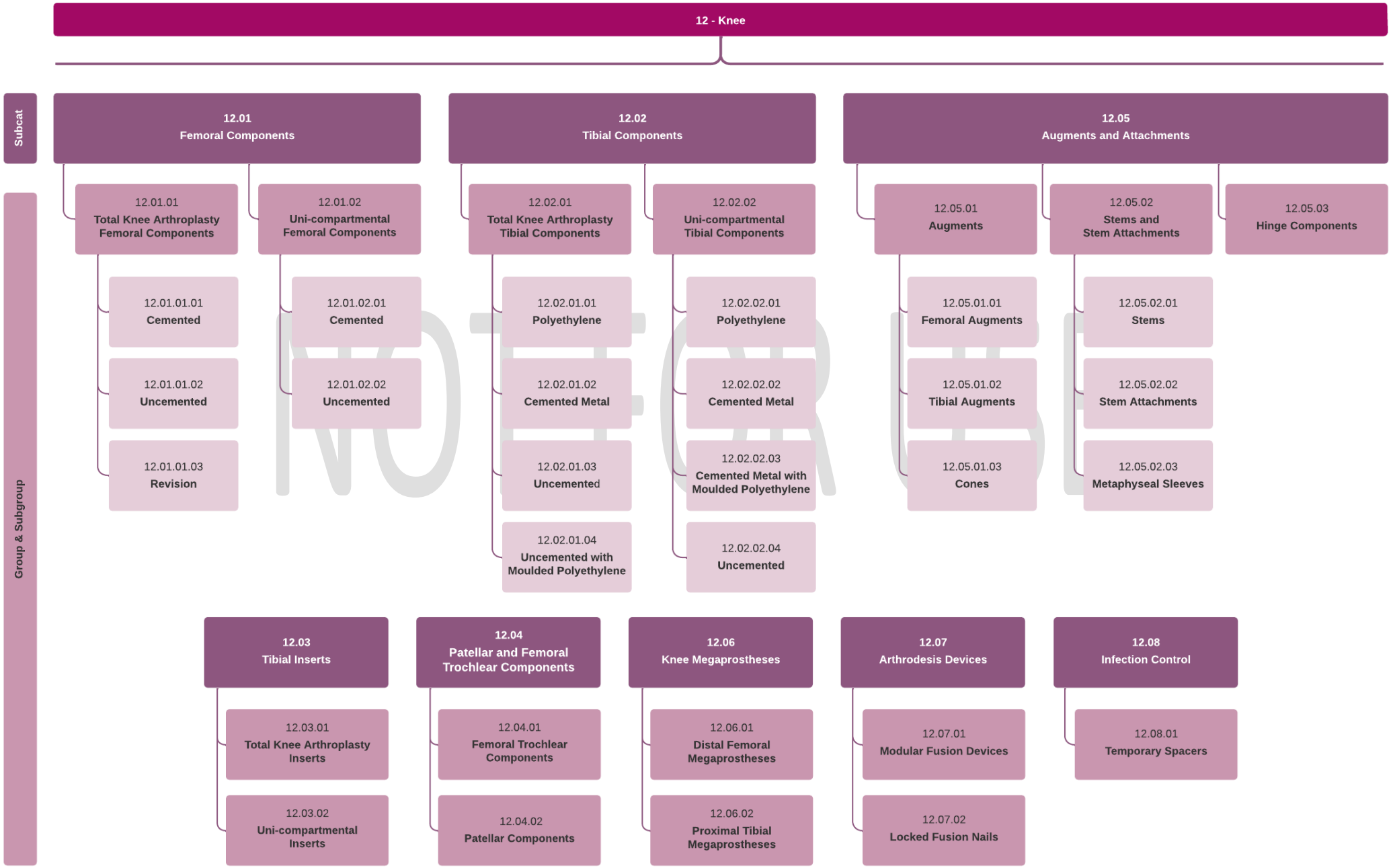
The current Accessories Subcategory includes a number of Billing codes that have either been moved to the new Skeletal Reconstruction Category (bone screws) or rolled up with other components with which they are used (component-to-component screws, pegs and lugs, end caps etc).

The remaining Billing Codes in the Accessories Subcategory have been allocated to one of three groups: Augments; Stems and Stem Attachments; and Hinge Components, allowing this subcategory to be renamed “Augments and Attachments".

The proposal includes a new subcategory – Infection Control – created for the temporary spacer Billing Code. This aligns with the approach taken in the proposal for the Hip Category, where the temporary spacers are now placed in a subcategory for devices that are not part of a permanent joint replacement construct.

The proposal also includes a new subcategory for arthrodesis devices, and these take the form of either modular fusion devices or locked fusion nails. The locked fusion nails and one of the modular fusion devices were re-allocated from Skeletal Reconstruction.

Figure 13 Proposed Structure of Knee Category



2.13 Spinal Category

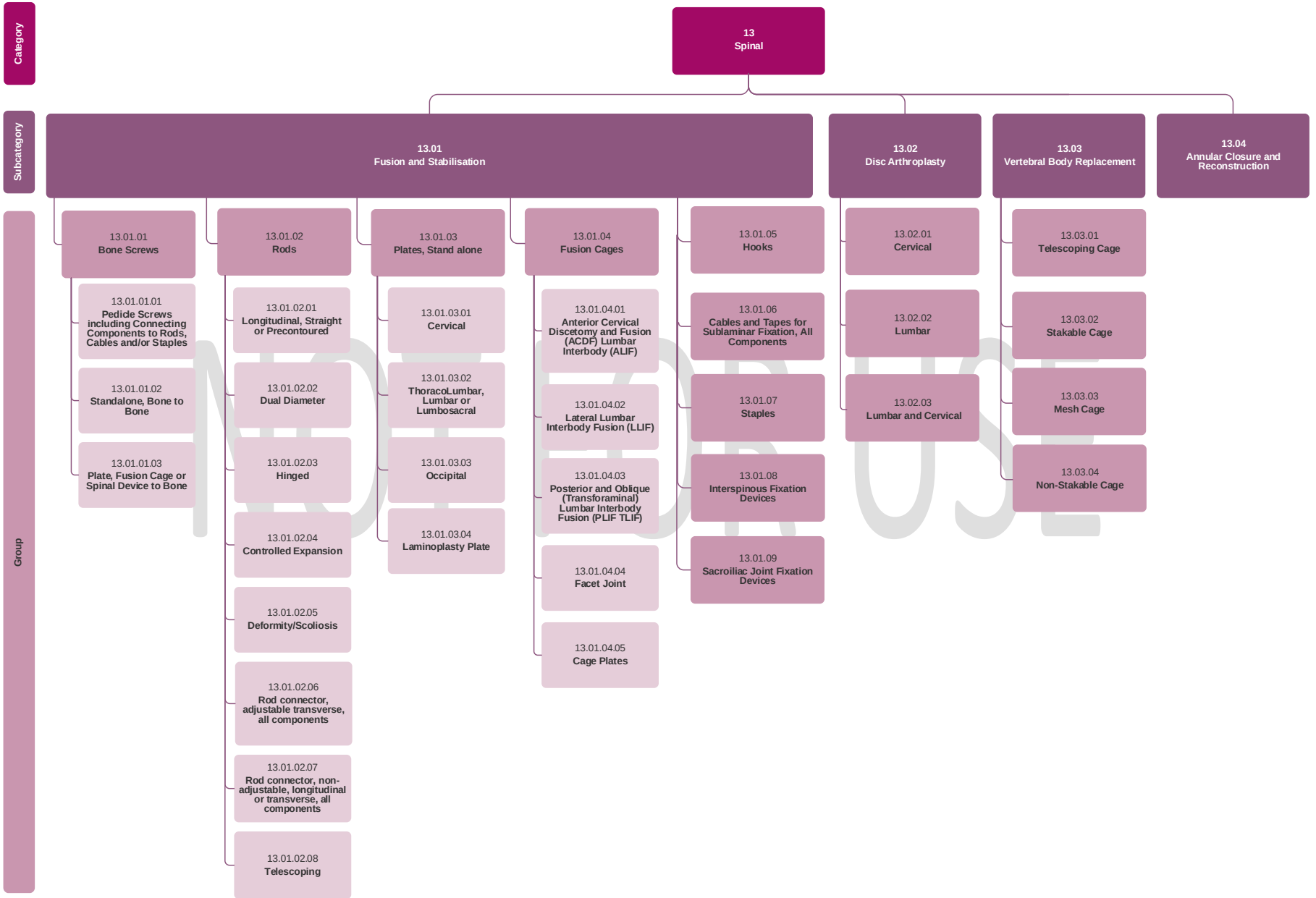
The Spinal Category has a large number of billing codes (2,063) many of which are screws, plates and accessories. Similar devices are found in the Specialist Orthopaedic category.

All plates have been regrouped based on their anatomic use. Bone screws have also been grouped based on their clinical role (standalone fixation or fixation of a plate, cage or other device) rather than device features. Pedicle screws remain separate due to their specific role in spinal surgery.

The accessories in the Spinal Category have been largely rolled up with the main device, however due to the number of billing codes, this has not been implemented at the billing code level (i.e., for all individual devices and accessories). Rather, the descriptors of the groupings have been expanded to note that components are included. Individual components of disc arthroplasty and vertebral body replacement devices have been removed.

The group level distinction common across the Spinal Category of 'integral vs no integral' fixation has been removed. However, a new group has been created for cage plates which can only be used with a spinal fusion cage. These plates are either part of a cage-plate system in which the plate directly interfaces with the cage, or they are small plates which cannot be used as stand-alone plates.

Figure 14 Proposed Structure for Spinal Category



2.14 Upper Limb, Ankle and Foot Category

The current Ankle and Foot Subcategory and Upper Limb Subcategory are in the Specialist Orthopaedic Category. It is proposed that these Subcategories are taken out and placed in the proposed new Upper Limb, Ankle and Foot Category.

Ankle and Foot

The Specialist Orthopaedic Category is currently split into three Subcategories: Ankle and Foot, Upper Limb, and Skeletal Reconstruction. It is proposed that the Upper Limb Subcategory and the Ankle and Foot Subcategory are taken out and placed in a new category called Upper Limb, Ankle and Foot.

Ankle and foot devices are currently separated at the group level by total joint replacement (either liner or tibial-tarsal component), metatarsophalangeal (MTP) joint replacement or subtarsal implants. The proposed structure is similar, except there is a single group for all components of total ankle joint replacement, and the group that includes subtarsal implants also has a subgroup for arthrodesis/osteotomy wedges. The current distinction between fixed and mobile liners and tibial components has been removed, as the trend towards fixed constructs is phasing out the use of mobile systems. The many subgroups for MTP joint replacement have been consolidated so that the construct for a total MTP joint replacement will be claimed through a single Billing Code in a single subgroup. Devices for resurfacing of either side of the MTP joint are now grouped together, removing the distinction between metatarsal and phalangeal implants.

A new subgroup has been created for the foot-specific osteotomy and arthrodesis wedges that are currently allocated to the Skeletal Reconstruction Subcategory (Meshes subgroup and Bone Graft Substitute subgroup). These sit under the newly named Arthroereisis, Arthrodesis and Osteotomy Group, along with the Subtarsal Implants Subgroup.

A Billing Code for a synthetic cartilage implant designed for the greater MTP joint has been moved from Skeletal Reconstruction (Soft Tissue Substitute Group; Non-biological cartilage substitute subgroup) and grouped with the silastic flexible hinge toe in the newly named Non-articulating MTP Joint Spacer Subgroup.

Wrists

Wrist devices have been separated by joint type – that is, radio-carpal replacement or distal radio-ulnar joint (DRUJ) replacement. Under that, devices are grouped according to component type. This approach is consistent with that taken with other orthopaedic categories. Apart from this separation by procedure type, subgroups remain relatively unchanged, with the main differences being:

- the creation of new subgroups for DRUJ-specific components and
- the separation of carpal spacers into:
- those that make up part of a total radio-carpal joint replacement and
    - those that are single-piece, non-fixed implants, now placed in a new subgroup called Radio-carpal Interpositional Devices.

Three Billing Codes from the Interpositional Devices Subgroup of Finger Joint Articulations have also been allocated to this subgroup as they are carpal and carpometacarpal spacers rather than digit spacers.

Finger Joint Articulations

In Finger Joint Articulations, distinctions are no longer made between devices for different parts of the hand, with all proximal and distal components for any digit grouped together in a single subgroup. Two systems for thumbs have three Billing Codes – one for a proximal component and two for the modular components of the distal part of the construct. It is proposed that these Billing Codes are rolled up into a single Billing Code as they are used together and would rarely, if ever, be used separately during revision. One Billing Code in the current 'Thumb, carpometacarpal - distal component' Subgroup is actually an interpositional device, and this has been moved to the Interpositional Devices Subgroup in the proposed structure.

Elbows

The eight subgroups under the current Elbow Group have been rationalised into two groups according to surgery type – replacement of only the proximal radius, or replacement of the humeral-ulnar articulation (i.e., elbow joint). The Radial Head Replacement Group currently includes separate Billing Codes for the radial heads and the radial stems. However, as these are always used together, it is proposed these Billing Codes are rolled into one Billing Code for a head with stem.

The Elbow Joint Replacement Group includes three subgroups – one for each of the component types used in all systems – the humeral component and the ulnar component – and one for parts required to assemble the articulating mechanism, which is currently separately listed for more complex systems. These parts have been allocated to Elbow Articulation Components Subgroup. One system has bundled these articulating parts into a single Billing Code, but another system has multiple Billing Codes for individua parts, and it is proposed these are rolled up into a single Billing Code.

Shoulder

The creation of the new Upper Limb, Ankle and Foot Category allows for more levels of organisation for shoulder devices, which are currently spread across three groups under the existing Upper Limbs Subcategory.

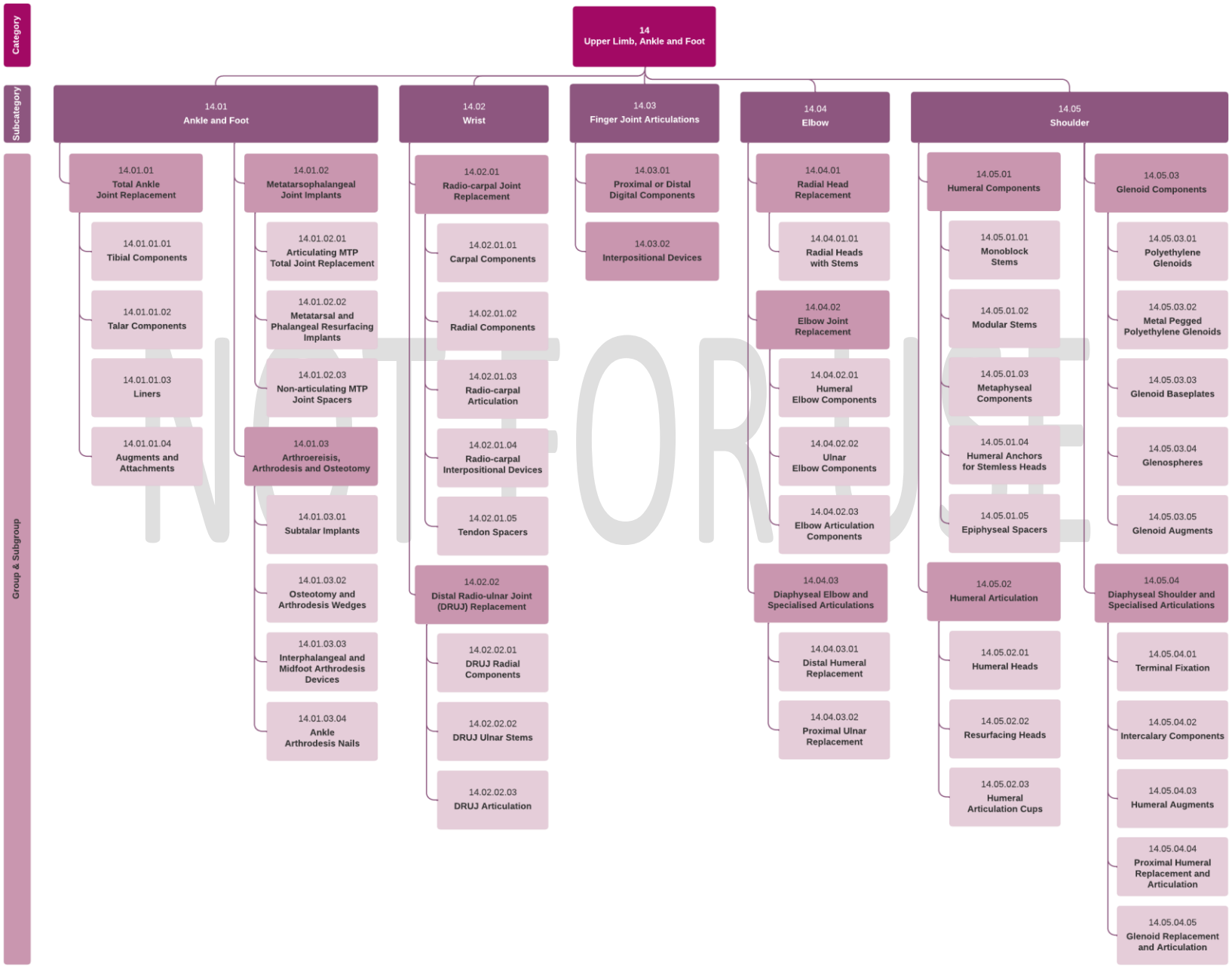
Like the current structure for shoulder, the proposed structure includes a group for humeral components and one for glenoid components. However, all components that include the humeral articulating surface are included in a third group, Humeral Articulation. The current Shoulder – accessories group has been removed, and all Billing Codes have been re-allocated elsewhere or rolled up with the main component they are used with (such as the screws that attach glenospheres to the glenoid baseplate).

The proposed structure includes devices currently allocated to the Tumor/Limb Deficiency Group in the Skeletal Reconstruction Subcategory of Specialist Orthopaedic. Where they replace large amounts of the diaphysis or are large and complex articulating assemblies, they have been moved into subgroups in a new group named Diaphyseal Shoulder and Specialised Articulations. Where they resemble standard components, such as polyethylene glenoids, they have been allocated to the relevant subgroups in the other shoulder groups.

The criteria no longer recognised for humeral components include fixation method, stem length and, for monoblock stems, whether the component is for a reverse construct (reverse suffix). For humeral heads, the EL suffix, which indicates a larger articulating surface, is no longer recognised, as the devices are considered to be insufficiently different to standard humeral heads.

Separate grouping for the components of modular anatomic glenoid components have not been retained as the poly insert with the articulating surface is considered insufficiently different to a standard, single-piece, poly glenoid. In fact, for some systems, the metal backings used with these modular poly inserts can also be used as glenosphere baseplates for a reverse construct. So, these poly inserts are now allocated to the standard Polyethylene Glenoids Subgroup and the metal backing plates are allocated to the Glenoid Baseplates Subgroup. It is acknowledged that modular glenoid constructs will attract two claims rather than one for single-piece glenoids.

Figure 15 Proposed Structure of Upper Limb, Ankle and Foot Category



Appendix A Rationale Tables for the Regrouping

A.1 Ophthalmology

Table 1 Rationale for the proposed regrouping of the Ophthalmology Category

Criteria	Options	Distinction	Comment	Supporting information
Intraocular lenses				
Presbyopia correcting	Multifocal or accomodative vs. monofocal	✓	Spectacle independence and improved vision may not be outweighed by adverse effects such as glare and halos. Could justify removing this distinction, however would limit patient choice.	2016 Cochrane Systematic review (de Silva, 2016), 2014 Cochrane Systematic review (Ong, 2014), CADTH (2018)
Astigmatism correcting	Toric lenses	✓	Improves post-operative astigmatism and spectacle independence. Maintains patient choice.	2019 Cochrane Systematic review (Lake, 2019)
Level of correction for toric lenses	T1 <7 diopter vs T2 >7 diopter	×	Lower supply volume for higher diopter not a justification for separate groups.	
Lens position	Anterior chamber vs posterior chamber	×	Anterior lenses rarely used and superseded for cataract treatment	
Clinical purpose	Aphakic vs phakic	×	Phakic lenses are rarely used for cataract treatment (for vision correction while natural lens remains intact)	
Lens material	Rigid vs foldable	×	Rigid lenses have been largely superseded	
Surgical approach	Microincision vs larger incision	×	Microincision now standard practice	
Edge modification	Yes vs no	×	Edge modification now standard practice	
Preloaded	Yes vs no	×	Delivery devices not justification for a different goup.	

Criteria	Options	Distinction	Comment	Supporting information
Violet blue light filtering	Yes vs no	×	VBLF is intended to reduce macular degeneration. No evidence of clinical difference.	2018 Cochrane Systematic review (Downie, 2018).
Other Ophthalmic				
Minimally invasive glaucoma surgery devices	Device type (at vs external to Schlemm's canal)	×	Insufficient evidence of different clinical outcomes	MSAC assessments 1483, 1496, 1541, CADTH 2019
Scleral buckling devices	Sleeve vs belts vs bands vs buckles vs sponges	×		
Tamponade substances	Liquids vs gasses vs oils		Combined liquids and oils, kept gasses separate	

A.2 Ear, Nose and Throat

Table 2 Rationale for proposed regrouping of the ENT Category

Criteria	Options	Distinction	Hereco comments	Supporting information
Cochlear Implant Speech Processors				
Surgery type	**initial speech processors** vs **replacement speech processors**	×	Initial and replacement devices are the same device Initial speech processor is currently listed at a higher Benefit than the replacement device based on additional clinical time Additional time should not be captured via PL Benefits	
Additional features	**Electroacoustic** vs **autoscan** vs **2.4GHz wireless** vs **generation 4**	×	There is no high-quality comparative evidence that these different features are associated with different health outcomes	
Ossicle/Middle Ear Prosthesis				
Type of middle ear/mastoid reconstruction	**partial ossicle replacement (PORPs)** vs **total ossicle replacement (TORPs)** vs **malleus**	×	Devices are sufficiently similar to group together	

Criteria	Options	Distinction	Hereco comments	Supporting information
Implantable Bone Conduction Hearing System				
Shape	**concave** vs **not concave**	×	The concave design allows for preservation of hair and skin around the abutment This additional feature does not add clinical benefit	
Speech processor additional features	**programmable** vs **wireless-enabled** vs **autoscan**	×	There is no high-quality comparative evidence that these different features are associated with different health outcomes	
Abutment coating	**HA** vs **no HA**	×	HA coated abutments are intended to allow for improved integration with soft tissue Comparative evidence on tissue integration lacking to support Benefit premium	
Xenografts				
Large vs small	**small xenografts (≤10cm^2)** vs **medium xenografts (>10cm to 50cm^2)**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	
Ventilation Tube/Grommets				
Coating	**antibiotic** vs **no antibiotic**	×	Devices are sufficiently similar to group together	
Throat				
Airway patency	**cannula** vs **tracheal stents**	×	Similar clinical indication (to maintain airway patency)	
Tracheal stent material	**nitinol** vs **silicone**	×	There is no high-quality comparative evidence that these different features are associated with different health outcomes	

A.3 Thoracoabdominal and Internal Oncology

Table 3 Rationale for proposed regrouping of the Thoracoabdominal and Internal Oncology Categories

Criteria	Options	Distinction	Comments	Supporting information
Brachytherapy				
Type	**hepatic** vs **prostatic**	✓	Different therapies and clinical indications	MSAC Application 1029, MSAC Application 1493

Criteria	Options	Distinction	Comments	Supporting information
Prostatic dosage number	**standard dose** vs **single seed or partial dose**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	
Tissue expander/separator size	**gel 3ml** vs **gel 10ml or balloon**	×	No distinction made on the basis of size, correct size for patient should not affect grouping. Balloon has been removed as a descriptor as no balloons are listed.	
Infusion Ports				
Lumen number	**single** vs **multiple**	×	Device characteristics insufficiently different	
Gastric Bands				
Gastric band feature	**with port** vs **without port**	✓	Difference in adjustability of the gastric bands where the use of a port allows the band to be adjustable	
Luminal Stents				
Wall material	**non-reinforced** vs **reinforced**	✓	Distinction retained as sufficiently different clinical indications. Renamed to plastic and metal – plastic stents used for benign cases and can also be temporary while metal stents used when a tumour is present	
Metal type	**uncovered/bare** vs **covered**	×	No sufficient difference in clinical indication or population between uncovered/bare metal stents and covered metal stents	
Delivery system	**complex** vs **delivery system** vs **no delivery system**	×	The delivery system of the stent is not recognised which is consistent with other delivery devices on the PL	
	pusher vs **non-pusher**	×	A pusher is not always needed and acts as a delivery system for the stent. Delivery systems are not recognised elsewhere on the PL	
Oesophageal stent material	**reinforced** vs **biodegradable**	×	Device characteristics and indications insufficiently different	
Expandability	**self-expanding** vs **non-self-expanding**	×	The standard of care are self-expanding stents, where most are self-expanding due to expansion after implantation through a delivery device	

Criteria	Options	Distinction	Comments	Supporting information
Additional pancreatic stent features	**electrocautery** vs **non-electrocautery**	✓	The use of an electrocautery system is specific for a different clinical indication	
Mesh				
Material	**polypropylene/polyester** vs **composite** vs **complete biomaterial** vs **PTFE/ePTFE**	×	Distinction by material does not align with organising principles. Material groupings used to separate meshes into non-resorbable, partially resorbable and resorbable	International Guidelines for Groin Hernia Management at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5809582/
Material	**non-resorbable** vs **partially resorbable** vs **fully resorbable**	✓	Different clinical indications between the various absorbability types, particularly where implantation is near nerves or where there is infection	
Coating	**coated** vs **non-coated**	×	Coating suffix has not been allocated correctly. Partially absorbable is a general proxy for coated meshes	
Shape	**contoured** vs **non-contoured**	×	Contoured devices are infrequently used and interchangeable with non-contoured devices	Refer to product IFUs
Delivery system	**integrated delivery system** vs **non-integrated delivery system**	×	Delivery systems not shown to be clinically superior and not necessary for device function	Refer to product IFUs
Thickness	**2mm thickness** vs **thickness not specified**	×	No distinction made on the basis of thickness, correct size for patient should not affect grouping	
Size	**≤200cm²** vs **201-400cm²** vs **401-600cm² vs 601-800cm²** vs **>800cm²** vs **601-800cm² vs 601cm²-1000cm²** vs **>600cm²** vs **>1000cm²** vs **>600-<2500cm²** vs **≥2500cm²**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	
Ligation Devices				
Diagnostic feature	**doppler guided** vs **non-doppler guided**	×	Device indications and populations insufficiently different. Diagnostic features not recognised by the regrouping.	
Procedure type	**endoscopic** vs **non-endoscopic**	×	Device characteristics and indications insufficiently different	

Criteria	Options	Distinction	Comments	Supporting information
Device type	**haemorrhoid** vs **haemostatic**	✓	Distinction recognised due to sufficiently different populations and indications	
System	**standard** vs **over-the-scope**	✓	Distinction retained as systems are sufficiently different	

A.4 Neurosurgical

Table 4 Rationale for proposed regrouping of the Neurosurgical Category

Criteria	Options	Distinction	Comments	Supporting information
Aneurysm Clips				
Structure	**complex** vs **not complex**	×	Device characteristics insufficiently different	
Dura Defect Repair Grafts				
Material	**biological** vs **non-biological**	×	Device characteristics insufficiently different	
Large vs small	**small (≤10cm^2)** vs **medium (>10 to 50cm^2)** vs **large (>50 to 100cm^2)** vs **extra large (>100cm^2)**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	
Hydrocephalus				
Valve type	**externally adjustable** vs **non-externally adjustable**	✓	Retained	
Additional valve features	**antisyphon function** vs **reservoir/priming function** vs **coating** vs **lumboperitoneal**	×	Device characteristics insufficiently different	
Shunt type	**unitised shunt assembly, with proximal/distal catheter** vs **valve with catheter**	×	Devices are sufficiently similar to group together	
Neuromodulation				
Neurotransmitter type	**rechargeable** vs **non-rechargeable**	×	Devices are sufficiently similar to group together	MBS Reviews taskforce. Taskforce final report – Pain Management MBS items

Criteria	Options	Distinction	Comments	Supporting information
Neurotransmitter additional features	**adaptive stimulation** vs **multi waveforms** vs **recharge protection** vs **unlimited deep discharge battery** vs **32 electrode IPG** vs **integrated leads** vs **10kHz stimulation**	×	No high-quality evidence that these different features are associated with different health outcomes	Refer to product IFUs
Number of channels	**single** vs **dual**	✓	Devices are sufficiently different in application	
Lead type	**percutaneous** vs **epidural paddle**	✓	Consistent with MBS item numbers	

A.5 Urogenital

Table 5 Rationale for the proposed regrouping of the Urogenital Category

Criteria	Options	Distinction	Comment	Supporting information
Bulking agents				
Volume	1 vs 2 vs 2.5 vs 3 ml	×	No distinction made based on volume, should match clinical indication.	Note none of these devices have valid ARTG numbers.
Male slings				
Function	Adjustable vs fixed	×	Insufficient comparative evidence of benefit from adjustable slings. ATOMS device to be grouped as a sling.	MSAC (App 1369) found inferior safety for adjustable slings
Inflatable incontinence prostheses				
Mechanism	Circumferential vs non-circumferential	✓	Retained due to different mechanism. Limited evidence of effectiveness of non-circumferential device.	European Association of Urology (2018) Guidelines on Urinary Incontinence in Adults
Ureteric stents				
Length	Fixed vs multi length	×	No distinction made. Length should be based on clinical indication.	
Material	Polyurethane vs other synthetic	×	No distinction made	
	Polyurethane/other synthetic vs metal	✓	Retained	
Penile prostheses				
Component number	Inflatable two vs three component	×	Combined. Two component rarely used.	

Criteria	Options	Distinction	Comment	Supporting information
Tubal obstruction devices				
Structure	Clip vs band	×	Same clinical indication	

A.6 Skeletal Reconstruction

Table 6 Rationale for proposed regrouping of the Skeletal Reconstruction Category

Criteria	Options	Distinction	Comments
Intramedullary Nails			
Locality	**femoral, proximal short (<220mm)** vs **femoral, proximal long (≥220mm)** vs **femoral, distal** vs **tibial/fibular** vs **humeral** vs **radial/ulnar** vs **calcaneal**	×	Device characteristics insufficiently different
Specialisation	**paediatric** vs **non-paediatric**	✓	Distinction retained as devices sufficiently different in complexity
	arthrodesis vs **non-arthrodesis**	✓	Distinction retained as devices sufficiently different in function Devices reallocated to Ankle & Foot and Knee Categories
Additional features	**growth** vs **interphalangeal** vs **complex** vs **compression** vs **cannulated**	×	Device characteristics insufficiently different
	Growth and dynamic distraction	✓	Clinical role is different, devices moved to internal fixatateaurs and distractors subcategory
Plates			
Size	**50 size options available**	×	No distinction made on the basis of size, correct size for patient should not affect grouping
Specialisation	**periarticular anatomic** vs **non-periarticular anatomic**	×	Device characteristics insufficiently different Term 'periarticular anatomic' is unclear and is not clinically supported
	Non-preformed vs Preformed, Anatomically Specific	✓	New distinction introduced to separate out plates which are not anatomically specific to a particular bone
	cable plate vs **non-cable plate**	✓	Distinction retained as sufficiently different but only for hip periprosthetic fracture cable plates. Whether the plate is supplied with or without a cable is not recognised in the grouping. This distinction is not retained in the Structural Heart Category for sternal closure plates.

Criteria	Options	Distinction	Comments
Additional features	**simple** vs **complex, locking** vs **non-locking** vs **variable angle locking**	×	Device characteristics insufficiently different
Screws			
	Size: standard vs small vs mini vs micro	×	No distinction made on the basis of size, correct screw size needs to be used for the correct indication
	Dynamic/Break Off/Dual threaded	×	Distinctions not retained, however many of these screws are standalone bone screws and therefore grouped separately to device screws
	Cannulated vs solid	×	Device characteristics insufficiently different. Consistent with Spinal Category decisions.
	Locking vs non-locking	×	Now standard technology and not considered sufficiently different to justify separate grouping.
Soft Tissue Repair			
Material	**permanent** vs **absorbable**	×	Device characteristics insufficiently different. Consistent with prior decisions.
	hydroxyapatite coated vs **uncoated**	×	Device characteristics insufficiently different. Consistent with prior decisions.
Size	**small** vs **medium** vs **large suture anchors**	×	Device characteristics insufficiently different. Consistent with prior decisions.
Surgical Accessories			
Cable fixation	**in-built locking device** vs **>1 locking device**	×	Device characteristics insufficiently different
Wires additional features	**absorbable** vs **complex** vs **olive wire** vs **threaded**	×	Device characteristics insufficiently different
Staples			
Additional features	**compression** vs **memory metal** vs **multi implant**	×	Device characteristics insufficiently different
Bone Cement			
Treatment	**antibiotic** vs **non-antibiotic**	×	Antibiotic bone cement is used as a part of routine care and is minimal additional cost
Delivery system	**complex** vs **non-complex**	×	Device characteristics insufficiently different Complexity of delivery system does not make an impact on the bone cement
Bone Graft Substitute			
Size	**8 size options available across all materials**	×	No distinction made on the basis of size, correct size for patient should not affect grouping. Volume/size groups may be necessary for benefit setting.

Criteria	Options	Distinction	Comments
Material	**ceramic** vs **demineralised bone matrix** vs **composite**	✓	Distinction between ceramic and demineralised bone matrix retained as sufficiently different Composite devices reallocated to either ceramic or demineralised bone matrix
Delivery system	**complex** vs **non-complex**	×	Device characteristics insufficiently different
External Fixateurs			
Sizing suffices	**Small size** vs **Mini size** vs **standard size**	×	This suffix was not consistently attributed Sizing differences have not been recognised in the proposed structure as it was deemed the devices perform similar functions and are not sufficiently different to warrant separate grouping The only exception is the separation of complete frame or frame kits according to anatomical categories, which captures some sizing differences
3D suffix	**Poly-axial couplers (and pin clamps)** vs **Fixed angle couplers (and pin clamps)**	×	This suffix was not consistently attributed Devices with any plane of rotation are now distinguished from those with no plane of rotation
CDD suffix	**Compression and/or distraction (dynamization)** vs **No CDD**	✓	This suffix was not consistently attributed This attribute is now recognised at the subgroup level The attribute was defined as components designed to be continuously or incrementally adjusted in length after the construct is implanted, by either the patient or the physician
Osseointegration implants in Tumour / Limb Deficiency			
Component type	**abutment screw** vs **abutment**	×	The Billing Codes for abutment screws are to be rolled up with the abutments as they are always required to attach the abutment and form part of the abutment component
Component type	**permanent stem screw** vs **stem**	×	The two Billing Codes for permanent stem screws are currently allocated to the Central Screw Subgroup (06.03.17.04) and an Intramedullary Nail Accessories subgroup (06.03.02.03) The Billing Codes for stem screws are to be rolled up with the stems as they form part of the fixation component
Component type	**temporary components** vs **stem**	×	The five Billing Codes for temporary components are currently allocated to the Healing Cylinder Subgroup (06.03.17.05), the Healing Screw Subgroup (06.03.17.06) or an Intramedullary Nail Accessories subgroup (06.03.02.04) The Billing Codes for temporary components are to be rolled up with the stems as they form part of the fixation component in the first surgery

Criteria	Options	Distinction	Comments
Component type	**osseointegrated components** vs **non-osseointegrated components**	✓	Currently recognised by various subgroupings Retained distinction as these components are often implanted at separate times and may undergo revision at different rates
Component type	**percutaneous non-osseointegrated components** vs **internal non-osseointegrated components**	✓	The polyethylene spacer of internal systems and the metal abutments of percutaneous systems are sufficiently different in form and function to warrant retaining distinction.

A.7 Plastic and Reconstructive

Table 7 Rationale for regrouping of the Plastic and Reconstructive Category

Criteria	Options	Distinction	Comments	Supporting information
Mesh				
Size	**27 size options available for all materials**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	
Material	**metal** vs **non-metal** vs **composite**	×	Clinical indication and population of materials insufficiently different to retain	Refer to product IFUs
Complexity	**complex** vs **non-complex**	×	Device characteristics insufficiently different. Complexity not clearly defined.	Refer to product IFUs
Non-mesh				
Size	**<6cm^2** vs **>6cm^2** **<8cm^2** vs **>8cm^2**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	
Material	**resorbable** vs **polymer** vs **block**	✓	Materials sufficiently different to retain Polymer and block devices combined into 'non-resorbable'	Refer to product IFUs
Plates				
Size	**20 size options available**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	

Criteria	Options	Distinction	Comments	Supporting information
Additional plate features	**burr** vs **compression** vs **resorbable** vs **complex** vs **complex, locking** vs **3D**	×	Device characteristics insufficiently different	Refer to product IFUs
Craniomaxillofacial Implants				
Locality	**chin** vs **cranium** vs **ear** vs **malar** vs **mandible, maxilla and temperomandibular joint (TMJ)** vs **nose and zygoma** vs **orbit**	✓	Locality for customised implants retained and simplified to cranium, maxillofacial and orbital	
Complexity	**complex** vs **non-complex**	×	Device characteristics insufficiently different. Complexity not clearly defined.	Refer to product IFUs
Customisability	**biomodelled** vs **non-biomodelled**	✓	Biomodelled sufficiently different due to customisability to patients' anatomy All non-biomodelled implants reallocated to plates, mesh or non-mesh groups	Refer to product IFUs
Additional features	**angled/offset** vs **coated** vs **compression** vs **concave** vs **fixation plate** vs **hemimandible** vs **maxilla** vs **polymer** vs **symphysis**	×	Device characteristics insufficiently different	Refer to product IFUs
Dental Implants				
Coating	**hydrophilic** vs **non-hydrophilic**	×	Device characteristics insufficiently different	Refer to product IFUs
Distractor Systems				
Complete system features	**multivector** vs **single vector**	×	Device characteristics insufficiently different	Refer to product IFUs
Footplate features	**dual plate** vs **single plate**	×	Device characteristics insufficiently different	Refer to product IFUs
Tissue Expanders				
Indication	**skin** vs **mammary**	✓	Device indications sufficiently different anatomically	
Functionality	**temporary** vs **permanent**	✓	Device characteristics sufficiently different. Permanent expanders can be used as mammary implants after expansion.	Refer to product IFUs
Artificial Skin				
Size	**<50cm^2** vs **>50-149cm^2** vs **<150-400cm^2** vs **>400cm^2**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	

Criteria	Options	Distinction	Comments	Supporting information
Mammary Implants				
Size	**<500cc** vs **≥500cc**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	
Fill	**gel filled** vs **saline filled**	×	Only one saline implant on the PL and appears to have diminishing use compared to gel filled	ABDR
Shape	**round** vs **anatomical (pre-shaped)**	✓	Has more similar utilisation and different indications – mostly anatomical for unilateral reconstructions and mostly round for bilateral reconstructions	ABDR
Texture	**smooth** vs **microtextured**	×	Smooth and textured suffices previously recognised in PL until MSAC decision (2019) that found that there was limited good quality comparative evidence between the two types of implants.	MSAC
Anastomotic Coupler				
Additional Features	**including pre-attached probe** vs **standalone**	✓		

A.8 Internal Oncology

Decisions are captured in Table 3.

A.9 Cardiac and Cardiothoracic

Table 8 Rationale for regrouping the Cardiac and Cardiothoracic Category

Device	Options	Distinction	Hereco comments	Supporting information
ICDs	Single vs dual chamber	✓	Determined by clinical indication: whether is pacing required in the right ventricle alone, or in both the right atrium and the right ventricle	Refer to product IFUs

Device	Options	Distinction	Hereco comments	Supporting information
	Other product features such as volume, product life, lead performance, software functions and data collection and storage capabilities	×	There is no high-quality comparative evidence that these different features are associated with different health outcomes	
Pacemakers	Single vs dual chamber	✓	Determined by clinical indication: whether is pacing required in the right ventricle alone, or in both the right atrium and the right ventricle	Refer to product IFUs
	Other product features such as rate responsiveness, and communication capability	×	There is no high-quality comparative evidence that these different features are associated with different health outcomes	
CRTs	Defibrillators vs Pacemakers	✓	Determined by clinical indication: with CRT-defibrillators indicated for patients who require pacing and who are also at high risk for sudden cardiac death	Refer to product IFUs
	Other product features such as pacing adaptability, programming outputs, auto capture threshold, and impedance tests	×	There is no high-quality comparative evidence that these different features are associated with different health outcomes	
CIED Leads	Left vs right ventricular leads	✓	Determined by clinical indication: right ventricular leads are indicated for single and dual chamber ICDs and pacemakers, whilst left ventricular leads are indicated for CRTs. Different subgroups for different right ventricular leads is warranted based on different clinical indications	Refer to product IFUs
	Other product features such as Transvenous v non-transvenous; steroid v non-steroid; passive v active leads	×	There is no high-quality comparative evidence that these different features are associated with different health outcomes	
Remote monitoring hardware	Include or exclude remote monitoring hardware	✓	Include – keep a separate subgroup for remote monitoring hardware to support patients with the corresponding CIED.	MSAC Assessment 1197.1
Stents	Thoracic Coarctation Stents uncovered vs covered & balloon in balloon vs standard	×	Same product with four billing codes	ARTG PSD, product IFU

Device	Options	Distinction	Hereco comments	Supporting information
	Bare metal vs drug eluting	×	Distinction could be removed on the basis that bare metal is largely superseded (<1%). Controversy regarding the incremental benefit of drug eluting stents.	Victorian Cardiac Outcomes Registry, Annual Report 2020 Feinberg (2017) Cochrane Review: BM vs DES
	Bare metal & drug eluting vs covered coronary	✓	Covered coronary stents have a different clinical indication (coronary artery perforations & coronary bypass-vein grafts)	ARTG PSDs, product IFU
Tube grafts	Length: 11-20cm vs 21-49cm vs ≥50cm	×	No distinction made on the basis of length, correct size for patient should not affect grouping	ARTG PSD and product IFU
	Unbranched vs one branch vs multiple branches	×	Determined by clinical indication	Refer to product IFUs
Heart defect occluders	Other occluders vs Left atrial appendage occluders	✓	Similar devices but distinct clinical roles (congenital defects vs. stroke prevention)	MSAC Assessment 1615
Cardiac patch	Material: synthetic vs. tissue	×	There is no high-quality comparative evidence that these different features are associated with different health outcomes	
	Size: < 25cm² vs 25-75cm² vs >75cm²	×	No distinction made on the basis of size, correct size for patient should not affect grouping	ARTG PSD and product IFU

A.10 Vascular

Table 9 Rational for regrouping of the Vascular Category

Criteria	Options	Distinction	Hereco comments	Supporting information
Stents				
Structure	Balloon vs self-expandable	×	Self-expandable are more technological but still require ballooning. No distinction made.	

Criteria	Options	Distinction	Hereco comments	Supporting information
Length	Longer vs shorter	×	No distinction made on the basis of length, correct size for patient should not affect grouping. Risk of using multiples rather than single large stent.	
Material	Bare metal vs drug eluting	✓	Used for different anatomical locations. Drug eluting remains new technology for peripheral indications.	
Stent Grafts				
Size	Longer vs shorter Larger vs smaller diameter	×	No distinction made on the basis of length or diameter, correct size for patient should not affect grouping	
Structure	Branched vs fenestrated	×	Determined by clinical indication	
Anatomical location	Thoracic vs abdominal (accessory components)	×	Thoracic is newer, however otherwise little difference. Infrequently used additional components.	
Grafts				
Length	Longer vs shorter	×	No distinction made on the basis of length, correct size for patient should not affect grouping	
End treatment/ shape	Tapered or end-modified Heparin coated	×	There is evidence that these different features are **not** associated with different health outcomes	
Material	Ringed Biological	✓	Sufficiently different device characteristics	
Vascular Patches				
Size	Various size options	×	No distinction made	
Peripheral coil				
Type	Standard vs Retractable	×	Standard becoming obsolete	

A.11 Hip

Table 10 Rationale for regrouping of the Hip Category

Criteria	Options	Distinction	Comment	Supporting information
Femoral Stems				
Fixation	cemented vs uncemented	✓	Cementless revision rates higher at all time points for patients ≥75 yrs of age, and at 1 month for 55-74 yrs	NJRR 2021 p107
Stem length	standard vs longer stems	✓	Proxy for revision vs primary surgery, although longer stems can be used in primary procedures (and vice versa). Low usage of longer stems for less frequent revision surgeries supports Benefit differential.	
Modularity (fixed vs exchangeable necks)	single piece stems vs modular systems	✓	Higher revision rates for exchangeable neck (i.e., modular systems)	NJRR 2021: p107; & Table HT24 p114
Modularity (head vs no head)	monoblock hemis vs headless stem	✓	Monoblock hemis include the femoral head. A diminishing technology, substantially cheaper than headless stems. Grouping with standard stems would support inappropriate Benefits.	
Stem shape	calcar vs standard	×	Calcar stem has modified shape but is essentially same as standard stem.	
Coating or finish	grit blast vs beaded vs plasma vs polished vs unpolished	×	Device characteristics insufficiently different	
Modular proximal components	Components that attach to modular stems and have a neck for attaching to a femoral heads	new	Femoral Necks Group renamed and expanded to include similar proximal components currently allocated to stem groups (some currently have a 'Body' suffix). Cones, trochanteric wings and extension pieces have been moved to Augments and Attachments Group.	
Femoral Heads				
Size	≤32 mm vs > 32 mm	×	Device characteristics insufficiently different	

Criteria	Options	Distinction	Comment	Supporting information
Head type	resurfacing vs conventional	✓	Different componentry with different purpose – resurfacing heads replace only the surface of the femoral head.	
Head type	metal-on-metal vs conventional	×	All codes in metal-on-metal group have since been deleted from PL, so this distinction has become obsolete	
Head type	bipolar vs conventional	✓	Supported with improved outcomes using bipolar	NJRR 2021 p9
Head type	bipolar vs tripolar	×	Tripolar devices are bipolar heads that articulate with a specialised liner rather than the native acetabulum. The femoral componentry is not substantially different.	
Material	stainless steel vs cobalt chrome	×	Combine all metal heads into metal subgroup as they perform similarly	
Material	cobalt chrome vs cobalt chrome with LFIT	×	Low-friction ion treatment, or LFIT, is denoted on the PL by the suffix “Low Frequency Ion Treatment”. Insufficient evidence of superior outcomes, and identification of appropriate patient population – metal sensitivity – is problematic.	
Material	alumina vs ceramic mix	×	Combine into ceramic subgroup – alumina is being replaced with second generation ceramic mix.	
Acetabular Components				
Fixation	cemented vs uncemented	✓	Consistent with femoral components	
Component type	cups/shells* vs insert/liner	✓	Different component of acetabular construct – pairs with acetabular component	
Component type	cups/shells* vs bonded shell/liner	✓	Assemblage of two component types – factory bonded acetabular component AND liner.	
Component type	cups/shells* vs resurfacing cup	×	Device characteristics insufficiently different	

Criteria	Options	Distinction	Comment	Supporting information
Component type	cups/shells* vs acetabular reconstruction	✓	Technology somewhat different for specific populations with more extensive bone loss, needing more substantial components to allow spanning across the acetabulum – low usage	
Component type (acetabular reconstruction)	shell vs cage	✓	Different component types	
Material (cups or inserts/liners)	unmodified vs modified polyethylene	×	Diminishing use of unmodified poly, for which outcomes are worse	
Material (inserts/liners)	ceramic vs ceramic mix	×	Combine into ceramic subgroup – alumina is being replaced with second generation ceramic mix.	
Material (inserts/liners)	polyethylene vs ceramic	✓	Different device characteristics due to difference in materials.	
Material (inserts/liners)	polyethylene vs metal	✓	Different device characteristics due to difference in materials.	
Constraint (cups or inserts/liners)	constrained vs unconstrained	×	Device characteristics insufficiently different	
Coating or finish (shells, resurfacing cup)	grit blast vs beaded vs mesh vs plasma vs porous metal vs HA coated	×	Device characteristics insufficiently different	
Augments and Attachments				
Anatomical	Femoral vs acetabular	new	Augments and attachments separated by anatomical location	
Femoral component type	Cones vs diaphyseal extensions vs trochanteric wings/calcar blocks	new	Various femoral component attachments grouped by component type	
Acetabular component type	Acetabular augments vs insert attachments vs insert orientation cup	new	Various acetabular component attachments grouped by component type	
Hip Megaprostheses				
-	-	new	Billing Codes from systems designed for major reconstruction were identified and re-allocated here.	

Criteria	Options	Distinction	Comment	Supporting information
Infection Control and Bone Reconstruction				
-	-	new	Temporary spacers allocated to separate subcategory as they are not components of a permanent hip replacement construct	
-	-	new	Re-allocated from Skeletal Reconstruction. Meshes for impaction bone grafting allocated to separate subcategory as they are not components of a hip replacement construct.	

A.12 Knee

Table 11 Rationale for the proposed regrouping of the Knee Category

Criteria	Options	Distinction	Hereco comments	Supporting information
Femoral Components				
Fixation	**cemented** vs **uncemented**	✓	• Uncemented more commonly used but cemented components are appropriate for certain clinical situations	
Material	**alloy** (CoCr, other?) vs **non-alloy** (ceramicised surface)	×	• Oxinium is a metal (zirconium) with a ceramicised surface, that is, oxidised (zirconia) surface • Billing Codes: ○ are allocated to non-alloy groups and ○ have a "Ceramic Surface" suffix	Insufficient evidence to support Benefit premium. There are claims that patients with metal allergies have better outcomes with ceramicised surfaces but this population is not readily identified.

Criteria	Options	Distinction	Hereco comments	Supporting information

Surface treatment	**alloy** (CoCr, other?)
	vs
	alloy with surface finish
		×	• Two surface finishes:
			  ○ Titanium nitride
			  ○ Zirconium nitride
			• Billing Codes:
			  ○ are allocated to alloy groups
			  ○ also have a "Ceramic Surface" suffix
				Insufficient evidence to support Benefit premium.
				There are claims that patients with metal allergies have better outcomes with ceramicised surfaces but this population is not readily identified.

Constraint level	**minimally stabilised** vs **posterior stabilised**	×	• Subtle differences in form confer significant differences in function • Designed for use in different but overlapping patient populations (with/without posterior cruciate ligament etc)	Clinical advice is not to distinguish as they are not sufficiently different in material or form.
	minimally or posterior stabilised vs **totally constrained** (includes hinged implants)	×	• More substantial differences in form confer significant differences in function • Designed for use in different patient populations	The majority of these devices will remain separated according to surgical procedure: standard versus revision/complex primary procedures.
Surgery type	**revision** vs **primary**	✓	• Revision suffix on over 20% of Billing Codes • Confers ~80% premium on Benefit • Components with revision suffix are often used for non-complex primary procedures. • For femoral components only, create separate subgroups for standard and revision devices based on device or system design (i.e., can take augments and/or stems) ○ the Benefit premium can be applied to these components – tibial revision components differ little to those used for primaries.	

Criteria	Options	Distinction	Hereco comments	Supporting information
Tibial Components				
Fixation	**cemented** vs **uncemented**	✓	• Cemented is more commonly used	
Material	**alloy** vs **polyethylene**	✓	• Polyethylene has lower Benefits than alloy • Polyethylene used in different populations (elderly or low-stress joints) and in resource limited settings	Clinician advice is that poly inserts are an original design, but are falling out of favour because they're not modular. This means you can't easily do revisions (replace part of the device) and when implanting them, you can't build up to the desired height. They are also more likely to result in tibial failure as they transfer force unevenly, placing focused stress on one point. However, they are selectively used in older patients (less stress on the joint) in cost-sensitive settings.
Material	**alloy** vs **alloy with moulded polyethylene**	✓	• Alloy with moulded polyethylene is a tibial tray (tibial component) with a poly insert attached, so a separate tibial insert is not needed.	Separate grouping appropriate to allow additional cost of the insert in addition to the tibial tray component
Coating	**PMMA or HA coating** vs **no coating**	×		Insufficient evidence to support Benefit premium.
Mobility	**mobile** vs **fixed**	×	• Additional lateral motion conferred by axis of rotation between tibial component and insert • Minimal difference in form confers different mechanism of function	Clinical advice is not to distinguish as they are not sufficiently different in patient outcomes.

Criteria	Options	Distinction	Hereco comments	Supporting information
Surgery type	**revision** vs **primary**	×	• Revision suffix on almost 30% of Billing Codes • Confers ~60% premium on Benefits	Components with revision suffix are often used for primary procedures. Devices not sufficiently different to support Benefit premium.
Tibial Inserts				
Constraint level	**minimally stabilised** vs **posterior stabilised**	×	• Subtle differences in form confer significant differences in function • Designed for use in different but overlapping patient populations (with/without posterior cruciate ligament etc)	Clinical advice is not to distinguish as they are not sufficiently different in material or form.
	minimally or posterior stabilised vs **totally constrained** (includes hinged implants)	×	• More substantial differences in form confer significant differences in function • Designed for use in different patient populations	The majority of these devices will remain separated according to surgical procedure: standard versus revision/complex primary procedures.
Patello Femoral Replacement - Femoral Component				
Material	**alloy** (CoCr) vs **non-alloy** (ceramicised surface)	×	• Oxinium is a metal (zirconium) with a ceramicised surface, that is, oxidised (zirconia) surface • Billing Code (n=1): ○ is allocated to non-alloy group and ○ has a "Ceramic Surface" suffix	Insufficient evidence to support Benefit premium. There are claims that patients with metal allergies have better outcomes with ceramicised surfaces but this population is not readily identified.
Patellar Component				
Material	**polyethylene** vs **metal-backed polyethylene**	×	• Low-level use of metal-backed poly • Group together as premium not justified	Clinical advice is not to distinguish as there is insufficient evidence to support Benefit premium for metal-backed polyethylene
Mobility	**mobile** vs **moulded** (fixed)	×	• Mobile confers ~70% premium on Benefits	Insufficient evidence to support Benefit premium.

Criteria	Options	Distinction	Hereco comments	Supporting information
Surgery type	**revision** vs **primary**	×	• One of four Billing Codes have revision suffix • Confers ~60% premium on Benefits	Devices not sufficiently different to support Benefit premium.

A.13 Spinal

Table 12 Rationale for proposed regrouping of the Spinal Category

Criteria	Options	Distinction	Comments	Supporting information
Screws				
Structure	**monoaxial** vs **polyaxial**	×	Device characteristics insufficiently different	
	cannulated vs **non cannulated**	×	Device characteristics insufficiently different	
	Dual thread/expansion screw/expansion head	×	Distinctions not retained, however many of these screws are standalone bone screws and therefore grouped separately to device screws	
Plates				
Fixation	**Integral** vs **no integral fixation**	×	Device characteristics insufficiently different. Additional benefit is obtained via claiming of screws separately.	
Large vs small	**<55cm vs > 55cm**	×	No distinction made on the basis of size, correct size for patient should not affect grouping	
Anatomic location	**Cervical vs thoracolumbar vs occipital vs laminoplasty**	✓	Retained but subject to reconsideration when plates are regrouped in Specialist Orthopaedic	
Fusion cage				
Fixation	**Integral** vs **no integral fixation**	×	Device characteristics insufficiently different. Additional benefit is obtained via claiming of screws separately.	
Anatomic location	**Cervical** vs **thoracolumbar**	×	Device characteristics insufficiently different	

Criteria	Options	Distinction	Comments	Supporting information
Number used per episode	**Single vs paired**	×	Devices are the same, correct number of devices should be determined by patient need.	
Surgical approach	**Anterior** vs **lateral** vs **posterior**	✓	Device characteristics sufficiently different. Enables HTA approach regarding risks and benefits of each surgical approach.	NICE IPG574 https://www.nice.org.uk/guidance/ipg574 NICE IPG620 https://www.nice.org.uk/guidance/ipg620
Artificial Disc Replacement				
Anatomic location	**Cervical** vs **Lumbar**	✓	Consistent with HTA approach	MSAC Application 1145 http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1145-public

A.14 Upper Limb, Ankle and Foot

A.14.1 Ankle and Foot

Table 13 Rationale for the proposed regrouping of the Ankle and Foot Subcategory of the Upper Limb, Ankle and Foot Category

Criteria	Options	Distinction	Comment	Supporting Information
Total Ankle Joint Replacement Group				
Tibial component mobility	**Mobile vs fixed**	×	• Mobile bearing devices have diminishing use as evidence supports fixed bearing constructs	

Criteria	Options	Distinction	Comment	Supporting Information
Liner mobility	**Mobile vs fixed**	×	• Mobile bearing devices have diminishing use as evidence supports fixed bearing constructs	
Metatarsophalangeal Joint Implants Group				
Bone of MTP joint	**Metatarsal vs phalangeal**	×	• No distinction retained – considered insufficiently different to warrant separate grouping	
Component of MTP joint replacement	**Metatarsal head vs metatarsal stem vs phalangeal component**	×	• No distinction retained – three Billing Codes to be rolled up into a single Billing Code for entire construct. • Parts of these constructs are not individually revised	

A.14.2 Wrists, Finger Joint Articulations and Elbow

Table 14 Rationale for the proposed regrouping for Wrist, Finger Joint Articulations and Elbow – now subcategories of the new Upper Limb, Ankle and Foot Category

Criteria	Options	Distinction	Comment	Supporting Information
Wrist Group				
Component type	**Radial components** vs other component types	✓	• Placed under n**ew Radio-carpal Joint Replacement Group**. • Except 1 Billing Code re-allocated to new **DRUJ Group** ○ SK623 – Stability Sigmoid Notch (replaces radio-ulnar joint)	
Finger Joint Articulations Group				
Digit type	**Thumb** vs **finger**	×	• No distinction retained – considered insufficiently different to warrant separate grouping	
Digit bone	**metacarpophalangeal finger** vs **interphalangeal finger**	×	• No distinction retained – considered insufficiently different to warrant separate grouping	
Joint type	**proximal** vs **distal**	×	• No distinction retained – considered insufficiently different to warrant separate grouping	

Criteria	Options	Distinction	Comment	Supporting Information
Elbow Group				
Component type	**Proximal radial stem** vs **proximal radial head/neck**	×	• Grouped together in **Radial Head Components** • Almost always used together • Roll up Billing Codes for stems and heads	
Component type	**Elbow pin** vs **accessories** (bushings or clips or cement restrictor)	×	• Combine elbow pin with elbow accessories in **Elbow Articulation Components** • Roll up multiple Codes from a system into a single Billing Code • There is one Billing Code to be reviewed (Stryker's HW223: Howmedica Modular Resection System, Ulna Joint - Vitallium. Currently allocated to 'Accessories - cement restrictor' with a Benefit of $3,954. This system has 4 Billing Codes in Elbow but there were no claims for any of them since July 2021, so these Codes should be earmarked for removal after checking with Stryker (they may still be available, just low usage).	

A.14.3 Shoulder

Table 15 Rationale for the proposed regrouping for shoulder – now a subcategory of the new Upper Limb, Ankle and Foot Category

Criteria	Options	Distinction	Comment
Shoulder - Humeral			
Fixation	**Cemented** vs **uncemented**	×	Not sufficiently different.
Surgery type	**Short stem** vs **long stem** (i.e., revision)	×	Not sufficiently different – one Billing Code only for a long stem, but it also includes the short stem version, and there are no claims.
Component type	**Humeral neck assembly** vs **metaphyseal component**	×	The two Billing Codes for neck assemblies in the Necks/collar (modular) subgroup have been proposed for rolling up with the respective metaphyseal components

Criteria	Options	Distinction	Comment
Modularity (reverse constructs)	**Modular stem for reverse construct** vs **modular stem for anatomic construct**	×	Currently recognised with 'reverse' suffix There is not currently a Benefit premium for modular vs monoblock anatomic constructs, and the rationale for a Benefit premium for modular vs monoblock reverse constructs is unclear.
Extended lip (humeral heads)	**Extended lip humeral head** vs **standard humeral head**		Currently recognised with 'EL suffix Not sufficiently different.
Shoulder - Glenoid			
Componen t type	**All poly glenoid** vs **glenoid insert** (articulating surface for attachment to separate metal baseplate)	×	Distinction not retained – small polyethylene articulating surfaces are considered insufficiently different to warrant separate grouping Acknowledge that for modular systems there will be two claims rather than one for the glenoid part of construct
Componen t type	**Glenoid baseplate for anatomic construct** vs **glenoid baseplate for reverse construct**	×	Distinction not retained – considered insufficiently different to warrant separate grouping For some systems the same baseplate can be used for either the anatomic or reverse construct
Shoulder - Accessories			
Componen t type	**Reverse humeral tray** vs **anatomic metaphyseal component**	×	Distinction not retained – the new subgroup includes proximal parts of modular humerus for both anatomic and reverse constructs ○ while physically dissimilar, these are functionally similar in that they provide the metaphyseal portion of the construct

Appendix B Billing Codes for Review

Table 16 Billing Codes marked for review

Category	Billing Code(s)	Device/s	Action/Issue	Comments
02 – Ear, Nose & Throat	OI027	Ponto Healing Cap	Flagged for removal	Removal of device because acts as an external dressing for the protruding implant rather than a cover screw
02 Ear, Nose & Throat	CO032 OI026 CO063 CO053 OI031	Flange fixture - self tapping fixture with pre-mounted abutment Ponto Abutment and Implant Cochlear ™ Baha® BIA400 Implant with Abutment Baha BIA300 implants with abutments Ponto BHX Implant and Abutment	Flagged for removal	Removal of multi-component Billing Codes as individual components are also listed separately
02 – Ear, Nose & Throat	WA007 WA006	Biodesign Otologic Repair Graft (small) Biodesign Otologic Repair Graft	Error in current listing	The product subgroup for these repair grafts are 02.01.08.01 - Xenografts, Small (≤10cm2) and 02.01.08.02 - Xenografts, Medium (>10cm2 to 50cm2). The largest size for the devices however is 5cm x 5cm and it appears that the current measurements are incorrect and perhaps should be mm instead of cm
02 – Ear, Nose & Throat	JI001 JI007 JI008	Tracheobronxane Silmet *(nitinol)* Aerstent *(nitinol)* GSS & Dumon *(silicone)*	Large benefit heterogeneity	These 3 tracheal stents have a a large benefit - the two nitinol stents have a benefit of $2256 while the silicone stent is $903. It's unclear what, if any, additional clinical benefits the nitinol stents provide given that the clinical advice is that they are rarely used in ENT and are rather used in cardiothoracic for palliative care.

Category	Billing Code(s)	Device/s	Action/Issue	Comments
02 – Ear, Nose & Throat	BQ007	ProTrach DualCare Set	Device eligibility	This device is at a higher benefit ($628) than the other five tracheal speaking valves ($92) in this group. This is because it is a set which includes additional devices (180pc HME Regular, 1pc Speaking Valve, 1pc ProTrach HME DigiTop, 1 Removal Aid and 1 connection strap). The tracheal speaking valve in this kit is also listed separately. It is unclear whether this should be grouped separately.
03 – General Miscellaneous	12 Billing Codes flagged in spreadsheet	Pleural and Para/Thoraceulesis Drainage Catheters	Remove Device	Single use items for a transient purpose. The pleural catheters are analogous to abdominal wound drains and the para/thoraceulesis catheters are analogous to IV drips, both of which are not listed on the PL. CIRG advised ineligible.
03 – General Miscellaneous	ET092 ET093	Surgisis Biodesign Anal Fistula Plug Surgisis Biodesign Recto-Vaginal Fistula Plug	Remove Device	Similar to topical fibrin glue as it is not permanent and also absorbs. Topical fibrin glue has been removed from the PL. CIRG advised ineligible.
04 – Neurosurgical	84 Billing Codes flagged in spreadsheet	Revision Kits and Accessories	Device eligibility	These devices are either already included in the kit of the implanted device or are standalone devices that are not implanted and are assistive devices for implantation.
04 – Neurosurgical *and* 10 – Vascular	All Billing Codes in proposed group 04.01.04 and 10.03.07	Microcatheters and embolisation balloons	Eligibility of devices for listing is unclear	Devices are used to deliver other devices listed on the PL, however catheters brands are interchangeable and not specific to a specific device.
05 – Urogenital	GN001, GN002, LH376, SC001, LH379	Injectable bulking agents; Opsys Injectable, BULKAMID Uretheral Bulking System and Durasphere	No valid ARTG for 5 of 6 Billing Codes in the group	

Category	Billing Code(s)	Device/s	Action/Issue	Comments
05 – Urogenital	BS185, BS186, BS187, BS188	Xenform Soft Tissue Repair Matrix (multiple sizes)	ARTG number not valid and has been withdrawn from market worldwide	Withdrawal follows the United States Food and Drug Administration (US FDA) decision to withdraw all surgical mesh indicated for transvaginal repair of pelvic organ prolapse in the US market due to insufficient clinical evidence available to assure that the benefits of these devices outweigh their probable risks. Note that slings remain on the PL and have valid ARTG numbers (05.01.02 - Slings)
06 – Specialist Orthopaedic	HW375 ZI182 LV071(?)	All (incorrectly) classified as suture anchors. No longer in commercial distribution.	Remove listing - not commercially available	
06 – Specialist Orthopaedic	LC187 SK216 SK245 ST043	Set Screw/Locking Bolt for Intramedullary Nails	Devices unclear	Unclear whether the device is a set screw or locking bolt. Further information is needed to regroup the devices.
06 – Specialist Orthopaedic	OY001, OY002 and OY003	Intramedullary Femoral Stem Type A, B & C	Collapse superfluous Billing Codes into one Billing Code	There are three types of femoral fixtures, each with a separate Billing Code. But they all have the same Benefit ($35,055), so a single Billing Code would suffice. The device description in the ARTG Public Summary is “External Adapter - extra-cutaneous attachment for the artificial limb”, which does not match the component type (intramedullary femoral stem).
06 – Specialist Orthopaedic	12 Billing Codes listed in Comments	External Fixator components	Clarify component types with sponsor	Unable to allocate the following Billing Codes due to insufficient information: SY236, HW854, SY746, ST971, ST972, SY237, VK003, VK004, VK005, SY200, SY239, SY242
06 – Specialist Orthopaedic	HW845 and HW960	SALVATION Limb Salvage Full Rings	Flagged duplicated Billing Code for removal	Duplicate Billing Codes HW845 has a subset of sizes specified in HW960, so HW845 could be removed. Neither Billing Code has any claims.
06 – Specialist Orthopaedic	HW846 and HW959	SALVATION Limb Salvage Partial Ring	Flagged duplicated Billing Code for removal	Duplicate Billing Codes with overlapping sizes. Neither Billing Code has any claims.
06 – Specialist Orthopaedic	HW854 and HW964	SALVATION Limb Salvage Struts	Flagged duplicated Billing Code for removal	Duplicate Billing Codes with same sizes, just slight differences in Product Name and Description. Neither Billing Code has any claims.

Category	Billing Code(s)	Device/s	Action/Issue	Comments
06 – Specialist Orthopaedic	HW481	HOFFMANN LRF - THREADED TELESCOPIC ROD	Product Name in Billing Code mislabelled	The rods in the Hoffmann LRF system are NOT telescopic.
06 – Specialist Orthopaedic	ST947, ST945 and ST946	Anodized metal alloy, dynamic tube assembly rod (sic) i.e., red, yellow & blue	Flagged redundant Billing Codes for removal	These assemblies are simply one tube and two couplers, and each of these components are also listed separately.
06 – Specialist Orthopaedic	HU209	iBalance HTO System – Medial High Tibial Osteotomy Implant Device System	Billing Code not yet allocated to a category	This device is allocated to Skeletal Reconstruction> Surgical Accessories> Wedges in the current PL, but this subgroup has been deleted in the proposed structure. The device is a specifically shaped implant designed to insert into the gap created during tibial osteotomy. As it is not part of a knee joint replacement, it does not belong in the Knee Category. Peter Lewis suggested it could be allocated with preformed, anatomically specific plates (06.02.02.01 – Proximal and Distal Long Bones). However, it is made of PEEK (polyether ether ketone), while all the plates are metal. This has not been discussed at CIRG.
07 – Plastic and Reconstructive	WC264	SYSTEM- Doppler Blood Flow Monitoring System. COMPONENT - Cook-Swartz Implantable Doppler Flow Probe	Device eligibility	The clinical advice was that it is not left in permanently and therefore may not be eligible for listing.
07 – Plastic and Reconstructive	KT022 SY406	Cross Bar/Rods	Duplicate listing	Cross bars/rods are already included in the complete sets for the Martin Distraction Osteogenesis Rigid External Distraction (Polley RED II) and External Midface Distractor System. There are rarely any procedures where more cross bars/rods than the amount supplied are used.
07 – Plastic and Reconstructive	KT020	External Distractor Component	Device unclear	Device appears to be a component of the Martin Distractor System however it is unclear what the device is. Unable to regroup device without further information.
09 – Cardiac and Cardiothoracic	BS329	Emblem MRI S-ICD Pulse Generator	Query eligibility for listing given no corresponding MBS number	Subcutaneous ICDs are a significantly different technology compared to standard transvenous ICDs. Currently there is no MBS item for the insertion of a subcutaneous lead after MSAC deferred its advice on the technology in April 2021 (see MSAC PSD). Note that MSAC has recently considered the related question of leadless pacemakers.

Category	Billing Code(s)	Device/s	Action/Issue	Comments
09 – Cardiac and Cardiothoracic	Group 09.01.05	Implantable Cardiac Event Recorders and Remote Monitoring Hardware	Eligibility of devices and mechanism for funding	Majority of devices in these categories are from Part C. Eligibility and funding dependent on further review.
10 – Vascular	VA001	Vessel Bands - Venous Valve Ring	No valid ARTG and not clinically supported	
11 – Hip	Femoral heads	Conventional Femoral Heads, ≤32mm vs >32mm	Collapse large and small size Billing Codes into single Billing Code	Size is no longer recognised for femoral heads, which allows over 80 femoral head Billing Codes to be collapsed into other existing Billing Codes. Size information will need to be updated.
11 – Hip	DP173	PLAD Acetabular Rim Augment	Flagged for removal	Technology found to be problematic and is no longer used.
11 – Hip	BI125 BI131	Modular Calcar Mallory Head Revision Hip System	Flagged for removal	Corresponding stem no longer listed
11 – Hip	BI131	Mallory Head Hip System	Flagged for removal	Corresponding stem no longer listed
11 – Hip	ZI025	Zimmer VerSys CRC Hip Systems Femoral Stem	Flagged for splitting to create additional Billing Code for short stems	This Billing Codes includes stem lengths from 170 - 300 mm. Since 8 of 11 options are ≥200 mm, proposed allocation is 11.01.01.02 - Cemented Stems, Long (≥200 mm).
11 – Hip	ZI376	Cone Hip prosthesis	Wrong ARTG#	Correct one: 216270
11 – Hip	MU058	Quadra-R Hip Revision Stem	Flagged for splitting to create additional Billing Code for longer stems	This Billing Codes includes the following stem lengths: 170, 180, 195, 200 & 215 mm. Since 3 of the 5 options are <200mm, proposed allocation is 11.01.01.03 - Uncemented Stems.

Category	Billing Code(s)	Device/s	Action/Issue	Comments
11 – Hip	LC158	H-Max M Femoral Stem Ti6AI4V	Query sponsor about unlisted neck (is it included with stem?)	H-Max M - the M is for modular but the corresponding neck is not listed. This stem is being claimed, however.
11 – Hip	LO026	Link spacer	Flagged for removal	ARTG# is invalid, but this appears to have been made redundant by more recently listed LO187 for same thing (Link MP Reconstruction Proximal Spacer)
11 – Hip	TG003	Furlong Hemi Range	Flagged for removal	This is a bipolar head but no bipolar heads are currently listed on the ARTG for this sponsor.
11 – Hip	SF047	Signature Delta Femoral Head >=36mm	Clarify material with sponsor	This is described as a "Cobalt Delta Femoral Head" so it is unclear whether this is a ceramic or metal head. The ARTG Public Summary says it is Biolox Delta ceramic, yet it's allocated to the CoCr subgroup on the current PL.
12 – Knee	20 Billing Codes listed in Comments	Femoral or tibial augments	Flagged for splitting to create additional Billing Code for tibial augments	Some Billing Codes specify either femoral or tibial augments, but these are to be allocated to separate subgroups in the proposed structure. The following Billing Codes have been allocated to the proposed Femoral Augments Subgroup, but need to be split to create additional Billing Codes to allocate to the proposed Tibial Augments Subgroup: LH614, BV043, BB380, GO260, MN225, MA508, BB320, LO180, BB355, SN330, CR255, LO166, LH652, LH678, BI866, LI065, ST018, SF133, CR253, CR264
12 – Knee	DP004 and DY368	LCS Complete Knee System femoral component	Clarify difference with sponsor	Billing Code product name and descriptions, sizes and ARTG# are the same, but one (DY368) has a revision suffix and twice the Benefit. The Billing Code without the suffix is claimed more frequently. It may be these are the same device but the Billing Code with the suffix is intended for claims where revision surgery is performed.
12 – Knee	CR249 and CR258	Unity Knee - Cruciate Retaining Femur Cemented	Flagged duplicated Billing Code for removal	Duplicated Billing Code - CR249 is claimed while CR258 is not, so flagging CR258 for removal.
12 – Knee	EX031 and FA008	Optetrak (Logic) Total Knee System Femoral Component	Flagged superseded Billing Code for removal	EX031 has an invalid ARTG# and appears from claims pattern to have been superseded by FA008, which has a valid ARTG#. FA0087 includes 'Logic' in the Product Name, but is otherwise identical to EX031.
12 – Knee	BB196	E.motion Total Knee System – Posterior Stabilised Knee Component cemented	Specify revision version in Product Name	Billing Code needs to indicate this relates to the revision component of this system, to distinguish it from non-revision components

Category	Billing Code(s)	Device/s	Action/Issue	Comments
12 – Knee	LI063	Score Knee System Femoral Component	Specify revision version in Product Name	Billing Code needs to indicate this relates to the revision component of this system, to distinguish it from non-revision components
12 – Knee	GO284	Apex Revision Knee Modular Tibia Cup	Product Name may include a typo – clarify with sponsor	Product Name is “Apex Revision Knee Modular Tibia Cup” but this is allocated to the End Caps Group in the current PL, and there is no such thing as a tibial cup. This Billing Code is not being claimed so perhaps query whether sponsor wished to delete the Billing Code instead.
12 – Knee	BH134 and BH135	Orthopaedic Salvage System – Tibial Component, Resurfacing or Segmental, Non-Modular tray, CoCr, Ti	Flagged duplicated Billing Code for removal	Duplicated Billing Code – both are being claimed.
13 – Spinal	LH456 LH457	DSS fusion coupler and spinal fusion system	Error in listing and device eligibility	The DSS fusion coupler (LH457) and the set screw (LH456) are currently listed as 'rod, telescoping'. Clinical advice is that it is not approved for use and should not be listed without further assessment (the system is designed for dynamic (ie. non rigid) stablisation). It is not completely clear that the listing is for the Fusion coupler rather than the Dynamic coupler (a non-fusion device). The ARTG number (151022) listed for the device system is incorrect and refers to a different device, Colflex (LH483). The pedicle screw and its components also have the incorrect ARTG# (LH450, LH452, LH451, LH453)
14 – Upper Limb, Ankle and Foot	HW381	Radial Head Prostheses	Flagged for removal	No corresponding radial stem listed.
14 – Upper Limb, Ankle and Foot	ZA110	Comprehensive Reverse Humeral Cup	**Remove suffix**	The ZA110 Billing Code is for a UHMWPE articulating insert and was listed in Mar22. However, it has been inappropriately attributed a ‘reverse’ suffix, which was created for monoblock reverse stems, i.e., a completely different component type. ZA110 differs from BH055 only in being impregnated with Vitamin E and 4mm smaller in diameter (for mini tray), yet the suffix means the Benefit is $2,358 instead of $774.
14 – Upper Limb, Ankle and Foot	HW860 and HW965	INVISION Talar Component – Talar Dome	Flagged duplicated Billing Code for removal	These Billing codes are identical except HW965 size specifies both standard and thick while HW860 does not specify thickness. HW860 is being claimed but HW965 is not.

Category	Billing Code(s)	Device/s	Action/Issue	Comments
14 – Upper Limb, Ankle and Foot	LH673 and LH685	MUTARS Ulna Anchorage Component	Flagged duplicated Billing Code for removal	These Billing codes are identical except LH685 has range of sizes (70-100mm) while LH673 has one size (70mm). Both are claimed, albeit very infrequently.