EXPLANATORY STATEMENT

Private Health Insurance Act 2007

Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023

Purpose

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* (MDHTP Rules) is to remake the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023* (Previous Rules) to update the list of the kinds of medical devices and human tissue products for which a benefit must be paid, where the listed item is provided in the conditions and circumstances specified in the *Private Health Insurance Act 2007* (Act). The MDHTP Rules set out the minimum benefit payable for each listed item.

Listed items and their minimum benefits are set out in Schedule 1 to the MDHTP Rules. Schedule 1 to the MDHTP Rules is known as the List of medical devices and human tissue products (Prescribed List).

The Prescribed List has four parts:

- Part 1 - Part A – Medical Devices
- Part 2 - Part B – Human Tissue Products
- Part 3 - Part C – Other Medical Devices
- Part 4 - Part D – General Use Items (medical devices)

The MDHTP Rules also outline circumstances in which various assessments in relation to listing and variation applications are required and the associated fee for that assessment, and cost-recovery provisions, including the timing for when cost-recovery fees become due and payable, and when cost-recovery fees can be refunded and waivers can be granted.

In line with Australian Government Cost-Recovery Guidelines, the MDHTP Rules will be updated annually to ensure they accurately reflect the efficient costs of providing services. Fees are calculated using an activity-based cost model. This ensures that the contemporary costs incurred by the Department of Health and Aged Care (the Department) when providing services relating to the assessment of applications to list or vary the Prescribed List, are accurately reflected in fees.

The MDHTP Rules differ from the Previous Rules by:

- adding 207 new listed items (billing codes) to Part A of the Prescribed List as a result of listing medical devices following successful new applications [including 6 billing codes listed with the new conditions], 5 billing codes as the result of expansion applications, and 35 new billing codes due to transfer of billing codes from one sponsor to another;
- changing the listing details of 153 billing codes in Part A of the Prescribed List following the successful amendment applications from the sponsors;
- deleting 40 billing codes from Part A of the Prescribed List, as a result of accepting4 deletion applications submitted by the sponsors, removing 34 billing codes after transferring billing codes to the new sponsors, removing 2 billing codes following completion of expansion applications;
- adding 11 new billing codes to Part B of the Prescribed List as a result of listing the human tissue products following successful new applications;
- changing the listing details of 30 billing codes in Part B of the Prescribed List following successful amendment applications from the sponsors;
- deleting 14 billing codes from Part B of the Prescribed List as a result of accepting deletion applications submitted by the sponsor;

- adding 11 new billing codes to Part C of the Prescribed List, following successful new applications;
- changing the listing details of 1 billing code in Part C of the Prescribed List following a successful application
- changing the listing details of 2 billing codes in Part D of the Prescribed List following successful applications to clarify current billing codes.

The numbers of Prescribed List billing codes were taken from reports produced by the Prostheses Listing Management System (PLMS) when the final list was run.

In addition to the changes described above, the MDHTP Rules also add one listing criterion for medical devices to be listed in Part C of Schedule 1. This criterion is in paragraph 16(2)(p): *a medical device that is a radiofrequency delivery device for transurethral water vapour ablation (TUWA)*.

The MDHTP Rules also change the condition stated for 11 billing codes in Part A of the Prescribed List. The devices listed under the billing codes are manufactured from material Carbon/Peek that provides clinical benefit when implanted in patients with advanced stage tumours and metastases where frequent magnetic resonance imaging (MRI), computerised tomography (CT), Radiotherapy and Proton therapy are required for radiotherapy planning and treatment and evaluation of tumour progression. There is no sufficient evidence available to demonstrate that for any other indications the devices are no less effective than other medical devices listed on the Prescribed List. The condition specifies that the billing codes: *Only to be reimbursed when used in patients with spinal tumours requiring regular magnetic resonance imaging (MRI) and/or computerised tomography (CT) imaging and or adjuvant radiotherapy and/or proton therapy*.

Further, the MDHTP Rules apply the condition onto 35 billing codes for surgical guides and biomodels in Part A of the Prescribed List, that must be satisfied in relation to the provision of the listed items. This follows a post-listing review of these devices to test whether they satisfy the criteria for listing and the circumstances in which they should be reimbursed. The review found that there is evidence to demonstrate that surgical guides and biomodels are clinically effective when used in craniomaxillofacial surgery procedures involving insertion of a medical device, but there is insufficient evidence to support listing of these billing codes for any other types of surgeries and that the PL reimbursement of the devices should be restricted in respect to number of devices reimbursed per procedure. Accordingly, the condition specifies that: *Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1, and for no more than 3 devices per procedure*.

The MDHTP Rules also change the benefits for 12 billing codes in Part D in subgroups of pleural and para/thoraceulesis drainage catheters to correct the benefits due to missing reductions in March and July 2023 and change the benefits for 3 billing codes in Part A.

When Prescribed List billing codes are transferred from one sponsor to a different sponsor, or billing codes are compressed or expanded following the respective application, the Prescribed List billing codes that they are transferred, or expanded, or compressed from are deleted.

Background

The table in subsection 72-1(2) of Part 3-3 of the Act (Table) provides for benefit requirements a complying health insurance policy that covers hospital treatment must meet. Under item 4 of the Table, there must be a benefit for the provision of a medical device or human tissue product, of a kind listed in the MDHTP Rules, in specified circumstances and under any specified conditions. The specified circumstances are that the listed item is provided in circumstances in which a medicare benefit is payable or in other circumstances which may be set out in the MDHTP Rules. The specified conditions are any that may be set out in the MDHTP Rules.

If the complying health insurance policy also covers hospital-substitute treatment then under item 4 of the Table, the same requirements apply.

Subsection 72-10(2) of the Act provides that a person may apply to the Minister to have the Private Health Insurance (Medical Devices and Human Tissue Products) Rules list a medical device or human tissue product of the kind to which the application relates to (listed item). The applicant for these applications is known as the 'applicant' and for a listed item, the 'sponsor' is the person who made the listing application as a result of which the device or product was listed.

Authority

Item 4 of the table in section 333-20 of the Act provides that the Minister may make Private Health Insurance (Medical Devices and Human Tissue Products) Rules, providing for matters required or permitted by Part 3-3 of the Act, or necessary or convenient in order to carry out or give effect to Part 3-3 of the Act.

Subsection 72-10(5) of the Act applies if the Minister grants the application and the applicant pays any cost-recovery fee that the applicant is liable to pay in relation to the initial listing of the kind of medical device or human tissue product to which the application relates. If the Minister grants the application and the applicant pays the cost-recovery fee then the Minister must list the kind of medical device or human tissue product the next time the Minister makes or varies the MDHTP Rules.

Subsection 72-10(6) of the Act provides that the Private Health Insurance (Medical Devices and Human Tissue Products) Rules may set out criteria that must be satisfied in order for an application to be granted.

Section 72-15 of the Act provides for the MDHTP Rules to specify cost-recovery fees for activities carried out by, or on behalf of, the Commonwealth in connection with the performance of functions, or the exercise of powers, conferred by or under the Act in relation to the listing of kinds of medical devices and human tissue products in the MDHTP Rules.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

In addition to the power to make this instrument under section 333-20 of the Act, subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Commencement

The MDHTP Rules commence on 1 November 2023.

Consultation

The rule-maker had regard to recommendations made by the Prostheses List Advisory Committee (PLAC) and the Medical Device and Human Tissue Advisory Committee (MDHTAC) (whatever committee was in place at that time). The PLAC and MDHTAC took into consideration advice provided by clinicians with appropriate knowledge and expertise in the (then) Clinical Advisory Groups, (then) Panel of Clinical Exerts, and Expert Clinical Advisory Groups, and advice provided by the Medical Services Advisory Committee where required.

Applicants who applied under subsection 72-10(2) of the Act for the listing of medical devices or human tissue products in the MDHTP Rules or amending the existing billing codes for listed items

had opportunities to provide further information and clarification regarding their devices and products during assessment of their applications.

Further, the MDHTP Rules have been made following consultation with the sponsors of the medical devices and human tissue products affected by the changes which are explained below. Specifically, consultation with stakeholders occurred in relation to the listing criteria and the cost-recovery fees. Measures for these matters were developed through the use of consultation papers and webinars.

Prescribed List reforms
The Prescribed List (former Prostheses List) and its arrangements have been subject to the reforms announced in the 2021-22 Budget, building on the previous reform activities. These reforms are being implemented over a number of years with transitional arrangements.

The aim of these reforms includes improving sustainability of private health insurance and measures include better aligning the Prescribed List benefits with the prices paid in the public hospital system, better defining the scope of the Prescribed List, and clarifying that the general use items are not eligible for listing on the Prescribed List.

General

The MDHTP Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the MDHTP Rules are set out in **Attachment A.**

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the Human Rights (Parliamentary Scrutiny) Act 2011. A full statement of compatibility is set out in **Attachment B**.

ATTACHMENT A

Details of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023*

Part 1 − Preliminary

Section 1 Name

Section 1 provides that the name of the instrument is the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023.*

Section 2 Commencement

Section 2 provides that the instrument commences on 1 November 2023.

Section 3 Authority

Section 3 provides that the instrument is made under item 4 of the table in section 333-20 of the *Private Health Insurance Act 2007*.

Section 4 Repeal

Section 4 repeals the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023.*

Section 5 Definitions

Section 5 defines certain terms used in the instrument, and notes that some expressions used in the instrument have the same meaning as in the Act.

Section 5 includes a definition of 'implantable medical device' and 'active implantable medical device' with the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* (regulations). These regulations are incorporated by reference into the MDHTP Rules, as in force from time to time. These regulations and the MDHTP Rules are both subject to Parliamentary scrutiny and are disallowable legislative instruments. Therefore, as provided for by paragraph 14(1)(a) of the *Legislation Act 2003*, the regulations may be incorporated by reference into the MDHTP Rules, as in force from time to time. The regulations are freely available online on the Federal Register of Legislation.

Section 5 includes a definition of 'listed item' to refer to the kinds of medical devices and human tissue products that are listed in Schedule 1 of this instrument. The list of medical devices and human tissue products in Schedule 1 is known as the Listed medical devices and human tissue products (**Prescribed List**).

Section 5 also includes a definition of 'National Law' which refers to state and territory legislation that regulates health practitioners. The definition defines the National Law on the basis of the legislation in force at the commencement of the MDHTP Rules (not as amended from time to time). This National Law is freely available on state and territory legislation registers.

Section 5 also includes a definition of 'specified listed item' to refer to those particular listed items, for which the method for calculating specified benefits are outlined in section 10.

Section 6 Meaning of *medical device*

Section 6 provides that a medical device listed in Part D of the Prescribed List is taken to meet the definition of *medical device* in paragraph 72-11(1)(b) of the Act, if listed immediately before 1 July 2023 in the 'former prostheses list'. Reference to the 'former prostheses list' means the Schedule to the *Private Health Insurance (Prostheses) Rules (No. 1) 2023* (as in force before that instrument was repealed).

Part 2 Benefit requirements for private health insurance policies that cover hospital treatment and hospital-substitute treatment

Section 7 Listing of medical devices and human tissue products

The table in subsection 72-1(2) of the Act (the Table) sets out requirements a policy that covers hospital treatment must meet in order for the policy to be a complying health insurance policy under section 63-10 of the Act. Item 4 of the Table provides that there must be a benefit for hospital treatment covered under the policy and hospital-substitute treatment, where the policy also covers hospital-substitute treatment. The benefit applies for hospital treatment or hospital-substitute treatment that involves the provision of a listed item:

- in the circumstances in which a medicare benefit is payable or those other circumstances set out in the MDHTP Rules; and
- when the conditions set out in the MDHTP Rules, if any, are also satisfied. If the conditions are not satisfied, there is no benefit required even if the listed item is provided in the circumstances as set out either under the Act or the MDHTP Rules.

Section 7 specifies the list of medical devices and human tissue products for the purposes of item 4 of the Table. Section 7 provides that Prescribed List sets out these listed items.

The first note under Section 7 provides that if the Minister grants a listing application, the instrument must list the medical device or human tissue product to which the application relates and must set out the minimum benefit for the device or product, and if considered appropriate, set out the maximum benefit for the device or product.

The second note under Section 7 provides that if an applicable cost-recovery fee is not paid for the application to list a medical device or human tissue product, then that medical device or human tissue product may be removed from the Prescribed List.

Section 8 Circumstances in which listed items are provided—other than circumstances in which a medicare benefit is payable

Section 8 specifies circumstances for the purposes of paragraph (d) of the column headed "There must be a benefit for…" in item 4 of the Table in subsection 72-1(2) of the Act. A benefit must be payable under a complying health insurance policy for covered hospital treatment and hospital-substitute treatment (if the policy covers hospital-substitute treatment) for provision of a listed item that is associated with podiatric treatment by a registered podiatric surgeon.
This is the case even if a medicare benefit is not payable for the provision of that listed item.

The note in section 8 provides that the provision of a listed item in circumstances in which a medicare benefit is payable is dealt with in paragraph (c) of the column headed "There must be a benefit for…" in item 4 of the Table in subsection 72(1)(2) of the Act.

Section 9 Conditions to be satisfied in relation to the provision of listed items

Section 9 specifies conditions that must be satisfied in relation to the provision of a listed item. Under paragraphs (c) and (d) of the column headed "There must be a benefit for…" in item 4 in the Table in subsection 72-1(2) of the Act, the MDHTP Rules may set out conditions that must be satisfied in

relation to the provision of a listed item in circumstances in which a medicare benefit is payable, or in the circumstances set out in section 7. If these conditions are not satisfied, no benefit is payable under a complying health insurance policy that covers hospital treatment or hospital-substitute treatment.

Subsection 9(2) provides that the conditions that must be satisfied in the case of a listed item are those conditions specified (if any) under the heading 'Condition' for that listed item in the Prescribed List. There are 120 billing codes listed in the Prescribed List which have a condition.

If the listed item is for an insulin infusion pump, in addition to any statement of requirement which is set out in the Schedule, the professional service associated with providing the insulin infusion pump to the patient must be:

(i) a professional attendance by a consultant physician in the practice of the consultant physician's specialty;
(ii) be provided as a certified Type C procedure or a certified overnight Type C procedure;
(iii) provided for the purpose of administering insulin.

The note in section 9 provides that item 4 of the table sets out other requirements in relation to benefits for the provision of listed items that a policy that covers hospital treatment must meet. These requirements relate to benefits for hospital treatment and, if the policy covers hospital substitute treatment, to the benefits of that coverage as well.

The listed items and billing codes with conditions include:

- AT076 (*Anatomics Biomodel*)*;*
- AT085 (*Anatomics Surgical Guide*);
- AT085 (*Anatomics Patient Specific Surgical Guide*);
- AT008 (*Anatomics Patient Specific Surgical Guide*);
- BF025 (*Pedicle Screw*);
- BF026 (*Pedicle Screw*);
- BF027 (*Locking Element*);
- BF028 (*Rods, Curved*);
- BF029 (*Rods*);
- BF031 (*MixMax Bone Cement*);
- BX343 (*HEMOSTAT SEALING HAEMOSTAT*);
- BX344 (*HEMOSTAT SEALING HAEMOSTAT*);
- CR032 (*Lars Ligament Augmentation reconstruction system*);
- CR201 (*Ligament Augmentation & Reconstruction System (LARS) AC30RA*);
- CR202 (*Ligament Augmentation & Reconstruction System (LARS) LAC 20*);
- CR203 (*Ligament Augmentation & Reconstruction System (LARS) LAC 30*);
- CR204 (*Ligament Augmentation & Reconstruction System (LARS) MCL 32*);
- CR205 (*Ligament Augmentation & Reconstruction System (LARS) - Rotator Cuff CR 25*);
- CR206 (*Ligament Augmentation & Reconstruction System (LARS) - Rotary Cuff CR 30*);
- CR214 (*LARS Reinforcer Ligament*);
- DE669 (*icotec Pedicle System Polyaxial Screw);*
- DE670 (*icotec Pedicle Screw System Rod*);
- DE671 (*icotec Pedicle Screw System set screw*);
- DE678 (*icotec Anterior Cervical Plate System – Screw*);
- DE679 (*icotec Anterior Cervical Plate*);
- DE680 (*icotec Anterior Cervical Plate*);
- DE818 (*BlackArmour Carbon Fibre/PEEK Curved / Multicurved Rods*);

- HI001 (*DDN Guide*);
- HI002 (*DDN Biomodel*);
- HI005 (*DDN Biomodel*);
- HI006 (*DDN Guide*);
- HU267 *(Cerclage System);*
- HW544 (*Stryker Anatomical Biomodel for Mandible*);
- HW546 (*Stryker Anatomical Biomodel for PEEK);*
- HW650 (*VSP Orthognathics Bundle (Surgical Guide and Implants));*
- HW651 (*VSP Orthognathics Bundle (Custom Biomodel and Implants));*
- HW652 (*VSP Reconstruction Maxillofacial Case Bundle);*
- HW653 (*VSP Reconstruction Mandibular/Maxillary Case Bundle);*
- HW678 *(Monterey AL, Cage with integral fixation);*
- HW776 (*Cayman United Plate*);
- HW785 (*AutoPlex Mixer and Delivery System with VertaPlex HV);*
- HW856 (*Augment Bone Graft – rhPDGF-BB component*);
- IJ022 (*Regenerative Dural Repair Patch (ReDuraTM*));
- IJ023 (*Regenerative Dural Repair Patch (ReDuraTM));*
- IJ024 (*Regenerative Dural Repair Patch (ReDuraTM));*
- IJ025 *(Regenerative Dural Repair Patch (ReDuraTM));*
- KN004 (*Invictus Spinal Cement System*);
- KT004 (*UNIQOS Patient Specific Anatomical Biomodel*);
- KT005 (*UNIQOS Patient Specific Surgical guides*);
- LB088 (*CREO Stabilization System Locking Cap);*
- LB089 (*CREO Stabilization System Preassembled Monoaxial Screw*);
- LB181 (*REFLECT STAPLE*);
- LH719 (*TissuePatchDural 50* 25*);
- LH720 (*TissuePatchDural 50 * 50*);
- LH721 (*TissuePatchDural 50*100*);
- LH722 (*TissuePatchDural 100*100;)*
- LH723 (*TissuePatchDural 100*25*);
- LH765 (*Neodura Dural Repair Patch ≤10cm^2*)
- MA545 (*Ligamys DIS Suture with button*);
- MI402 (*Cobalt™ XT DR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI403 (*Cobalt™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI404 (*Crome™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI405 (*Cobalt™ XT DR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI406 (*Cobalt™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI407 (*Cobalt™ XT VR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI408 (*Cobalt™ VR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI409 (*Crome™ VR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI410 (*Cobalt™ XT VR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI411 (*Cobalt™ VR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI412 (*Crome™ VR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI413 (*Crome™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring*);

- MI416 (*Cobalt™ HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI417 (*Cobalt™ HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI418 (*Crome™ HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI419 (*Crome™ HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI420 (*Cobalt™ XT HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI421 (*Cobalt™ XT HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI422 (*Crome™ HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI423 (*Crome™ HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI424 (*Cobalt™ XT HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI425 (*Cobalt™ XT HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI426 (*Cobalt™ HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI427 (*Cobalt™ HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring*);
- MI439 (*Percepta Quad MRI SureScan CRT-P with BlueSync mobile remote monitoring*);
- MI440 (*Percepta MRI SureScan CRT-P with BlueSync mobile remote monitoring*);
- MI441 (*Serena Quad MRI SureScan CRT-P with BlueSync mobile remote monitoring*);
- MI442 (*Serena MRI SureScan CRT-P with BlueSync mobile remote monitoring*);
- MI446 (*Azure XT SR MRI SureScan with BlueSync mobile remote monitoring*);
- MI447 (*Azure S SR MRI SureScanTM with BlueSync mobile remote monitoring*);
- MI448 (*Azure XT DR MRI SureScan with BlueSync mobile remote monitoring*);
- MI449 (*Azure S DR MRI SureScan with BlueSync mobile remote monitoring;*
- MI480 *(Intervertebral Fusion Staple);*
- MV007 (*MGuide*);
- OG001 (*OMX Solutions patient Optimized Guide system*);
- OG004 (*The OMX Solutions Biomodel*);
- OW014 *(StabiliT Bone Cement & Saturate Mixing System);*
- SJ417 *(Gallant VR ICD Model CDVRA500Q);*
- SJ418 *(Gallant DR ICD Model CDDRA500Q;*
- SJ424 *(Gallant HF CRT-D Model CDHFA500Q);*
- SJ482 *(Navitor™ Transcatheter Aortic Valve).*
- SK494 *(DuraMatrix);*
- SY775 (*PSI)*;
- SY777 (*ProPlan)*;
- SY778 (*ProPlan)*;
- SY779 (*ProPlan)*;
- SY823 (*SynpliciTi System – Surgical Guides)*;
- SY825 (*Surgical Guide for OBL PSI System - Cranium)*;
- SY827 (*SynpliciTi System – Surgical Guides)*;
- SY829 (*Custom made plates (including Megaplates) – Surgical Guides)*;
- SY830 (*Surgical Guide for OBL PorousiTi® PSI System – Orbital Floor)*;
- SY835 (*Surgical Guide for OBL PorousiTi® PSI System – Mandible & Maxilla)*;
- UI001 (*OsGuide)*;
- UI002 (*BIOMODEL)*;

- UI003 (*DGUIDE)*;
- UI004 (*OMF Model)*;
- ZZ046 (*OrthoTin Anatomic Biomodel)*;
- ZZ047 (*OrthoTin Surgical Guide)*;
- ZZ049 (*Lyka Smith Patient Specific Guides)*; and
- ZZ050 (*Lyka-Smith Anatomical Biomodel)*.

The specific conditions for these 78 codes are below.

Part A

- AT076, AT081, AT085, AT088, HI001, HI002, HI005, HI006, HW544, HW546, HW650, HW651, HW652, HW653, KT004, KT005, MV007, OG001, OG004, SY775, SY777, SY778, SY779, SY823, SY825, SY827, SY829, SY830, SY835, UI001, UI002, UI003, UI004, ZZ046, ZZ047, ZZ049 and ZZ050 - Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1, and for no more than 3 devices per procedure;
- BX343, BX344 – that the medical device is only to be used in a surgical procedure described in item 39612, 39615, 39641, 39710 and 39712 in Group T8 of the Regulations;
- CR032, CR201, CR202, CR203, CR204, CR205, CR206, CR214, and MA545 – that an Artificial Ligament should only be funded for intra-articular cases where no non-synthetic graft sources (allografts and autografts) are available;
- HU267 – only to be reimbursed when used in a surgical procedure described in item 47450, 47528 or 47565 in Group T8 of the Regulations;
- BF025, BF026, BF027, BF028, BF029, DE669, DE670, DE671, DE678, DE679, DE680 and, DE818 – Only to be reimbursed when used in patients with spinal tumours requiring regular magnetic resonance imaging (MRI) and/or computerised tomography (CT) imaging and or adjuvant radiotherapy and/or proton therapy;
- HW678 – this billing code is for Monterey AL Cage but only when it is used with screws to achieve integral fixation. It was noted that when the cage is used without screws it should be listed on Prescribed List in the grouping 13.10.02.02 Spinal, Fusion cage, interbody, no integral fixation, ThoracoLumbar/Lumbar;
- HW776 – to be reimbursed only when used with posterior supplemental fixation with other implants;
- BF031, HW785, KN004, OW014 - No PL benefit will be payable if the device is used for kyphoplasty surgery, as there is no MBS item available for this procedure*;*
- HW856 - The Prescribed List benefit is limited to reimbursement for the use of the device as an alternative to autograft in hindfoot and ankle fusion procedures that require supplemental graft material, including tibiotalar, tibiocalcaneal, talonavicular and calcaneocuboid fusions, or any other procedure if stated in the Intended Purpose in the Australian Register of Therapeutic Goods (ARTG) entry 191454;
- IJ022, IJ023, IJ024, and IJ025 - The Prescribed List benefit will be limited to use of the device for procedures related to dura defect repair in spinal and neurosurgical procedures.);
- LB088, LB089 and LB181 - The Prescribed List billing code does not cover the use of the device for vertebral body tethering (VBT) for the management of adolescent idiopathic scoliosis (AIS);
- LH719, LH720, LH721, LH722, LH723, LH765 and SK494 - payment of the Prescribed List benefit will be limited to use of the devices for procedures related to dura defect repair in spinal and neurosurgical procedures only;
- MI402, MI403, MI404, MI405, MI406, MI407, MI408, MI409, MI410, MI411, MI412, MI413, MI416, MI417, MI418, MI419, MI420, MI421, MI422, MI423, MI424, MI425, MI426, MI427, MI439, MI440, MI441, MI442, MI446, MI447, MI448, MI449, SJ417, SJ418, and SJ424 – The benefit includes a component for remote monitoring services provided via a remote monitoring system or a smart device application. A separate benefit cannot be claimed in respect of a remote monitoring system listed on Part C of the Schedule;

- MI480 – for single level ACDF (Anterior cervical discectomy and fusion) only;
- SJ482 - The listed item covers the Navitor System, containing Transcatheter Aortic Valve (cat. numbers NVTR-23, NVTR-25, NVTR-27, NVTR-29), FlexNav™ Delivery System (cat. numbers FNAV-DS-SM, FNAV-DS-LG) and Loading System (NVTR-LS-SM and NVTR-LS-LG), and the benefit is payable for the listed item if the Navitor System is used for the surgical procedure described in item 38495 in Group T8 of the Regulations.

10 Benefits for listed items provided as part of hospital treatment

Section 10 provides for the minimum benefits paid for listed items provided as part of hospital treatment. Subsection 10(1) provides that this section is made for the purposes of paragraph (a) of the column headed "The amount of the benefit must be…" in item 4 of the Table in subsection 72-1(2) of the Act, which provides that the minimum benefit is the amount that is set out, or worked out, in the MDHTP Rules.

Subsection 10(2) provides that the minimum benefit for a listed item (other than specified listed item) that is provided to a private patient in a private hospital is the amount specified in the column headed "Minimum benefit" of the table in Prescribed List for that listed item.

Subsection 10(3) provides that the method for calculating the minimum benefit for a specified listed item for a private patient in a private hospital is outlined in subsection 10(6). These specified listed items are defined in section 5 of the MDHTP Rules.

In relation to treatment provided in a public hospital, subsection 10(4) specifies the method for calculating the minimum benefit amount for a listed item (other than specified listed item), and subsection 10(5) specifies the method for calculating the minimum benefit amount for a specified listed item.

The provision of listed items and specified listed items in public hospitals are subject to different arrangements that reflect the public hospital procurement activities and therefore the cost for a specified listed item in a public hospital may be lower than in a private hospital. To reflect this, subsections 10(4) and 10(5) provide for a lower payable benefit for a listed item or a specified listed item that is consistent with the insured person's liability to the public hospital for the provision of that listed item or specified listed item. This only applies if the listed item or specified listed item is provided in a public hospital for an amount that is lower than the amount specified for that listed item or specified listed item in the Prescribed List.

Subsection 10(6) provides the method for the minimum benefit amount for a specified listed item. The method described as:

(a) if the sum of the default minimum benefits for the treatment in which the specified listed item was used is $6,399 or less, the minimum benefit is the default minimum benefit for the listed item; or
(b) if the sum of the default minimum benefits for the procedure treatment in which the specified listed item was used is more than $6,399, the benefit is worked out by dividing the default minimum benefit for the specified listed item by the sum of the default minimum benefits for the treatment in which the specified listed item was used and multiplying the result by $6,399.

The note under subsection 10(6) provides an example of calculating the minimum benefit for the purpose of paragraph 10(6)(b). The example states that if an irrigated cardiac ablation catheter, a mapping catheter for catheter cardiac ablation and a patch for cardiac ablation each listed in the Prescribed List are used in a relevant procedure in accordance with any conditions, and if:

(a) the default minimum benefit of the irrigated cardiac ablation catheter is X; and
(b) the default minimum benefit of the mapping catheter for cardiac ablation is Y; and
(c) the default minimum benefit of the patch for cardiac ablation is Z;

then the sum of the default minimum benefits for the procedure is (X+Y+Z). If the sum of the default minimum benefits for the procedure (X+Y+Z) is more than $6,399, the minimum benefit for the irrigated cardiac ablation catheter is calculated by taking X, dividing it by (X+Y+Z), then multiplying the result by $6,399.

Subsection 10(7) defines the expressions 'default minimum benefit' and 'sum of default minimum benefits' for the purposes of section 10.

Section 11 Benefits for listed items provided as part of hospital-substitute treatment

Section 11 provides for the minimum benefits paid for listed items provided as part of hospital-substitute treatment. Subsection 11(1) provides that this section is made for the purposes of paragraph (a) of the column headed "The amount of the benefit must be…" in item 4 of the Table in subsection 72-1(2) of the Act, which provides that the minimum benefit is the amount that is set out, or worked out, in the MDHTP Rules.

Subsection 11(2) provides that, for a listed item provided as part of an episode of hospital-substitute treatment, the minimum benefit is the amount specified in the column headed "Minimum benefit" in the Prescribed List for that listed item.

The note under section 11 states that as part of hospital-substitute treatment, private health insurers cannot cover a service for which a medicare benefit is payable unless the service is specified in the *Private Health Insurance (Health Insurance Business) Rules*.

Part 3 Listing criteria

Section 12 Purpose

Section 12 explains the purpose of Part 3 which sets out the listing criteria.

Subsection 72-10(6) of the Act provides that the MDHTP Rules, may set out listing criteria that must be satisfied in order for an application to be granted. The listing criteria operate with all the provisions in the Act, including the definitions of 'medical device' and 'human tissue product'.

Subsection 72-10(7) of the Act provides that the Minister must not grant a listing application if any applicable listing criteria are not satisfied in relation to the application. The Minister may refuse to grant a listing application even if the listing criteria are satisfied.

Note 4 in the section provides that this Part does not apply to items in Part D of the Prescribed List on the basis that these listed items are subject to transitional provisions.

Section 13 General listing criteria

Section 13 provides that a medical device or human tissue product must not be listed in Parts A, B or C of the Prescribed List unless it is included in the Australian Register of Therapeutic Goods maintained under section 9A of the *Therapeutic Goods Act 1989*. This is to ensure that the Department can independently verify that the medical device or human tissue product may be legally supplied in Australia.

Section 14 Listing criteria for medical devices to be listed in Part A of Schedule 1

Section 14 provides listing criteria for medical devices which are to be listed in Part A of the Prescribed List. This criteria reflects what has historically been applied administratively when assessing applications for listing medical devices in the MDHTP Rules (or its predecessor).

Subsection 14(1) provides that a medical device must not be listed in Part A of the Prescribed List unless the criteria in subsections 14(2) to 14(5) are satisfied.

Subsection 14(2) specifies conditions that must be met for a medical device to be listed in Part A of the Prescribed List. Paragraph 14(2)(a) provides that the medical device must be an implantable medical device, or an active implantable medical device designed to either replace an anatomical body part, or combat a pathological process, or modulate a physiological process. Reference in relation to a 'modulating a physiological process' can include blocking or facilitating a process.

Subsection 14(2) is also for associated products that are essential and specifically designed to enable the implantation (outlined in paragraph 14(2)(b)) or maintaining the implant (outlined in paragraph 14(2)(c)) of this subsection.

To meet these criteria, the device must be specifically designed as an integral single-use aid and be essential for implanting a device mentioned in paragraph 14(2)(a), or be critical to the continuing function of an implanted device mentioned in paragraph 14(2)(a), and only be suitable for use post-implantation by the patient in whom the device in subsection 14(2)(a) is implanted.

Single-use device means a device that is intended to be used on one individual during a single procedure, and once it is used, the device cannot be used again and may only be discarded, and the expression 'integral' has its common meaning (i.e. not defined).

The note in Section 14 clarifies that these criteria effectively mean that there is a device in paragraph 14(2)(a) (with which the device in (b) or (c) is designed to be used with) that is a listed item or will be a listed item following successful listing application or variation application. The non-implantable devices do not meet the criteria for listing if such connection in the design does not exist.

Subsection 14(3) provides that the medical device for listing in Part A of the Prescribed List must not be designed to be solely used for diagnosis, prediction or prognosis.

Subsection 14(4) provides that the medical device for listing in Part A of the Prescribed List must be for a specific treatment and indication. This means that the medical device is specifically designed to deliver the main treatment or be part of the main treatment rather than be designed to be supplementary to the main treatments or provide general support during a variety of different procedures.

The purpose of this criterion is to reflect the current administrative practice and exclude general use items from inclusion in Part A of the Prescribed List.

Subsection 14(5) provides that a medical device for listing in Part A of the Prescribed List must be assessed to be no less clinically effective than the alternative devices listed in the Prescribed List or the alternative treatments and the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device.

This criterion reflects what is currently applied administratively for including items in the MDHTP Rules (or its predecessor). This criterion is included with the intention that comparative clinical effectiveness and relative cost be considered.

The term 'alternative treatments' is included to allow for new products or technology to be compared with current treatments for the same clinical condition, as not all products to be considered have an existing comparator on the Prescribed List. The alternative treatment is generally expected to be the current standard of care for the condition or indication.

The wording 'no less clinically effective' is used because products are rarely identical and a range of factors may need to be balanced against each other when comparing clinical effectiveness.

A product's cost should be compared to alternative treatments and considered in relation to its clinical benefits.

Section 15 Listing criteria for human tissue products to be listed in Part B of Schedule 1

Section 15 provides that only human tissue products may be listed in Part B of the Prescribed List. This is consistent with what is currently applied administratively for including items in the MDHTP Rules (or its predecessor).

Section 16 Listing criteria for medical devices to be listed in Part C of Schedule 1

Section 16 provides listing criteria for medical devices which are to be listed in Part C of the Prescribed List.

Subsection 16(1) provides that a medical device must not be listed in Part C of the Prescribed List unless subsections 16(2) and 16(3) are satisfied.

Subsection 16(2) specifies the list of existing groups of medical devices that are currently eligible to be listed in Part C of the Prescribed List. Unless a medical device is one of these items, it is not eligible to be listed.

The note under this subsection provides that the MDHTP Rules may be varied from time to time to add additional devices to, or remove devices from this subsection.

Subsection 16(3) provides that a medical device must be assessed to be no less clinically effective than the alternative devices listed in the Prescribed List or the alternative treatments and the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device.

This criterion is included with the intention that comparative clinical effectiveness and relative cost be considered for including items in Part C of the Prescribed List.

The term 'alternative treatments' is included to allow for new products or technology to be compared with current treatments for the same clinical condition, as not all products to be considered have an existing comparator on the Prescribed List. The alternative treatment is generally expected to be the current standard of care for the condition or indication.

Part 4 – Cost-recovery fees

<u>Division 1 – Cost-recovery fees relating to medical devices</u>

Section 17 Cost-recovery fees that may be charged

Section 17 outlines cost-recovery fees that may be charged for the purposes of section 72-15 of the Act. Subsection 17(1) outlines that cost-recovery fees will be charged for the activities undertaken to consider listing or variation applications relating to a medical device on the Prescribed List. Cost-recovery fees will not apply to listing or variation applications relating to human tissue products in Part B of the Prescribed List.

This fee is charged by the Department to recover the cost of providing services in response to applications to list a medical device on the Prescribed List. Fees have been determined via an activity-based charging model following a review of all costs associated with the administration of the Prescribed List.

Subsection 17(2) specifies a standard application fee of $1,370, and any additional fees that will be applied according to the level and type of assessment (assessment pathway) required.

The standard application fee recovers the costs associated with the initial Departmental assessment of eligibility of the medical device for listing, correctness of the grouping, and appropriateness of the information the sponsor has provided in the application.

The additional fees include a clinical assessment fee if a clinical assessment is required, an economic assessment fee if an economic assessment is required, and a full health technology assessment pathway fee if a full health technology assessment is required.

Section 18 Clinical assessment fee

Section 18 outlines circumstances in which a clinical assessment is required and the fee for that assessment.

Subsection 18(1) prescribes when a clinical assessment is required for listing or variation applications relating to medical devices. A clinical assessment is required in circumstances where expert clinical advice from a clinical expert with relevant expertise is necessary, or where the Minister is satisfied on any other grounds that the application for a listing or variation requires a clinical assessment.

Expert advice is required to determine whether a medical device is no less clinically effective than alternative devices, products or treatments and meets the listing inclusion criteria for the relevant Part A or C of the Prescribed List.

Subsection 18(2) prescribes the applicable clinical assessment fee of $4,090. This fee has been determined through an activity-based costing model, which has been developed to align with the principles outlined in the Australian Government Charging Framework.

The fee associated with this assessment type is charged to recover the costs of obtaining a clinical assessment from a clinical expert with relevant expertise as part of the assessment by the Expert Clinical Advisory Groups (ECAGs) and the Medical Device and Human Tissue Advisory Committee (MDHTAC).

In relation to this fee, in the circumstance where the Minister or delegate is required to determine to their satisfaction that the application requires clinical assessment, this constitutes a reviewable decision.

Section 19 Economic assessment fee

Section 19 outlines circumstances in which an economic assessment is required and the fee for that assessment.

Subsection 19(1) prescribes when an economic assessment is required for a listing or variation application relating to a medical device. An economic assessment is required in circumstances where expert advice from an expert with health economics expertise is necessary, or where the Minister is satisfied on any other grounds that the application for a listing or variation requires an economic assessment.

Economic assessment occurs where expert advice is required to determine whether the benefit amount proposed for the device is proportionate to the clinical effectiveness of the device. The fee associated with this assessment type is charged to recover the costs of obtaining an economic assessment, the development of a focused commentary (or appraisal) of the economic claims made in the application, and for the assessment performed by the MDHTAC.

Subsection 19(2) prescribes the following three applicable economic assessment fee types:

(a) a simple fee of $8,940;
(b) a complex fee of $17,080; and
(c) an other fee of $27,940.

These fees have been determined through an activity-based costing model, which has been developed to align with the principles outlined in the Australian Government Charging Framework.

Subsection 19(3) specifies that the simple economic assessment fee applies to listing and variation applications requiring economic assessment to establish cost-effectiveness for a single device with a single purpose.

This fee includes the development of a commentary (or appraisal) of the economic claims and providing a critique on information supplied by the applicant, and for the evaluation performed by the ECAGs and MDHTAC.

Subsection 19(4) specifies that the complex economic assessment fee applies to listing and variation applications requiring economic assessment to establish cost-effectiveness for a single device to which multiple clinical purposes are attributed, or for 'related' devices.

This fee includes the development of a commentary (or appraisal) of the economic claims and providing a critique on information supplied by the applicant, and for the evaluation performed by the ECAGs and MDHTAC.

Subsection 19(5) specifies that the other economic assessment fee applies to applications requiring the preparation of 'fit-for-purpose' cost-effectiveness advice to establish that extends beyond a critique of the information supplied by the applicant, and for the evaluation performed by the ECAGs and MDHTAC.

In relation to this fee, in the circumstance where the Minister or delegate is required to determine to their satisfaction that the application requires clinical assessment, this constitutes a reviewable decision.

Section 20 Full health technology assessment pathway fee

Section 20 outlines circumstances in which a full health technology assessment is required and the fee for that assessment.

Subsection 20(1) provides that a listing or variation application relating to a medical device requires a full health technology assessment if subsection 20(2) applies, or if the Minister is satisfied that such an assessment is required.

Subsection 20(2) applies if the applicant has not paid both a clinical assessment fee and an economic assessment fee in relation to an application, and the application is, or will be, subject to a request to the Medical Services Advisory Committee (MSAC) to:

(i) establish a Medicare Benefits Schedule (MBS) item in relation to a medical service involving the medical device;
(ii) amend an existing MBS item to cover a medical service involving the medical device; or
(iii) provide advice about the cost effectiveness or clinical effectiveness of the medical device.

If the applicant has already incurred both the clinical and economic assessment fee in relation to their application at the point it is established that MSAC services are required, the full health technology assessment fee will not be payable. This ensures that the applicant is not required to pay a duplicate

fee for an application that has already undergone assessment and administration in relation to the Prescribed List.

Services provided under this pathway are required when a full and comprehensive health technology assessment is required to establish comparative safety, clinical effectiveness, cost-effectiveness and total cost of the medical device and related medical service. In such cases there may be financial impact to the health system more broadly than just the Prescribed List.

As the full health technology assessment is performed by MSAC, this fee recovers only the activities performed in establishing eligibility for listing; correctness of the grouping; appropriateness of the information provided in the application; and final advice considered by the ECAGs and MDHTAC directly in relation to listing the medical device product on the Prescribed List.

Subsection 20(3) prescribes the full health technology assessment pathway fee of $3,300. This fee has been determined through an activity-based costing model, which has been developed to align with the principles outlined in the Australian Government Charging Framework.

In relation to this fee, in the circumstance where the Minister or delegate is required to determines to their satisfaction that the application requires full health technology assessment, this constitutes a reviewable decision.

Division 2—Payment of cost-recovery fees

Section 21 When cost-recovery fee must be paid

Subsection 21(1) provides the timing for when cost-recovery fees become due and payable for the purposes of section 72-30 of the Act.

This subsection notes that the Minister:

- may not list a medical device product in the Schedule until all relevant cost-recovery fees are paid; and
- may remove the medical device from the Schedule should the applicant fail to pay the relevant cost-recovery fees.

This subsection also notes that the Commonwealth:

- may not carry out activities on assessment of the medical device application until relevant cost-recovery fees are paid at the time they are due and payable; and
- may commence debt-recovery activities in relation to any unpaid cost-recovery fees.

Subsection 21(2) provides that the standard application fee for listing is due and payable at the time that the listing application is made.

Subsection 21(3) provides that the standard application fee for a variation is due and payable at the time that the variation application is made.

Subsection 21(4) provides that a clinical assessment fee, economic assessment fee, or full health technology pathway fee are due and payable within 28 days from the day a demand for payment of the relevant fee is made.

Section 22 Person liable to pay cost-recovery fee

Section 22 provides that the person liable to pay the related cost-recovery fee is the person who made the relevant listing application or variation application.

Division 3—Refunds and waiver of cost-recovery fees

Section 23 Refunds

Subsection 23(1) provides that this section is made for the purposes of paragraph 72-45(d) of the Act and specifies the circumstances in which the Minister, or delegate, may refund relevant cost-recovery fees.

Subsection 23(2) provides that subject to subsections 23(3) and 23(4), a cost-recovery fee is not refundable in any circumstance, including where:

- the applicant chooses to withdraw the listing or variation application;
- the Minister decides not to grant the listing application; or
- the Minister decides not to grant a variation application.

In relation to the withdrawal of applications, both listing and variation applications are to be submitted through the Health Products Portal (HPP). This system provides applicants with adequate indications and messaging, including an immediate request for payment that once submitted, the standard application fee cannot be refunded. Processing of an application occurs as soon as possible following receipt of the payment, and therefore it is assumed that the two-step process (HPP submission and payment) indicate agreement that processing should occur as soon as practicable on the application. In circumstances where a submission is made through the HPP, and no payment is received, no processing of the application will commence.

In relation to listing applications that are not successful in obtaining the relevant listing, this provision outlines that the applicant is still liable to pay fees incurred for the services that have been provided for the assessment of their application.

In relation to variation applications that are not successful in obtaining the relevant variation, this provision outlines that the applicant is still liable to pay fees incurred for the services that have been provided for the assessment of their application.

Subsection 23(3) provides that in the circumstance where the person making the application pays more than what is required, the Department must refund an amount equal to the amount that was overpaid.

This will ensure that where a waiver or an exceptional circumstance exists and the applicant has paid fees that are not required to be paid, the applicant is assured of a refund equal to that which was overpaid. For example, this provision will apply where an applicant is eligible to receive a waiver for all services but has paid all cost-recovery fees prior to the waiver being granted. In such a case, the Department will refund the full amount that was waived.

Subsection 23(4) provides that if the Minister is satisfied that exceptional circumstances exist, the whole, or part of the cost-recovery fee that has been paid may be refunded.

This provision is intended to provide applicants with refunds in specific circumstances which the Minister or delegate may determine that it is appropriate to provide a refund. For example, where an error in the administration of the application has a material impact on the listing or requires the applicant to remake the application.

Subsection 23(5) provides the Minister or delegate with the discretionary power to issue a refund for a reviewable decision, following receipt of a written application from the relevant applicant. This provision is intended to allow the applicant to receive a refund where a reviewable decision, for example such as whether the application in question is eligible for a cost-recovery fee waiver, has

been made, and the applicant has successfully obtained a favourable review in which the Minister or delegate determines that the relevant fees should be waived.

Section 24 Waiver of cost-recovery fees

Subsection 24(1) provides that this section is made for the purposes of paragraph 72-15(2)(e) of the Act and specifies the circumstances in which the Minister, or delegate, may waive relevant cost-recovery fees.

Waivers have been incorporated to provide for circumstances where it is inappropriate to charge cost-recovery fees and to ensure that applications that are likely to be financially unviable but will still provide benefit to the Australian public and will continue to be submitted to the Department for consideration.

Subsection 24(2) provides that a waiver of some of the clinical assessment fees or the economic assessment fees may be applicable for listing or variation applications (the relevant application) that relates to a medical device if:

- one or more than one, listing or variation applications (the 'other applications') are made in addition to the relevant application; and
- the relevant application and the other applications are made specifically in relation for the assessment of related devices; and
- in relation to the clinical assessment fee, the Minister is satisfied that:
    - a single clinical assessment or one or more abridged clinical assessments can be conducted for the related medical devices, and
    - the fee for at least one clinical assessment has not otherwise been waived; and
- in relation to the economic assessment fee, the Minister is satisfied that:
    - a single economic assessment or one or more abridged economic assessments can be conducted for the related medical devices, and
    - the fee for one economic assessment has not otherwise been waived; and
- the applicant requested the waiver at the time of making an application; and
- the applicant provided reasons why the clinical assessment fee or the economic assessment fee should not apply to their application.

In relation to this waiver, in the circumstance where the Minister or delegate is required to determine to their satisfaction that the application does not qualify for a waiver, this constitutes a reviewable decision.

Medical devices are ***related*** if the main equipment and the accessory and ancillary medical devices are designed to be utilised together for an expected clinical outcome. Related medical devices are covered under the same product material (product brochure, surgical technique, instructions for use, etc) and the clinical data for these devices is provided under the same report from the same source (clinical trial, registry, etc) and this information allows the assessment of all devices together. The device requires the submission of more than one application (an application for each component of the system) resulting in the incurrence of multiple cost-recovery fees.

As these related medical devices may be assessed together, some applications may be subjected to the same or abridged clinical and/or economic assessment(s). As such, the Minister or delegate may determine that one or more of the payable clinical and/or economic assessment fee(s) could be waived. This subsection provides applicants who are required to submit multiple applications to list all the respective components of the related devices on the Prescribed List, an option to request a waiver of each of the duplicative cost-recovery fees.

Division 4—Review

Section 25 Reviewable decisions

Section 25 outlines that the following decisions made by the Minister, or delegate, which are subject to internal review (are reviewable):

- that an application requires clinical assessment on any grounds other than those specified in the listing criteria.
- that an application requires economic assessment on any grounds other than those specified in the listing criteria.
- that an application requires a full health technology assessment on any grounds other than requests for MSAC advice to include or amend an MBS items, or where advice on cost-effectiveness or clinical-effectiveness is sought.
- that exceptional circumstances do not exist to justify the refund of either the whole or part of a cost-recovery fee.
- that cost-recovery fee(s) should not be waived for applications made for related devices on the grounds that fewer or abridged clinical and/or economic assessment may be conducted on some of the relevant applications.

Section 26 Notice of review rights

Subsection 26(1) provides that in the event that a reviewable decision is made, the Minister must notify the applicant of the decision in writing within 10 business days of making the decision. Written notice of the decision must be accompanied by a statement of the applicant's rights to review.

Subsection 26(2) provides that the written notice must provide instructions on how the applicant may respond to the notice for the purpose of requesting a review of the decision.

Under subsection 26(3), reviewable decisions remain valid in circumstances where the Minister does not provide written notice of the decision along with the applicants review rights within 10 days business days of making the decision.

Section 27 Internal review of decisions made by delegates

Subsection 27(1) permits an applicant to request to the Minister, in writing, to request an internal review of a reviewable decision that has been made in the course of the assessment process.

This provision provides applicants with the means to dispute and request review of discretionary decisions made throughout the course of the application assessment process. As reviewable decisions have a direct impact on determining the total amount payable in relation to cost-recovery fees, the use of the review process may alter the total amount payable by the applicant.

The review provisions rely on the necessary and convenient power in paragraph 333-20(1)(b) of the Act.

The purpose of the internal review is to provide applicants with the means to request reconsideration of the circumstances informing the outcome of a reviewable decision. It provides applicants with the opportunity to submit additional relevant information (justification) to inform either the level of assessment necessary on their application, or the circumstances that enhance their eligibility to qualify for a waiver. Each stage of the internal review will be conducted fairly by appropriate delegates of the Minister that have not been involved in making the reviewable decision, or if required, have not been involved in making the subsequent internal review decision.

The utilisation of an internal review process allows for the fair and efficient resolution of disputed reviewable decisions. The efficient resolution of all disputes in relation to the payable cost-recovery

fees are of high importance to ensure that the application in dispute may still have sufficient time and resources allocated to the assessment to be able to obtain an outcome from the MDHTAC, and if recommended, timely inclusion on the Prescribed List. This ensures that applicants will not be delayed in accessing the public market, and the Australian public will continue to access new medical devices and human tissue products without delay. The internal review process aligns that process which is also in place for similar committees that also conduct a Health Technology Assessment (HTA) review.

The significant volume of highly technical applications requires the Department to efficiently manage all resources allocated and contracted to assessment of applications within each cycle. It was considered that there was a significant risk to the efficient provision of services if an external process, (requiring dedicated Departmental resources to facilitate) was implemented. An external process was judged likely to adversely impact other applicants (those who make applications within the same cycle) due to the disruption to services, and the likely need to continue to allocate resources to the application in dispute. Such external processes were considered likely to have extensive timelines, and likely to significantly delay access to market for the applicant, and access to the product for consumers.

Subsection 27(2) provides that the application seeking a review of a reviewable decision must be made within 10 business days (or longer if approved by the Minister) of receipt of the written notice of the decision. The application must also include the reasons for requesting review of the decision.

Subsection 27(3) provides that within 10 business days of receipt of a written application, an authorised employee must review the reviewable decision, and determine whether to affirm or vary the decision, or revoke the decision and make any other decision that is appropriate. The applicant must be notified in writing of the outcome of the 'initial review decision' within that period.

Subsection 27(4) provides that an applicant may subsequently apply to review the reviewable decision by making an application in writing to the Minister within 10 days of receipt of the outcome to the initial review decision.

Subsection 27(5) provides that within 10 days of receipt of a written application to review the initial review decision, the Minister or an authorised employee who differs from the previous decision maker (further reviewer), must review the initial review decision. The Minister or the further reviewer must determine whether to affirm or vary the initial review decision, or to revoke the initial review decision. The applicant must be notified of the outcome of the further review decision within that period.

Subsection 27(6) provides the Minister may in writing authorise an SES (or acting SES) employee in the Department to act on behalf of the Minister in conducting an initial internal review or further internal review of reviewable decisions.

Subsection 27(7) provides that where an initial internal review is being conducted, the person authorised to act must not have been involved in the originating reviewable decision. This subsection also provides that where a further internal review is being conducted, the person authorised to act must not have been involved in making either the initial review decision, or the reviewable decision to which the initial review relates to.

Section 28 Notice of overpayment as a result of a review decision

Section 28 provides that if an applicant is found to have overpaid their cost-recovery fees as a result of either an initial review decision or a further review decision, the Minister must within 20 business

days of the decision being made notify the applicant of the overpayment and refund the amount equal to the amount overpaid.

Part 5 – Miscellaneous

Section 29 Minister may have regard to recommendations and advice

Section 29 provides that, in making a decision under section 72-10 of the Act, the Minister may have regard to a recommendation or advice from the MDHTAC when deciding whether or not to grant the application to list a kind of medical device or human tissue product.

The MDHTAC provides recommendations and advice to the Minister for Health and Aged Care and the Department about the listing of products on the Prescribed List and the benefits payable by private health insurers. This section is made for the purposes of paragraph 333-20(1)(b) of the Act, which provides for the MDHTP Rules to deal with matters that are necessary or convenient to be provided for in order to carry out or give effect to Part 3-3 of the Act.

Section 30 Repeal of Part D of Schedule 1

Section 30 provides that Part D of the Prescribed List is repealed from 1 July 2024.

Schedule 1 – Listed medical devices and human tissue products

Schedule 1 lists kinds of medical devices and human tissue products and contains the 'Minimum Benefit' and conditions for provision of the kinds of medical devices and human tissue products for private and public hospital treatment, and hospital-substitute treatment. Schedule 1 is to be known as the Prescribed List of Benefits for Medical Devices and Human Tissue Products (Prescribed List).

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023

This instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The table in subsection 72-1(2) of Part 3-3 of the Act (Table) provides for benefit requirements a complying health insurance policy that covers hospital treatment must meet. Under item 4 of the Table
there must be a benefit for the provision of a medical device or human tissue product, of a kind listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, in specified circumstances and under any specified conditions. The specified circumstances are that the listed item is provided in circumstances in which a medicare benefit is payable or in other circumstances which may be set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules. The specified conditions are any that may be set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* (**MDHTP Rules**) is to remake the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023* to update the prescribed list of the kinds of medical devices and human tissue products for which a benefit must be paid, where the listed item is provided in the conditions and circumstances specified in the Act. The MDHTP Rules set out the minimum benefit payable for each listed item.

The MDHTP Rules also outline circumstances in which various assessments in relation to listing and variation applications are required and the associated fee for that assessment, and cost-recovery provisions, including the timing for when cost-recovery fees become due and payable, and when cost-recovery fees can be refunded and waivers can be granted.

The MDHTP Rules differ from the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023* by

- adding 207 new listed items (billing codes) to Part A of the Prescribed List as a result of listing medical devices following successful new applications [including 6 billing codes listed with the new conditions], 5 billing codes as the result of expansion applications, and 35 new billing codes due to transfer of billing codes from one sponsor to another;
- changing the listing details of 153 billing codes in Part A of the Prescribed List following the successful amendment applications from the sponsors;
- deleting 40 billing codes from Part A of the Prescribed List, as a result of accepting4 deletion applications submitted by the sponsors, removing 34 billing codes after transferring billing codes to the new sponsors, removing 2 billing codes following completion of expansion applications;
- adding 11 new billing codes to Part B of the Prescribed List as a result of listing the human tissue products following successful new applications;
- changing the listing details of 30 billing codes in Part B of the Prescribed List following successful amendment applications from the sponsors;
- deleting 14 billing codes from Part B of the Prescribed List as a result of accepting deletion applications submitted by the sponsor;

- adding 11 new billing codes to Part C of the Prescribed List, following successful new applications;
- changing the listing details of 1 billing code in Part C of the Prescribed List following a successful application
- changing the listing details of 2 billing codes in Part D of the Prescribed List following successful applications to clarify current billing codes.

The numbers of Prescribed List billing codes were taken from reports produced by the Prostheses Listing Management System (**PLMS**) when the final list was run.

In addition to the changes described above, the MDHTP Rules also add one listing criterion for medical devices to be listed in Part C of Schedule 1. This criterion is in paragraph 16(2)(p): *a medical device that is a radiofrequency delivery device for transurethral water vapour ablation (TUWA)*.

The MDHTP Rules also change the condition stated for 11 billing codes in Part A of the Prescribed List. The devices listed under the billing codes are manufactured from material Carbon/Peek that provides clinical benefit when implanted in patients with advanced stage tumours and metastases where frequent magnetic resonance imaging (MRI), computerised tomography (CT), Radiotherapy and Proton therapy are required for radiotherapy planning and treatment and evaluation of tumour progression. There is no sufficient evidence available to demonstrate that for any other indications the devices are no less effective than other medical devices listed on the Prescribed List. The condition specifies that the billing codes: *Only to be reimbursed when used in patients with spinal tumours requiring regular magnetic resonance imaging (MRI) and/or computerised tomography (CT) imaging and or adjuvant radiotherapy and/or proton therapy*.

Further, the MDHTP Rules apply the condition onto 35 billing codes for surgical guides and biomodels in Part A of the Prescribed List, that must be satisfied in relation to the provision of the listed items. This follows a post-listing review of these devices to test whether they satisfy the criteria for listing and the circumstances in which they should be reimbursed. The review found that there is evidence to demonstrate that surgical guides and biomodels are clinically effective when used in craniomaxillofacial surgery procedures involving insertion of a medical device, but there is insufficient evidence to support listing of these billing codes for any other types of surgeries and that the PL reimbursement of the devices should be restricted in respect to number of devices reimbursed per procedure. Accordingly, the condition specifies that: *Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1, and for no more than 3 devices per procedure*.

The MDHTP Rules also change the benefits for 12 billing codes in Part D in subgroups of pleural and para/thoraceulesis drainage catheters to correct the benefits due to missing reductions in March and July 2023 and change the benefits for 3 billing codes in Part A.

When billing codes are transferred from one sponsor to a different sponsor, or billing codes are compressed or expanded following the respective application, the codes that they are transferred, or expanded, or compressed from are deleted.

Human rights implications

This instrument engages article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the right to health.

Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in article 12(1) of the ICESCR. Whilst the UN Committee on Economic Social and Cultural Rights has stated that the right to health is not to be understood as a right to be healthy, it does entail a right to a system of health protection which provides equality of opportunity for people to enjoy the

highest attainable level of health. In addition, the right to health must meet certain key requirements, including that health care must be scientifically and medically appropriate and of good quality.

Analysis

The addition of new items in the Prescribed List will increase the amount of choice an insured person can have in relation to the kind of medical device or human tissue product for which they must receive a minimum private health insurance benefit. This will impact positively on the right to health of insured persons.

The MDHTP Rules also remove entries at the request of the sponsors of these devices or products. The sponsors of these devices or products are no longer supplying these devices or products for use to privately insured persons in Australia.

Generally, the devices and products removed from the MDHTP Rules have been replaced by newer models due to upgraded technologies or advancements in surgical procedures, or are still available for privately insured patients, but are supplied by different sponsors.

Conclusion

The instrument is compatible with human rights because it enables advances in the protection of human rights, in particular the right to health.

Penny PARRISH
Acting Assistant Secretary
Prostheses List Reform Taskforce
Technology Assessment and Access Division
Health Resourcing Group
Department of Health and Aged Care