

EXPLANATORY STATEMENT

Private Health Insurance Act 2007

Private Health Insurance (Prostheses) Rules (No. 1) 2022

Authority

Section 333-20 of the *Private Health Insurance Act 2007* (the Act) provides that the Minister may make Private Health Insurance (Prostheses) 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.

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.

Subsection 72-10(6) of the Act provides that the Private Health Insurance (Prostheses) Rules may set out listing criteria that must be satisfied in order for an application for a prosthesis to be listed to be granted.

Background

The table in subsection 72-1(2) of Part 3-3 of the Act provides for benefit requirements that a complying health insurance policy that covers hospital treatment must meet. Under item 4 of that table there must be a benefit for the provision of a prosthesis, of a kind listed in the Private Health Insurance (Prostheses) Rules (i.e. a listed prosthesis), in specified circumstances and under any specified conditions. The specified circumstances are that the listed prosthesis 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 (Prostheses) Rules. The specified conditions are any that may be set out in the Private Health Insurance (Prostheses) Rules.

If the complying health insurance policy also covers hospital-substitute treatment, under item 4 of the table in subsection 72-1(2) of Part 3-3 of the Act, the same requirements apply.

Purpose

The *Private Health Insurance (Prostheses) Rules (No. 1) 2022* (Prostheses Rules) are made for the purposes of subsection 333-20(1) of the Act. Listed prostheses and their minimum benefits are set out in the Schedule to the Prostheses Rules. The list of prostheses in the Schedule is commonly referred to as the Prostheses List.

The Schedule to the Prostheses Rules has three parts:

- Part A – Prostheses;
- Part B – Human Tissue;
- Part C – Other Prostheses; and

The purpose of the Prostheses Rules is to update the list of the kinds of prostheses for which a benefit must be paid where the prosthesis is provided in the conditions and circumstances specified in the Act,

and set out the minimum and, where applicable, maximum benefit payable. The Prostheses Rules repeal and replace the *Private Health Insurance (Prostheses) Rules (No. 3) 2021* (Previous Rules).

The Prostheses Rules differ from the Previous Rules by:

- adding 316 new Prostheses List billing codes to Part A of the Schedule, as a result of listing 196 prostheses for the first time following successful new applications (including 5 new codes that will be subject to the specific conditions that must be satisfied in relation to the provision of these prostheses), creating 2 new codes due to the compression of existing codes, and 118 new codes due to transfer of prostheses from one sponsor to another;
- adding 41 new Prostheses List billing codes to Part B of the Schedule following successful applications;
- adding 18 new Prostheses List billing codes to Part C of the Schedule following successful new applications;
- changing the listing details of 76 Prostheses List billing codes in Part A of the Schedule following the successful requests from the sponsors;
- changing the listing details of 59 Prostheses List billing codes in Part B of the Schedule following the successful requests from the sponsors;
- changing the listing details of 9 Prostheses List billing codes in Part C of the Schedule following the successful requests from the sponsors; and
- deleting 322 Prostheses List billing codes from Part A of the Schedule, as a result of accepting 155 deletion applications submitted by the sponsors, deleting 118 current codes after transferring prostheses to the new sponsors, deleting 5 current codes as the result of successful compression application, deleting 40 existing billing codes for surgical mesh prostheses as a result of the reclassification and subsequent need for cancellation of their entries from the Australian Register of Therapeutic Goods (ARTG), deleting 2 current codes following advice received from the MSAC and removing 2 current codes due to incorrect listing.

The further changes to the Prostheses Rules are:

- removing suffix Textured for 13 Prostheses List billing codes for breast implants and tissue expanders listed in Part A of the Schedule with the respective changes to the benefits that must be paid for these prostheses, following advice received from the Medical Services Advisory Committee (MSAC);
- changing the listing details of 1 Prostheses List billing code in Part A of the Schedule by placing the condition that must be satisfied in relation to the provision of this prosthesis, aligning the obligation to pay the benefit for the prosthesis with the intended use stated on its ARTG entry.

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

When Prostheses List codes are expanded or compressed, or transferred to different sponsors, the Prostheses List codes that they are expanded or compressed or transferred from are deleted.

Consultation

The delegate had regard to recommendations made by the Prostheses List Advisory Committee (PLAC). The PLAC took into consideration advice provided by clinicians with appropriate knowledge and expertise in the Clinical Advisory Groups and the Panel of Clinical Experts, and advice provided by the MSAC.

Applicants who applied under subsection 72-10(2) of the Act for the listing of prostheses were consulted during the assessment process.

Further the Prostheses Rules have been made following consultation with the sponsors of the prostheses affected by the changes explained below.

Surgical mesh devices

According to the *Therapeutic Goods (Medical Devices) Regulations 2002*, all surgical mesh devices have been reclassified from Class IIb to Class III (high-risk). In order to meet the transitional arrangements (and be able to continue to legally supply their products), sponsors of the surgical mesh devices entered on the ARTG as Class IIb had to submit applications to the Therapeutic Goods Administration (TGA) for their devices as Class III. The deadline for submitting such an application was 1 December 2021.

Some sponsors did not reclassify their surgical meshes prior to the specified date and their Class IIb ARTG entries have to be cancelled.

The Commonwealth Department of Health (Department) contacted the sponsors and advised that where a Class IIb ARTG entry for the surgical mesh device was cancelled or not eligible for the TGA transitional arrangements, the sponsor needs to submit a deletion application for the relevant billing code, or the Department would be recommending to the Minister's delegate to remove the respective billing code from the Prostheses List.

The sponsors' responses had been given due consideration prior to making the decision about deleting the respective billing codes.

Breast implants and tissue expanders

The MSAC previously compared the clinical and cost-effectiveness of textured and smooth breast implants and tissue expanders (MSAC application 16261) and advised that there had been no sufficient clinical evidence available to substantiate better clinical performance and cost-effectiveness of textured breast implants and tissue expanders over the smooth devices.

The PLAC accepted the MSAC advice and recommended to remove suffix Textured in category 07 - Plastic and Reconstructive of Part A of the Schedule with the respective reduction in the Prostheses List benefits.

Deletion of some billing codes from the Prostheses List

The PLAC sought advice from MSAC on the comparative safety, clinical effectiveness, and cost-effectiveness of both the CARGEL/BST-CarGel and JointRep.

MSAC advised that BST-CarGel is not cost-effective as there is insufficient evidence to support non-inferior safety and superior effectiveness of BST-CarGel compared with microfracture surgery alone (MSAC application 1569), and that there is insufficient evidence to demonstrate non-inferior safety, superior effectiveness and cost-effectiveness of JointRep™ in conjunction with microfracture compared with microfracture alone, and that the comparison of JointRep™ plus microfracture versus BST CarGel™ plus microfracture was uninformative and did not demonstrate non-inferior safety and effectiveness (MSAC application 1578).

The PLAC accepted the MSAC advice and recommended deleting billing codes SL072 and DE681 from the Prostheses List.

The PLAC also noted two billing codes that were listed in grouping 06.03.07.05 - Specialist Orthopaedic- Soft Tissue Fixation Devices - Button/thread/tape or Button/thread/button, but did not have either fixation button or anchor [only fixation tapes] and agreed that these PL billing codes were listed incorrectly.

Consistently with the above, it was decided to delete these billing codes from the PL.

Billing code HW856 for Augment Bone Graft - rhPDGF-BB component

The PLAC considered the ARTG entry related to the Augment Bone Graft - rhPDGF-BB component and noted that the intended use approved by the TGA specifically refers to the use of the prosthesis in the hindfoot and ankle fusion procedures. PLAC agreed that limiting reimbursement for the PL billing code HW856 to the use in hindfoot and ankle fusion procedures is warranted and recommended placing the condition.

A provision by provision description of the Prostheses Rules is set out in Attachment 1.

The Prostheses Rules commence on 1 March 2022.

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

Provision by provision description of the *Private Health Insurance (Prostheses) Rules (No. 1) 2022*

Part 1 – Preliminary

Rule 1 Name

Rule 1 provides that the title of the Rules is the *Private Health Insurance (Prostheses) Rules (No. 1) 2022 (Prostheses Rules)*.

Rule 2 Commencement

Rule 2 provides that the Prostheses Rules commence on 1 March 2022.

Rule 3 Authority

Rule 3 provides that the Prostheses Rules are made under item 4 of the table in section 333-20 of the *Private Health Insurance Act 2007* (the Act).

Rule 4 Repeal

Rule 4 provides that the *Private Health Insurance (Prostheses) Rules (No. 3) 2021* is repealed.

Rule 5 Definitions

Rule 5 defines certain terms used in the Rules, and notes that some terms used in the Rules have the same meaning as in the Act.

The **Regulations** means the *Health Insurance (General Medical Services Table) Regulations 2021* made under section 4 of the *Health Insurance Act 1973*. The Regulations are to be construed as originally enacted from time to time.

Part 2 Benefit requirements

Rule 6 Listing of, and benefits for, prostheses

The table in subsection 72-1(2) of the Act (the Table) sets out some requirements that 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 such treatment) that is the provision of a listed prosthesis both:

- in the circumstances in which a medicare benefit is payable or those other circumstances set out in the *Private Health Insurance (Prostheses) Rules*; and
- when the conditions set out in the *Private Health Insurance (Prostheses) Rules* (if any) are also satisfied. If the conditions are not satisfied, there is no benefit required even if the listed prosthesis is provided in the circumstances set out either under the Act or the *Private Health Insurance (Prostheses) Rules*.

Rule 6 provides the list of prostheses, and the benefits in relation to the prostheses for the purpose of item 4 of the Table in subsection 72-1(2) of the Act.

Paragraph 6(a) provides that the Schedule to the Prostheses Rules sets out listed prostheses. The listed prostheses are:

- kinds of prostheses in relation to which the Minister has granted an application for listing under subsection 72-10(5) of the Act, and for which the applicant has paid any initial listing fee imposed under the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* within the specified timeframe; and
- kinds of prostheses that were, immediately before the commencement of the Act on 1 April 2007, listed as a no gap prosthesis or a gap permitted prosthesis for the purposes of the *National Health Act 1953* (see section 12, *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007*).

Paragraph 6(aa) provides that the circumstances in which there must be a benefit payable for the provision of a listed prosthesis, other than circumstances in which a Medicare benefit is payable, are set out in rule 7 of the Prostheses Rules.

Paragraph 6(ab) provides the conditions that must be satisfied in relation to the provision of a listed prosthesis in order for a benefit to be payable for the purposes of paragraph (c) or (d) of Item 4 of the Table in subsection 72-1(2) of the *Private Health Insurance Act 2007*, are set out in rule 8 of the Prostheses Rules. These conditions further limit when a benefit is required to be payable for the provision of a listed prosthesis in the circumstances where a Medicare benefit is payable (refer to paragraph (c), item 4 of the Table) or in the circumstances which are set out in the Prostheses Rules (refer to paragraph (d), item 4 of the Table).

Paragraph 6(b) provides that rule 9 sets out the method for working out the minimum and maximum benefit for hospital treatment, covered under a complying health insurance policy that is the provision of a listed prosthesis.

Paragraph 6(c) provides that rule 10 sets out the method for working out the minimum benefit and maximum benefit for hospital-substitute treatment, covered under a complying private health insurance policy that is the provision of a listed prosthesis.

Where a private health insurer covers hospital treatment or hospital-substitute treatment under a policy, the private health insurer cannot exclude coverage of the provision of a listed prosthesis. This coverage requirement is provided for in Rule 8 of the *Private Health Insurance (Complying Product) Rules 2015*.

Rule 7 Circumstances in which a prosthesis is provided other than circumstances in which a Medicare benefit is payable

Rule 7 specifies circumstances for the purposes of paragraph (d) of 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) that is the provision of a listed prosthesis which is associated with podiatric treatment by a registered podiatric surgeon. This is the case even if a Medicare benefit is not payable for that provision.

A note to rule 7 provides that the provision of a listed prosthesis in circumstances in which a Medicare benefit is payable is dealt with in paragraph (c) of item 4 of the Table.

Rule 8 Conditions in relation to provision of listed prostheses

Under paragraphs (c) and (d) of item 4 in the Table in subsection 72-1(2) of the Act, the Private Health Insurance (Prostheses) Rules may set out conditions that must be satisfied in relation to the provision of a listed prosthesis in circumstances in which a Medicare benefit is payable, or in the circumstances set out in rule 7, whatever the case may be. If these conditions are not satisfied, no

benefit is payable under a complying health insurance policy that covers hospital treatment and hospital-substitute treatment.

Rule 8 specifies that the conditions that must be satisfied in the case of any listed prosthesis for which there is a statement of a requirement under the heading 'Condition' in the Schedule under the listing for that kind of prosthesis, that requirement (paragraph 8(a)). There are 78 Prostheses List billing codes listed in the Schedule which have a condition. These codes with conditions include:

72 codes listed in the Schedule in the Previous Rules:

- BF025 (*Pedicle Screw*);
- BF026 (*Pedicle Screw*);
- BF027 (*Locking Element*);
- BF028 (*Rods, Curved*);
- BF029 (*Rods*);
- 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*);
- HU267 (*Cerclage System*);
- HW678 (*Monterey AL, Cage with integral fixation*);
- HW776 (*Cayman United Plate*);
- HW785 (*AutoPlex Mixer and Delivery System with VertaPlex HV*);
- IJ022 (*Regenerative Dural Repair Patch (ReDura™)*);
- IJ023 (*Regenerative Dural Repair Patch (ReDura™)*);
- IJ024 (*Regenerative Dural Repair Patch (ReDura™)*);
- IJ025 (*Regenerative Dural Repair Patch (ReDura™)*);
- 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 SureScan™ 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)
- SJ417 (*Gallant VR ICD Model CDVRA500Q*);
- SJ418 (*Gallant DR ICD Model CDDRA500Q*);
- SJ419 (*Entrant DR ICD Model CDDRA300Q*);
- SJ420 (*Entrant VR ICD Model CDVRA300Q*);
- SJ421 (*Neutrino NxT DR ICD Model CDDRA600Q*);
- SJ422 (*Neutrino NxT VR ICD Model CDVRA600Q*);
- SJ424 (*Gallant HF CRT-D Model CDHFA500Q*);
- SJ425 (*Neutrino NxT HF CRT-D Model CDHFA600Q*); and
- SJ426 (*Entrant HF CRT-D Model CDHFA300Q*)

5 new codes following successful new applications that are subject to the specific conditions that must be satisfied in relation to the provision of these prostheses

- LH719 (TissuePatchDural 50*25)
- LH720 (TissuePatchDural 50*50)
- LH721 (TissuePatchDural 50*100)
- LH722 (TissuePatchDural 100*100)
- LH723 (TissuePatchDural 100*25)

and 1 existing code, ongoing listing of which, is subject to placing the specific conditions on it

- HW856 (Augment Bone Graft – rhPDGF-BB component)

The specific conditions for these 78 codes are below.

Part A

- BX343, BX344 – that the prosthesis 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;
- DE669, DE670, DE671, BF025, BF026, BF027, BF028, and BF029 – to be reimbursed only when used in patients with spinal tumours;
- DE678 – limited to use in patients with spinal tumours only;
- DE679, DE680 – to be provided only to patients with spinal tumours;
- 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 PL 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;
- HW785 – No benefit will be payable if the device is used in kyphoplasty surgery, as there is no evidence presented and no MBS item available for this procedure;
- IJ022, IJ023, IJ024, IJ025 – The PL benefit is limited to use of the device 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, SJ419, SJ420, SJ421, SJ422, SJ424, SJ425, and SJ426 – 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;
- HW785 (*AutoPlex Mixer and Delivery System with VertaPlex HV*);
- IJ022, IJ023, IJ024, and IJ025 - The PL benefit will be limited to use of the device for procedures related to dura defect repair in spinal and neurosurgical procedures.);
- LH719, LH720, LH721, LH722 and LH723 payment of the PL benefits will be limited to use of the devices for procedures related to dura defect repair in spinal and neurosurgical procedures; and
- HW856 (Augment Bone Graft – rhPDGF-BB component) - to be reimbursed 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.

Part C

- in the case of a listed prosthesis that is 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:
 - a professional attendance by a consultant physician in the practice of his or her speciality;
 - provided as a certified Type C or certified overnight Type C procedure; and
 - provided for the purpose of administering insulin.

Rule 9 Benefits for prostheses provided as part of hospital treatment

Subrule 9(1) provides that, for a no gap prosthesis (other than those referred to in Subrule 1A) provided as part of an episode of hospital treatment by a private hospital, the minimum and maximum benefit are each the amount for that prosthesis set out under the column heading ‘Minimum Benefit’ in the Schedule to the Rules.

Subrule 9(1A) describes the method for calculating minimum and maximum benefits for no gap irrigated cardiac ablation catheters, mapping catheters for catheter cardiac ablation, patches for cardiac ablation, monopolar devices for surgical cardiac ablation, bipolar devices for surgical cardiac ablation, systems for cardiac ablation, probes for cardiac ablation, non-irrigated cardiac ablation catheters, and intracardiac electrophysiology catheters for a private patient in a private hospital. The method described is:

- if the sum of the default minimum benefits for the procedure in which the prosthesis was used is \$6399 or less, the minimum benefit and the maximum benefit are each the default minimum benefit for the prosthesis;
- if the sum of default minimum benefits for the procedure in which the prosthesis was used is more than \$6399, the minimum benefit and the maximum benefit are each to be calculated using the following method: divide the default minimum benefit for the prosthesis by the sum of the default minimum benefits for the procedure in which the prosthesis was used, and multiply the result by \$6399. For example, if an irrigated cardiac ablation catheter, a mapping catheter for catheter cardiac ablation and a patch for cardiac ablation each listed in the Schedule are used in a relevant procedure in accordance with any conditions, and the default minimum benefit of the irrigated cardiac ablation catheter is X, the default minimum benefit of the mapping catheter for cardiac ablation is Y, and the default minimum benefit of the patch for cardiac ablation is Z, 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 \$6399, the minimum benefit and maximum benefit for the irrigated cardiac ablation catheter is calculated by taking X, dividing it by (X+Y+Z), then multiplying the result by \$6399.

Subrule 9(2) provides that, for a gap permitted prosthesis provided as part of an episode of hospital treatment in a private hospital, the minimum benefit and the maximum benefit are the amounts set out in the Schedule for that prosthesis under the column headings 'Minimum Benefit' and 'Maximum Benefit'.

Subrule 9(3) provides that, for a no gap prosthesis (other than those referred to in Subrule 3A) provided as part of an episode of hospital treatment in a public hospital, the minimum benefit is the lesser of:

- the amount for that prosthesis set out in the Schedule under the column heading 'Minimum Benefit'; or
- the amount of the insured person's liability to the public hospital for that prosthesis.

The maximum benefit is the amount for that prosthesis set out under the column heading 'Minimum Benefit' in the Schedule to these Rules.

Subrule 9(3A) provides that for no gap irrigated cardiac ablation catheters, mapping catheters for cardiac ablation, patches for cardiac ablation, monopolar devices for surgical cardiac ablation, bipolar devices for surgical cardiac ablation, systems for cardiac ablation, probes for cardiac ablation, non-irrigated cardiac ablation catheters, and intracardiac electrophysiology catheters for a private patient in a public hospital, the minimum benefit is the lesser of:

- the amount for that calculated in accordance with subrule 9(3B); or
- the amount of the insured person's liability to the public hospital for that prosthesis.

The maximum benefit is the amount for the prosthesis calculated in accordance with subrule 9(3B).

Subrule 9(3B) describes the method for calculating the amount for maximum benefit for no gap irrigated cardiac ablation catheters, mapping catheters for catheter cardiac ablation, patches for cardiac ablation, monopolar devices for surgical cardiac ablation, bipolar devices for surgical cardiac ablation,

systems for cardiac ablation, probes for cardiac ablation, non-irrigated cardiac ablation catheters, and intracardiac electrophysiology catheters for a private patient in a public hospital. The method is the same as that set out in subrule 9(1A).

Subrule 9(4) provides that, for a gap permitted prosthesis provided as part of an episode of hospital treatment by a public hospital, the minimum benefit is the lesser of:

- the amount for that prosthesis set out in the Schedule under the column heading ‘Minimum Benefit’; or
- the amount of the insured person’s liability to the public hospital for that prosthesis.

The maximum benefit is the amount for that prosthesis set out under the column heading ‘Maximum Benefit’ in the Schedule.

Subrule 9(5) defines certain terms used in rule 9.

Rule 10 Benefits for prostheses provided as part of hospital-substitute treatment

Subrule 10(1) provides that, for a no gap prosthesis provided as part of an episode of hospital-substitute treatment, the minimum and maximum benefit are each the amount for that prosthesis set out under the column heading ‘Minimum Benefit’ in the Schedule.

Subrule 10(2) provides that, for a gap permitted prosthesis provided as part of an episode of hospital-substitute treatment, the minimum benefit and the maximum benefit are the amounts set out in the Schedule for that prosthesis under the column headings ‘Minimum Benefit’ and ‘Maximum Benefit’.

Part 3 – Other

Rule 11 Timing of applications

Rule 11 provides that, as a matter of normal administrative practice, applications for listing of a prosthesis in the rules will be considered after they have been received and, if the Minister grants an application, then the prosthesis will be listed in the Schedule the next time the Minister makes or varies the Prostheses Rules.

Rule 12 Minister may have regard to recommendations and advice

Rule 12 provides that, in making a decision under section 72-10 of the Act, the Minister may have regard to a recommendation from the Prostheses List Advisory Committee when deciding whether or not to grant the application to list a kind of prosthesis.

Rule 13 Listing criteria for prostheses to be listed in Part C of the Schedule

Rule 13 sets out the listing criterion that must be met for a listing application to be granted for listing a kind of prosthesis in Part C of the Schedule. This criterion is that the kind of prosthesis is either an insulin infusion pump, an implantable cardiac event recorder, a cardiac home/remote monitoring system, an irrigated cardiac ablation catheter, a mapping catheter for catheter cardiac ablation, a patch for cardiac ablation, a monopolar device for surgical cardiac ablation, a bipolar device for surgical cardiac ablation, a system for surgical cardiac ablation, a probe for surgical cardiac ablation, a non-irrigated cardiac ablation catheter or an intracardiac electrophysiology catheter.

Notes to rule 13 provide that:

- the power to make listing criteria is found in subsection 72-10(6) of the Act; and

- the Minister may not grant a listing application if any applicable listing criteria have not been met, and the Minister has the power to refuse to grant a listing application even if the listing criteria have been satisfied (see subsection 72-10(7) of the Act).

Schedules

The Schedule Prostheses List

The Schedule lists kinds of prostheses and contains the ‘Minimum Benefit’ and ‘Maximum Benefit’ and conditions for kinds of prostheses for private and public hospital treatment, and hospital-substitute treatment. The Schedule also lists general use prostheses identified for removal.

Statement of Compatibility with Human Rights

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

Private Health Insurance (Prostheses) Rules (No. 1) 2022

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 *Private Health Insurance Act 2007* (the Act) provides for benefit requirements that a complying health insurance policy that covers hospital treatment must meet. Under item 4 of that table there must be a benefit for the provision of a prosthesis, of a kind listed in Private Health Insurance (Prostheses) Rules (i.e. a listed prosthesis), in specified circumstances and under any specified conditions.

The *Private Health Insurance (Prostheses) Rules (No. 1) 2022* (the Rules):

- repeal the *Private Health Insurance (Prostheses) Rules (No. 3) 2021* (the Previous Rules); and
- provides for an updated list of the kinds of prostheses in relation to the provision of which a benefit must be paid in the conditions and circumstances specified, and set out the minimum and, where applicable, maximum benefit payable.

The Prostheses Rules differ from the Previous Rules by:

- adding 316 new Prostheses List billing codes to Part A of the Schedule, as a result of listing 196 prostheses for the first time following successful new applications (including 5 new codes that will be subject to the specific conditions that must be satisfied in relation to the provision of these prostheses), creating 2 new codes due to the compression of existing codes, and 118 new codes due to transfer of prostheses from one sponsor to another;
- adding 41 new Prostheses List billing codes to Part B of the Schedule following successful applications;
- adding 18 new Prostheses List billing codes to Part C of the Schedule following successful new applications;
- changing the listing details of 76 Prostheses List billing codes in Part A of the Schedule following the successful requests from the sponsors;
- changing the listing details of 59 Prostheses List billing codes in Part B of the Schedule following the successful requests from the sponsors;
- changing the listing details of 9 Prostheses List billing codes in Part C of the Schedule following the successful requests from the sponsors; and
- deleting 322 Prostheses List billing codes from Part A of the Schedule, as a result of accepting 155 deletion applications submitted by the sponsors, deleting 118 current codes after transferring prostheses to the new sponsors, deleting 5 current codes as the result of successful compression application, deleting 40 existing billing codes for surgical mesh prostheses as a

result of the reclassification and subsequent need for cancellation of their entries from the Australian Register of Therapeutic Goods (ARTG), deleting 2 current codes following advice received from the MSAC and removing 2 current codes due to incorrect listing.

The further changes to the Prostheses Rules are:

- removing suffix Textured for 13 Prostheses List billing codes for breast implants and tissue expanders listed in Part A of the Schedule with the respective changes to the benefits that must be paid for these prostheses, following advice received from the Medical Services Advisory Committee (MSAC);
- changing the listing details of 1 Prostheses List billing code in Part A of the Schedule by placing the condition that must be satisfied in relation to the provision of this prosthesis, aligning the obligation to pay the benefit for the prosthesis with the intended use stated on its ARTG entry.

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 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 will increase the amount of choice an insured person can have in relation to the type of prostheses for which they must receive a minimum private health insurance benefit. This will impact positively on the right to health of insured persons.

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

Generally the prostheses removed from the 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.

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