

EXPLANATORY STATEMENT

Private Health Insurance Act 2007

Private Health Insurance (Prostheses) Rules (No. 1) 2023

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) 2023* (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 Schedule 1 to the Prostheses Rules. The list of prostheses in Schedule 1 is commonly referred to as the Prostheses List.

Schedule 1 to the Prostheses Rules has four parts:

- Part 1 - Part A – Prostheses;
- Part 2 - Part B – Human Tissue;
- Part 3 - Part C – Other Prostheses
- Part 4 - Part D – General Use Items

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) 2022* (Previous Rules).

The Prostheses Rules differ from the Previous Rules by:

- adding 192 new Prostheses List billing codes to Part A of Schedule 1, as a result of listing 137 prostheses for the first time following successful new applications, 1 new code due to duplication of a billing code, and 54 new codes due to transfer of prostheses from one sponsor to another;
- changing the listing details of 106 Prostheses List billing codes in Part A of Schedule 1 following the successful amendment applications from the sponsors;
- deleting 252 Prostheses List billing codes from Part A of Schedule 1, as a result of accepting 198 deletion applications submitted by the sponsors, removing 54 current codes after transferring prostheses to the new sponsors,
- adding 8 new Prostheses List billing codes to Part B of Schedule 1 as a result of listing the human tissue items following successful new applications;
- changing the listing details of 94 Prostheses List billing codes in Part B of Schedule 1 following successful amendment applications from the human tissue facilities;
- adding 2 new Prostheses List billing codes to Part C of Schedule 1, following successful new applications;
- changing the listing details of 1 Prostheses List billing code in Part C of Schedule 1 following successful amendment applications from the sponsors; and
- changing the listing details of 2 Prostheses List billing code in Part D of Schedule 1.

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

In addition to the changes resulted from completion of the applications, the Prostheses Rules implement changes arising from the reforms to the Prostheses List arrangements and post-listing reviews:

- reducing benefits for 220 billing codes for the general use items, listed in Part D of Schedule 1, consistently with the Prostheses List reforms (this also includes 3 billing codes for which other changes have been made following successful amendment applications);
- deleting 24 billing codes in Part A of Schedule 1 for microcatheter devices listed in subgroups 04.08.03.01 – Neurosurgical–NEURO INTERVENTION–Assist Devices–Catheters and 10.08.06.01 – Vascular–Occlusion Devices–Delivery Device for Occlusion Media–Catheter, following completion of the Prostheses List post-listing review;
- reducing benefits for 4 billing codes in Part A of Schedule 1 for metal-backed patellas listed in subgroups 12.08.02 – Knee–PATELLAR COMPONENT–Cemented, Polyethylene, Metal Backed and 12.08.03 – Knee–PATELLAR COMPONENT–Uncemented, Polyethylene, Metal Backed, following completion of the Prostheses List post-listing review;
- correcting the listing details for 12 billing codes by moving them from Part A to Part D of Schedule 1 following further consideration of the devices;
- correcting the listing details for 6 billing codes by moving them from Part D to Part A of Schedule 1 following further consideration of the devices.

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

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

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 Medical Services Advisory Committee where required.

Applicants who applied under subsection 72-10(2) of the Act for the listing of their prostheses on the Prostheses List or amending the existing billing codes had opportunities to provide further information and clarification regarding their products during assessment of their applications.

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

Prostheses List reforms

In the 2021-22 Budget, \$22 million were committed over four years to improve the Prostheses List and its arrangements, building on the previous reform activities. These reforms are implemented over a number of years with transitional arrangements.

The aim of the Prostheses List reforms includes improving sustainability of the private health insurance and measures include better aligning the Prostheses List benefits with the prices paid in the public hospital system, better defining the scope of the Prostheses List, and clarifying that the general use items are not eligible for listing on the Prostheses List. Clinical Implementation Reference Group was established to assist in defining which products are general use items (that are all are now listed in Part D of Schedule 1) and should be removed in July 2023 from the Prostheses List.

Aligning the Prostheses List benefits with the public hospital prices has been supported by benchmark pricing developed by the Independent Health and Aged Care Pricing Authority (IHACPA). The IHACPA consulted extensively with the relevant stakeholders prior to publishing the Methodology for Determining the Benchmark Price for Prostheses in Australian Public Hospitals outlining the process used to determine the benchmark price for prostheses in the public sector. The Prostheses List benefits reductions occur in three instalments (in 2022, 2023, and 2024), with the reduction commencing in July 2022 Prostheses List.

The March 2023 Prostheses List is the previously announced deadline for reducing the benefits for all general use items in Part D by 40 percent of the difference between the Prostheses List benefits and the Weighted Average Prices.

Prostheses List reviews

Sponsors of billing codes being deleted or where the benefits are being reduced following the Prostheses List post-listing reviews were also consulted during the reviews.

Commencement

The Prostheses Rules commence on 1 March 2023.

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

Provision by provision description of the *Private Health Insurance (Prostheses) Rules (No. 1) 2023*

Part 1 – Preliminary

Rule 1 Name

Rule 1 provides that the title of the Rules is the *Private Health Insurance (Prostheses) Rules (No. 1) 2023* (Prostheses Rules).

Rule 2 Commencement

Rule 2 provides that the Prostheses Rules commence on 1 March 2023.

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) 2022* 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.

Rule 5 contains a definition of the **Regulations** as meaning the *Health Insurance (General Medical Services Table) Regulations 2021* made under section 4 of the *Health Insurance Act 1973*. The Regulations are incorporated by reference into the Rules, as in force from time to time. The Rules are a disallowable legislation instrument and there is no contrary intention that would not permit the Regulations to be incorporated as in force 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 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 Schedule 1 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 Act, 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 Schedule 1 under the listing for that kind of prosthesis, that requirement (paragraph 8(a)). There are 83 Prostheses List billing codes listed in Schedule 1 which have a condition. These codes with conditions include:

- 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*);
- 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)*);
- 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*);

- 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*);
- OW014 (*StabiliT Bone Cement & Saturate Mixing System*);
- 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*);
- SJ426 (*Entrant HF CRT-D Model CDHFA300Q*); and
- SK494 (*DuraMatrix*).

The specific conditions for these 83 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 Prostheses 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;
- HW785 - No PL benefit will be payable if the device is used for kyphoplasty surgery, as there is no evidence presented and no MBS item available for this procedure;
- HW856 - The Prostheses 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 Prostheses 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 Prostheses List (PL) 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 and SK494 - payment of the Prostheses 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, 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; and
- OW019 - No PL benefit will be payable if the device is used for kyphoplasty surgery, as there is no MBS item available for this procedure.

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 8 (b) specifies that in relation to a listed prosthesis that is an insulin infusion pump, also:

- (i) the professional service associated with the provision of the insulin infusion pump must be a professional attendance by a consultant physician in the practice of his or her specialty; and
- (ii) the professional service must be provided as a certified Type C procedure or certified overnight Type C procedure; and
- (iii) the insulin infusion pump must be 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 Schedule 1 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 Schedule 1 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 Schedule 1 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 Schedule 1 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 Schedule 1 to the Prostheses 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 Schedule 1 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 Schedule 1 to the Prostheses Rules.

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 both the amount for that prosthesis set out under the column heading ‘Minimum Benefit’ in Schedule 1.

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

Schedule 1 for that prosthesis under the column headings ‘Minimum Benefit’ and ‘Maximum Benefit’.

Part 3 – Other

Rule 11 Timing of applications to have a prosthesis listed

Rule 11 provides that, as a matter of normal administrative practice, applications for listing of a prosthesis in the rules (in accordance with subsection 72-10(2) of the Act) will be considered after they have been received and, if the Minister grants an application, then the prosthesis will be listed in Schedule 1 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. This committee provides recommendations and advice to the Minister for Health and Aged Care and the Department of Health and Aged Care about the listing of products on the Prostheses List and the benefits payable by private health insurers.

Rule 13 Listing criteria for prostheses to be listed in Part C of Schedule 1

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 Schedule 1. 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 must 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

Schedule 1 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.

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) 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 *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) 2023* (the Rules):

- (a) repeal the *Private Health Insurance (Prostheses) Rules (No. 3) 2022* (the Previous Rules); and
- (b) provide 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 192 new Prostheses List billing codes to Part A of Schedule 1, as a result of listing 137 prostheses for the first time following successful new applications, 1 new code due to duplication of a billing code, and 54 new codes due to transfer of prostheses from one sponsor to another;
- changing the listing details of 106 Prostheses List billing codes in Part A of Schedule 1 following the successful amendment applications from the sponsors;
- deleting 252 Prostheses List billing codes from Part A of Schedule 1, as a result of accepting 198 deletion applications submitted by the sponsors, removing 54 current codes after transferring prostheses to the new sponsors,
- adding 8 new Prostheses List billing codes to Part B of Schedule 1 as a result of listing the human tissue items following successful new applications;
- changing the listing details of 94 Prostheses List billing codes in Part B of Schedule 1 following successful amendment applications from the human tissue facilities;
- adding 2 new Prostheses List billing codes to Part C of Schedule 1, following successful new applications;
- changing the listing details of 1 Prostheses List billing code in Part C of Schedule 1 following successful amendment applications from the sponsors; and
- changing the listing details of 2 Prostheses List billing code in Part D of Schedule 1.

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

In addition to the changes resulted from completion of the applications, the Prostheses Rules implement changes arising from the reforms to the Prostheses List arrangements and post-listing reviews:

- reducing benefits for 220 billing codes for the general use items, listed in Part D of Schedule 1, consistently with the Prostheses List reforms (this also includes 3 billing codes for which other changes have been made following successful amendment applications);
- deleting 24 billing codes in Part A of Schedule 1 for microcatheter devices listed in subgroups 04.08.03.01 – Neurosurgical–NEURO INTERVENTION–Assist Devices–Catheters and

10.08.06.01 – Vascular–Occlusion Devices–Delivery Device for Occlusion Media–Catheter, following completion of the Prostheses List post-listing review;

- reducing benefits for 4 billing codes in Part A of Schedule 1 for metal-backed patellas listed in subgroups 12.08.02 – Knee–PATELLAR COMPONENT–Cemented, Polyethylene, Metal Backed and 12.08.03 – Knee–PATELLAR COMPONENT–Uncemented, Polyethylene, Metal Backed, following completion of the Prostheses List post-listing review;
- correcting the listing details for 12 billing codes by moving them from Part A to Part D of Schedule 1 following further consideration of the devices;
- correcting the listing details for 6 billing codes by moving them from Part D to Part A of Schedule 1 following further consideration of the devices.

When Prostheses List codes are transferred from one sponsor to a different sponsor, the Prostheses List codes that they are expanded or compressed or transferred 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 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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