

EXPLANATORY STATEMENT

Private Health Insurance Act 2007

Private Health Insurance (Prostheses) Rules (No. 4) 2019

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.

Section 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. 4) 2019* (Prostheses Rules) are made for the purposes of section 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 three parts:

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

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) 2019* (Previous Rules) and

also updates the devices in the Protheses List. The Protheses Rules differ from the Previous Rules by changing (reducing) the minimum benefit for prostheses groups as defined in the Government / MTAA Agreement, and the deletion of Stratafix (MN237).

Consultation

The Minister of Health consulted with the MTAA, as an advocate for the Australian medical device industry, as well as a number of individual Sponsors.

A provision by provision description of the Protheses Rules is set out in [Attachment 1](#).

The Protheses Rules commence on 1 February 2020.

The Protheses 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. 4) 2019*

Part 1 – Preliminary

Rule 1 Name

Rule 1 provides that the title of the Rules is the *Private Health Insurance (Prostheses) Rules (No. 4) 2019 (Prostheses Rules)*.

Rule 2 Commencement

Rule 2 provides that the Prostheses Rules commence on 1 February 2020.

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 5 provides that the *Private Health Insurance (Prostheses) Rules (No. 3) 2019*, made on 24 October 2019, 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.

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 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 *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 Schedule 1 under the listing for that kind of prosthesis, that requirement (paragraph 8(a)). There are 55 prostheses listed in Schedule 1 which have a condition:

- BS359 (*IntellaMap Orion High Resolution Mapping Catheter*);
- BS360 (*Rhythmia Location Reference Patch Kit*);
- BS361 (*IntellaNav Open-Irrigated Ablation Catheter*);
- BT221 (*AlCath Force*);
- BT222 (*AlCath G FullCircle*);
- BT223 (*AlCath Flux G eXtra*);
- BT224 (*AlCath Flutter Flux G eXtra*);
- BT225 (*AlCath Flutter LT G*);
- CT016 (*Restorelle M Smartmesh*);
- 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*);
- ER489 (*Cayman United Plate*);
- LH590 (*Pedicle Screw*);
- LH591 (*Pedicle Screw*);
- LH592 (*Locking Element*);
- LH593 (*Rods, Curved*);
- LH594 (*Rods*);
- MA545 (*Ligamys DIS Suture with button*);
- MI300 (*PVAC Gold Phased RF catheter*);
- MI301 (*Artic Front Advance Cardiac CryoAblation Catheter*);

- MI302 (*Achieve / Achieve Advance Mapping Catheter*);
- MI309 (*Cardioblate Surgical Ablation Pen XL*);
- MI308 (*Cardioblate BP2 RF Surgical Ablation Device*);
- MI312 (*Cardioblate BP2 RF Surgical Ablation System*);
- MI310 (*Cardioblate Gemini Surgical Ablation System*);
- MI311 (*CryoFlex Surgical Ablation Probe*);
- MI307 (*SurgiFrost 10*);
- MI306 (*CryoFlex Surgical Clamp and Probe*);
- MN238 (*CARTO: SMARTTOUCH / SMARTTOUCH SF*);
- MN239 (*CARTO Reference*);
- MN240 (*LASSO / PENTARAY*);
- NK106 (*Intervertebral Fusion Staple*)
- SO041 (*Osmed Sphere / Hemisphere tissue expander*);
- SJ404 (*Inquiry Optima Diagnostic Catheter*)
- SJ405 (*Reflexion Spiral Variable Radius Catheter*)
- SJ406 (*Advisor Mapping Catheter*)
- SJ407 (*Afocus II EB Inquiry Steerable Catheter*)
- SJ408 (*Ensite Patch*)
- SJ409 (*Flexibility Ablation Catheter*)
- SJ410 (*TactiCath Contact Force Ablation Catheter*)
- ZZ055 (*ATRICURE ISOLATOR SYNERGY RF CLAMPS*)
- ZZ056 (*Isolator Synergy Access*)
- ZZ057 (*cryoICE Cryoablation Surgical Probes*)

The specific conditions for the 55 prostheses with the following billing codes are:

Part A

- CT016 – the provision of the prosthesis is only to be funded when used in conjunction with MBS Item No. 35597. See rule 5B for effect of Condition;
- 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;
- DE669, DE670, DE671, LH590, LH591, LH592, LH593, and LH594 – 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;
- ER489 – to be reimbursed only when used with posterior supplemental fixation with other implants;

- SO041 – the provision of the prosthesis is for a child who is under 18 years of age. See rule 5B for effect of Condition; and
- NK106 – for single level ACDF (Anterior cervical discectomy and fusion) only.

Part C

- MI306, MI307, MI308, MI309, MI310, MI311, MI312, ZZ055, ZZ056, ZZ057 - the prosthesis is only to be used in a surgical procedure described in item 38512 or 38515 in Group T8 of the *Health Insurance (General Medical Services Table) Regulations 2018*;
- BS359, BS360, BS361, BT221, BT222, BT223, BT224, BT225, MI300, MI301, MI302, MN238, MN239, MN240, SJ404, SJ405, SJ406, SJ407, SJ408, SJ409, SJ410 – the prosthesis is only to be used in a surgical procedure described in item 38290 or 38287 in Group T8 of the *Health Insurance (General Medical Services Table) Regulations 2018* and where the procedure is for the treatment of atrial fibrillation; and
- 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 Schedule 1, 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 specialty;
 - 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 Schedule 1 to the Rules.

Subrule 9(1A) describes the method for calculating minimum and maximum benefits for 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 and probes for cardiac ablation 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 a 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 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 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 by 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 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 these Rules.

Subrule 9(3A) provides that for no gap 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 and probes for cardiac ablation 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 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 and probes for cardiac ablation 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 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

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 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.

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, a 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, or a probe for surgical cardiac ablation.

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

Schedule 1 Prosthesis List

Schedule 1 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. 4) 2019

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. 4) 2019* (the Rules):

- (a) repeal the *Private Health Insurance (Prostheses) Rules (No. 3) 2019* (the Previous Rules); and
- (b) 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 reducing the minimum benefit for prostheses categories identified in the October 2017 announcement by the Minister Health to reduce the minimum benefit. Each group or subgroup has been reduced by a specific amount as set out in the Government / MTAA Agreement. The effect of reducing the minimum benefit reduces the overall benefits payable by private health insurers. Stratafix was also 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

These rules are the final reduction (in a series of three) to the minimum benefit payable for a prosthesis. The benefit reductions are an important step in improving the value of private health insurance. The Stratafix sutures are considered general use surgical equipment and not suitable to be funded by the Prostheses List.

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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