EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

Private Health Insurance Act 2007

Private Health Insurance (Prostheses) Rules 2018 (No. 2)

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.

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 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 Private Health Insurance (Prostheses) Rules. The specified conditions are any that may be set out in Private Health Insurance (Prostheses) Rules. Currently there are specified conditions in relation to insulin pumps, and in relation to prostheses with billing codes CT016, CR032, CR201, CR202, CR203, CR204, CR205, CR206, CR214, DE669, DE670, DE671, ER489, LH590, LH591, LH592, LH593, LH594, MA545, and SO041.

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.

The purpose of the *Private Health Insurance (Prostheses) Rules 2018 (No. 2)* (the 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, and set out the minimum and, where applicable, maximum benefit payable.

The Rules repeal the *Private Health Insurance (Prostheses) Rules 2018 (No. 1)* (the Previous Rules).

The Schedule to the Rules has three parts:

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

The Rules differ from the Previous Rules by:

- adding 523 new prostheses to Part A of the Schedule;
- changing the current listing of 213 existing prostheses in Part A of the Schedule including:
  - amending the names, descriptions and/or sizes of prostheses; and
  - changing the grouping of and minimum benefit for prostheses;

- deleting 526 items from Part A of the Schedule;
- adding 34 new human tissue items to Part B of the Schedule;
- changing the current listing of 244 existing human tissue items in Part B of the Schedule, including
  - amending the descriptions of human tissue items; and
  - changing the minimum benefit of human tissue items; and
- adding four new prostheses to Part C of the Schedule.

In Part A of the Schedule, prostheses are grouped according to their clinical effectiveness, as assessed by Clinical Advisory Groups (CAGs) or the Panel of Clinical Experts (the Panel). The purpose of the groupings is to identify products of similar clinical effectiveness or clinical design, in order to assist in determining the minimum benefits payable for the prostheses and to assist with clinical choice.

Minimum benefits payable for new prostheses have been developed either as part of the implementation of recommendation 12 (paragraphs b-e) of the *Review of Health Technology Assessment in Australia 2009* (the HTA Review) or by the Health Economists Sub Committee (HESC) of the Prostheses List Advisory Committee (PLAC). Implementation of the HTA Review recommendation involved the refinement of grouping schemes and the development of group benefits for clinically similar products. This process was guided by the Health Technology Assessment Consultative Committee and the benefits developed were endorsed by the PLAC. The benefits developed by the HESC were also endorsed by the PLAC.

Consultation

The Rules have been made having regard to recommendations made by the PLAC, which is a ministerially appointed committee comprised of members from health insurers, hospitals, clinicians, prostheses sponsors and consumer representatives.

In making its recommendations, the PLAC was advised by CAGs, other clinical experts in the Panel, and the HESC.

Applicants who applied to list prostheses and human tissue items were also consulted.

Details of the Rules are set out in the Attachment.

The Rules commence on 14 September 2018.

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

Authority: Section 333-20 of the *Private Health Insurance Act 2007*

ATTACHMENT

DETAILS OF THE *PRIVATE HEALTH INSURANCE (PROSTHESES) RULES 2018 (No. 2)*

PART 1 PRELIMINARY

1. Name of Rules

Rule 1 provides that the title of the Rules is the *Private Health Insurance (Prostheses) Rules 2018 (No. 2).*

2. Commencement

Rule 2 provides for the Rules to commence on 14 September 2018.

3. Authority

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

4. Definitions

Rule 4 defines certain terms used in the Rules, and notes that terms used in the Rules have the same meaning as in the Act.

5. Repeal

Rule 5 provides for the repeal of the *Private Health Insurance (Prostheses) Rules 2018 (No. 1)* (the Previous Rules).

PART 2 BENEFIT REQUIREMENTS

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.

Paragraph 6(a) provides that the Schedule to the 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, including those 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 Rules.

Paragraph 6(ab) provides that conditions that must be satisfied in relation to the provision of a listed prosthesis in order for a benefit to be payable are set out in subsection 72-1(2) of the *Private Health Insurance Act 2007*, as set out in rule 8 of the 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 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.

It is not possible for a private health insurer to cover hospital treatment or hospital-substitute treatment under a policy, but exclude coverage of the provision of an associated listed prosthesis. This coverage requirement is provided for in Rule 8 of the *Private Health Insurance (Complying Product) Rules 2015*.

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. 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 an accredited podiatrist. 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.

8. Conditions in relation to provision of listed prostheses

Under paragraphs (c) and (d) of item 4 in the Table, 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 required to be payable under a complying health insurance policy that covers hospital treatment.

Rule 8 specifies that the conditions that must be satisfied are:

- 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 20 prostheses in the Schedule which have a condition:
    - 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*);
    - DE670 (*icotec Pedicle Screw System Rod*);
    - DE671 (*icotec Pedicle Screw System set screw*);
    - ER489 (*Cayman United Plate*);
    - LH590 (*Pedicle Screw*);
    - LH591 (*Pedicle Screw*);
    - LH592 (*Locking Element*);
    - LH593 (*Rods, Curved*);
    - LH594 (*Rods*);
    - MA545 (*Ligamys DIS Suture with button*); and,
    - SO041 (*Osmed Sphere / Hemisphere tissue expander*);

    The specific conditions for the 20 prostheses with the following billing codes are:

    - CT016 – the provision of the prosthesis must only be funded when used in conjunction with a particular item in the General Medical Services Table;

- CR032, CR201, CR202, CR203, CR204, CR205, CR206, CR214, and MA545 – an Artificial Ligament must be used for intra-articular cases where no non-synthetic graft sources (allografts and autografts) are available;
- ER489 – must be used as posterior supplemental fixation with other implants;
- DE669, DE670, DE671, LH590, LH591, LH592, LH593, and LH594 –must be used only in patients with spinal tumours.
- SO041 – the provision of the prosthesis must be for a child who is under 18 years of age; 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 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 specialty; and
  - provided as a certified Type C or certified overnight Type C procedure; and
  - provided for the purpose of administering insulin.

9. Benefits for prostheses provided as part of hospital treatment

Subrule 8(1) provides that, for a no gap prosthesis 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.

Subrule 8(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 8(3) provides that, for a no gap 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 'Minimum Benefit' in the Schedule.

Subrule 8(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.

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'.

11. Timing of applications

Rule 11 provides that, as a matter of normal administrative practice, applications for listing 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 Rules.

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.

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 or a cardiac home/remote monitoring system.

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).

SCHEDULE

The Schedule lists kinds of prostheses and contains the 'Minimum Benefit' and 'Maximum Benefit' 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 2018 (No. 2)

This Legislative 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 2018 (No. 2)* (the Rules):

(a) repeal the *Private Health Insurance (Prostheses) Rules 2018 (No. 1)* (the Previous Rules); and

(b) update the 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 Rules differ from the Previous Rules by:

- adding 523 new prostheses to Part A of the Schedule as no gap prostheses;
- changing the current listing of 213 existing prostheses in Part A of the Schedule including:
  - amending the names, descriptions and/or sizes of products; and
  - changing the grouping of and minimum benefit for products;
- deleting 526 prostheses from Part A of the Schedule;
- adding 34 new human tissue items to Part B of the Schedule;
- changing the current listing of 244 existing human tissue items in Part B of the Schedule, including
  - amending the descriptions of human tissue items; and
  - changing the minimum benefit of human tissue items; and
- adding four prostheses to Part C of the Schedule.

Human rights implications

The Rules engage the following human rights:

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 International Covenant on Economic Social and Cultural Rights (ICESCR). Whilst the UN Committee on Economic Social and Cultural Rights (the Committee) 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.

The addition of 561 prostheses and human tissue items to the Schedule of the Rules as no gap prostheses or gap permitted prostheses will ensure that an insured person with appropriate cover will receive a minimum benefit for the provision of the prosthesis as hospital treatment or, where applicable hospital-substitute treatment, and:

- the prosthesis is provided in circumstances where a medicare benefit is payable and any relevant conditions in the Rules are met; or
- the prosthesis is provided in other circumstances specified in the Rules and any relevant conditions are met.

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.

Amendments to the names of prostheses already listed on the Previous Rules and changing sponsor names to reflect new sponsorship arrangements ensures that the Rules are kept up to date and maintain minimum benefit requirements for patients.

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 Rules are compatible with human rights because they advance the protection of human rights.

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