PHI 66/23 Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023

This circular provides information about the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 and other changes.

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The Prescribed List of Medical Devices and Human Tissue Products (PL) will be updated on 1 November 2023.

The delegate of the Minister for Health and Aged Care has made the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023, to replace the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023.

The Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 (MDHTP Rules) were registered on the Federal Register of Legislation on 18 October 2023 and will commence on 1 November 2023.

The changes effected in the MDHTP Rules

The MDHTP Rules give effect to all changes resulting from completion of the Prescribed List applications (new, amendment, deletion and sponsors' transfers) and other changes.

Other changes

General Use Items (Part D)

As part of the Prostheses List reforms, in June 2023, the Minister agreed to retain general use items (GUI) on the PL until 1 July 2024. Included in this announcement was that the Prescribed List benefits for GUIs would be subject to a further 10% reduction from 1 November 2023, to bring the benefits closer to the lowest public benchmark price.

However, following further consultation and consideration of the matter, the Minister decided that the 10% benefit reduction for Part D of the Prescribed List will not proceed. Therefore there will be no benefit reductions for the billing codes listed in Part D, except billing codes listed in subgroups 03.07.01.01 - General Miscellaneous – PULMONARY/PERITONEAL DEVICES – Drainage Catheters – Pleural and 03.07.01.04 - General Miscellaneous – PULMONARY/PERITONEAL DEVICES – Drainage Catheters – Para/Thoraceulesis, that due to oversight did not have a scheduled reduction in March or July 2023. There also will be one billing code for which the benefit will be increased to rectify the previous error.

New groups in Part A and Part C

A new group in Part A has been added for the Cardiac Leadless pacemaker. There are also two new groups added to Part C, including for coronary drug coated balloon catheters following change to the criteria for listing for Part C in July 2023.

Further, a radiofrequency delivery device for transurethral water vapour ablation (TUWA) has been added to the Part C criteria for listing and the respective new group. This new group will take effect from 1 March 2024 when the Medicare Benefit Schedule (MBS) item will be introduced.

Condition on billing codes for surgical guides and biomodels

The department undertook the Prescribed List post-listing review of surgical guides and biomodels, triggered by questions whether these devices meet the PL Part A criteria for listing. The review concluded that there is evidence to demonstrate that surgical guides and biomodels are clinically effective when used in craniomaxillofacial surgery procedures involving insertion of a medical device, but there is insufficient evidence to support listing of these billing codes for any other types of surgeries and that the PL reimbursement of the devices should be restricted in respect to number of devices reimbursed per procedure.

Surgical guides and biomodels are currently listed on the PL in the Plastic and Reconstructive category, in subcategories of devices used in craniomaxillofacial (CMF) surgery (in subgroups 07.02.02.04, 07.02.05.07, 07.02.06.06, 07.02.07.05 and group 07.02.09), and there is no evidence to support listing of these devices on the PL in any other categories at this point.

Medical Devices and Human Tissue Advisory Committee (MDHTAC) discussed this review in September 2023, and agreed that listing of these devices needs to be subject to the condition restricting the benefit payable for the PL listed devices consistently with the findings of the review.

Consistently, the MDHTP Rules apply the condition onto the existing billing codes for surgical guides and biomodels listed in Part A that is: Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1, and for no more than 3 devices per procedure.

The condition does not restrict the number of devices clinicians can use in any single procedure, but rather provides that in any specific case, when more than 3 surgical guides are required to be used due to the clinical need for a particular patient, hospital and insurer discuss and negotiate reimbursement for any additional devices.

Stakeholders are strongly encouraged to continue considering claims for reimbursement during the next few months to ensure that all surgeries already scheduled for which devices have been manufactured for specific patients, proceed as planned, so that patients are not negatively impacted.

Other

The MDHTP Rules also clarify the condition for the spinal devices made from Carbon/Peek material, change the benefits for 3 billing codes in Part A, and provides for other changes.

The PL (Part A, Part B, Part C and Part D) reports on changes are provided in Excel and Portable Document Format at Prescribed List of Medical Devices and Human Tissue Products / Australian Government Department of Health and Aged Care.