Australian Government
Department of Health and Aged Care

Surgical guides and biomodels – condition for Prescribed List reimbursement

Frequently Asked Questions

Version Control

This table is to record the document's history as changes are made. As each version is drafted and submitted for acceptance, update the version number and in the table record the changes made to the prior version.

Version	Date	Change Description
1.0	**21 December 2023**	**Original version**
2.0	**1 February 2024**	• Move Background to beginning of document • Introduce question numbers • Add ex gratia terminology • Add further explanation and examples to question 5 • Add note to question 6 • Add note to question 10

Background

Surgical guides and biomodels are relatively new technology manufactured using 3D printing. There have been growing concerns whether these devices meet the Prescribed List (formerly known Prostheses List) (PL) criteria for listing.

Specifically, Part A criteria for listing require (among other things) devices to be either implantable or active implantable medical devices; or be specifically designed as an integral single-use aid and be essential for implanting an implantable or active implantable medical device; or be critical to the continued functioning of an implanted device and be used by the patient with the implant. The medical device must be for a specific treatment and indication and is not used solely for diagnosis, prediction or prognosis (refer criteria for Part A in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules).

In order to consider whether surgical guides and biomodels are eligible for listing on the Prescribed List, a post listing review was undertaken. Stakeholder consultation was part of the review, and the review outcomes were provided to the Medical Devices and Human Tissue Advisory Committee (MDHTAC) for consideration.

The post-listing review concluded that in order to meet the PL criteria for listing and remain listed, surgical guides and biomodels are required to be used intraoperatively for implanting/inserting an implantable device used in craniomaxillofacial procedures; that the procedures need to be complex; and there should be an upper limit on the number of devices to be reimbursed per procedure.

Reflecting on the above, the decision was made to place the condition on the existing and any new Prescribed List billing codes for surgical guides and biomodels.

For more information, please refer to the following Private Health Insurance circulars:

- PHI circular 74/23
- PHI circular 72/23
- PHI circular 67/23
- PHI circular 66/23.

Introduction

On 18 October 2023, the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 set a new condition for PL reimbursement on billing codes for surgical guides and biomodels, based on the outcome of the post-listing review on these devices.

We received a range of questions and feedback from stakeholders on the intent and operation of the condition.

On 13 November 2023, the Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 2) 2023 amended the condition clarifying the terms, based on stakeholder feedback.

> We have compiled additional stakeholder questions into these FAQ.

Condition for Prescribed List (PL) reimbursement

The condition for Prescribed List reimbursement on billing codes for surgical guides and biomodels provides that:

Prescribed List reimbursement is restricted to the use of the device in craniomaxillofacial surgery procedures involving insertion of an implantable medical device, where that implantable device is listed in either sub-category 07.01 - Craniomaxillofacial Reconstruction & Fixation, or 07.02 – Craniomaxillofacial Implants, or 07.04 – Distractor Systems of Schedule 1, or sub-category 07.03 - Dental Implants, but only if the (dental) implantable medical device is explicitly identified in the product name or description of the billing code for the surgical guide or biomodel and is used in hospital.

Not limiting the above, for a claim for any implantation procedure (defined by the respective MBS items stated in the claim) for a patient, the Prescribed List reimbursement is limited to 3 or less PL benefits for any billing codes for surgical guides or biomodels, or no more than 6 benefits if both surgical guides and biomodels (maximum 3 for each) have been used in an implantation procedure for a patient. This restriction is not impacted by a number of devices implanted during a procedure. The condition is taking effect on 1 February 2024.

FREQUENTLY ASKED QUESTIONS

1. When will the condition take effect?

The condition will commence on 1 February 2024. Any billing codes for surgical guides or biomodels used in surgical procedures on or after 1 February 2024 will need to be claimed according to the new condition.

2. What is the meaning of craniomaxillofacial surgery procedure?

For the purposes of the condition, 'craniomaxillofacial surgery procedures' means a surgical procedure with single admission to theatre, during which at least one implantable medical device listed in either sub-category 07.01, or 07.02, or 07.03, or 07.04 is implanted into a patient with assistance of at least one surgical guide or biomodel.

3. Are surgical guides and biomodels eligible for PL reimbursement when they are used for assisting in implantation of implantable devices listed in the PL categories 06 - Specialist Orthopaedic, or 12 - Knee, or 13 - Spinal?

There is no obligation on private health insurers to pay PL benefits for surgical guides or biomodels used with implantable devices outside sub-category 07.01, or 07.02, or 07.03, or 07.04. However, it is at the health insurer's discretion to make ex gratia payments if they agree making payment for these devices is warranted.

4. Are surgical guides and biomodels eligible for PL reimbursement if these devices are used for virtual planning, preparation or manufacturing of patient-specific implants?

Virtual planning, patient preparation, or device manufacturing do not meet the Prescribed List listing criteria. Therefore, surgical guides and biomodels used for virtual planning, patient preparation or device manufacturing are not eligible for PL reimbursement.

5. What is the meaning of defined by the respective MBS items stated in the claim?

One of the legislative requirements for a device to be eligible for listing on the PL is that a Medicare benefit must be payable in respect of the professional service associated with the use of the device, provided as part of hospital or hospital substitute treatment. Therefore, in the context of this condition, there must be at least one valid MBS item that covers the implantation of at least one of the implantable medical devices listed in either of the following sub-categories: 07.01, or 07.02, or 07.03, or 07.04.

The descriptor of MBS item may not explicitly mention the implantable device but it needs to describe the procedure/medicare service that involves and is relevant to an implantation of a device listed on the PL in one of the sub-categories: 07.01, or 07.02, or 07.03, or 07.04.

Example 1

Pre-anaesthetic and anaesthetic MBS items do not cover implantation of medical devices listed on the PL, therefore these MBS items are not relevant / do not meet the requirements of the condition.

Example 2

MBS item 40600 Cranioplasty, reconstructive, may involve the implantation of at least one device listed in the PL subcategories 07.01, or 07.02, or 07.03, or 07.04. Therefore, when

this MBS item is stated on the claim together with at least one of the implantable medical devices listed on the PL in one of these sub-categories, not more than 3 of each of surgical guide and biomodels, would be considered eligible for claiming.

6. What will happen if a claim for surgical guides or biomodels only includes items from the Australian Schedule of Dental Services but does not include any MBS items?

The requirement is that there is at least one valid MBS item related to a surgical guide or biomodel used in hospital as a single-use aid for implantation of one of the prescribed device. If there is no MBS item included in the claim, there is no obligation on private health insurers to pay for the device under the PL. However, it does not preclude health insurers to consider paying ex gratia for the device in the claim with the Dental Services item, although this is at the health insurer's discretion.

Note: It is one of the legislative requirements for any device to be eligible for reimbursement under the PL that there is at least one valid MBS item covering the use of the implantable device. There is no mention of the Australian Schedule of Dental Services items for the purpose of PL reimbursement eligibility.

7. How are billing codes for surgical guides and biomodels required to identify the dental implantable medical device?

The product name or description of the billing code for the surgical guide or biomodel is required to state the billing code/s for the dental implants.

8. What do I need to do to amend the product name and description of the billing code for my surgical guide or biomodel?

For any sponsors requiring changes to the details of their billing codes, the sponsors are required to submit an amendment application via Health Product Portal (HPP). The deadline for submitting applications for 1 July 2024 Prescribed List will be at midnight on 14 January 2024 (the 2nd Sunday of January). Sponsors are required to submit applications clearly outlining the required changes and providing information that will inform the assessment.

9. What is the meaning of the reference Not limiting the above?

It means the first and the second part of the condition complement each other (not exclude each other).

10. Can you clarify the meaning of the Prescribed List reimbursement is limited to 3 or less PL benefits for any billing codes for surgical guides or biomodels, or no more than 6 benefits if both surgical guides and biomodels (maximum 3 for each)?

This means that a maximum of 3 surgical guides and/or 3 biomodels are eligible for reimbursement for a craniomaxillofacial procedure (a surgical procedure with single admission to theatre for a patient). Below are some sample scenarios.

Scenario 1

During a surgical procedure with single admission to the theatre, 2 implantable medical devices listed in sub-category 07.02, and 4 implantable devices listed in sub-category 07.01 have been implanted in the patient, with the aid of 1 surgical guide and 1 biomodel.

In this case, 1 surgical guide and 1 biomodel are eligible for PL reimbursement.

Scenario 2

During the surgical procedure with single admission to the theatre, 4 implantable medical devices listed in sub-category 07.02, and 6 implantable devices listed in sub-category 07.01 have been implanted with the aid of 4 surgical guides and 2 biomodels.

In this case, 3 surgical guides and 2 biomodels are eligible for PL reimbursement.

Scenario 3

During a procedure with single admission to the theatre, no medical devices have been implanted but 6 surgical guides have been used.

In this case, there are no surgical guides or biomodels that will be eligible for PL reimbursement

Note: Scenarios 1 and 2 above are based on the assumption that at least one valid MBS item is used that covers the implantation of at least one of the implantable medical devices listed in either of the following sub-categories: 07.01, or 07.02, or 07.03, or 07.04., To be eligible for reimbursement, the surgical guides and biomodels must be used intraoperatively to aid device implantation, and not for virtual planning, preparation or manufacturing of patient-specific implants.

11. Can you clarify the meaning of this restriction is not impacted by a number of devices implanted during a procedure?

This means that the maximum number of surgical guides and biomodels per single patient in a single admission to the theatre, eligible for PL reimbursement does not depend on the total number of implantable medical devices implanted during the procedure.

Instead, the maximum number of surgical guides and biomodels depends on the sub-category in which the implantable medical devices are listed in and the actual number of surgical guides and biomodels used.

12. Does the Prescribed List reimbursement limit to 3 or less PL benefits for any billing codes for surgical guides or biomodels apply per surgeon?

The maximum number of surgical guides and biomodels that may be claimed on the PL per single patient in a single admission to the theatre is not affected by the number of surgeons involved in the procedure.

13. Will a report of the post-listing review be available to stakeholders?

The review report and recommendations will be published on the department's website in the first half of 2024.