Australian
Private Hospitals
Association

MBS Review: Report from the Ophthalmology Clinical Committee 2019

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Contents

Introduction

The Australian Private Hospitals Association (APHA) is appreciative of the opportunity to make a submission to the Medicare Benefits Schedule (MBS) Review in response to the recommendations in the report from the Ophthalmology Clinical Committee.

In this response, the APHA has focused on issues that could arise for private hospitals if these recommendations were adopted. Some of these issues lie outside the scope of the terms of reference for the MBS Review, for example they pertain to potential implications for the regulations governing private health insurance.

The Private Health Insurance (Benefit Requirements) Rules 2011 (Compilation No. 61, as of 1 November 2019: "the Rules") make detailed reference to relevant MBS items, and it is therefore essential to consider whether recommendations from the MBS Review will give rise to the need for changes to private health insurance regulation.

The issues in this submission are raised with the intention of informing implementation of the proposed recommendations should they be adopted by the Australian Government.

The APHA also advocates there should be sufficient time allocated by the Department of Health for the implementation of the flow-on changes when changes are made to the MBS, such as the Rules (above) and the National Procedure Banding Committee processes, especially when there are changes to a large number of MBS items simultaneously. The sector needs at least 90 days between the publication of the revised MBS Schedule and the Rules, and the implementation date when these changes come into effect.

In making these comments, APHA remains fully supportive of the objectives of the MBS Review and recommendations intended to promote sound, evidence-based clinical practice.

The APHA will address recommendations which may cause implementation issues below.

Ophthalmology recommendations

Reclassification of item 42738 (Recommendation 7)

MBS item 42738 is currently classified Type B, non-band specific Type B day procedure in the Rules. The clinical committee has put forward the opinion this item is claimed too frequently as an in-hospital procedure, and their recommendation is this item should be made a Type C in the Rules(Recommendation 7). The clinical committee wishes to exclude Modified Monash Model areas 5, 6 and 7 from this change.

The APHA is strongly opposed to this recommendation due to a number of reasons, including inequity for patients, hospitals being the best practice environment for injections and cost shifting to the patient. The APHA also notes supporting evidence provided by the clinical committee has been cherry picked to support a pre-determined position rather than create evidence-based clinical argument for changing this classification.

Whilst a Type C classification can still become a Type B for a patient where there is certification provided to satisfy the clinical necessity for in-hospital care, this does not take into account the invasiveness of the procedure itself and the associated risks with injecting into the sterile vitreous cavity or the patient cohort involved.

Private hospital patient cohort
In the private hospital sector, MBS item 42738 is mostly administered in an older cohort of patients; 86% of patients receiving a procedure in private hospitals are aged 70 or older[1].

Due to the nature of the diseases this procedure treats (including age-related macular degeneration and diabetic retinopathy), patients generally require repeat injections at regular intervals. The treatment is invasive and confronting, but patients will endure the discomfort to retain their eye sight. Macular degeneration is already the leading cause of legal blindness in Australia; responsible for half of all cases of blindness[2].

Clinically, this older cohort of patients are more likely to develop complications such as endophthalmitis than younger patients.

Clinical risks
Intravitreal injections are invasive procedures, and although the benefit derived by patients makes them clinically necessary, they also come with clinical risks.

Endophthalmitis is a recognised risk and can, in the worst case scenario, render a patient blind and/or necessitate the removal of the eye. To minimise the risk of infection, the

[1] APHA Benchmarking data, 2017-18.
[2] Macular Disease Foundation Australia 2019. Available at: https://www.mdfoundation.com.au/content/macular-degeneration-about

provision of a dedicated operating room with sterile and aseptic techniques in place from admission through discharge is essential. Private hospitals provide such an environment for patients.

In patients with compromised retinal circulation the intravitreal injection will cause an **acute intraocular pressure rise** resulting in immediate and transient loss of vision due to reduced retinal perfusion. The pressure usually normalises under observation within 15 minutes. However, it may be necessary to perform a *second* intraocular penetration in the form of an anterior chamber paracentesis with a needle to release the pressure. If intraocular pressure is not promptly controlled, permanent damage and loss of vision may ensue.

Patients may develop a **reaction to the topical anaesthetic drops** and antiseptic preparation resulting in corneal epithelial changes and loss. This results in irritation to severe pain. Nursing staff are aware of the potential and hospitals accreditation standards require close observation of patients for symptoms prior to discharge.

Potential exists for injection of the **wrong drug** or injection into the **wrong eye**. Application of standard private hospital surgical safety protocols (e.g. Surgical safety check lists, Time Out and medication protocols) significantly reduce this risk.

Best practice versus acceptable practice
Intravitreal injections currently occur both in hospitals and in outpatient settings.

However, in-hospital treatment for intravitreal injections is best practice, and should not be confused with acceptable practice. In-hospital operating rooms or a dedicated clean room is regarded internationally as the best practice setting because intravitreal injections should be performed with sterile techniques, ventilation and uninterrupted in order to reduce the incidence of endophthalmitis. The National Institute for Health and Care Excellence and the United Kingdom Royal College of Ophthalmologists recently recommended (in 2018) the use of an operating theatre or a dedicated clean room for intravitreal injections[3].

Private hospitals and their operating rooms are regulated to a high standard for safety and quality purposes. Outpatient settings do not have to comply with the same safety and quality standards. Outpatient administration of intravitreal injections has a higher risk for infection compared to the in-hospital counterpart.

These points are further explored below.

Private hospitals are a safe and regulated environment
Private hospitals are required to adhere to a raft of regulation and clinical standards ensuring safety and quality for the patient. These include the National Standards from the

[3] Ophthalmic Service Guidance Intravitreal injection therapy May 2018 Revised August 2018 (Section 4). Available: https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy-August-2018-2.pdf.

Australian Commission on Safety and Quality in Health Care which prescribe anti-septic techniques and sterility as well as operating room minimum requirements. These operating room standards of sterility and ventilation ensure the risk of infection are extremely low, because the environment is regulated and stable. State/territory licencing requirements also impose additional strict requirements on hospitals and day hospitals.

Furthermore, there are strict guidelines in place for in-hospital surgery, including ensuring the patient is 'fit to leave' post-operation.

These regulations and standards ensure hospitals provide care that meets best practice and patient expectations in terms of preventing adverse outcomes such as infection.

Risk of infection

Whilst the Royal Australian and New Zealand College of Ophthalmologists' (RANZCO) guidelines for the administration of intravitreal injections specify 'protocols' including the use of standard aseptic technique, topical antiseptic in the conjunctival sac. It also notes sterile gloves 'should' be worn, and a face mask is 'recommended'[4].

The RANZCO guidelines do not specify requirements for a clean room or ventilation of any kind. However, more recent international statements go further. The *Update on Intravitreal Injections*[5] did an extensive literature review of recent data and concluded the clinical setting for intravitreal injections should be:

> "operating theater, *adequate* room or in-office setting." [emphasis added].

As already cited above, the National Institute for Health and Care Excellence and the United Kingdom Royal College of Ophthalmologists recently recommended (in 2018) the use of an operating theatre or a dedicated clean room for intravitreal injections[6].

Furthermore, the Ophthalmology Clinical Committee cites the United States as an example of a jurisdiction where most intravitreal injections occur 'in office'. However, recent studies show 'all settings' infection rates are higher than in an operating room: a recent case series in the United States of over 500,000 intravitreal injections found an infection rate of

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[4] RANZCO 2017. Guidelines for performing intravitreal therapy. Section 2.4. Available: https://ranzco.edu/wp-content/uploads/2018/11/IVI-Guidelines-for-Performing-Intravitreal-Therapy-2017.pdf

[5] Grzybowski A. et al. 2018. 2018 Update on Intravitreal Injections: Euretina Expert Consensus Recommendations. Ophthalmologica DOI: 10.1159/000486145. Available at: https://www.karger.com/Article/FullText/486145

[6] Ophthalmic Service Guidance Intravitreal injection therapy May 2018 Revised August 2018 (Section 4). Available: https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy-August-2018-2.pdf.

0.036%[7]. Freiberg et al. with a series of 134,701 intravitreal injections performed in an operating room with laminar airflow had an infection rate markedly lower at 0.0074%[8].

The studies referred to in the *Update on Intravitreal Injections* either found better results in an operating room with 'laminar airflow', or no statistical difference (only one study and one literary review, see quote below). No studies have found infection rates to be statistically higher in-theatre than in outpatient rooms.

> A consecutive case series including a total of 11,710 IVI and comparing office-based (8,647) and OR (3,063) settings reported no significant difference in [endophthalmitis] rates (0.035 and 0.065%, respectively). This has also been confirmed by a literature review summarizing data of 445,503 IVI, which did not show a significant difference between [operating room] and office-based IVI. [9]

It is important to note when considering the relevance of international studies to Australia, ophthalmology outpatient settings in Australia are not subject to standards and requirements around dedicated clean rooms, uninterrupted procedures and ventilation, and when these precautions are not in place, the risk of infection increases.

Access to services

Most of the patients receiving intravitreal injections in private hospitals are elderly and some of these elderly patients will not understand why their care will change. This will cause unnecessary anxiety in many of these patients.

If the classification of MBS item 42738 changes from a Type B to a Type C, many of the patients who now receive intravitreal injections in hospital will find the cost prohibitive (see below on out of pocket costs). In some areas in Australia, private hospitals are the only option because the local public hospital does not or cannot offer the service. As a result some patients will no longer have access the care as a direct result of these changes, and will deteriorate into blindness.

In the interest of providing patients with the continuity of care and the access to care they require, patients should continue to be given the opportunity to have an in-hospital procedure for intravitreal injections.

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[7] Rayess N. et al. 2016. Postinjection endophthalmitis rates and characteristics following intravitreal bevacizumab, ranibizumab and aflibercept. American Journal of Ophthalmology 2016; 165: 88–93.

[8] Freiberg FJ. Et al. 2017. Low endophthalmitis rates after intravitreal anti-vascular endothelial growth factor injections in an operation room: a retrospective multicenter study. Retina 2017; 37: 2341–2346.

[9] Grzybowski A. et al. 2018. 2018 Update on Intravitreal Injections: Euretina Expert Consensus Recommendations. Ophthalmologica DOI: 10.1159/000486145. Available at: https://www.karger.com/Article/FullText/486145

Cost shifting and patient out of pocket

Changing the treatment environment from in-hospital (Type B) to out of hospital settings (Type C) is shifting costs from health insurers to the patient. In many cases, when this procedure is done in-hospital, the patient will not be charged any out-of-pocket costs due to 'no gap' agreements with the private health funds the hospitals contract with.

When procedures are performed in doctor's rooms, the private health insurer provides no cover. Patients have no assistance in meeting medical out of pocket costs associated with treatments in doctor's rooms.

These out of pocket costs will be significant for patients, as each procedure will incur a cost and the patient may require eight such procedures a year. These cost pressures may in fact cause more patients to go to public hospitals (which is not always an option everywhere in Australia, such as Newcastle or Northern Tasmania where the local public hospital does not offer this procedure).

At worst, patients might no longer be able to afford to have the procedure at all, and combined with long waiting lists in public, these patients may go blind due to this change.

Clinical committee supporting evidence

The clinical committee has made their recommendation 7 based on a number of cherry picked sources supporting their argument. Unfortunately, some of their statements are also erroneous.

The clinical committee states

> "In the United Sates and the United Kingdom eye injections are not performed in hospital unless there are exceptional circumstances"[10]

However, the National Institute for Health and Care Excellence and the Royal College of Ophthalmologists recently recommended (in 2018) the use of a clean room or an operating theatre for intravitreal injections[11]. Section 4 in their Ophthalmic Service Guidance for Intravitreal injection therapy specifies (emphasis added):

- Procedures may be carried out in theatre or, more usually, in a suitable room in an outpatient setting with full sterile precautions.
- For outpatient delivery, an *enclosed, dedicated clean room* (as defined by the local Infection Control Team) is required which only deals with clean (noninfected) cases, and is free from interruption.
- The room should be of a sufficient size to enable a patient couch for the procedure and staff access to both sides of the head of the couch. There

[10] Opthalmology Clinical Committee report 2019, page 47.

[11] Ophthalmic Service Guidance Intravitreal injection therapy May 2018 Revised August 2018" (section 4-6)

should be storage cupboards for clinical stock and injection packs, a compliant hand wash basin or surgical trough, waste disposal bins (including sharps), a medicine fridge and computer desk/notes area.

- *Ventilation* (see below).
- The room must have good illumination and comply with infection control requirements including a washable floor, no cloth curtains, and be in good condition e.g. no chipped paint.
- The ceiling and walls of the room should be non-particulate in nature (i.e. no dust or debris should be able to fall on to operative field during procedure)
- Air inlets should not be situated above the patient head during the procedure.
- Nearby facilities for slit lamp biomicroscopy/ indirect ophthalmoscopy and viewing retinal imaging (FFA/OCT) are advantageous.
- Resuscitation facilities, based upon local risk assessment, should be available in all settings where IVT is administered. As a minimum standard, all healthcare staff undertaking IVT must have evidence of up to date basic cardiopulmonary resuscitation training.[12]

Recommendation 18

Recommendation 18 adjust the current MBS fee for intravitreal injections down from $301 to be in line with other MBS items currently attracting a $70-94 fee.

The APHA categorically rejects the appropriateness of such a reduction in fees and the assertion by the Taskforce that non-ophthalmologists should be able to perform the procedure. As stated above, best practice is to perform this procedure in-hospital or in a dedicated clean room, aligned with strict standards of anti-septic techniques.

Recommendation 10

The APHA notes the proposed descriptor for items 42509, 42510, 42530, 42533, 42536, 42539, 42542, 42590, 42623, 42626, 42629, 42863 and 42866, the words "(Anaest.) (Assist.)" and are omitted. For the proposed descriptor for item 42872, the word "(Anaest.)" is omitted. Whilst this is most likely a draft report issue, it would be essential these qualifiers are not lost in the amended descriptors once finalised.

Recommendation 13

The clinical committee has recommended an ongoing review of ophthalmology items. The APHA requests better representation by the private sector on such a review committee

[12] Ophthalmic Service Guidance Intravitreal injection therapy May 2018 Revised August 2018 (Section 4) pages 4-5. Available: https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy-August-2018-2.pdf.

should the Government agree to this recommendation, as the private sector currently provides 71% of all admitted patient eye procedures in Australia[13].

Recommendations 16 and 17

The APHA notes Recommendation 16 seeks to reduce out of pocket costs for patients, and highlights the irony in Recommendation 7 having the opposite effect of increasing out of pockets for patients.

The APHA fully supports Recommendation 17 and the objective of more transparency in specialist services, and commends the Government's progress to date in addressing this issue through the development of the clinician website and other measures.

Clinician education

There are a number of recommendations (under recommendations 9, 10 and 11) in the Ophthalmology clinical committee report making changes to restrict the use of items. Some of these items are, according to the clinical committee, being claimed erroneously or incorrectly.

The APHA suggests the Department of Health should provide clinical information and education to those clinicians incorrectly claiming these items to ensure they are made aware of best practice and the changes being proposed.

New items

New items under Recommendation 4
This recommendation is to split MBS item 42738 to distinguish procedures done on the left and right eyes. The current item 42738 is classified in the Rules as Type B, Non-band specific. The APHA asks the Department of Health to ensure both the resulting items remain classified as Type B, Non-band specific in the Rules.

New items under Recommendation 12
The new telehealth items proposed under Recommendation 12 are similar to MBS items 104 and 105, which are currently classified as Type C, Category 1, Table A1. The APHA suggests the new items should be classified as Type C, Category 1, Table A1 where appropriate.

New items under Recommendation 15
The APHA reserves our view on the classification of these new items until more detail is provided by the Department of Health on comparators, descriptors and MBS fees should this recommendation be accepted by Government.

[13] Australian Institute of Health and Welfare 2019. Admitted patient care.

Private hospitals in Australia

The private hospital sector makes a significant contribution to health care in Australia, providing a large number of services and taking the pressure off the already stretched public hospital system.

The private hospital sector treats:

- 4.5 million hospitalisations a year.

In 2017–18 it delivered:

- 60% of all surgery
- 71% of eye procedures
- Almost half of all heart procedures
- 74% of procedures on the brain, spine and nerves.

Australian private hospitals by the numbers (2016–17):

- Almost half (49%) of all Australian hospitals are private
- 657 private hospitals made up of:
    - 300 overnight hospitals
    - 357 day hospitals
- That amounts to: 34,339 beds and chairs (31,029 in overnight hospitals and 3,310 in free-standing day surgeries)
- Employs more than 69,000 full-time equivalent staff.

The Australian Private Hospitals Association

The Australian Private Hospitals Association (APHA) is the peak industry body representing the private hospital and day surgery sector. About 70% of overnight hospitals and half of all day surgeries in Australia are APHA members.