Australian Government
Medical Services Advisory Committee

STAKEHOLDER MEETING FINAL MINUTES
MSAC APPLICATION 1541 – MICRO-BYPASS GLAUCOMA SURGERY (MBGS) DEVICE IMPLANTATION AS A STANDALONE PROCEDURE IN PATIENTS WITH OPEN-ANGLE GLAUCOMA (OAG)

Monday 4 March 2019

Attendees

Meeting attendees were the chair of the Medical Services Advisory Committee (MSAC); representatives of the applicants; clinicians with expertise in ophthalmology; a representative of a consumer organisation and representatives from the Department of Health.

1. Meeting open

The MSAC Chair opened the meeting at 12.30pm.

The Chair thanked participants for attending and clarified that the stakeholder meeting was not an MSAC decision-making forum, but would inform the issues considered by MSAC following its November 2018 consideration of Application 1541: micro-bypass glaucoma surgery device implantation as a standalone procedure in patients with open-angle glaucoma (OAG). Key objectives of the meeting were to seek input from the applicants and clinicians regarding issues raised in the assessment and discuss how the application can be further progressed.

The Chair informed participants that minutes of the stakeholder meeting would be provided to all attendees for endorsement. The Chair indicated that these minutes would not attribute any of the discussion to any identified individual.

2. Background

At its November 2018 meeting, MSAC did not support public funding for micro-bypass glaucoma surgery device implantation as a standalone procedure in patients with open angle glaucoma. MSAC considered that patient population and eligibility criteria were poorly defined with uncertain comparative safety, clinical effectiveness and cost-effectiveness.

3. Summary of discussion

Patient population

Participants noted there are patients without cataracts for whom MBGS device implantation as a standalone procedure provides an alternative between medication and major surgery.

Participants discussed the need for an appropriate item descriptor in addition to implementation factors that will ensure this procedure is confined to those who genuinely need it. Participants noted that trabeculectomy is an invasive procedure and patients do not lightly proceed with this intervention. On the other hand, MBGS is less invasive than

trabeculectomy and hence doesn't in itself serve as a natural constraint for the patient or clinician.

In addition to item descriptors, participants agreed to consider options such as a secondary referral pathway and/or a register of selected practitioners able to claim the MBS item for MBGS. Participants estimated that, of the 990 ophthalmologists in Australia, approximately 250 are performing stent procedures and 50 of these are glaucoma fellowship trained. This could form the basis of such a 'register'. A list of practitioners could be registered with the Department of Human Services. Audits would be made by the Department of Health to ensure that claims made by the registered providers were consistent with the anticipated volume of patients.

Participants noted potential unintended consequences of requiring a secondary referral for rural patients and/or indigenous patients. Alternative ways of obtaining a second opinion such as 'in consultation with' was discussed.

MBS item descriptor

Participants discussed the following modifications to the proposed MBS item descriptors in the Public Summary Document (PSD):

Table 1 Proposed MBS item descriptor for MGBS stent implantation

Category 3 – THERAPEUTIC PROCEDURES
MBS item number GLAUCOMA, implantation of, a micro-bypass glaucoma surgery stent system into the trabecular meshwork, in patients diagnosed with glaucoma, where conservative therapies have failed, are likely to fail, or are contraindicated and are now considered patients who are candidates for incisional glaucoma surgery. Multiple Services Rule (Anaes.) (Assist.) **Fee:** $699.45 **Benefit**: 75% = $524.60

Table 2 Proposed alternative MBS item descriptor for MGBS stent implantation

Category 3 – THERAPEUTIC PROCEDURES
MBS item number GLAUCOMA, implantation of, a micro-bypass glaucoma surgery stent system into the trabecular meshwork, in a patient diagnosed with glaucoma, who is not adequately responsive to topical anti-glaucoma medications or who is intolerant of anti-glaucoma medication. Multiple Services Rule (Anaes.) (Assist.) **Fee:** $699.45 **Benefit**: 75% = $524.60

Table 3 Proposed MBS item descriptor for MGBS stent removal

Category 3 – THERAPEUTIC PROCEDURES
MBS item number GLAUCOMA, removal of a micro-bypass glaucoma surgery stent system from the trabecular meshwork. Multiple Services Rule (Anaes.) **Fee: [Fee to be determined]**

Outcomes/Evidence base

Participants noted that age and other factors place patients at risk for glaucoma and discussed that it's important to treat patients who are at high risk of blindness.

In estimating the number of people who receive a stent, relapse and require a trabeculectomy, participants discussed the need to collect data from clinics. This should include follow-up monitoring of patients who receive stents but then go on to require trabeculectomy. MBS data could also be analysed to determine which patients had stents and go on to receive a trabeculectomy.

Participants noted an existing Cypass study that demonstrates stent failure rates and noted the inclusion of failure rates across other studies as well as real-world data would be useful in a resubmitted application.

Participants agreed a cost-minimisation analysis should be used, against trabeculectomy.

Safety concerns related to withdrawal of Cypass from the market

Participants noted the insertion technique used for the Cypass device is different from that of the iStent/Hydrus devices. This parallel insertion technique means it is not possible for the iStent/Hydrus to push against the cornea.

Given the withdrawal of Cypass from the market, participants agreed that the Cypass application should be withdrawn from the MSAC process. However, a future MSAC application can be pursued if and when Cypass returns to the market.

Next steps

A revised submission should present data to address the identified issues and outline the specific changes made to the original application, including changes to item descriptors to ensure the correct population is being captured. The application should include accurate estimates of the number of eligible patients, the referral pathways and how use could be confined to those individuals who are candidates for trabeculectomy. It would also be important to demonstrate how equitable access to the procedure could be supported. This can initially be provided to MSAC Executive meetings for guidance before a resubmission is prepared.

Following feedback from the MSAC Executive a new submission can be provided directly to the MSAC.

Participants discussed the standard level of evidence required by MSAC and alternative ways of generating this evidence. Participants noted funding sources such as the Medical Research

Future Fund can provide research funding to develop an evidence base in an area of high need.

4. **Meeting close**

Participants were thanked for their valuable insights and it was hoped they found the meeting a positive step forward.

The meeting closed at 2.30pm.