

Application for MBS eligible service or health technology

ID:

HPP200067

Application title:

Micro-bypass glaucoma surgery device implantation into the suprachoroidal space as a standalone procedure in patients with open angle glaucoma

Submitting organisation:

iSTAR Medical

Submitting organisation ABN:

Application description

Succinct description of the medical condition/s:

Glaucoma is group of complex eye diseases leading to chronic and progressive damage to the optic nerve and progressive, irreversible vision loss. It is a major public health problem, as glaucoma is the leading cause for irreversible visual impairment and the second leading cause for blindness worldwide. Reduction of intraocular pressure is the only known modifiable glaucoma risk factor that can reduce progressive loss of vision and is associated with improved health outcomes including reduced visual loss and improvements in quality of life.

Succinct description of the service or health technology:

Reduction of intraocular pressure is the only known modifiable glaucoma risk factor. Micro-bypass glaucoma surgery can be used to reduce intraocular pressure in open angle glaucoma (in patients with no current cataract co-morbidity or patients who have already undergone cataract surgery) following failure or intolerance to more conservative therapies (medication to reduce intraocular pressure and laser trabeculoplasty) when the patient is a candidate for incisional surgery. MINject micro-bypass stent system can be inserted into the suprachoroidal space during micro-bypass surgery to enhance drainage of aqueous outflow into the suprachoroidal space to reduce intraocular pressure, reducing reliance on topical hypotensive medication. Relevant to this application is MSAC PSD 1541, "ESC recalled that MSAC previously accepted that the two types of MBGS devices [trabecular bypass and suprachoroidal] are comparable and should be covered under one MBS item in the cataract surgery setting."

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Consultant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Is the applicant organisation the organisation you are representing in the HPP today?

Yes

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prostheses List?

Yes

Which list/schedule will the other health technologies be listed on?

Prostheses List

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

Amendment

What is the nature of the amendment?

An amendment to the way the service is clinically delivered under the existing item(s)

Justification for amendment:

Item 42504 is proposed to be amended to allow implantation of a micro-bypass surgery stent system into the suprachoroidal space, in addition to allowing insertion into the trabecular meshwork. No other change to the item is proposed.

Please select any relevant MBS items.

MBS item number	Selected reason type
42504	Other

What is the type of service or health technology?

Therapeutic

Application 1764 - Micro-bypass glaucoma surgery device implantation into the suprachoroidal space as a standalone procedure in patients with open angle glaucoma

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	Implantation of MINject micro-bypass surgery stent system into the suprachoroidal space

Implantation of MINject micro-bypass surgery stent system into the suprachoroidal space

Supporting documentation

Document type	File name(s)
Application PICO set documents	iSTAR MBS Application PICO set document FINAL.docx; iSTAR MBS Application PICO set document FINAL.pdf
Reference list	Application HPP200067 Reference list.docx; Application HPP200067 Reference list.pdf

Population

Describe the population in which the proposed health technology is intended to be used:

Patients with glaucoma requiring implantation of a micro-bypass surgery (MBGS) stent system into the suprachoroidal space, if:

- (a) conservative therapies have failed, are likely to fail, or are contraindicated; and
- (b) the service is performed by a specialist with training that is recognised by the Conjoint Committee for the Recognition of Training in Micro-Bypass Glaucoma Surgery

For the purpose of this application, the population does not include patients requiring concomitant cataract surgery. This population is already address in MBS code 42705.

Search and select the most applicable Medical condition terminology (SNOMED CT):

Open-angle glaucoma

Intervention

Name of the proposed health technology:

MINject micro-bypass surgery device

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being

available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

The comparator is implantation of an alternative micro-bypass surgery stent system via the trabecular meshwork, specifically the most used stent in Australia iStent (Glaukos).

The resources required to deliver the intervention (i.e. MBGS with the stent system (MINject) delivered via the suprachoroidal space) would not change from that required to implant the comparator product (i.e. currently required for item 42504). Resources required for MBGS (using either the comparator or the intervention) include the requirement for anaesthesia, use of Ophthalmic Viscosurgical Devices (OVD), gonioscopy for visualisation and surgical knife for the incision.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

There would be no change to patient management using the MINject MBGS device in comparison with current treatment using MBGS covered under item number 42504. The following outcomes apply to all MBGS covered under item number 42504.

Major health outcomes:

- Intraocular pressure (IOP) change from baseline (mmHg, % reduction).
- Change from baseline in the mean number of IOP-reducing medications used
- Adverse events (AE), including ocular serious AEs (SAE) (number, % of patients) related to the device or surgical procedure

Minor health outcomes

- Proportion of patients with IOP \leq 18 mmHg at endpoint
- Proportion of patients who are medication-free at follow-up

Implantation of MINject micro-bypass surgery stent during standalone surgery results in increased aqueous humour outflow into the suprachoroidal space leading to reduced IOP. Lowering of IOP is the only known modifiable risk factor for glaucoma progression and is hence the key clinically important outcome, being a marker of important long-term outcomes including visual acuity and quality of life.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

42504

Please search and select the proposed category:

THERAPEUTIC PROCEDURES

Please search and select the proposed group:

SURGICAL OPERATIONS

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Glaucoma, implantation of a micro-bypass surgery stent system into the trabecular meshwork or suprachoroidal space, if: (a) conservative therapies have failed, are likely to fail, or are contraindicated; and (b) the service is performed by a specialist with training that is recognised by the Conjoint Committee for the Recognition of Training in Micro-Bypass Glaucoma Surgery (Anaes.)

Proposed MBS fee:

\$329.40

Indicate the overall cost per patient of providing the proposed health technology:

\$0.00

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

The same fee is proposed for MBGS via the suprachoroidal space, as with existing item 42504 and the same overall costs per patient and out of pocket costs are expected for MINject as for the existing MBGS devices covered under the 42504 MBS code.

It should be noted that in the PSD 1541 (p. 17, August 2019) that recommended a standalone MBGS surgery item "ESC noted that MBGS devices include a variety of implanted, minimally invasive ocular stents and scaffolds that are placed via a corneal incision into the trabecular meshwork (TB MBGS) or suprachoroidal space (SC MBGS) of the eye. The exact positioning of implantation is specific to each device. These devices aim to improve aqueous humour outflow and lower intraocular pressure, which in turn reduces the reliance on topical hypotensive medication. ESC noted that although MBGS devices differ in design and manufacturer specifications, the complexity and resource burden of the implantation procedure is comparable."

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

MINject is not currently available in Australia. MBGS surgery (using alternative MBGS stents) is funded via the MBS (except in the public system), with the stents reimbursed via the Prostheses List for private patients.

State-based funding is applicable for MBGS surgery undertaken in public hospitals.

There has been an application submitted for Prostheses List funding of MINject.

Please provide a cost break down attachment:

Document type	File name(s)
Cost breakdown attachment	Cost breakdown attachment.docx

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Non-inferior

Please state what the overall claim is, and provide a rationale:

Implantation of the MINInject MBGS system into the suprachoroidal space provides non-inferior effectiveness and non-inferior safety to stents inserted into the trabecular meshwork, as part of standalone MBGS for patients with open-angle glaucoma who have failed or are intolerant to conservative therapies.

The claim of non-inferior effectiveness and safety is based on an indirect comparison of the generally similar mean level of IOP lowering achieved in patients undergoing the two procedures and similar adverse event profiles. IOP lowering is a recognised modifiable risk factor associated with improvements in long term, patient-relevant outcomes including reduced rate of visual deterioration and improved quality of life.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

It was noted that the 42504 MBS code was claimed 390 times in 2021-2022 and 393 times in July 2022 to May 2023.

Reference:

http://medicarestatistics.humanservices.gov.au/statistics/do.jsp?_PROGRAM=%2Fstatistics%2Fmbs_item_standard_report&DRILL=ag&group=42504&VAR=services&STAT=count&RPT_FMT=by+state&PTYPE=finyear&START_DT=202107&END_DT=202206

In order to predict MBS code claims in 2023-2024, we would assume a consistent 9.7% growth as between the 2 prior financial years referred to above, which would suggest 470 claims in 2023-2024. The prior year 2020-2021 was not considered as this was the first year of approval of the standalone 42504 code, and it is expected that patients who could not be treated previously were treated in a "catch-up" fashion in this first year. Assuming the same growth rate in the year 2024-2025, it would be expected that 516 total claims would be made. Note that this estimate does not consider the usage in the public system, for which figures do not exist for standalone MBGS implantation of stents. In addition through discussion with the clinical experts mentioned, it is understood that performing MBGS in general are not standard procedures in public hospitals, and depends state to state and hospital to hospital.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

Redacted

Year 2 estimated uptake(%):

Redacted

Year 3 estimated uptake(%):

Redacted

Year 3 estimated uptake(%):

Redacted

Estimate the number of patients who will utilise the proposed technology for the first full year:

Redacted

Optionally, provide details:

Redacted

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

MINIject is a permanent implant.

Optionally, provide details:

MINIject is a permanent implant and is expected to remain in the patient's eye for life.

Redacted

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

One per eye.

Optionally, provide details:

MINIject is a permanent implant and is expected to remain in the patient's eye for life.

Provide references to support these calculations.

Document type	File name(s)
Estimated utilisation references	Estimate utilisation of MINIject references.pdf

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

Professional body name:

Australian and New Zealand Glaucoma Society

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:

Professional body name:

The Royal Australian and New Zealand College of Ophthalmologists

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

Number of organisations listed: 1

Professional body name:

Glaucoma Australia

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

Professional body name:

Australian Society of Ophthalmologists (ASO)

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
400268	MINIJect Glaucoma supraciliary implant

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes

Codependent details

Will a submission be made to the Prostheses List Advisory Committee (PLAC)?

No

Please provide a rationale for the codependency:

An application for listing of ARTG-listed MINInject was submitted to the Prostheses List May 2023 deadline and is currently under evaluation and consideration. There are two existing MBS items that already apply to use of MINInject, i.e. items 42705 and 42505. Item 42705 allows implantation of supraciliary stents to treat glaucoma during concomitant cataract surgery (or stent removal via item 42505).

Redacted.

Are there any other sponsor(s) and / or manufacturer(s) that have similar prosthesis or device component in the Australian market place which this application is relevant to?

Yes

Please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Sponsor details

Sponsor name:

RQSolutions Medical Devices Distribution Support

Manufacturer details

Manufacturer name:

Glaukos Corporation

Describe and explain the similarities:

iStent Inject is designed to implant stents via an injector into Schlemm's canal, creating a patent opening in the trabecular meshwork to re-establish normal physiological outflow
Intended Purpose The iStent inject W System Trabecular Micro-Bypass System is intended to reduce intraocular pressure in adult patients diagnosed with mild to moderate primary open-angle glaucoma (POAG) currently treated with ocular hypotensive medication. The device can be implanted with or without cataract surgery.

Sponsor details

Sponsor name:

Emergo Asia Pacific Pty Ltd T/a Emergo Australia

Manufacturer details

Manufacturer name:

Ivantis Inc

Describe and explain the similarities:

Application 1764 - Micro-bypass glaucoma surgery device implantation into the suprachoroidal space as a standalone procedure in patients with open angle glaucoma

The Hydrus Microstent is intended for the reduction of intraocular pressure (IOP) in patients with primary open angle glaucoma (POAG) as a standalone treatment or in conjunction with cataract surgery.

Are there any single and/or multi-use consumables delivered as part of the service or health technology?

No