



Australian Government

Department of Health

MSAC Application 1649

Modification of the wording of minimally invasive glaucoma surgery existing item number to encompass the use of a microcatheter

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Corporation name: Nova Eye Medical Ltd

ABN: 15 007 702 927

Business trading name: Nova Eye Medical

Primary contact name: REDACTED

Primary contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

Alternative contact name: REDACTED

Alternative contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

2. (a) Are you a lobbyist acting on behalf of an Applicant?

- Yes
 No

(b) If yes, are you listed on the Register of Lobbyists?

- Yes
 No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Modification of the wording of minimally invasive glaucoma surgery (MIGs) existing item number to encompass the use of a microcatheter to decrease outflow resistance in the trabecular meshwork, Schlemm's canal and distal outflow system.

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Glaucoma is a chronic progressive optic neuropathy characterised by atrophy of the optic nerve and loss of retinal ganglion cells resulting in progressive vision loss and possible blindness¹. Open angle glaucoma (OAG) is the most common form of the disease caused by high intraocular pressure (IOP). The drainage angle formed by the cornea and iris remains open, but the trabecular meshwork is partially blocked. This causes pressure in the eye to gradually increase.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Similarly, to stents placed into Schlemm's canal, a microcatheter is first inserted into Schlemm's canal via the trabecular meshwork and circumnavigated 360° within Schlemm's canal. The microcatheter breaks inner lumen adhesions and opens stenotic areas of the canal. The microcatheter dilates the canal with high molecular weight Ocular Viscosurgery Device (OVD) fluid (viscodilation) and separates herniations of the trabecular meshwork into the collector channels, thereby reducing IOP.

6. (a) Is this a request for MBS funding?

- Yes
 No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)
 New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

42504

Group

T8 - Surgical Operations

Subgroup

9 - Ophthalmology

Glaucoma, implantation of a micro-bypass surgery stent system into the trabecular meshwork, 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

Multiple Operation Rule

(Anaes.)

Fee: \$310.15 **Benefit:** 75% = \$232.65 85% = \$263.65

¹ Sheybabi A et al 'Open-Angle Glaucoma: Burden of Illness, Current Therapies and the Management of Nocturnal IOP Variation' Ophthalmol Ther (2020) 9:1-14

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

- i. An amendment to the way the service is clinically delivered under the existing item(s)
- ii. An amendment to the patient population under the existing item(s)
- iii. An amendment to the schedule fee of the existing item(s)
- iv. An amendment to the time and complexity of an existing item(s)
- v. Access to an existing item(s) by a different health practitioner group
- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below):

The applicant believes that the wording of the current item number, has the unintended consequence of excluding currently used technology (microcatheters).

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

- Yes
- No

(g) If yes, please advise:

Not applicable

7. What is the type of service:

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

Not Applicable

- i. To be used as a screening tool in asymptomatic populations
- ii. Assists in establishing a diagnosis in symptomatic patients
- iii. Provides information about prognosis
- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
- Prosthesis or device
- No

In addition to micro-bypass stents currently specified in the item number, the service relies on the use of a microcatheter that visco-dilates Schlemm's canal. High molecular weight OVD fluid is injected into Schlemm's canal during the procedure.

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

Not applicable

- Yes
 No

(b) If yes, please list the relevant PBS item code(s):

Not applicable

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

Not applicable

- Yes (please provide PBAC submission item number below)
 No

Not applicable

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Not applicable

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

- Yes
 No

The services are reliant on either micro bypass stent systems or high molecular weight OVD when using microcatheters.

There is one known microcatheter system in use in Australia. This is the iTrack Surgical System. Microcatheters are not included on the Prosthesis list.

(b) If yes, please provide the following information (where relevant):

Billing code(s): ER501

Trade name of prostheses: Hydrus Microstent

Clinical name of prostheses: Hydrus Microstent

Other device components delivered as part of the service:

Billing code(s): RQ075

Trade name of prostheses: iStent Inject System

Clinical name of prostheses: iStent Inject System

Other device components delivered as part of the service: Preloaded injection system

Billing code(s): RQ084

Trade name of prostheses: Glaukos iStent Inject W S

Clinical name of prostheses: iStent Inject System W S

Other device components delivered as part of the service: Preloaded injection system

Billing code(s): AO008

Trade name of prostheses: Healon, Intraocular Viscoelastic fluid

Clinical name of prostheses: Sodium Hyaluronate

Other device components delivered as part of the service:

Billing code(s): AO010

Trade name of prostheses: Healon GV, Intraocular Viscoelastic fluid

Clinical name of prostheses: Sodium Hyaluronate

Other device components delivered as part of the service:

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

Not applicable

Yes

No

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

Yes

No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Not applicable

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables: The iTrack Surgical System is a single use device.

Multi-use consumables: Not Applicable

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

- 13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:**

Type of therapeutic good: Ophthalmic cannular, irrigation/aspiration, fibreoptic, single use

Manufacturer's name: Ellex iScience Inc

Sponsor's name: Medical Manufacturers Pty Ltd

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**

- Class III
 AIMD
 N/A

- 14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?**

- Yes (If yes, please provide supporting documentation as an attachment to this application form)
 No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?**

- Yes (if yes, please provide details below)
 No

ARTG listing, registration or inclusion number: 244570

TGA approved indication(s), if applicable:

TGA approved purpose(s), if applicable: Fluid infusion and aspiration during surgery; catheterisation and viscodilation during surgery; placement of a tensing suture within the canal to reduce the IOP of patients with glaucoma.

- 15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?**

Not applicable

- Yes (please provide details below)
 No

Date of submission to TGA: Not applicable

Estimated date by which TGA approval can be expected: Not applicable

TGA Application ID: Not applicable

TGA approved indication(s), if applicable: Not applicable

TGA approved purpose(s), if applicable: Not applicable

- 16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

Not applicable

- Yes (please provide details below)
 No

Estimated date of submission to TGA: Not applicable

Proposed indication(s), if applicable: Not applicable

Proposed purpose(s), if applicable: Not applicable

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	Retrospective comparative consecutive case series	Gallardo MJ, Supnet RA, Ahmed, II, ' <i>Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach</i> ' Clinical Ophthalmology 2018;12 2149-2155	Retrospective comparative consecutive case series for patients with uncontrolled primary open angle treated with microcatheter dilation of Schlemm's Canal. Primary outcome measures: Mean lower IOP and mean number of glaucoma medications.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6205145/	2018
2.	Non-randomised single centre retrospective chart review	Khaima MA, Dvorak JD, Ding K ' <i>An Analysis of 3-Year Outcomes Following Canaloplasty for the Treatment of Open-Angle Glaucoma</i> ' Hindawi Journal of Ophthalmology Vol 2017, Article 2904272	277 eyes were treated with canaloplasty or combined cataract-canaloplasty surgery. Primary endpoints: Mean IOP and mean number of glaucoma medications. Secondary endpoints: visual acuity and surgical/postsurgical complications	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5642877/	2017

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
3.	Prospective multicentre non-randomised	Lewis RA, von Wolff K, Tetz, m, Koerber N, Kearney JR, Shingleton, BJ, Samuelson, TW 'Canaloplasty: Three-year results of circumferential viscodilation of Schlemm canal using a microcatheter to treat open-angle glaucoma' J Cataract Refract Surg 2011; 37:682-690	Prospective multicentre trial of 157 eyes treated with a flexible microcatheter to viscodilate Schlemm's canal followed for three years. Primary outcome measures were mean IOP and mean glaucoma medication use. Secondary outcomes: visual acuity and surgical and post-surgical complications	https://journals.lww.com/jcrs/Abstract/2011/04000/Canaloplasty__Three_year_results_of.11.aspx	2011
4.	Consecutive case series	Korber 'Ab interno canaloplasty for the treatment of glaucoma: a case series study' Spektrum Augenhelkd (2018) 32:223-227	Single centre consecutive case series study of 20 patients treated with ab-interno canaloplasty. Primary outcome measures: Mean IOP and mean number of antiglaucoma medications	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6280802/	2016

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.

*** If the publication is a follow-up to an initial publication, please advise.

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	Prospective, multi-centre registry study.	Lubek D, Singh I & Noecker R, <i>Evaluation Of Endothelial Cell Density and Loss Following i-Track Ab-Interno Canal Based Surgery</i>	Preliminary results of a prospective, multi-center RWE study evaluating the endothelial cell density in patients who underwent iTrack™ in addition to efficacy outcomes i.e. IOP and reduction in medication burden. Preliminary 6-month results demonstrate minimal change in endothelial cell density following iTrack™ that is comparable to cataract surgery alone at -3.1%.	https://ascrs.confex.com/ascrs/20am/meetingapp.cgi/Paper/68712	Interim 12-month data to be published in 2021

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

***Date of when results will be made available (to the best of your knowledge).

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):

REDACTED

20. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):

The same professionals provide the services associated with the current wording of the item number. Modifying the wording of the item number would only increase the choice of device.

21. List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):

REDACTED

22. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:

The following devices are also used in the trabecular network and are included in the current wording of the item number

Sponsor: Ophthalmico Pty Ltd, Manufacturer: Ivantis Inc, Device: Hydrus Microstent

Sponsor: RQSolutions, Manufacturer: Glaukos Inc, Device: IStent Inject

23. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):

Name of expert REDACTED

Telephone number(s): REDACTED

Email address: REDACTED

Justification of expertise: M.B.B.S, B. Human Bio, F.R.A.N.Z.C.O.

REDACTED

Name of expert 2: REDACTED

Telephone number(s): REDACTED

Email address: REDACTED

Justification of expertise: B. Sc, M.B.B.S., FRCOPH, FEBO, FAMS, FRANZCO, Specialist glaucoma surgeon

REDACTED

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

Open angle glaucoma (OAG) is a progressive disease, which is characterised by atrophy of the optic nerve and loss of retinal ganglion cells, resulting in progressive vision loss and possible blindness. 80% of all cases of glaucoma are likely to be classified as OAG².

High intraocular pressure (IOP) is the primary modifiable risk factor associated with progression of OAG. A second significant risk factor is aging³ as it is possible that the optic nerve becomes more vulnerable to IOP with age. Family history of glaucoma is also a risk factor with a 10-fold increase in risk for those with a first degree relative with glaucoma⁴. As glaucoma is a painless condition, the disease can progress and damage the optic nerve before the condition is diagnosed. National Health and Medical Research Council (NHMRC) guidelines recommend that people over the age of 50 should have a regular comprehensive eye examination, or that people over 40 with a family history of glaucoma or other risk factors⁵.

OAG can be classified by stages. There are several methods for grading glaucoma, the most common being that of the American Academy of Ophthalmology (AAO)⁶.

- **Mild:** Optic disk or retinal nerve fibre layer abnormalities consistent with glaucoma and a normal visual field as tested with standard automated perimetry.
- **Moderate:** Optic disk or retinal nerve fibre layer abnormalities consistent with glaucoma and visual field abnormalities in one hemifield that are not within 5 degrees of fixation as tested with standard automated perimetry.
- **Severe:** Optic disk or retinal nerve fibre layer abnormalities consistent with glaucoma as and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with standard automated perimetry.
- **Indeterminate:** Optic disk or retinal nerve fibre layer abnormalities consistent with glaucoma as detailed above, inability of patient to perform visual field testing, unreliable/uninterpretable visual field test results.

Glaucoma is the leading cause of vision loss in Australia⁷ and results in a significant societal financial burden⁸. It is estimated that 198,923 non-indigenous Australians over 50 and 2139 indigenous Australians over 40 have glaucoma⁹.

² Vajaranant TS et al 'The Changing Face of Primary Open-Angle Glaucoma in the United States: Demographic and Geographic changes from 2011 to 2050' Am J Ophthalmology, 2012

³ Quigley HA et al 'The number of people with glaucoma worldwide in 2010 and 2020' Br J Ophthalmology 2006; 262-267

⁴ Shiga Y et al 'Genome-wide association with study identifies seven novel susceptibility loci for primary open-angle glaucoma' Hum Mol Gen 2018;27: 1486-1496

⁵ National Health and Medical Research Council. NHMRC guidelines for the screening, prognosis, diagnosis, management and prevention of glaucoma. Canberra NHMRC 2010.

⁶ Sihota R et al 'Simplifying 'target' intraocular pressure for different stages of primary open-angle glaucoma and primary angle-closure glaucoma' Indian J Ophthalmol. 2018 Apr; 66(4): 495-505

⁷ Dimitriv PN et al 'Five-year incidence of bilateral cause-specific visual impairment in the Melbourne Visual Impairment Project' Invest Ophthalmol. Vis . Sci 2003;44:5075-81

⁸ Taylor HR et al 'The economic impact and cost of visual impairment in Australia' Br J Ophthalmol. 2006 Mar; 90(3): 272-275

⁹ Keel S et al 'Prevalence of glaucoma in the Australian National Eye Survey' Br J Ophthalmol. 2019;103:191-195

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Patients who are eligible for the treatment encompassed by item number 42504 are those patients who have been diagnosed with OAG and who have failed conservative therapies. The primary goal of interventions to treat OAG is the lowering of IOP so as to prevent progressive pressure induced injury to the optic nerve. Normal IOP is often considered to be less than 21mmHg, however this number is statistically derived and therefore an appropriate 'target' IOP must be determined based on an individual's risk factors, age and clinical presentation (Shiga 2018).

First line therapy for OAG is topical medication designed to reduce aqueous production, promote aqueous outflow or both. Patients may be prescribed single medications or a combination of medications. Types of medications include:

- Alpha agonists
- Beta blockers
- Carbonic anhydrase inhibitors
- Cholinergic (miotic)
- Prostaglandin analogs
- Rho kinase inhibitors
- Combined medications

The NHMRC estimates that adherence to topical adherence drops is poor, ranging from 24-59%. This may be due to patients experiencing side effects from medications to treat a condition which may be symptomless for a prolonged period¹⁰. Different medications may be trialled and often a combination of medications is required. Patients should be monitored for any progression of the disease.

Should medication be ineffective, or a patient has difficulty in adhering to the medication regime, laser trabeculoplasty may be considered. Laser trabeculoplasty reduces IOP by increasing aqueous outflow through the trabecular meshwork with an outpatient procedure. Laser procedures include argon laser therapy and selective laser trabeculoplasty (SLT). The procedure is considered safe and patients are likely to recover quickly¹¹.

Surgery is a third line therapy should medication, then laser trabeculoplasty not sufficiently reduce IOP. Surgery may include trabeculectomy, also known as 'filtering surgery'. An incision is made in the sclera to create an alternate channel through which aqueous fluid can drain into a bleb. Microsurgery using stents encompassed by item number 42504 or a trabecular microcatheter can be considered to reduce the need for the more invasive filtering surgery.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

As noted in Question 25, patients with glaucoma may be identified by routine screening during an eye examination or patients are identified as being at risk of glaucoma by a General Practitioner. Referral to an ophthalmologist is required when there is significant suspicion of glaucoma. The ophthalmologist will prescribe topical medication and monitor the response. Additional or alternative medications may be trialled. Should medication not sufficiently lower IOP, then laser trabeculoplasty would be performed. Should IOP still not be lowered to the target range then microsurgery may be considered.

¹⁰ Kong Y X et al 'Glaucoma in perspective' MJA 210 (4) 4 March 2019

¹¹ Gazzard G et al 'Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma (LiGHT): a multicentre randomised controlled trial' Lancet 2019;393:1505-16

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

Similarly, to micro stents, microcatheters are inserted via a small goniotomy into Schlemm’s canal. The microcatheter is filled with viscoelastic fluid and circumnavigates Schlemm’s canal. The tip of the microcatheter is lubricious and atraumatic and has an illuminated fibre-optic tip so that its progress can be tracked. As it traverses the canal the microcatheter separates herniations of the meshwork into the collector channels. It also breaks inner lumen adhesions and opens the stenotic segments of the canal.

Once the microcatheter has completed the circumnavigation it is slowly withdrawn while delivering a precise amount of viscoelastic fluid into the canal. The process of viscodilation separates the compressed tissue planes of the meshwork and triggers the withdrawal of the herniated inner wall tissue from the collector channels. It also dilates and flushes the newly opened collector channel. Once this process is completed the microcatheter is removed.

The procedure may be performed under local or general anaesthetic and may be performed as a day procedure.

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

ITrack is a trademark of Nova Eye Medical Ltd

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

The microcatheter is indicated for the same patients in whom micro-bypass is indicated.

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

Not applicable

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

Not applicable

32. If applicable, advise which health professionals will primarily deliver the proposed service:

An Ophthalmologist must deliver the service.

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

The service cannot be delegated.

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

The service should only be delivered by an ophthalmologist who is recognised by the Conjoint Committee for the Recognition of Training in Micro-Bypass Glaucoma Surgery

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

The service should be delivered by Ophthalmologists who have met the requirements to be admitted as a Fellow of the Royal Australian and New Zealand College of Ophthalmologists (RANZCO). Additionally, the Ophthalmologist should also have undergone training that is recognised by the Conjoint Committee for the Recognition of Training in Micro-Bypass Glaucoma Surgery.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)

- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient’s home
- Laboratory
- Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

The proposed service may be carried out under local anaesthesia and is suitable for a day surgery setting. In some cases, it may be appropriate for the patient to be placed under general anaesthesia or a patient may require additional observation so an overnight admission may be required.

37. Is the proposed medical service intended to be entirely rendered in Australia?

- Yes
- No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. 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 (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

The comparator is micro stents for the treatment of open angle glaucoma when conservative therapies have failed, are likely to fail or are contraindicated. Mean IOP and use of IOP lowering medications are the main outcomes reported in clinical trials. There is currently evidence of a sustained treatment effect for 3 years in clinical trials. (Lewis et al 2011, Gallardo 2018).

39. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

- Yes (please list all relevant MBS item numbers below)
- No

42504

Group

T8 - Surgical Operations

Subgroup

9 - Ophthalmology

Glaucoma, implantation of a micro-bypass surgery stent system into the trabecular meshwork, 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

Multiple Operation Rule

(Anaes.)

Fee: \$310.15 **Benefit:** 75% = \$232.65 85% = \$263.65

40. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):

Altering the wording of item number 42504 to include the use of microcatheters will not alter the subsequent treatment options. Should IOP not sufficiently reduce following the use of a stent or microcatheter, then a patient may progress to further filtering surgery to reduce IOP. Filtering surgeries include trabeculectomy, tube shunt implantation and cyclophotocoagulation. Please see the attached document 'Clinical Algorithm 2'. It is possible that either a failed microcatheter surgery could present to stent surgery or vice versa. To our knowledge there is no published evidence that failed stent patients are subsequently treated with microcatheter surgery. That being said, the possibility of this occurring cannot be ruled out.

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

In addition to (i.e. it is an add-on service)

Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

Outline service/comparator substitution here

Micro-catheters are an alternative to micro-stents. It is possible that either a failed microcatheter surgery could present to stent surgery or vice versa. Lewis (2011) with three years follow up of microcatheter surgery did not have patients progress to micro-stents, but this may have been because micro-stents were not a readily available therapy at that time.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):

It is not anticipated that altering the wording of the item number to encompass the use of microcatheters will change the current clinical management pathways or cause any significant change in the subsequent use of resources.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

- 43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):**

Use of a microcatheter is non-inferior to the use of micro stents in terms of clinical effectiveness and safety

- 44. Please advise if the overall clinical claim is for:**

- Superiority
 Non-inferiority

- 45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:**

Safety Outcomes:

Intraoperative adverse events

Postoperative adverse events

Clinical Effectiveness Outcomes:

Mean IOP reduction

Change in number of ocular hypotensive medications

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

The most accurate estimation of the prevalence of glaucoma in Australia is likely to be the Blue Mountains Eye study conducted in the late 1990's¹². Prevalence of definite or probable AOG was estimated to be 3% overall, prevalence for those aged under 60 was estimated to be 0.4%, those aged 60-69, 70-79 and those aged over 80 to be 1.4%, 4.7% and 11.4% respectively.

The AIHW estimates that 2.32% of people over 55 in Australia will have OAG.¹³ Therefore the estimated prevalence, updated to present population estimates (ABS Demographic Statistics 2019), is likely to be 160,380.

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

The service is delivered once only per glaucomatous eye in one year.

48. How many years would the proposed medical service(s) be required for the patient?

Microcatheter surgery should only be performed once per eye in each calendar year, however it is possible that the procedure could be performed again in subsequent years

49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

While the prevalence of OAG is high, it is unlikely that this number of patients will access the item number as many patients will be successfully managed by medications and/or laser trabeculoplasty. A more accurate indication of utilisation may be provided by Medicare Item Number Statistics¹⁴.

As MBS item 42504 has only been in existence since May 2020, this cannot be used to reliably estimate utilisation. The applicant understands that MBS Item 42758 was claimed for insertion of a micro stent prior to a change in description which excluded the use of minimally invasive glaucoma devices. In 2016/2017 financial year, this item number was claimed 3,809 times. This number is likely to include a limited number of patients being treated for primary congenital glaucoma. In the subsequent years (2017/2018 and 2018/2019) following the change in wording of the item number, there were 78 claims and 17 claims respectively. Assuming a population growth of 1.6% a year since 2016, it is likely that the new item number 42504 will be utilised up to 4056 times in 2020/2021.

Incorporating the use of microcatheters in the wording of MBS Item 42504 will not change the utilisation of the item number but will only offer an alternative choice of device used during the procedure.

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

It is not anticipated that a change of wording of the item number to encompass the use of microcatheters will change the anticipated uptake in any way and increased uptake will largely be due to demographic changes.

As clinical guidelines for OAG are well established, and the intervention is only suitable for OAG, leakage to other populations is not considered likely. Please see Table 1 for an estimate of utilisation

¹² Mitchell P et al 'Prevalence of Open-angle Glaucoma in Australia. The Blue Mountains Eye Study'. Ophthalmology 1996; 103: 1661- 1669

¹³ AIHW 'Vision problems among older Australians' July 2005.

¹⁴ http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp

Table 1: Projected Utilisation 42504

Year	Utilisation
2021/2022	4120
2022/2023	4185
2022/2024	4251

PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

The current fee for MBS item number 42504 of \$310.15 is sufficient to encompass the use of microcatheters. The microcatheter has a similar cost to micro stents so there is no additional cost for devices should the item number be reworded.

Service	Source	Fee/Cost	Benefit	Frequency	Cost
Pre-surgical services					
Specialist Consultation	MBS 104	\$45.00	\$38.25	1	\$38.25
Pre-Anaesthesia Consultation	MBS Item 17610	\$45.00	\$38.25	1	\$38.25
Surgical Services					
Anaesthesia	MBS 23035	\$61.20	\$45.90	1	\$45.90
	MBS 20140	\$102	\$76.50	1	\$76.50
Ophthalmologist	MBS 42504	\$310.15	\$232.65	1	\$232.65
Hospitalisation	AR-DRG C15B	\$4,489	N/A	1	\$4,338.00
Total					\$4769.55

52. Specify how long the proposed medical service typically takes to perform:

30 to 45 minutes

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category - Therapeutic Procedures
<p>42504</p> <p>Glaucoma, implantation of a micro-bypass surgery stent system or insertion of a micro-catheter into the trabecular meshwork, if:</p> <p>a) conservative therapies have failed, are likely to fail, or are contraindicated; and</p> <p>(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</p> <p>Multiple Operation Rule</p> <p>(Anaes.)</p> <p>Fee: \$310.14 Benefit: 75% = \$232.65 85% = \$263.65</p>