

Trabecular Micro-Bypass Surgery with Microstents for Open-Angle Glaucoma

Policy Number: **M20201029106**
 Effective Date: **12/1/2020**
 Sponsoring Department: **Health Care Services**
 Impacted Department(s): **Health Care Services**

Type of Policy: ☐ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☒ Child Health Plus; ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
☒ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth the medical necessity criteria for trabecular bypass microstent surgery with for **open-angle glaucoma** in conjunction with cataract surgery.

Policy:

Commercial and Self-Funded

One or two Food and Drug Administration (FDA) approved trabecular micro-bypass stents is considered medically necessary for when **ALL** the following criteria are met:

- Adults with mild or moderate open-angle glaucoma and a cataract; AND
- When the individual is currently being treated with an ocular hypotensive medication; AND

- The procedure is being performed in conjunction with cataract surgery.

Contraindications for trabecular micro-bypass stents are:

- Quick or sudden increase in eye pressure
- Inflammation of the eye tissue
- Neovascular glaucoma
- Noticeable birth irregularities on the front of the eye
- Orbital tumor
- Thyroid eye disease
- Sturge-Weber Syndrome (neurological/nerve disorder marked by a distinctive port-wine stain on the forehead, scalp or around the eye)
- Any other type of condition that may cause elevated pressure in the veins of the eye (episcleral venous pressure)

Medicare Advantage

There is currently a Local Coverage Determination (LCD) and a Local Coverage Article (LCA) for micro-invasive glaucoma surgery utilizing trabecular micro-bypass stents. Please refer to the links listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, Child Health Plus and Essential Plan

Trabecular micro-bypass stents are not covered for MediSource, MediSource Connect, Child Health Plus and Essential Plan.

Background

Primary open-angle glaucoma is the most common form of glaucoma. The eye intraocular pressure rises because the correct amount of fluid is unable to drain out of the eye, causing clogging problems to occur further inside the drainage canals. Open-angle glaucoma develops slowly and sometimes without loss of sight for many years, and patients may be asymptomatic or do not receive early warning signs. If caught early and treated, it responds well to primary open-angle glaucoma medications.

Examples of trabecular micro-bypass stents include the **iStent** and the **Hydrus Microstent**. The iStent inject Trabecular Micro-Bypass System is FDA approved and is intended for use in conjunction with cataract surgery for the reduction of intraocular pressure in adult patients with mild-to-moderate primary open-angle glaucoma. The iStent inject Trabecular Micro-Bypass System consists of two small titanium stents that are pre-loaded into a stent delivery tool. During cataract surgery, these stents are implanted into the eyes of patients with primary open angle glaucoma (POAG) to help drain fluid that has accumulated. The Hydrus Microstent flexible aqueous drainage device is designed to be placed ab-interno where it bypasses the trabecular meshwork and dilates approximately three clock hours of Schlemm's canal. Implantation of the Hydrus is performed via a peripheral clear corneal incision using a preloaded hand-held injector.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required. Criteria above will be utilized upon retro-review.

Definitions

Open-angle glaucoma is a chronic condition causing eye pressure on the optic nerve slowly over time and is the most common type of glaucoma. The increased pressure produces damage to the optic nerve which results in blind spots in vision.

iStent Inject Trabecular Micro-Bypass System is designed to control intraocular pressure in the eye by creating a drainage pathway from the fluid filled anterior chamber and the major channel that directs fluid out of the eye, bypassing the tissue where the fluid normally flows through.

Hydrus Microstent is a flexible aqueous drainage device is designed to be placed ab-interno where it bypasses the trabecular meshwork and dilates approximately three clock hours of Schlemm's canal.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Glaucoma Research Foundation [web site]. What is Primary Open-Angle Glaucoma? Available at: <https://glaucoma.org/types/open-angle-glaucoma> Accessed on July 1, 2025

Hayes, Inc. Health Technology Assessment iStent inject Trabecular Micro-Bypass System (Glaukos Corp) In Combination with Cataract Surgery for the Management of Open-Angle Glaucoma. Lansdale PA: July 2019.

Hayes, Inc. Health Technology Assessment iStent Inject Trabecular Micro-Bypass Stent (Glaukos Corp.) as a Standalone Procedure for Open-Angle Glaucoma. Lansdale PA: September 2019.

Le JT, Bicket AK, Wang L, et al. Ab interno trabecular bypass surgery with iStent for open-angle glaucoma. Cochrane Database Syst Rev. 2019 Mar 28;3(3):CD012743.

National Institute for Health and Care Excellence (NICE) [web site]. Trabecular stent bypass microsurgery for open-angle glaucoma. February 22, 2017. Available at: <https://www.nice.org.uk/guidance/ipg575/resources/trabecular-stent-bypass-microsurgery-for-openangle-glaucoma-pdf-1899872109871045> Accessed July 1, 2025

Samet S, Ong JA, Ahmed IIK. Hydrus microstent implantation for surgical management of glaucoma: a review of design, efficacy and safety. Eye Vis (Lond). 2019 Oct 22;6:32.

Samuelson TW, Sarkisian SR Jr, Lubeck DM, et al. Prospective, Randomized, Controlled Pivotal Trial of an Ab Interno Implanted Trabecular Micro-Bypass in Primary Open-Angle Glaucoma and Cataract: Two-Year Results. Ophthalmology. 2019;126(6):811-821.

United States National Library of Medicine Medline Plus [web site]. Glaucoma. Review Date 8/22/2022. Available at: <https://medlineplus.gov/ency/article/001620.htm> Accessed July 1, 2025

Regulatory References

Centers for Medicare and Medicaid (CMS) [web site]. Local Coverage Article: Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS) (A56588). Available at: [Article - Billing and Coding: Micro-Invasive Glaucoma Surgery \(MIGS\) \(A56588\)](#) Accessed July 1, 2025

Centers for Medicare and Medicaid (CMS) [web site]. Local Coverage Determination (LCD): Micro-Invasive Glaucoma Surgery (MIGS) (L37244). Available at: [LCD - Micro-Invasive Glaucoma Surgery \(MIGS\) \(L37244\)](#) Accessed July 1, 2025

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest). October 13, 2020.

United States Food and Drug Administration (FDA) [web site]. iStent inject Trabecular Micro-Bypass System (Model G2-M-IS) – P170043. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170043> Accessed July 1, 2025

United States Food and Drug Administration (FDA) [web site]. Hydrus Microstent – P170034 . Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170034> Accessed July 1, 2025

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
11/1/2025	Health Care Services	Reviewed
11/1/2024	Health Care Services	Reviewed
11/1/2023	Health Care Services	Revised
11/1/2022	Health Care Services	Revised
11/1/2021	Health Care Services	Reviewed