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Aqueous Shunts and Stents for Glaucoma

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Related Policies (if applicable)
None

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 Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

CAREFULLY CHECK STATE REGULATIONS AND/OR THE MEMBER CONTRACT

Ab Externo Aqueous Shunts

Insertion of ab externo aqueous shunts approved by the U.S. Food and Drug Administration **may be considered medically necessary** as a method to reduce intraocular pressure in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure.

Use of an ab externo aqueous shunt for all other conditions, including in individuals with glaucoma when intraocular pressure is adequately controlled by medications, **is considered experimental, investigational and/or unproven.**

Ab Interno Aqueous Stents

Insertion of ab interno aqueous stents approved by the U.S. Food and Drug Administration as a method to reduce intraocular pressure in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure **may be considered medically necessary**.

Implantation of 1 or 2 U.S. Food and Drug Administration approved ab interno stents in conjunction with cataract surgery **may be considered medically necessary** in individuals with mild-to-moderate open-angle glaucoma treated with ocular hypotensive medication.

NOTE 1: Refer to Policy Guidelines for definition of mild to moderate open-angle glaucoma.

Use of ab interno stents for all other conditions **is considered experimental, investigational and/or unproven**.

Policy Guidelines

Shunts and stents are only able to reduce intraocular pressure to the mid-teens and may be inadequate when very low intraocular pressure is needed to reduce glaucoma damage.

The American Academy of Ophthalmology defines the severity of glaucoma according to the following categories (4):

- Mild: definite optic disc or retinal nerve fiber layer (RNFL), or macular imaging abnormalities consistent with glaucoma and a normal visual field as tested with standard automated perimetry;
- Moderate: definite optic disc or RNFL, or macular imaging abnormalities consistent with glaucoma and visual field abnormalities in one hemifield that are not within 5 degrees of fixation as tested with SAP;
- Severe: definite optic disc or RNFL, or macular imaging abnormalities consistent with glaucoma and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with SAP;
- Indeterminate: definite optic disc or RNFL, or macular imaging abnormalities consistent with glaucoma inability of patient to perform visual field testing, unreliable/uninterpretable visual field test results, or visual fields not performed.

Description

Glaucoma surgery is intended to reduce intraocular pressure when the target IOP cannot be reached using medications. Due to complications with established surgical approaches (e.g., trabeculectomy), a variety of shunts and stents are being evaluated as alternative surgical treatments for individuals with inadequately controlled glaucoma. Microstents are

also being evaluated in patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Glaucoma

Glaucoma is the leading cause of irreversible blindness worldwide and is characterized by elevated intraocular pressure. In 2020, glaucoma affected approximately 52.7 million individuals globally, with a projected increase to 79.8 million in 2040. (1) Glaucoma has been reported to be 7 times more likely to cause blindness and 15 times more likely to cause visual impairment in Black individuals as compared to White individuals. In the U.S. in 2010, Black individuals had the highest prevalence rate of primary open angle glaucoma at 3.4% compared to 1.7% among White individuals.

In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork and/or the inner wall of the Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

Treatment

Ocular Medication

First-line treatment typically involves pharmacologic therapy. Topical medications either increase the aqueous outflow (prostaglandins, alpha-adrenergic agonists, cholinergic agonists, Rho-kinase inhibitors) or decrease aqueous production (alpha-adrenergic agonists, beta-blockers, carbonic anhydrase inhibitors). Pharmacologic therapy may involve multiple medications, have potential side effects, and may be inconvenient for older adults or incapacitated patients.

Surgery

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Surgical procedures for glaucoma aim to reduce IOP from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm canal. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, which involves dissecting the conjunctiva, creating a scleral flap and scleral ostomy, then suturing down the flap and closing the conjunctiva, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir, which can effectively reduce IOP, but commonly results in filtering “blebs” on the eye, and is associated with numerous complications (e.g., hemorrhage, scarring, hypotony, infection, leaks, bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed herein) include trabecular laser ablation, deep sclerectomy (which removes the outer wall of the Schlemm canal and excises deep sclera and peripheral cornea), and viscocanalostomy (which unroofs and dilates the Schlemm canal without penetrating the trabecular meshwork or anterior

chamber). Canaloplasty involves dilation and tension of the Schlemm canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack illuminated microcatheter (iScience Interventional) to access and dilate the entire length of the Schlemm canal and to pass the suture loop through the canal.

Insertion of shunts from outside the eye (ab externo) is another surgical option to lower IOP. Examples of ab externo devices cleared by the U.S. Food and Drug Administration include the Ahmed, Baerveldt, Molteno, and EX-PRESS mini-shunt, which shunt aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ by explant surface areas, shape, plate thickness, presence or absence of a valve, and details of surgical installation. Generally, the risk of hypotony (low pressure) is reduced with aqueous shunts compared with trabeculectomy, but IOP outcomes are worse than after standard guarded filtration surgery. The risk of postoperative infection is lower with shunts than with trabeculectomy, and failure rates are similar (»10% of devices fail annually). The primary indication for aqueous shunts is for failed medical or surgical therapy, although some ophthalmologists have advocated their use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

Minimally Invasive Glaucoma Surgeries

Minimally invasive glaucoma surgeries are alternative, less invasive techniques that are being developed and evaluated. MIGS, which use microscopic-sized equipment and smaller incisions, involve less surgical manipulation of the sclera and the conjunctiva compared with other surgical techniques. There are several categories of MIGS: miniaturized trabeculectomy, trabecular bypass, milder laser photocoagulation, and totally internal or suprachoroidal stents. Shunts and stents can be administered through an external flap of the conjunctiva and sclera (ab externo) or in a small incision in the cornea with the devices inserted through the anterior chamber of the eye (ab interno). Some ab interno microstents may be inserted with injectors.

Examples of ab interno devices either approved or given marketing clearance by the FDA include the iStent, which is a 1-mm long stent inserted into the end of the Schlemm canal through the cornea and anterior chamber, iStent inject, iStent infinite, and XEN gelatin stent.

Because aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system is critical for reaching the target IOP. Therefore, some devices may be unable to reduce IOP below the pressure of the distal outflow system used (e.g., <15 mm Hg) and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma). It has been proposed that stents such as the iStent, iStent inject, and Hydrus Microstent may be useful in patients with early-stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is patients

with glaucoma who require cataract surgery. An advantage of ab interno stents is that they may be inserted into the same incision and at the same time as cataract surgery. Also, most devices do not preclude subsequent trabeculectomy if needed. It is possible to insert more than 1 stent to achieve desired IOP.

Regulatory Status

The regulatory status of the various ab externo and ab interno aqueous shunts and microstents are summarized in Table 1.

The first-generation Ahmed™ (New World Medical), Baerveldt® (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno® (Molteno Ophthalmic) ab externo aqueous shunts were cleared for marketing by the FDA through the 510(k) process between 1989 and 1993; modified Ahmed and Molteno devices were cleared in 2006. They are indicated for use “in patients with intractable glaucoma to reduce IOP where medical and conventional surgical treatments have failed.” The AquaFlow™ Collagen Glaucoma Drainage Device (STAAR Surgical) was approved by the FDA through the premarket approval process for the maintenance of the subscleral space following nonpenetrating deep sclerectomy. In 2003, the ab externo EX-PRESS® Mini Glaucoma Shunt was cleared for marketing by the FDA through the 510(k) process.

In 2016, the XEN® Glaucoma Treatment System (Allergan), which consists of the XEN45 Gel Stent preloaded into the XEN Injector, was cleared for marketing by the FDA through the 510(k) process as an ab interno aqueous stent for management of refractory glaucoma. The approval was for patients with refractory glaucoma who failed previous surgical treatment or for patients with primary open-angle glaucoma unresponsive to maximum tolerated medical therapy. The FDA determined that this device was substantially equivalent to existing devices, specifically the Ahmed™ Glaucoma Valve and the EX-PRESS® Glaucoma Filtration Device.

In 2018, the first microstent, the iStent® Trabecular Micro-Bypass Stent preloaded into the iStent *inject* device (Glaukos), was approved by the FDA through the 515(d) process for use in conjunction with cataract surgery for the reduction of IOP in adults with mild-to-moderate OAG currently treated with ocular hypotensive medication. In 2022, iStent infinite® was FDA-approved for primary OAG when medical and surgical treatment have failed. Notably, this device is not required to be performed in conjunction with cataract surgery and contains 3 stents preloaded into an injector system.

In August 2018, Alcon announced an immediate voluntary recall of the CyPass microstent, which had been approved by the FDA in 2016 for use in conjunction with cataract surgery in adults with mild-to-moderate OAG. The recall was based on 5 year postsurgery data from the COMPASS-XT long-term safety study. Results showed a statistically significant

increase in endothelial cell loss among patients receiving the CyPass microstent compared with patients receiving cataract surgery alone.

In September 2023, a randomized controlled trial (NCT01881425) reported two-year follow-up outcomes comparing the PRESERFLO MicroShunt (Santen) to trabeculectomy in patients with mild to severe primary OAG inadequately controlled by maximum tolerated medical therapy. (2) As of September 2025, FDA approval of the device is still pending.

Table 1. Regulatory Status of Aqueous Shunts and Stents

Device	Manufacturer	Type	FDA Status	Date
AquaFlow™	STAAR Surgical	Drainage device	PMA	2001
Ahmed™	New World Medical	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Baerveldt®	Advanced Medical Optics	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Krupin	Eagle Vision	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Molteno®	Molteno Ophthalmic	Aqueous glaucoma shunt, ab externo	510(k)	<1993
EX-PRESS®	Alcon	Mini-glaucoma shunt, ab externo	510(k)	2003
XEN® Gel Stent; XEN injector	AqueSys/Allergan	Aqueous glaucoma shunt, ab interno	510(k)	2016
iStent®; iStent inject®	Glaukos	Microstent, ab interno	515(d) in conjunction with cataract surgery	2018
iStent supra®	Glaukos	Suprachoroidal stent	Not approved; in clinical trial	N/A
CyPass®	Alcon	Suprachoroidal stent, ab interno	Company voluntarily recalled	2018
Hydrus™	Ivantis	Microstent, ab interno	PMA approval	2018
Beacon Aqueous Microshunt	MicroOptx	Micro-Shunt, ab externo	Not approved; in clinical trial	N/A
PRESERFLO™ MicroShunt (previously InFocus)	Santan	Micro-Shunt, ab externo	Not approved; in clinical trial	N/A

iStent Infinite®	Glaukos	Microstent, ab interno	510(k)	2022
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FDA: Food and Drug Administration; N/A: non-applicable; PMA: premarket approval.
 FDA product codes: OGO, KYF.

Rationale

This policy is based on a review of relevant professional guidelines and position statements.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

The American Academy of Ophthalmology (AAO; 2008) published a technology assessment on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices, which was last reviewed for currency in 2014. (3) The assessment indicated that, in general, intraocular pressure (IOP) would settle at higher levels (≥ 18 mm Hg) with shunts than after standard trabeculectomy (14 to 16 mm Hg). Five-year success rates of 50% were found for the 2 procedures, indicating that aqueous shunts are comparable with trabeculectomy for IOP control and duration of benefit (based on level I evidence; well-designed randomized controlled trials). The assessment also indicated that although aqueous shunts have generally been reserved for intractable glaucoma when prior medical or surgical therapy has failed, indications for shunts have broadened (based on level III evidence; case series, case reports, and poor-quality case-control or cohort studies). The AAO concluded that, based on level I evidence, aqueous shunts offer a valuable alternative to standard filtering surgery and cyclodestructive therapy for many patients with refractory glaucoma.

In 2020, the AAO updated its preferred practice pattern on primary open-angle glaucoma. (4) The document notes that aqueous shunts have traditionally been used to manage medically uncontrolled glaucoma when trabeculectomy has failed to control IOP or is deemed unlikely to succeed; however, the indications for using aqueous shunts have been broadening, and these devices are being increasingly used in the surgical management of glaucoma. The preferred practice pattern notes that "several studies have compared aqueous shunts with trabeculectomy" and that the "selection of aqueous shunts or trabeculectomy should be left to the discretion of the treating ophthalmologist, in consultation with the individual patient."

American Glaucoma Society

In 2020, the American Glaucoma Society published a position paper on microinvasive glaucoma surgery. (5) The Society supports efforts that facilitate patient access to these procedures, including more flexible regulatory pathways for new devices, expansion of the

indications for already approved devices, and greater availability of information obtained by regulatory authorities.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2017) updated guidance on trabecular stent bypass microsurgery for open-angle glaucoma. (6) The guidance stated that “Current evidence on trabecular stent bypass microsurgery for OAG raises no major safety concerns. Evidence of efficacy is adequate in quality and quantity.”

The National Institute for Health and Care Excellence (2018) published guidance entitled "Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for POAG." (7) The guidance states that evidence is limited in quantity and quality and therefore, the procedure should only be used with special arrangements and that patients should be informed of the uncertainty of the procedure.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT06822738 ^a	A Prospective, Multicenter Clinical Study to Evaluate the Safety and Effectiveness of Gel Stent (XEN63) Implantation Using Ab Interno and Ab Externo Approaches in Subjects With Glaucoma	130	Nov. 2028
NCT06741774 ^a	Efficacy and Safety of Trabecular Meshwork Microstent Drainage System in Reducing Intraocular Pressure in Adult Patients with Mild to Moderate Open-angle Glaucoma Combined with Cataract: a Prospective, Multicenter, Randomized, Open Label, Parallel Controlled, Superiority Clinical Trial	207	May 2026
NCT05439161	Multicentric Evaluation of Best Corrected Visual Acuity of the XEN Implant Versus Classic Trabeculectomy in Open Angle Glaucoma Subjects	196	Sept. 2026
NCT05411198 ^a	A Prospective, Multicenter Clinical Study to Evaluate the Safety and Effectiveness	65	Jan. 2026

	of Ab Externo Implantation of Glaucoma Gel Stent		
NCT04624698 ^a	iStent Inject Trabecular Micro-Bypass System New Enrollment Post-Approval Study	358	May 2026
NCT06066645 ^a	Multicenter, Randomized, Double-masked Trial to Evaluate the Safety and Efficacy of iDose [®] TR (Travoprost Intraocular Implant) in Conjunction With the Placement of iStent Infinite vs. iStent Infinite Alone in Subjects With Open-angle Glaucoma or Ocular Hypertension	150	Nov. 2025
NCT06057051 ^a	A Prospective, Multicenter Study of the Glaukos [®] iStent Infinite Trabecular Micro-Bypass System Model iS3 in Subjects With Mild to Moderate Primary Open-angle Glaucoma	245	Aug. 2027
NCT04635020 ^a	A Prospective Randomised Trial Comparing Selective Laser Trabeculoplasty (SLT) and iStent Trabecular Micro-bypass Stent Implantation Combined With Cataract Surgery in Exfoliation Glaucoma	285	Sept. 2033
NCT05280366 ^a	A Prospective, Randomized, Multi-center Evaluation of the Safety and Effectiveness of the STREAMLINE [®] SURGICAL SYSTEM Compared to iStent Inject W [®] in Patients With Open-Angle Glaucoma	150	June 2026
NCT06289491 ^a	Randomized Trial of Hydrus Microstent Versus Goniotomy	243	Apr. 2029
NCT04553523 ^a	The Hydrus [®] Microstent New Enrollment Post-Approval Study: A Prospective, Non-Randomized, Multicenter, Single Arm, Clinical Trial	545	June 2028
NCT05949242 ^a	Comparison of Clinical Outcomes in Patients Undergoing Cataract Surgery With OMNI Canaloplasty vs Cataract Surgery With OMNI Canaloplasty and Hydrus Stent	80	Oct. 2025
NCT05340647 ^a	NorMIGS - a Prospective Study of Micro-invasive Glaucoma Surgery	100	June 2028

NCT04440527	Intraocular Pressure After Preserflo/Innfocus Microshunt vs Trabeculectomy: a Prospective, Randomised Control-trial (PAINT-Study)	70	July 2024
NCT02327312 ^a	Multicenter Investigation of Trabecular Micro-Bypass Stents vs. Laser Trabeculoplasty	91	Aug. 2020
NCT04629521 ^a	An Observational Multicenter Clinical Study to Provide Additional Long-Term Follow-up Beyond 60 Months for Subjects Implanted With a CyPass Micro-Stent in the COMPASS Trial	54	Aug. 2023
NCT04658095 ^a	A Prospective, Randomized, Multicenter Study To Compare The Safety And Effectiveness Of The OMNI [®] Surgical System And The iStent Inject In Pseudophakic Eyes With Open Angle Glaucoma. The TRIDENT European Trial	20	Aug. 2022
NCT01841450 ^a	A Prospective, Randomized, Controlled, Parallel Groups, Multicenter 60 Post-Approval Study Of The Glaukos [®] iStent [®] Trabecular Micro-Bypass Stent System In Conjunction With Cataract Surgery.	360	Nov. 2021
NCT01444040 ^a	A Prospective, Randomized Evaluation of Subjects With Open-angle Glaucoma, Pseudoexfoliative Glaucoma, or Ocular Hypertension Naïve to Medical and Surgical Therapy, Treated With Two Trabecular Micro-bypass Stents (iStent <i>Inject</i>) or Travoprost Ophthalmic Solution 0.004%	196	March 2019
NCT01461278 ^a	A Prospective, Randomized, Single-Masked, Controlled, Parallel Groups, Multicenter Clinical Investigation of the Glaukos [®] Suprachoroidal Stent Model G3 In Conjunction With Cataract Surgery	505	March 2020

NCT: National clinical trial

^a Denotes industry-sponsored or co-sponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	66179, 66180, 66183, 66184, 66185, 66989, 66991, 66999, 0253T, 0449T, 0450T, 0474T, 0671T
HCPCS Codes	C1783, L8612

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

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Centers for Medicare & Medicaid Services

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at [cms.hhs.gov](https://www.cms.hhs.gov).

Policy History/Revision

Date	Description of Change
5/7/2026	<p>New medical document. Insertion of ab externo aqueous shunts approved by the U.S. Food and Drug Administration may be considered medically necessary as a method to reduce intraocular pressure in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure. Use of an ab externo aqueous shunt for all other conditions, including in individuals with glaucoma when intraocular pressure is adequately controlled by medications, is considered experimental, investigational and/or unproven. Insertion of ab interno aqueous stents approved by the U.S. Food and Drug Administration as a method to reduce intraocular pressure in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure may be considered medically necessary.</p> <p>Implantation of 1 or 2 U.S. Food and Drug Administration approved ab interno stents in conjunction with cataract surgery may be considered medically necessary in individuals with mild-to-moderate open-angle glaucoma treated with ocular hypotensive medication. Use of ab interno stents for all other conditions is considered experimental, investigational and/or unproven.</p>