

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Aqueous Drainage Devices (Stents and Shunts)
Policy Number	9.01.18
Category	Technology Assessment
Original Effective Date	03/20/14
Committee Approval Date	03/19/15, 03/17/16, 4/20/17, 04/19/18, 04/18/19, 04/16/20, 03/18/21, 03/24/22, 02/16/23
Current Effective Date	02/16/23
Archived Date	N/A
Archived Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>• If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</li> <li>• If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</li> <li>• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul>

## POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, insertion of an aqueous drainage device that has been approved by the United States Food and Drug Administration (FDA) has been medically proven to be effective and, therefore, is considered **medically appropriate** as a method to reduce intraocular pressure (IOP) in patients with glaucoma when:
  - A. Medical therapy has failed to adequately control the IOP; or
  - B. Oral or topical medications are not tolerated by the patient (e.g., oral medications cause significant gastrointestinal (GI) effects or topical medications cause contact sensitivity or systemic effects).
- II. Based upon our criteria and assessment of the peer-reviewed literature, implantation of **one** or **two** FDA-approved micro-stents (e.g., iStent or iStent Inject) in conjunction with cataract surgery has been medically proven to be effective and, therefore, is considered **medically appropriate** in patients with mild-to-moderate open-angle glaucoma (OAG) that is currently being treated with ocular hypotensive medication(s).
- III. Based upon our criteria and assessment of the peer-reviewed literature, **ALL** other uses of aqueous drainage devices, including but not limited to, use in patients with glaucoma when IOP is adequately controlled by medications, have not been medically proven to be effective and, therefore, are considered **investigational**.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, the use of aqueous drainage devices inserted into the suprachoroidal space or supraciliary space in patients with glaucoma have not been medically proven to be effective and, therefore, are considered **investigational**.

Refer to Corporate Medical Policy # 11.01.03 Experimental and Investigational Services.

## POLICY GUIDELINE

The FDA recalled the CyPass device on August 28, 2018; therefore, it is no longer available for use.

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### **DESCRIPTION**

Glaucoma is a chronic disorder involving increased pressure in the eye due to fluid build-up. There are several forms of glaucoma, with OAG being the most common. The increased pressure associated with OAG can lead to optic neuropathies characterized by visual field loss and structural damage to the optic nerve fiber. If left untreated, glaucoma can result in partial or complete visual impairment. Currently, IOP is the only treatable risk factor for glaucoma, and lowering IOP has proven beneficial in reducing the progression of loss of vision.

In most cases, topical or oral medication is the first treatment of choice. Glaucoma surgery (e.g., trabeculectomy) is intended to reduce IOP when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, a variety of devices, including aqueous shunts, are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma. Microstents are also being evaluated in patients with mild to moderate OAG that is currently treated with ocular hypotensive medication.

Aqueous shunts, also known as aqueous drainage devices, glaucoma drainage devices, setons, tube implants, and tube shunts, are implanted into the eye to create an alternate path for aqueous humor to drain from the anterior or posterior chamber of the eye to a space between the conjunctiva and the sclera where it is absorbed into the blood, thereby lowering the IOP. These devices differ depending on 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, in comparison with trabeculectomy, but IOP outcomes are higher than after standard guarded filtration surgery.

Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of post-operative infection is lower than after trabeculectomy, and failure rates are similar, with about 10% of devices failing each year. The primary indication for aqueous shunts is that prior medical or surgical therapy has failed, 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.

Other aqueous stents (e.g., microstents) are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into Schlemm's canal or the suprachoroidal space. These include the iStent (Glaukos), which is a 1-mm long stent inserted into the end of Schlemm's canal by an internal approach through the cornea and anterior chamber, and the third generation iStent *supra*, which is designed for *ab interno* implantation into the suprachoroidal space. An advantage of *ab interno* shunts is that they may be inserted into the same incision while cataract surgery is being performed. In addition, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than one shunt to achieve the desired IOP.

### **RATIONALE**

The first generation Ahmed (New World Medical), Baerveldt (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno (Molteno Ophthalmic) aqueous shunts received marketing clearance from the FDA between 1989 and 1993; modified Ahmed and Molteno devices were most recently cleared in 2006. Their indication for use is "in patients with intractable glaucoma to reduce IOP where medical and conventional surgical treatments have failed." The AquaFlow Collagen Glaucoma Drainage Device received premarket approval from the FDA in 2001 for the maintenance of sub-scleral space following nonpenetrating deep sclerectomy. The Ex-PRESS Mini Glaucoma Shunt received Section 510(k) marketing clearance in 2003. The Ex-PRESS shunt is placed under a partial thickness scleral flap and transports aqueous fluid from the anterior chamber of the eye into a conjunctival filtering bleb.

In 2012, the FDA approved the Glaukos Corporation's iStent Trabecular Micro-Bypass Stent, PMA P080030, as indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate OAG that is currently treated with ocular hypotensive medication.

Alcon (a division of Novartis) received FDA approval for its CyPass micro-stent in July 2016. CyPass is a micro-invasive glaucoma surgical (MIGS) device to treat patients with mild to moderate primary OAG in conjunction with cataract surgery. The CyPass Micro-Stent is designed to control IOP by creating a drainage pathway from the anterior chamber to the suprachoroidal space. The FDA approval was based on the COMPASS Study, which included two-year follow-up of over 500 patients undergoing cataract surgery.

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On August 29, 2018 Alcon Research, LTD voluntarily issued a recall of the CyPass Micro-Stent and withdrew this product from the global market. The decision for the withdrawal was based on five-year post-surgery data from the COMPASS XT long-term safety study. The study demonstrated a clinically and statistically significant increase in corneal endothelial cell loss in patients who received the CyPass Micro-Stent. Based upon its review of this data, the FDA issued a Safety Communication notifying physicians and patients of the risk associated with this device and recommended that the use of this device be discontinued.

On November 21, 2016, the FDA cleared Allergan's XEN Glaucoma Treatment System (consisting of the XEN45 Gel Stent and the XEN Injector). The XEN45 Gel Stent is a glaucoma implant designed to reduce IOP in eyes suffering from refractory glaucoma, including cases where previous surgical treatment has failed, in cases of primary OAG, and in cases of pseudo-exfoliative or pigmentary glaucoma with open angles that are unresponsive to maximal-tolerated medical therapy. The device creates a permanent channel through the sclera, allowing flow of aqueous humor from the anterior chamber into the subconjunctival space. The XEN45 Gel Stent is inserted via an *ab interno* approach, through a small corneal incision. A prospective, multi-center, single arm, open-label, clinical trial was conducted at 12 sites in the U.S. to evaluate the safety and effectiveness of the XEN45 Gel Stent in refractory glaucoma subjects where previous filtering or cilioablative procedures failed or IOP was unresponsive to maximally tolerated medical therapy. Sixty-five subjects were implanted with the XEN45 Gel Stent, and 18-month data were collected for safety. There were no intraoperative or surgical complications. Prior to the 12-month visit, two subjects died, and two subjects were considered lost to follow-up resulting, in 61 subjects available for the overall effectiveness analyses (observed data, without the use of imputed data). Fifty-four subjects (83.1%) completed the 12-month visit, and 49 subjects (75.4%) completed the 18-month visit. The medicated baseline IOP for the XEN45 Gel Stent subjects was 25.1 ( $\pm$  3.7) mmHg, and the 12-month mean IOP for the XEN45 Gel Stent population was 15.9 ( $\pm$  5.2) mmHg for the subjects who completed the 12-month visit (n=52). The mean baseline number of IOP-lowering medications was 3.5 ( $\pm$  1.0), as compared to the 12-month results where the 52 subjects who completed the 12-month visit were using on average 1.7 ( $\pm$  1.5) medications.

Randomized, controlled trials (RCTs) have shown that the use of large, externally placed shunts with extraocular reservoirs results in success rates as good as standard filtering surgery (trabeculectomy). Shunts have a different side effect profile and avoid some of the most problematic complications of trabeculectomy.

Gedde and colleagues (2012) reported five-year follow-up from an open-label, multicenter, randomized tube versus trabeculectomy (TVT) study. The study included 212 eyes of 212 patients (aged 18 to 85 years) who had previous trabeculectomy and/or cataract extraction with intraocular lens implantation, uncontrolled glaucoma with IOP of 18 mm Hg or greater, as well as 40 mm Hg or lower on maximal-tolerated medical therapy. Patients were assigned either a tube shunt (Baervelt implant, n=107) or trabeculectomy with mitomycin C (n=105). Excluding patients who had died, the study had 82% follow-up at five years, with a similar proportion of patients in the tube and trabeculectomy groups. At five years, neither IOP (14.3 mm Hg in the tube group and 13.6 mm Hg in the trabeculectomy group) nor number of glaucoma medications (1.4 in the tube group and 1.2 in the trabeculectomy group) were significantly different with intent-to-treat analysis. The cumulative probability of failure over the five years was lower in the tube group than the trabeculectomy group (29.8% versus 46.9%), and the rate of reoperation was lower (9% versus 29%). The rate of loss of two or more lines of visual acuity was similar in the two groups (46% in the tube group and 43% in the trabeculectomy group).

Implantation of the Ex-PRESS mini shunt under a scleral flap was compared with standard trabeculectomy in a randomized study of 78 patients (80 eyes) with a diagnosis of OAG that could not be controlled with maximal-tolerated medical therapy (de Jong et al., 2009). The two groups were similar after randomization, with the exception of difference in the mean age (62 years for the Ex-PRESS group and 69 years for the trabeculectomy group). At an average 12 months' follow-up, mean IOP had improved from 23 to 12 mm Hg in the Ex-PRESS group and from 22 to 14 mm Hg in the trabeculectomy group. Both groups of patients used fewer anti-glaucoma medications post-operatively than before the procedure (from 2.8 at baseline to 0.3 in the Ex-PRESS group and from 3.0 at baseline to 0.6 in the trabeculectomy group). Twelve-month Kaplan-Meier success rates (defined as an IOP of  $>$ 4 mm Hg and  $\leq$ 18 mm Hg without use of anti-glaucoma medications) were 82 percent for the Ex-PRESS shunt and 48 percent for trabeculectomy. There was a similar level of postoperative complications in the two groups.

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A literature review on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices, for an American Academy of Ophthalmology (AAO) technology assessment was published in 2008. This review indicated that the IOP will generally settle at higher levels (approximately 18 mm Hg) with aqueous shunts than after standard trabeculectomy (14-16 mm Hg) or after trabeculectomy with antifibrotic agents 5-fluorouracil or mitomycin C (8-10 mm Hg). In one study, mean IOPs with the Baerveldt shunt and adjunct medications were found to be equivalent to trabeculectomy with mitomycin C (13 mm Hg). Five-year success rates for the two procedures were found to be similar (50%). The assessment concluded that, based on level 1 evidence, aqueous shunts were comparable to trabeculectomy for IOP control and duration of benefit. The risk of postoperative infection was lower with aqueous shunts than after trabeculectomy. Complications of aqueous shunts were noted to include: immediate hypotony after surgery; excessive capsule fibrosis and clinical failure; erosion of the tube or plate edge; strabismus; and, very rarely, infection. The most problematic long-term consequence of anterior chamber tube placement was described as accelerated damage to the corneal endothelium over time.

The American Academy of Ophthalmology (AAO) Primary Open-Angle Glaucoma Preferred Practice Pattern published in 2020 states the indications for using aqueous shunts have been broadening, and these devices are being increasingly used in the surgical management of glaucoma. Several studies have compared aqueous shunts with trabeculectomy. A 2017 Cochrane Systematic Review found that there was insufficient information to conclude whether aqueous shunts or trabeculectomy yielded superior results, with heterogenous methodology and data quality across studies. Therefore, the selection of aqueous shunts or trabeculectomy should be left to the discretion of the treating ophthalmologist, in consultation with the individual patient. The term minimally invasive glaucoma surgery, or MIGS, refers to a group of surgical procedures that are performed using an ab interno approach and involve minimal trauma to ocular tissues. Limited long-term data are currently available for MIGS, given its relatively recent introduction. Modest IOP reduction has been reported following MIGS, and postoperative pressures are typically in the middle to upper teens. Although less effective in lowering IOP than trabeculectomy and aqueous shunt surgery, MIGS appears to have a more favorable safety profile in the short term. Currently available MIGS includes procedures targeting the trabecular meshwork/Schlemm's canal and the subconjunctival space. They are commonly combined with phacoemulsification; some are only FDA approved to be performed concurrently with phacoemulsification.

Use of microstents has been studied in patients with both cataracts and less advanced glaucoma, where the IOP is at least partially controlled with medication. Results from these studies indicate that IOP may be lowered below baseline with decreased need for medication, although the benefit appears to diminish after the first year. Samuelson et al. (2011) conducted a multi-center RCT to assess the safety and efficacy of cataract surgery with iStent (n=111) compared to cataract surgery without iStent (control group) (n=123). Patients had OAG and a plan to undergo phacoemulsification for cataracts. Follow-up occurred for up to 12 months. The primary outcome measure was IOP less than or equal to 21 mmHg without ocular hypotensive medication, and the secondary measure was greater than or equal to 20 percent reduction in IOP from baseline without medication. Additional efficacy measures included medication use and visual acuity. Compared to the control group, significantly more patients in the treatment group achieved primary and secondary outcomes ( $p<0.001$ ,  $p=0.003$ , respectively). At the 12-month follow-up, 70 percent of the treatment group versus 50 percent of the control group had achieved both the primary and secondary outcomes. There was a significant delay in the introduction of medication in the treatment group versus the control group ( $p<0.001$ ), and significantly more patients in the control group required medication at 12 months ( $p=0.001$ ). The overall adverse events were similar in both groups. Both groups improved in vision, with no significant differences between the groups.

Craven and colleagues (2012) reported two-year follow-up of the above-noted iStent study. There were 199 of the original 239 patients (83%) remaining in the study. The primary endpoint, IOP of 21 mm Hg or less without use of medication, was reached by 61 percent of patients in the treatment group, compared to 50 percent of patients in the control group ( $p=0.036$ ). The secondary outcomes of IOP reduction of 20 percent or more without medication (53% versus 44%) and mean number of medications used (0.3 versus 0.5) were no longer significantly different between the groups at two years. As noted by the FDA, this study was conducted in a restricted population of patients who had an unmedicated IOP of 22 mm Hg or higher and 36 mm Hg or lower. The results of this study indicate that treatment of this specific population with a microstent is likely to improve outcomes at one year, compared to cataract surgery alone.

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In August 2022 Glaukos' iStent Infinite was approved by the FDA to be inserted as a stand-alone procedure. iStent infinite consists of three micro stents on a single preloaded injector. The stents are designed to be implanted ab interno in three separate areas of the trabecular meshwork, creating a patent bypass through the trabecular meshwork into Schlemm canal to increase physiological aqueous outflow and reduce IOP.

### CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

### CPT Codes

Code	Description
0253T (E/I)	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)
0474T (E/I)	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

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<b>Code</b>	<b>Description</b>
C1783	Ocular implant, aqueous drainage assist device
L8612	Aqueous shunt

**ICD10 Codes**

<b>Code</b>	<b>Description</b>
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
E09.36	Drug or chemical induced diabetes mellitus with diabetic cataract
E10.36	Type 1 diabetes mellitus with diabetic cataract
E11.36	Type 2 diabetes mellitus with diabetic cataract
E13.36	Other specified diabetes mellitus with diabetic cataract
H25.011-H25.9	Age-related cataract (code range)
H26.011-H26.069	Infantile and juvenile cataract (code range)
H26.101-H26.139	Traumatic cataract (code range)
H26.20	Unspecified complicated cataract
H26.211-H26.219	Cataract with neovascularization (code range)
H26.221-H26.229	Cataract secondary to ocular disorders (degenerative) (inflammatory) (code range)
H26.231-H26.239	Glaucomatous flecks (subcapsular) (code range)
H26.30-H26.33	Drug-induced cataract (code range)
H26.40	Unspecified secondary cataract
H26.411-H26.419	Soemmering's ring (code range)
H26.491-H26.499	Other secondary cataract (code range)
H26.8	Other specified cataract
H26.9	Unspecified cataract
H28	Cataract in diseases classified elsewhere
H40.001-H40.009	Preglaucoma, unspecified (code range)
H40.011-H40.029	Open angle with borderline findings (code range)
H40.031-H40.039	Anatomical narrow angle (code range)
H40.041-H40.049	Steroid responder (code range)
H40.051-H40.059	Ocular hypertension (code range)
H40.061-H40.069	Primary angle closure without glaucoma damage (code range)
H40.10x0-H40.10x4	Unspecified open-angle glaucoma (code range)
H40.1210-H40.1294	Low tension glaucoma (code range)
H40.1310-H40.1394	Pigmentary glaucoma (code range)
H40.141-H40.1494	Capsular glaucoma with pseudoexfoliation of lens (code range)
H40.151-H40.159	Residual stage of open-angle glaucoma (code range)
H40.20x0-H40.20x4	Unspecified primary angle-closure glaucoma (code range)
H40.211-H40.219	Acute angle-closure glaucoma (code range)
H40.2210-H40.2294	Chronic angle-closure glaucoma (code range)
H40.231-H40.239	Intermittent angle-closure glaucoma (code range)
H40.241-H40.249	Residual stage of angle-closure glaucoma (code range)
H40.30x0-H40.33x4	Glaucoma secondary to eye trauma (code range)
H40.40x0-H40.43x4	Glaucoma secondary to eye inflammation (code range)
H40.50x0-H40.53x4	Glaucoma secondary to other eye disorders (code range)

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Code	Description
H40.60x0-H40.63x4	Glaucoma secondary to drugs (code range)
H40.811-H40.819	Glaucoma with increased episcleral venous pressure (code range)
H40.821-H40.829	Hypersecretion glaucoma (code range)
H40.831-H40.839	Aqueous misdirection (code range)
H40.89	Other unspecified glaucoma
H40.9	Unspecified glaucoma
H42	Glaucoma in diseases classified elsewhere
Q15.0	Congenital glaucoma

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\*Key Article

### **KEY WORDS**

Ahmed, Aqueous drainage device, Aquaflow, Baerveldt, CyPass, Ex-PRESS, glaucoma, glaucoma filtration device, IOP, iStent, Krupin, Molteno, open angle, seton, shunt, stent, trabecular, XEN

### **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based upon our review, there is currently a Local Coverage Determination (LCD) (L37244) addressing micro-invasive glaucoma surgery (MIGS). Please refer to the following LCD web site for Medicare members:

<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37244&ver=34&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD&PolicyType=Both&s=41&Keyword=micro-invasive+glaucoma+surgery&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=MAAABAAAAA&=>