# MEDICAL POLICY

| MEDICAL POLICY DETAILS | |
|---|---|
| **Medical Policy Title** | **AQUEOUS DRAINAGE DEVICES (STENTS AND SHUNTS)** |
| **Policy Number** | **9.01.18** |
| **Category** | **Technology Assessment** |
| **Effective Date** | **03/20/14** |
| **Revised Date** | **03/19/15, 03/17/16, 4/20/17, 04/19/18, 04/18/19** |
| **Product Disclaimer** | • *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*<br>• *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*<br>• *If a Medicare 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.* |

## 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 U.S. Food and Drug Administration (FDA) has been medically proven to be effective and 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 intraocular pressure; or
   B. Oral or topical medications are not tolerated by patient (e.g., oral medications causing significant GI effects or topical medications causing contact sensitivity or systemic effects).

II. Based upon our criteria and assessment of peer-reviewed literature, implantation of a single, FDA approved micro-stent (e.g., iStent®) in conjunction with cataract surgery has been medically proven to be effective and is considered **medically appropriate** in patients with mild to moderate open-angle glaucoma (OAG) 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**.

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

## POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the FDA may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity. The FDA recalled the CyPass® device on August 28, 2018, therefore, it is not longer available for use.

## 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 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 of the IOP. These devices differ depending on explant surface areas, shape, plate thickness, the 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 postoperative infection is less than after trabeculectomy, and failure rates are similar, with about 10% of devices failing each year. The primary indication for aqueous shunts is when 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; the third generation iStent *supra*®, which is designed for ab interno implantation into the suprachoroidal space; and the CyPass® (Transcend Medical) suprachoroidal stent. An advantage of ab interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. 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 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 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 device (MIGS) device to treat patients with mild to moderate primary OAG in conjunction with cataract surgery. The CyPass® Micro-Stent is designed to control eye pressure (intraocular pressure, or IOP) by creating a drainage pathway from the anterior chamber to the suprachoroidal space. The FDA approval was based on the COMPASS Study with two-year follow-up for over 500 patients undergoing cataract surgery. Data supporting the approval of this device included 374 subjects implanted with the CyPass® Micro-Stent device at the same time as cataract surgery, and 131 patients that had cataract surgery alone. In this study, 72.5 percent of patients who received the CyPass® Micro-Stent achieved a significant lowering of their IOP compared to 58 percent of patients who had cataract surgery alone. The lower IOP lasted through the 2-year-long study. Complications occurred in 39.3 percent of patients with CyPass® Micro-Stent and cataract surgery and in 35.9 percent of patients with cataract surgery alone.

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 on review of this data the FDA issued a Safety Communication notifying physicians and patients of the risk associated with this device and recommended the use of this device be stopped.

On November 21, 2016, the FDA cleared Allergen's XEN® Glaucoma Treatment System (consisting of the XEN®45 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, cases of primary open angle glaucoma, and pseudo-exfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum 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 (± 3.7) mmHg and the 12-month mean IOP for the XEN45 Gel Stent population was 15.9 (± 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 (± 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 (± 1.5) medications.

Randomized controlled trials 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 open-label multicenter randomized Tube Versus Trabeculectomy (TVT) study. The study included 212 eyes of 212 patients (18-85 years) who had previous trabeculectomy and/or cataract extraction with intraocular lens implantation and uncontrolled glaucoma with IOP of 18 mm Hg or greater and 40 mm Hg or lower on maximum 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% vs. 46.9%), and the rate of reoperation was lower (9% vs. 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 antiglaucoma medications postoperatively 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). 12-month Kaplan-Meier success rates (defined as an IOP of >4 mm Hg and $\leq$18 mm Hg without use of antiglaucoma medications) were 82% for the Ex-PRESS shunt and 48% for trabeculectomy. There was a similar level of postoperative complications in the two groups.

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-fluorouacil 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 with trabeculectomy for IOP control and duration of benefit. The risk of postoperative infection was less 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.

A comparative effectiveness review (CER) on glaucoma treatments was prepared by the Johns Hopkins Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ) in 2012. The CER found that the data available on the role of aqueous drainage devices in OAG (primary studies, systematic review) were inadequate to draw conclusions on the comparative effectiveness of these treatments in comparison with laser and other surgical treatments.

In a 2011 technology assessment, the California Technology Assessment Forum (CTAF) concluded that the use of aqueous shunts for the treatment of glaucoma not adequately controlled by medication and/or laser therapy met the CTAF technology assessment criterion for safety, effectiveness and improvement in health outcomes.

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 multicenter randomized controlled trial 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 were planned to undergo phacoemulsification for cataracts. Follow-up occurred for up to 12 months. The primary outcome measure was IOP $\leq$ 21 mmHg without ocular hypotensive medication and the secondary measure was $\geq$ 20% 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 ($p<0.001$, $p=003$, respectively). At the 12-month follow-up 70% of the treatment group vs. 50% 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 vs. 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% of patients in the treatment group compared to 50% of controls ($p=0.036$). (9) The secondary outcomes of IOP reduction of 20% or more without medication (53% vs. 44%) and mean number of medications used (0.3 vs. 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. However, given the two-year results of this study, it is not possible to conclude with certainty that health outcomes are improved at longer periods of follow-up.

## 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.*

**CPT Codes**

| Code | Description |
|---|---|
| 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 |

| Code | Description |
|---|---|
| 66184 | Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft |
| 66185 | Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft |
| 0191T | Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; initial insertion |
| 0376T | Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; each additional device insertion |
| 0253T | 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 |
| 0474T **E/I** | Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space |



**HCPCS Codes**

| Code | Description |
|---|---|
| C1783 | Ocular implant, aqueous drainage assist device |
| L8612 | Aqueous shunt |

**ICD10 Codes**

| Code | Description |
|---|---|
| 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) |
| H26.411-H26.419 | Soemmering's ring (code range) |
| H26.30-H26.33 | Drug-induced cataract (code range) |
| H26.40 | Unspecified secondary cataract |
| 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) |

| Code | Description |
|---|---|
| H40.10x0-H40.10x4 | Unspecified open-angle glaucoma (code range) |
| H4011x0-H40.11x4 | Primary 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 pseudofoliation 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) |
| 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 disease 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

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/details/ lcd-details.aspx?LCDId=37244&ver=28&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=41&KeyWord=glaucoma&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&

There is currently a Local Coverage Determination (LCD) for Category III CPT® Codes. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ContrId=298&ver=92&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=Active&bc=AAgAAAQAAAAA&