MEDICAL POLICY

SUBJECT:  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  

PAGE: 1 OF: 10

• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.  
• If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.  
• 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 Food and Drug Administration (FDA) has been medically proven to be effective and is considered medially appropriate as a method to reduce intraocular pressure 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 microstent (e.g., iStent®, CyPass®) in conjunction with cataract surgery has been medically proven to be effective and is considered medially appropriate in patients with mild to moderate open-angle glaucoma 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 intraocular pressure is adequately controlled by medications, have not been medically proven to be effective and therefore are considered investigational.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (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.

DESCRIPTION:

Glaucoma is a chronic disorder involving increased pressure in the eye due to fluid build-up. There are several forms of glaucoma with open-angle glaucoma (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, intraocular pressure (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 intraocular pressure (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 open-angle glaucoma 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.

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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 U.S. Food and Drug Administration (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 intraocular pressure 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 open-angle glaucoma 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 open-angle glaucoma 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 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 intraocular pressure 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 cilioablatice 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
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 open-angle glaucoma (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 intraocular pressure (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 open-angle glaucoma and were planned to undergo phacoemulsification for cataracts. Follow-up occurred for up to 12 months. The primary outcome measure was IOP ≤ 21 mmHg without ocular hypotensive medication and the secondary measure was ≥ 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=0.003, 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 2-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 2 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 1 year compared to cataract surgery alone. However, given the 2-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.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).

**CPT:**

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
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SUBJECT: AQUEOUS DRAINAGE DEVICES
(STENTS AND SHUNTS)

POLICY NUMBER: 9.01.18
CATEGORY: Technology Assessment

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)
H4011x0-H4011x4 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)
H40.1510-H40.1594 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
Q150 Congenital glaucoma

REFERENCES:
<table>
<thead>
<tr>
<th>Subject: Aqueous Drainage Devices (Stents and Shunts)</th>
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</tr>
</thead>
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</tr>
<tr>
<td>Category: Technology Assessment</td>
<td>Page: 7 of 10</td>
</tr>
</tbody>
</table>


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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

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a Local Coverage Determination (LCD) for Category III codes (L25275) addressing the insertion of an anterior segment aqueous drainage device, without extraocular reservoir, external approach. Please refer to the following LCD websites for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?Lcid=33392&ContraId=298&ver=50&ContrVer=1&CntrcrSelected=298*1&Cntrcr=298&name=National+Government+Services%2c+Inc.+%(13201%2c+A+and+B+and+HHH+MAC%2c+J+or+K)&s=All&DocType=Active&bc=AggAAAAQAAAAA%3d%3d&