Aqueous Shunts and Stents for Glaucoma

Policy Number: 9.03.21
Origination: 9/2008
Last Review: 1/2014
Next Review: 1/2015

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for aqueous shunts for glaucoma when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Insertion of aqueous shunts approved by the U.S. Food and Drug Administration (FDA) may be considered medically necessary as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure.

Implantation of a single FDA-approved microstent in conjunction with cataract surgery may be considered medically necessary in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

When Policy Topic is not covered
Use of an aqueous shunt for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered investigational.

Use of a micro-stent for all other conditions is considered investigational.

Considerations
Stents are only able to reduce intraocular pressure (IOP) to the mid-teens and may be inadequate when very low IOP is needed to reduce glaucoma damage.

Description of Procedure or Service
Glaucoma surgery 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. Micro-stents are also being evaluated in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

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

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical
procedure for glaucoma, 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., leaks or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed in this policy) include trabecular laser ablation, deep sclerectomy, which removes the outer wall of Schlemm’s canal and excises deep sclera and peripheral cornea, and viscocanalostomy, which unroofs and dilates Schlemm’s canal without penetrating the trabecular meshwork or anterior chamber.

More recently the Trabectome™, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm’s canal without external access or creation of a subconjunctival bleb. IOP with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. Canaloplasty involves dilation and tension of Schlemm’s 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 Schlemm’s canal and to pass the suture loop through the canal.

Aqueous shunts may also be placed between the anterior chamber (or vitreous chamber) and Schlemm’s canal to facilitate drainage of aqueous humor. Established shunts include the Ahmed (New World Medical), Baerveldt (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno (Molteno Ophthalmic). 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 shunts are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into an ocular reservoir. These include the iStent (Glaukos), which is a 1-mm long stent inserted into the end of Schlemm’s canal by either an internal (through the cornea and anterior chamber) or external approach (through the subconjunctiva); the third generation iStent supra, which is designed for ab interno implantation into the suprachoroidal space; the EyePass Bi-Directional Glaucoma Implant (GMP Companies), which is a Y-shaped shunt in which the 2 arms are placed ab externo into both lumina of Schlemm’s canal; the CyPass (Transcend Medical) suprachoroidal stent; and the Solx DeepLight Gold Micro-Shunt (Solx), which shunts aqueous humor between the anterior chamber and the suprachoroidal space.

Since aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system are 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., below 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 shunts may be useful to lower IOP in patients with early stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is for patients with glaucoma who require cataract surgery. 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. Therefore, health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy, complications, and durability of the device.

**Regulatory Status**

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Type</th>
<th>FDA Status</th>
<th>Date</th>
</tr>
</thead>
</table>


<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Approval Status</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>AquaFlow™</td>
<td>Staar Surgical</td>
<td>Drainage device</td>
<td>PMA</td>
<td>2001</td>
</tr>
<tr>
<td>Trabectome™</td>
<td>NeoMedix</td>
<td>Electrocautery device</td>
<td>510(k)</td>
<td>2006</td>
</tr>
<tr>
<td>Ahmed</td>
<td>New World Medical</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt; 1993</td>
</tr>
<tr>
<td>Baerveldt</td>
<td>Advanced Medical Optics</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt; 1993</td>
</tr>
<tr>
<td>Krupin</td>
<td>Eagle Vision</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt; 1993</td>
</tr>
<tr>
<td>Molteno</td>
<td>Molteno Ophthalmic</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt; 1993</td>
</tr>
<tr>
<td>Ex-PRESS™</td>
<td>Optonol</td>
<td>Mini- glaucoma shunt</td>
<td>510(k)</td>
<td>2003</td>
</tr>
<tr>
<td>iStent</td>
<td>Glaukos</td>
<td>Micro- glaucoma stent</td>
<td>PMA</td>
<td>2012</td>
</tr>
<tr>
<td>EyePass</td>
<td>GMP Companies</td>
<td>Aqueous glaucoma shunt</td>
<td>Not Approved</td>
<td></td>
</tr>
<tr>
<td>Solx gold</td>
<td>Solix</td>
<td>Micro-glaucoma shunt</td>
<td>Not Approved</td>
<td></td>
</tr>
<tr>
<td>iStent inject</td>
<td>Glaukos</td>
<td>Suprachoroidal stent</td>
<td>Not Approved</td>
<td></td>
</tr>
<tr>
<td>iStent supra</td>
<td>Glaukos</td>
<td>Suprachoroidal stent</td>
<td>Not Approved</td>
<td></td>
</tr>
<tr>
<td>CyPass</td>
<td>Transcend Medical</td>
<td>Suprachoroidal stent</td>
<td>Not Approved</td>
<td></td>
</tr>
</tbody>
</table>

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 non-penetrating 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.

The labeling describes the following precautions:

1. The safety and effectiveness of the iStent Trabecular Micro-Bypass Stent has not been established as an alternative to the primary treatment of glaucoma with medications. The effectiveness of this device has been demonstrated only in patients with mild to moderate open-angle glaucoma who are currently treated with ocular hypotensive medication and who are undergoing concurrent cataract surgery for visually significant cataract.

2. The safety and effectiveness of the iStent® Trabecular Micro-Bypass Stent has not been established in patients with the following circumstances or conditions, which were not studied in the pivotal trial:
   - In children
   - In eyes with significant prior trauma
   - In eyes with abnormal anterior segment
   - In eyes with chronic inflammation
   - In glaucoma associated with vascular disorders
   - In pseudophakic patients with glaucoma
   - In uveitic glaucoma
   - In patients with prior glaucoma surgery of any type including argon laser trabeculoplasty
   - In patients with medicated intraocular pressure greater than 24 mm Hg
- In patients with unmedicated IOP less than 22 mm Hg nor greater than 36 mm Hg after "washout" of medications
- For implantation of more than a single stent
- After complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitrectomy required, corneal injuries, or complications requiring the placement of an anterior chamber IOL [intraocular lens]
- When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract

Use of the iStent® has subsequently been reported for many of the circumstances or conditions listed above; most of the publications are case series. The SOLX gold shunt and Hydrus Microstent are currently in FDA-regulated trials. They have received regulatory approval in Europe, but are not FDA-approved/cleared for use in the U.S. at this time.

**Rationale**

A search of the MEDLINE database was initially performed through June 2008 on shunts that were in U.S. Food and Drug Administration (FDA) trials at the time. In 2009, the literature was updated to include aqueous shunts that had been previously cleared by the FDA. The policy has since been updated periodically; the most recent literature update was performed through August 13, 2013.

**FDA-Approved/Cleared Aqueous Shunts**

A 2006 Cochrane review evaluated 15 randomized or pseudo-randomized controlled trials (RCTs), with a total of 1,153 participants, on the Ahmed, Baerveldt, Molteno, and Schocket shunts. (1) Trabeculectomy was found to result in a lower mean intraocular pressure (IOP) (by 3.8 mm Hg) than the Ahmed shunt at 1 year. A limitation of this report is that complications were not compared, as the authors considered them to be too variably reported to allow comparative tabulation. There was no evidence of superiority of one shunt over another.

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. (2) 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 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. (3) 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.

**Baerveldt Glaucoma Shunt**

Early results from the open-label multicenter randomized Tube Versus Trabeculectomy (TVT) study were reviewed in the 2008 AAO technology assessment, and in 2012, Gedde et al. reported 5-year follow-up from this study. (2, 4) 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. Excluding patients who had died, the study had 82% follow-up at 5 years, with a similar proportion of patients in the tube and trabeculectomy groups. At 5 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 5 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 2 or more lines of visual acuity was similar in the 2 groups (46% in the tube group and 43% in the trabeculectomy group).

**Ex-PRESS Mini Shunt**
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 open-angle glaucoma that could not be controlled with maximal-tolerated medical therapy. (5) The 2 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). Twelve-month Kaplan-Meier success rates (defined as an IOP of >4 mm Hg and ≤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.

Results of a U.S. multi-center randomized trial of trabeculectomy compared to ExPress were presented at the 2012 American Academy of Ophthalmology annual meeting; publication is pending. (6)

**iStent**
Results from the iStent U.S. investigational device exemption (IDE) open-label 29 site multicenter randomized clinical trial were reported to the FDA in 2010, with 1-year results published in 2011 and 2-year results published in 2012. (7-9) The objective of the trial was to measure the incremental effect on IOP from iStent implantation over that of cataract surgery alone and to determine the potential benefit of combining 2 therapeutic treatments into 1 surgical event. A total of 240 patients (mean age of 73 years) with cataracts and mild to moderate open-angle glaucoma (IOP <24 mm Hg controlled on 1 to 3 medications) underwent a medication washout period. Patients were randomized to undergo cataract surgery with iStent implantation or cataract surgery only if the unmedicated IOP was 22 mm Hg or higher and 36 mm Hg or lower. The mean number of medications at baseline was 1.5. The medicated IOP at baseline was 18.7 mm Hg in the stent group and 18.04 in the control group. After washout, the mean IOP was 25 mm Hg and mean visual acuity (logMAR) was 0.36. Follow-up visits were performed at 1, 3, 6, and 12 months. Results were assessed by intent-to-treat analysis with the last observation carried forward and per protocol analysis. Of the 117 subjects randomized to iStent implantation, 111 underwent cataract surgery with stent implantation, and 106 (91%) completed the 12-month postoperative visit. Of the 123 subjects randomized to cataract surgery only, 117 underwent cataract surgery and 3 exited the study because of complications of cataract surgery. Of the remaining 114 subjects, 112 (91%) completed the 12-month visit. The proportion of eyes meeting both the primary (unmedicated IOP ≤21 mm Hg) and secondary outcomes (IOP reduction >20% without hypotensive medications) was higher in the treatment group than in the control group through 1-year follow-up. At 1-year follow-up, 72% of treatment eyes and 50% of control eyes achieved the primary efficacy endpoint. The proportion of patients achieving the secondary efficacy endpoint at 1 year was 66% in the treatment group versus 48% in the control group. Ocular hypotensive medications were initiated later in the postoperative period and used in a lower proportion of patients in the treatment group throughout 1-year follow-up (e.g., 15% vs. 35% at 12 months). The mean reduction in IOP was similar in the 2 groups, with a slightly higher level of medication used in the control group (mean of 0.4 medications) in comparison with the treatment group (0.2 medications) at 1 year.
At 2-year follow-up, 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). 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.

In 2010, Fea reported a randomized double-blind clinical trial of cataract surgery with or without iStent implantation (2:1 ratio) in 36 patients. Inclusion criteria were a previous diagnosis of primary open-angle glaucoma with an IOP above 18 mm Hg at 3 separate visits, and on 1 or more hypotensive medications. The stent was implanted using the same small temporal clear corneal incision (approximately 3.0 mm) that had been used for phacoemulsification and intra-ocular lens placement and was guided into Schlemm’s canal by an applicator and ab interno gonioscopy. Follow-up visits with investigators who were masked to the treatment condition were conducted at 24 hours, 1 week, and 1, 2, 3, 6, 9, 12, and 15 months. Prescription of hypotensive medications was performed according to preset guidelines. Primary outcomes were IOP and reduction in medication use over 15 months and IOP after a 1-month washout of ocular hypotensive agents (16 months postoperatively). At baseline, IOP was an average of 17.9 mm Hg with 2.0 medications in the stent group and 17.3 mm Hg with 1.9 medications in the control group. The mean IOP at 15 months was 14.8 mm Hg, with 0.4 medications in the stent group and 15.7 mm Hg with 1.3 medications in the control group. Eight patients in the stent group (67% of 12) and 5 in the control group (24% of 21) did not require ocular hypotensive medication. The authors commented that patient compliance is an ongoing concern for most ophthalmologists; therefore, a main goal is to keep the patient as free as possible from medications postoperatively. After washout of medications, mean IOP was 16.6 in the stent group and 19.2 in the control group. Two stents were malpositioned, but one of these appeared to be functioning, and there were no reported adverse events related to stent implantation. This small study suggests that without hypotensive medication, the iStent lowers IOP by about 2.5 mm Hg beyond that generated by cataract surgery alone (approximately 25% decrease in the risk of glaucomatous progression).

Use of multiple iStents in combination with cataract surgery was reported in an open-label prospective series of 53 eyes (47 patients) in 2012. Of the 53 eyes, 28 had implantation of 2 stents and 25 had implantation of 3 stents, based on the need for greater IOP control, as determined by the operating surgeon. Best-corrected visual acuity (BCVA) improved or remained stable in 89% of eyes. IOP decreased from a mean of 18.0 m Hg to 14.3 mm Hg, and the number of hypotensive medications decreased from a mean of 2.7 to 0.7 at 1 year postoperatively. Target IOP was reached in 77% of eyes, while 59% of patients discontinued use of all medications in the study eye. At 1 year, the mean number of hypotensive medications decreased to 1.0 in the 2-stent group and 0.4 in the 3-stent group. Medication use had been stopped in 46% of eyes in the 2-stent group compared to 72% in the 3-stent group. Stent blockage occurred in the early postoperative period in 15% of eyes and was successfully treated with laser.

**Aqueous Shunts and Stents Not Approved by the FDA**
Case series have been identified on the EyePass and CyPass microstent. The CyPass has not received FDA approval/clearance at this time. The EyePass is no longer being developed.

**Clinical Input Received through Physician Specialty Societies and Academic Medical Centers**
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.
In response to requests, input was received from 1 physician specialty societies and 2 academic medical centers while this policy was under review in 2013. The input supported use of aqueous shunts in patients with moderate to severe glaucoma uncontrolled by medication. Input supported use of a single microstent in patients with mild to-moderate glaucoma undergoing cataract surgery to reduce side effects of medications and to avoid noncompliance.

**Ongoing Clinical Trials**

Searches for aqueous shunts and glaucoma at online site www.clinicaltrials.gov found a number of clinical trials in progress.

**Summary**

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. Therefore, use of FDA-approved shunts may be considered medically necessary as a method to reduce intraocular pressure in patients with moderate to severe glaucoma in whom medical treatments have failed to adequately control intraocular pressure. Aqueous shunts that are not FDA-approved/cleared, as well as all conditions for the approved devices aside from reducing IOP in patients with glaucoma in whom medical therapy has failed, are considered investigational.

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. A microstent has received FDA approval 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. Based on the documented reduction in the need for medications and the clinical input received on this policy, use of a single FDA-approved microstent may be considered medically necessary when implanted concurrently with cataract surgery in patients who are unable to tolerate medication.

**Practice Guidelines and Position Statements**

A 2012 position statement by the American Glaucoma Society (AGS) states that new technology whose intraocular pressure-lowering effect allows for a reduction in medications, or a reduction in the need for more advanced surgical care, or improves patient adherence to care, would provide advantages to glaucoma patients. (14) If effective and safe, the AGS believe that these benefits and the fact that these technologies will not have bleb-related complications would represent an “improvement in net health outcomes.” In addition, the AGS states that some categories of new surgical devices and techniques are utilized at the time of concomitant cataract surgery. Since cataract surgery alone has been shown to lower intraocular pressure, a control group of patients with similar entry criteria undergoing cataract surgery alone may be appropriate for these technologies.

The American Academy of Ophthalmology (AAO) published a 2008 technology assessment on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices. (2) The assessment indicated that in general, the IOP will settle at higher levels (approximately 18 mm Hg) with shunts than after standard trabeculectomy (14–16 mm Hg). Five-year success rates of 50% have been found for the two 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 indicated that although aqueous shunts have been generally 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 or to cyclodestructive therapy for many patients with refractory glaucoma.

The 2010 Preferred Practice Patterns on primary open-angle glaucoma from the AAO states that glaucoma surgical procedures currently under evaluation are canaloplasty with a tensioning suture
(Prolene [Ethicon Inc., Somerville, NJ]), ab interno trabeculotomy using the Trabectome (NeoMedix, Tustin, CA), trabecular meshwork bypass stent, and the Ex-PRESS mini glaucoma shunt (Alcon Laboratories, Inc., Ft. Worth, TX). (15) The AAO considers laser trabeculoplasty as initial therapy in selected patients or an alternative for patients who cannot or will not use medications reliably due to cost, memory problems, difficulty with instillation, or intolerance to the medication. The AAO considers nonpenetrating glaucoma surgery to be an alternative to trabeculectomy, although the precise role of nonpenetrating surgery in the surgical management of glaucoma remains to be determined. Nonpenetrating glaucoma surgery avoids a continuous passageway from the anterior chamber to the subconjunctival space, reducing the incidence of complications such as bleb-related problems and hypotony. The nonpenetrating procedures have a higher degree of surgical difficulty compared with trabeculectomy and require special instrumentation. The two main types of nonpenetrating glaucoma surgery are viscocanalostomy and nonpenetrating deep sclerectomy.

A 2011 technology assessment from the AAO (literature search up to October 2009) reviewed the evidence on novel, or emerging, glaucoma procedures. (16) Included in the technology assessment were devices and procedures that either had FDA clearance or were in phase III clinical trials in the U.S. at the time. These included the Ex-PRESS™ mini glaucoma shunt, the SOLX Gold Shunt, and the iStent, along with various surgical procedures. The technology assessment concluded that these techniques and devices are still in the initial state (≤5 years) of clinical experience and lacking widespread use. The clinical studies generally provided only level III evidence in support of the procedures. Based on the literature available at the time, it was not possible to conclude whether the novel procedures were superior, equal to, or inferior to surgery such as trabeculectomy or to one another.

The U.K.’s National Institute for Health and Clinical Excellence provided guidance on trabecular stent bypass microsurgery for open angle glaucoma in 2011. (17) The guidance states that current evidence on trabecular stent bypass microsurgery for open angle glaucoma raises no major safety concerns. There is evidence of efficacy in the short term, but this is based on small numbers of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

Medicare National Coverage
There is no National Coverage Determination for aqueous shunts and stents for glaucoma.

References
7. U.S. Food and Drug Administration. FDA Executive Summary, Glaukos, Inc. iStent Trabecular Micro-Bypass Stent. 2010. Available online at:


**Billing Coding/Physician Documentation Information**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>66183</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach (effective 2014)</td>
</tr>
<tr>
<td>0191T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork</td>
</tr>
<tr>
<td>0253T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the suprachoroidal space</td>
</tr>
<tr>
<td>C1783</td>
<td>Ocular implant, aqueous drainage assist device</td>
</tr>
</tbody>
</table>

Category III code, 0177T, was deleted effective January 1, 2011.

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/1/08</td>
<td>New policy; considered investigational.</td>
</tr>
<tr>
<td>9/1/09</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/10</td>
<td>Policy revised; FDA-cleared aqueous shunts may be medically necessary when medical therapy has failed; all other uses considered investigational. Title changed to “Aqueous Shunts and Devices for Glaucoma”</td>
</tr>
<tr>
<td>9/1/10</td>
<td>No policy statement changes.</td>
</tr>
</tbody>
</table>
1/1/11  Coding updated
9/1/11  Policy revised to indicate canaloaplasty medically necessary under specified conditions
9/1/12  Section on canaloaplasty moved to new policy - Viscocanaloaplasty and Canaloaplasty. “and devices” removed from policy title; policy statements on shunts unchanged
9/1/13  “stent” added to title and new investigational policy statement.
1/1/14  a single iStent considered medically necessary in patients with mild to moderate glaucoma when implanted in conjunction with cataract surgery. CPT coding updated – new code 66183 added.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.