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

**Related Policies**

- 9.03.26 Visocanalostomy and Canaloplasty

**Policy**

Insertion of an aqueous shunt 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.

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**.

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.

Use of a microstent for all other conditions is considered **investigational**.

**Policy Guidelines**

Shunts and 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.

There is a new category I CPT code:

- 66183: Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach

This replaces the category III code 0192T which was deleted 12/31/13:

- 0192T: Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach
Continued CPT codes for these procedures are as follows:

- **0191T**: Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; initial insertion
- **0253T**: Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the suprachoroidal space
- **0376T**: Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion (List separately in addition to code for primary procedure)

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Rationale**

**Background**

Surgical procedures for glaucoma aim to reduce 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 (see Policy 9.03.26).

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. Canaoplasty 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 (see Policy 9.03.26).

Aqueous shunts may also be placed in the anterior or posterior chamber to facilitate drainage of aqueous humor. Established shunts include the Ahmed™ (New World Medical), Baerveldt® (Advanced Medical Optics), Molteno® (IOP), ExPress® mini-shunt (Alco); and the SOLX® DeepLight® Gold Micro-Shunt (SOLX), which shunts aqueous humor between the anterior chamber and the suprachoroidal space. 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 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.

Because 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 stents such as the iStent, Cypass, and Hydrus Microstent 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 1 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>
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</thead>
<tbody>
<tr>
<td>AquaFlow™</td>
<td>Staar Surgical</td>
<td>Drainage device</td>
<td>PMA</td>
<td>2001</td>
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<tr>
<td>Trabectome™</td>
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<td>Electrocautery device</td>
<td>510(k)</td>
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<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</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt;1993</td>
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</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 FDA in 2001 for the maintenance of subscleral 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, 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 IOP 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

Note: 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.

FDA product codes: OGO, KYF

Literature Review

FDA-Approved/Cleared Aqueous Shunts

A 2006 Cochrane review evaluated 15 randomized or pseudo-randomized controlled trials (RCTs), with a total of 1153 participants, on the Ahmed, Baerveldt, Molteno, and Schocket shunts. 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. 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 2 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 overtime.

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 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.
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. 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 intention-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

A 2014 publication described a U.S. multicenter randomized trial of trabeculectomy compared with EX-PRESS® implantation in 120 patients (120 eyes). The groups were comparable at baseline, with a preoperative IOP of 25.1 mm Hg on a mean of 3.1 medications for the EX-PRESS® group, compared with 26.4 mm Hg on a mean of 3.1 medications in the trabeculectomy group. Throughout 2 years of follow-up after surgery, the average IOP and number of medications were similar in the 2 groups. At 2 years, mean IOP was 14.7 mm Hg on 0.9 medications in the EX-PRESS® group and 14.6 mm Hg on 0.7 medications in the trabeculectomy group. Surgical success was 90% and 87% at 1 year and 83% and 79% at 3 years in the EX-PRESS® and trabeculectomy groups, respectively. Visual acuity returned to near baseline levels at 1 month after EX-PRESS® implantation and 3 months after trabeculectomy (p=0.041), with a median time to return to baseline vision of 0.7 months and 2.2 months, respectively. Postoperative complications were higher after trabeculectomy (41%) than after EX-PRESS® implantation (18.6%).

In 2009, de Jong reported a randomized study of the EX-PRESS® mini shunt compared with standard trabeculectomy in 78 patients (80 eyes) with a diagnosis of open-angle glaucoma that could not be controlled with maximal-tolerated medical therapy. Five-year follow-up was reported in 2011. The 2 groups were similar after randomization, with the exception of difference in the mean age (62 years for the EX-PRESS® group, 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, 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. At 5 years, the success rates were not significantly different between the 2 groups. In the EX-PRESS® group, IOP remained stable from year 1 (12.0 mm Hg) to year 5 (11.5 mm Hg), while in the trabeculectomy group, IOP decreased from year 3 (13.5 mm Hg) to year 5 (11.3 mm Hg). There were more complications after trabeculectomy than after EX-PRESS® implantation.
iStent

Results from the iStent U.S. investigational device exemption (IDE) open-label 29-site multicenter randomized controlled trial were reported to FDA in 2010, with 1-year results published in 2011 and 2-year results published in 2012.8-10 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, 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 intention-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 end point. The proportion of patients achieving the secondary efficacy end point 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, 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 end point, IOP of 21 mm Hg or less without use of medication, was reached by 61% of patients in the treatment group compared with 50% of controls (p=0.036).10 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 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 with 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.11 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 (≈3.0 mm) that had been used for phacoemulsification and intraocular lens placement and was guided into Schlemm 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 1 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 (≈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 improved or remained stable in 89% of eyes. IOP decreased from a mean of 18.0 mm 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 with 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 FDA

iStent inject®

An industry-sponsored multicenter unblinded randomized trial compared implantation of 2 iStent inject® devices versus 2 ocular hypotensive agents. The 192 patients enrolled in this unmasked trial had an IOP that was not controlled by 1 hypotensive medication. At 12-month follow-up, the 2 groups were comparable for IOP reduction of at least 20%, IOP of 18 mm Hg or less, and mean decrease in IOP. A greater proportion of patients in the iStent inject® group achieved an IOP reduction of at least 50% (53.2% vs 35.7%). One patient in the iStent inject® group experienced elevated IOP (48 mm Hg) and 4 required ocular hypotensive medication. Longer term studies are in progress.

Other

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.

Ongoing and Unpublished Clinical Trials

Online searches for aqueous shunts and glaucoma at www.ClinicalTrials.gov found a number of clinical trials in progress.
Summary of Evidence

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 adverse effect profile and avoid some of the most problematic complications of trabeculectomy. Therefore, use of U.S. Food and Drug Administration (FDA)-approved shunts may be considered medically necessary as a method to reduce intraocular pressure (IOP) in patients with glaucoma in whom medical treatments have failed to adequately control IOP. 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 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.

Supplemental Information

Practice Guidelines and Position Statements

A 2012 position statement by the American Glaucoma Society (AGS) states that new technology whose IOP-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. If effective and safe, AGS believes 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, AGS states that some categories of new surgical devices and techniques are used at the time of concomitant cataract surgery. Because cataract surgery alone has been shown to lower IOP, a control group of patients with similar entry criteria undergoing cataract surgery alone may be appropriate for these technologies.

American Academy of Ophthalmology (AAO) published a 2008 technology assessment on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices. The assessment indicated that in general, the IOP will settle at higher levels (≈18 mm Hg) with shunts than after standard trabeculectomy (14-16 mm Hg). Five-year success rates of 50% have been found for the 2 procedures, indicating that aqueous shunts are comparable with trabeculectomy for IOP control and duration of benefit (based on level I evidence; well-designed RCTs). 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). 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 AAO states that glaucoma surgical procedures currently under evaluation are canaloplasty with a tensioning suture (Prolene [Ethicon Inc., Somerville, NJ]), ab interno trabeculectomy using...
the Trabectome (NeoMedix, Tustin, CA), trabecular meshwork bypass stent, and the Ex-PRESS mini glaucoma shunt (Alcon Laboratories Inc., Ft. Worth, TX). 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. 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 2 main types of nonpenetrating glaucoma surgery are viscocanalostomy and nonpenetrating deep sclerectomy.

A 2011 technology assessment from AAO (literature search up to October 2009) reviewed the evidence on novel, or emerging, glaucoma procedures. 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. 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.

**U.S. Preventive Services Task Force Recommendations**

Use of aqueous shunts and stents in the treatment of glaucoma is not a preventive service.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**References**


Documentation Required for Clinical Review

Please provide the following documentation:

- History and physical
- Consultation report including: previous treatment and response
  - HX of Intraocular pressure and medical therapy failure
  - HX of Diagnosed Glaucoma
  - HX of Diagnosed mild to moderate open-angle Glaucoma

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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<thead>
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<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>CPT®</td>
<td>0191T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; initial insertion</td>
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<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach</td>
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<td>HCPC</td>
<td>C1783</td>
<td>Ocular implant, aqueous drainage assist device</td>
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**ICD-9 Procedure** None

**ICD-10 Procedure** For dates of service on or after 10/01/2015 None

**ICD-9 Diagnosis** All Diagnoses

**ICD-10 Diagnosis** For dates of service on or after 10/01/2015 All Diagnoses

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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</table>

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation...
of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.