Title: Aqueous Shunts and Stents for Glaucoma

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: • With refractory open-angle glaucoma</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td></td>
<td>• Aqueous shunts</td>
<td>• Ocular medication</td>
<td>• Change in disease status</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Trabeculectomy</td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td>Individuals: • With mild-to-moderate open-angle glaucoma who are undergoing cataract surgery</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>• Medication use</td>
</tr>
<tr>
<td></td>
<td>• Aqueous microstents</td>
<td>• Cataract surgery alone</td>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With indications for glaucoma treatment other than cataract surgery or refractory open-angle glaucoma</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td></td>
<td>• Aqueous shunts or microstents</td>
<td>• Standard care</td>
<td>• Change in disease status</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>• Functional outcomes</td>
</tr>
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</tbody>
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DESCRIPTION
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 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.

OBJECTIVE
The objective of this policy is to examine whether aqueous shunts or microstents improve health outcomes in individuals with open-angle glaucoma.

BACKGROUND
Glaucoma
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.

Treatment
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 (eg, 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.

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. Canaloneplasty 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 iTTrack illuminated microcatheter (iScience Interventional) to access and dilate the entire length of Schlemm’s canal and to pass the suture loop through the canal.

Contains Public Information
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), and ExPress mini-shunt (Alcon), which shunt aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ by 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.

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 an ocular reservoir. 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 second-generation iStent inject; the third-generation iStent supra, which is designed for ab interno implantation into the suprachoroidal space; and the CyPass (Transcend Medical) suprachoroidal stent.

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, eg, below 15 mm Hg, and are not indicated for patients for whom very low IOP is desired (eg, 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

The regulatory status of the various aqueous shunts and microstents is summarized in Table 1. The first-generation Ahmed™ (New World Medical), Baerveldt® (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno® (Molteno Ophthalmic) aqueous shunts were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process between 1989 and 1993; modified Ahmed and Molteno devices were 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 was approved by FDA through the premarket approval (PMA) process for the maintenance of the sub scleral space following nonpenetrating deep sclerectomy. The EX-PRESS® Mini Glaucoma Shunt was cleared for marketing by FDA through the 510(k) process 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 2016, the Xen® Glaucoma Treatment System (Allergan), which consists of the XEN45 Gel Stent preloaded into the XEN Injector, was cleared for marketing by FDA through the 510(k) process as an aqueous shunt for management of refractory glaucoma. FDA determined that this device was substantially equivalent to existing devices, specifically the Ahmed™ Glaucoma Valve and the EX-PRESS® Glaucoma Filtration Device.

### Table 1. Regulatory Status of Aqueous Shunts and Stents

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Type</th>
<th>FDA Status</th>
<th>Date</th>
</tr>
</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>
<td>NeoMedix</td>
<td>Electrocautery device</td>
<td>510(k)</td>
<td>2006</td>
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<tr>
<td>Ahmed™</td>
<td>New World Medical</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt; 1993</td>
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<tr>
<td>Baerveldt®</td>
<td>Advanced Medical Optics</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt; 1993</td>
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<tr>
<td>Krupin</td>
<td>Eagle Vision</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt; 1993</td>
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<tr>
<td>Molteno®</td>
<td>Molteno Ophthalnic</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt; 1993</td>
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<tr>
<td>EX-PRESS®</td>
<td>Alcon</td>
<td>Mini-glaucoma shunt</td>
<td>510(k)</td>
<td>2003</td>
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<td>XEN® Gel Stent</td>
<td>AqueSys/Allergan</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>2016</td>
</tr>
<tr>
<td>iStent®</td>
<td>Glaukos</td>
<td>Microstent</td>
<td>PMA</td>
<td>2012</td>
</tr>
<tr>
<td>CyPass®</td>
<td>Transcend Medical</td>
<td>Suprachoroidal stent</td>
<td>PMA</td>
<td>2016</td>
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<td>Hydrus™</td>
<td>Ivantis</td>
<td>Microstent</td>
<td>Not approved</td>
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<td>SOLX® Gold</td>
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<td>Micro-Shunt</td>
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<td>iStent inject®</td>
<td>Glaukos</td>
<td>Suprachoroidal stent</td>
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<tr>
<td>iStent supra®</td>
<td>Glaukos</td>
<td>Suprachoroidal stent</td>
<td>Not approved</td>
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</tbody>
</table>

FDA: Food and Drug Administration; PMA: premarket approval

In 2012, the iStent® Trabecular Micro-Bypass Stent (Glaukos) was approved by FDA through the premarket approval process for use in conjunction with cataract surgery for the reduction of intraocular pressure (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

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.

In 2016, the CyPass® Micro-Stent (Alcon Laboratories) was approved by FDA through the PMA process for use in combination with cataract surgery in adults with mild to moderate primary open-angle glaucoma.

The SOLX® DeepLight® Gold Micro-Shunt, Hydrus™ Microstent, and XEN Gel Stent are currently in FDA-regulated trials. They have received regulatory approval in Europe, but are not FDA-approved/cleared for use in the United States at this time.

FDA product codes: OGO, KYF.
POLICY

A. 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.

B. Use of an aqueous shunt for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered experimental / investigational.

C. 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 requiring treatment.

D. Use of a microstent for all other conditions is considered experimental / 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.

RATIONALE

The policy was updated with a literature review using MEDLINE; most recently through January 25, 2017.

Aqueous Shunts

This section reviews the evidence on aqueous shunts with FDA approval. Evidence on non-approved devices is included in a later section.

Systematic Reviews

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. 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 technology assessment on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices, from the American Academy of Ophthalmology (AAO) was published in 2008. It indicated that the IOP will generally settle at higher levels (~18 mm Hg) with aqueous shunts than with standard trabeculectomy (14-16 mm Hg) or trabeculectomy with antifibrotic agents 5-fluorouracil or mitomycin C (8-10 mm Hg). In 1 study, mean IOPs with the Baerveldt shunt and adjunct medications were equivalent to trabeculectomy with mitomycin C (13 mm Hg). Five-year success rates for the 2 procedures were similar (50%). The assessment
concluded that, based on level 1 evidence, aqueous shunts were comparable to trabeculectomy for IOP control and duration of benefit. The risk of postoperative infection was less with aqueous shunts than with 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 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 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, reported in the 5-year follow-up from this study by Gedde et al.2,4 The study included 212 eyes of 212 patients (age range, 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, 13.6 mm Hg in the trabeculectomy group) nor number of glaucoma medications (1.4 in the tube group, 1.2 in the trabeculectomy group) differed significantly from intention-to-treat analysis. The cumulative probability of failure over the 5 years was lower in the tube group than in 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, 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.6 Five-year follow-up was
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-month 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 preoperatively (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 >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 did not differ significantly between 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.

Two additional small RCTs were published in 2015 by Gonzalez-Rodriguez et al (N=63) and Wagschal et al (N=64). Both studies corroborated the results of the earlier RCTs, reporting no differences between trabeculectomy and Ex-PRESS shunt groups on the outcomes of mean IOP, success rates, number of medications used, or complication rates.

A 2015 Cochrane review evaluated the efficacy of adjunctive procedures for trabeculectomy. The EX-PRESS Mini Shunt was included and 3 RCTs included that compared trabeculectomy alone with trabeculectomy plus EX-PRESS Mini Shunt. The 3 trials were rated as having high or unclear risk of bias using the Cochrane risk of bias tool. None of the RCTs reported a significant improvement for the EX-PRESS group. Pooled analysis, IOP was slightly lower in the combination group than in the trabeculectomy alone group (weighted mean difference, -1.58; 95% confidence interval [CI], -2.74 to -0.42). Pooled analysis also showed that subsequent cataract surgery was less frequent in the combination group than in trabeculectomy alone (relative risk, 0.34; 95% CI, 0.14 to 0.74). The combination group had a lower rate of some complications (eg, hyphema, needling).

Xen Glaucoma Treatment System
FDA documents include the clinical study evaluating the effectiveness and safety of the Xen Glaucoma Treatment System in 65 patients with refractory glaucoma. Effectiveness data were collected for 12 months and safety data for 18 months. The mean diurnal IOP was 25 mm Hg at baseline on a mean of 3.5 IOP-lowering medications. Approximately 76% of patients had a 12-month mean diurnal IOP reduction of 20% or more without increasing IOP-lowering medications. The mean IOP reduction at 12 months was -6.4 on a mean of 1.7 medications. The most common adverse events were glaucoma surgery, hypotony, IOP increase of 10 mm Hg or more, and needling procedures. FDA concluded that the Xen System was as safe and effective as predicate devices.

Comparative Effectiveness of Shunts
Five-year results of 2 RCTs comparing the Ahmed and Baerveldt shunts have been published. The Ahmed Baerveldt Comparison (ABC) study was a multicenter international RCT evaluating the comparative safety and efficacy of the Ahmed Glaucoma Valve FP7 and Baerveldt Glaucoma Implant BG 101-350 (1:1 ratio) in 276 adults with previous incisional eye surgery or refractory glaucoma. ABC was funded by National Eye Institute, Research to Prevent Blindness and New World Medical. Mean IOP was 14.7 mm Hg in the Ahmed group and 12.7 mm Hg in the Baerveldt group at 5 years (p=0.01). The number of glaucoma medications in use at 5 years, cumulative probability of failure at 5 years, and visual acuity at 5 years did not differ statistically significantly.
between the 2 groups. The number of patients with inadequately controlled IOP or reoperation for glaucoma was 46 (80%) with the Ahmed shunt and 25 (53%) with the Baerveldt shunt (p=0.003). The 5-year cumulative reoperation rate for glaucoma was 21% in the Ahmed group versus 9% in the Baerveldt group (p=0.01). Late complications were defined as those developing after 3 months. Late complications occurred in 56 (47%) patients in the Ahmed group and 67 (56%) patients in the Baerveldt group during 5 years of follow-up (p=0.08). The cumulative incidences of serious complications at 5 years were 16% and 25% in the Ahmed and Baerveldt groups, respectively (p=0.03).

The Ahmed Versus Baerveldt (AVB) study was an international, multicenter RCT enrolling 238 patients with uncontrolled glaucoma despite maximum tolerated medical therapy. AVB is funded by the Glaucoma Research Society of Canada. Patients were randomized in a 1:1 ratio to the Ahmed FP7 implant and the Baerveldt 350 implant. Failure of the shunt implant was the primary outcome or was defined as any one of the following: IOP of less than 5 mm Hg or more than 18 mm Hg or less than a 20% reduction from baseline for 2 consecutive visits after 3 months; de novo glaucoma surgery required; removal of the implant; severe vision loss related to the surgery; or progression to no light perception for any reason. The cumulative failure rate was 53% in the Ahmed group and 40% in the Baerveldt group at 5 years (p=0.04). In the Ahmed and Baerveldt shunts, the mean percent reduction in IOP was 47% and 57% (p=0.001) and mean percent reduction in medication use was 44% and 61% (p=0.03), all respectively. Hypotony was reported in 5 (4%) patients in the Baerveldt group but not in the Ahmed group (p=0.02).

In summary, the comparative effectiveness of the Ahmed vs Baerveldt has been addressed in two trials, the Ahmed Versus Baerveldt (AVB) trial and the Ahmed Baerveldt Comparison (ABC) trial. The trials had similar results. Both of the devices lowered IOP. There was a small difference in reduction in IOP favoring Baerveldt (1.2 – 1.3 mmHg lower) and patients with Baerveldt required slightly fewer medications. The Baerveldt also had a higher rate of serious hypotony-related complications.

**Section Summary: Aqueous Shunts**
Evidence from RCTs exists for each of the FDA-approved aqueous shunts. Trial results are consistent that the magnitude of reduction in IOP following aqueous shunt placement is similar, or slightly inferior, to that following trabeculectomy. Shunts have fewer complications than trabeculectomy, and reduce the need for future operations. Overall, the risk-benefit ratio for shunts does not appear to differ substantially from that for trabeculectomy. The comparative effectiveness trials of the Ahmed and Baerveldt shunts showed similar overall improvement in health outcome with slightly larger reduction in IOP with Baerveldt but also higher rates of complications.

**Aqueous Microstents with Cataract Surgery**
Aqueous microstents have been used in conjunction with cataract surgery. The majority of evidence addresses a single stent as an adjunct to cataract surgery. Both the iStent and CyPass have RCTs comparing a single stent with cataract surgery to cataract surgery alone. There have also been studies of multiple implants which have all been performed with iStent devices.

**iStent**
Results from the iStent U.S. investigational device exemption (IDE) open-label 29-site multicenter RCT were reported to FDA in 2010, with 1-year results published in 2011 and 2-year results...
published in 2012. The objectives of the trial were 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 unmedicated IOP was 22 mm Hg or higher and 36 mm Hg or lower. Mean number of medications at baseline was 1.5. Medicated IOP at baseline was 18.7 mm Hg in the stent group and 18.04 in the control group. After washout, 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 and 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 (eg, 15% vs 35% at 12 months). 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) than in the treatment group (0.2 medications) at 1 year.

At 2-year follow-up, 199 of the original 239 patients (83%) remained in the study. The primary end point (IOP ≤ 21 mm Hg without use of medication) was reached by 61% of patients in the treatment group compared with 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 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. Study results indicated 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, it is not possible to conclude with certainty that health outcomes are improved at longer periods of follow-up.

In 2010, Fea et al reported a randomized, double-blind, trial of 36 cataract surgery patients who did or did not receive an iStent implantation (2:1 ratio). Inclusion criteria were a previous diagnosis of primary open-angle glaucoma with an IOP above 18 mm Hg at 3 separate visits and taking 1 or more hypotensive medications. Investigators were masked to the treatment condition and conducted follow-up 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 averaged 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. 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 (67%) of 12 patients in the stent...
group and 5 (24%) of 21 in the control group did not require ocular hypotensive medication. Because treatment compliance is an ongoing concern for most ophthalmologists, trialists sought to keep patients as medication-free as possible postoperatively. After washout of medications, mean IOP was 16.6 in the stent group and 19.2 in the control group. No adverse events related to stent implantation were reported. Four-year follow-up from this study was published in 2015.²⁹ Twenty-four of 36 patients were available at 4 years. Differences between treatment groups remained nonsignificant (mean IOP, 15.9 mm Hg in the stent group vs 17 mm Hg in the control group).

**CyPass**

FDA evaluated the clinical performance of the CyPass Micro-Stent system based on the pivotal COMPASS trial (NCT01085357). COMPASS was a multicenter RCT comparing the safety and efficacy of CyPass Micro-Stent plus cataract surgery with cataract surgery alone for treating mild-to-moderate primary open-angle glaucoma in patients undergoing cataract surgery. Vold et al published 2-year results in 2016.²⁰ A total of 505 patients (1 eye per patient) were assigned in a 1:3 ratio to phacoemulsification only (control) or to supraciliary microstenting with phacoemulsification (microstent). Baseline mean IOPs and number of IOP-lowering medications were similar in the 2 treatment groups (~24.4 mm Hg and 1.4 medications, respectively). In the intention-to-treat analysis, 58% of controls versus 73% of microstent patients achieved 20% or greater unmedicated IOP lowering at 24 months compared to baseline (p=0.002). The difference in mean IOP reduction at 24 months was 1.8 mm Hg (95% CI, 1.0 to 2.6 mm Hg; p<0.001), favoring the microstent group. In the control group, 59% were medication free at 24 months versus 85% in the microstent group. Mean medication use decreased to 0.6 drugs at 24 months in the control group and to 0.2 drugs in the microstent group (p<0.001). There were no vision-threatening microstent-related adverse events. Thirty-nine percent of microstent patients versus 36% of control patients experienced ocular adverse events in the 24-month period. The following ocular adverse events were reported: hypotony (3% microstent vs 0% control), maculopathy (1.3% microstent vs 0.8% control), corneal edema (4% microstent vs 2% control), cyclodialysis cleft greater than 2 mm in circumference (2% microstent vs 0% control), iritis (9% microstent vs 4% control), and subconjunctival hemorrhage (2% microstent vs 1% control). Best-corrected visual acuity was 20/40 or better in more than 98% of all patients. Eleven patients in the microstent group versus 1 patient in the control group died during the 24-month period; however, the deaths were classified as unrelated to the intervention.

**Multiple Stents**

Fernández-Barrientos et al (2010) compared 2 iStent devices plus cataract surgery to cataract surgery alone in 33 patients with open-angle glaucoma or ocular hypertension who were undergoing cataract surgery.²¹ The study was performed at a single center in Spain. Eligible eyes had a medicated IOP between 17 and 31 mm Hg (exclusive) and between 21 and 35 mm Hg after medication washout. Mean IOP reduction was greater in the iStent plus surgery group (6.6 mm Hg) than in the surgery alone group (3.9 mm Hg; p=0.002). The mean number of IOP-lowering medications was also significantly lower in the iStent group (0.0 vs 0.7, respectively; p=0.007).

Use of multiple iStent devices with cataract surgery was reported in an open-label, prospective series of 53 eyes (47 patients) in 2012.²² Twenty-eight of 53 eyes 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 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 all medications for 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 ceased in 46% of eyes in the 2-stent group and in 72% in the 3-stent group. Stent blockage occurred in the early postoperative period in 15% of eyes and was successfully treated with laser. At least 1 other prospective case series (2015) has been published. It enrolled 39 patients with open-angle glaucoma and IOP between 18 and 30 mm Hg. Each patient received 2 microstents and medications as needed, and was followed for 3 years. At study completion, mean reduction in IOP was 9.1 mm Hg (95% CI, 8.0 to 10.1 mm Hg). There was 1 postoperative complication (hyphema), which resolved without further intervention.

Section Summary: Aqueous Microstents With Cataract Surgery
Two identified RCTs compared cataract surgery plus a single iStent to cataract surgery alone. Results of these trials were mixed, with 1 showing a significant benefit in the stent group and the other reporting no statistically significant benefit but similar effect size. A trial comparing 2 iStents with cataract surgery versus cataract surgery alone reported similar results. One RCT compared CyPass plus cataract surgery to cataract surgery alone. Reduction in IOP was greater and fewer IOP-lowering medications were needed in the CyPass group at 2 years. A low rate of complications (eg, stent malposition, hyphema) was reported in all trials.

Aqueous Shunts and Stents Not Approved by FDA
iStent inject
A 2014 industry-sponsored, multicenter, unblinded, randomized trial compared implantation of 2 iStent inject devices to 2 ocular hypotensive agents. The 192 patients enrolled in this unmasked trial had an IOP 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%, respectively). 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.

Hydrus Microstent
In 2015, Pfeiffer et al reported a single-masked, randomized trial with 100 patients (100 eyes) that evaluated the effectiveness of the Hydrus Microstent plus cataract surgery to cataract surgery alone. At the 24-month follow-up, the proportion of patients with a 20% reduction in IOP was significantly higher with the Hydrus Microstent (80% vs 46%, p<0.001) and the mean IOP after medication washout was lower (16.9 mm Hg vs 19.2 mm Hg, p=0.009) compared with cataract surgery alone, respectively. The microstent group used significantly fewer medications (0.5 vs 1.0, p=0.019) and had a higher proportion of patients taking no hypotensive medications at the time of cataract surgery (73% vs 38%, p=0.001).

Other Indications for Glaucoma Treatment
Glaucoma shunts and microstent have also been studied in patients with other indications for glaucoma treatment. The following paragraphs describe the comparison of implantation of single versus multiple stents or multiple stents versus medical management.

One RCT comparing the efficacy of 1 iStent to multiple iStent devices was published in 2015. This study, from a single institution in Armenia, randomized 119 patients with open-angle
glaucoma and an IOP between 22 and 38 mm Hg (off medications) to 1 stent (n=38), 2 stents (n=41), or 3 stents (n=40). Randomization was performed using a pseudorandom number generator. The main outcome measure was IOP at 12 months. The primary end point was the percentage of patients with a 20% or more reduction in IOP off medications. This end point was reached by 89.2% (95% CI, 74.6% to 97.0%) of the 1-stent group, by 90.2% (95% CI, 76.9% to 97.3%) of the 2-stent group, and by 92.1% (95% CI, 78.6% to 98.3%) of the 3-stent group. The secondary end point (percentage of patients achieving an IOP ≤15 mm Hg off medication) was reached by 64.9% (95% CI, 47.5% to 79.8%) of the 1-stent group, by 85.4% (95% CI, 70.8% to 94.4%) of the 2-stent group, and by 92.1% (95% CI, 78.6% to 98.3%) of the 3-stent group. No between-group statistical comparisons were reported.

Vold et al (2016) reported results of an RCT comparing 2 standalone iStent implants to topical travoprost (1:1 ratio) in 101 phakic eyes with IOP between 21 and 40 mm Hg inclusive and newly diagnosed primary open-angle glaucoma, pseudo-exfoliative glaucoma, or ocular hypertension that had not undergone any prior treatment. The patients were not undergoing cataract surgery. The study was unmasked and methods for allocation concealment and calculation of power were not described. One hundred patients (54 iStent; 47 travoprost) completed 24 months of follow-up and 73 completed 36 months of follow-up. The trial was performed at a single center in Armenia. Statistical analyses were not provided. Baseline mean IOP was 25 mm Hg in both groups. Mean IOP at 3 years was 15 mm Hg in both groups. Medication (or second medication) was added in 6 eyes in the iStent group and 11 eyes in the travoprost group. Progression of cataract was reported in 11 eyes in the iStent group versus 8 eyes in the travoprost group, with cataract surgery being performed in 5 eyes in the iStent group and 1 eye in the travoprost group. The results suggest that 2 iStents might reduce the number of medications required to maintain target IOP compared to travoprost but also hasten time to cataract surgery. However, the study methods were poorly reported and statistical analyses were not reported. The study was funded by the iStent manufacturer.

Section Summary: Other Indications for Glaucoma Treatment
One RCT compared a single iStent to 2 or 3 stents; it reported similar rates of the primary outcome among groups (percentage of patients with ≥20% reduction in IOP). There were some numeric group differences in secondary outcomes, but statistical testing was not reported. One RCT compared 2 iStents to travoprost. Two iStents might reduce the number of medications required to maintain target IOP compared to travoprost but could also hasten time to cataract surgery but the RCT was not well reported.

SUMMARY OF EVIDENCE
For individuals who have refractory open-angle glaucoma who receive aqueous shunts, the evidence includes randomized controlled trials (RCTs) and single-arm studies. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. RCTs assessing U.S. Food and Drug Administration (FDA)–approved shunts have shown that the use of large externally placed shunts reduces intraocular pressure (IOP) to slightly less than standard filtering surgery ( trabeculectomy). Reported shunt success rates are as good as trabeculectomy in the long term. FDA-approved shunts have different adverse event profiles and avoid some of the most problematic complications of trabeculectomy. Two trials have compared the Ahmed and Baerveldt shunts. Both found that eyes treated with the Baerveldt shunt had slightly lower average IOP at 5 years than eyes treated with the Ahmed but the Baerveldt also had a higher rate of serious hypotony-related complications. The evidence is
sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have mild-to-moderate open-angle glaucoma who receive aqueous microstents during cataract surgery, the evidence includes RCTs and safety data from case series. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. Two microstents have received FDA approval for use in conjunction with cataract surgery for reduction of IOP in adults with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication. RCTs have been conducted in patients with cataracts and less advanced glaucoma, where IOP is at least partially controlled with medication. Trial results have shown that IOP may be lowered below baseline with decreased need for medication through the first 2 years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with indications for glaucoma treatment other than cataract surgery or refractory open-angle glaucoma who are treated with aqueous shunts or microstents, the evidence includes RCTs. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. One RCT compared a single microstent to multiple microstents. This study reported no difference on the primary outcome (percentage of patients with ≥20% reduction in IOP); secondary outcomes favored the multiple microstent group. One RCT compared 2 iStents to travoprost. The study did not report statistical comparisons. The evidence is insufficient to determine the effects of the technology on health outcomes.

**CLINICAL INPUT FROM 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 avoid noncompliance.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

American Glaucoma Society

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. 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.
Aqueous Shunts and Stents for Glaucoma

American Academy of Ophthalmology
The 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 (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.

AAO’s 2015 preferred practice patterns on primary open-angle glaucoma indicated that AAO considered laser trabeculoplasty as initial therapy in select 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 stated that aqueous shunts have traditionally been used to manage refractory glaucoma when trabeculectomy has failed to control IOP or is unlikely to succeed but these devices are being increasingly used in other indications for the surgical management of glaucoma. AAO also stated that micro-invasive glaucoma surgeries (MIGS) that are frequently combined with phacoemulsification have limited long-term data but seem to result in modest IOP reduction with postoperative pressures in the mid to upper teens. Although they are less effective in lowering IOP than trabeculectomy and aqueous shunt surgery, MIGS may have a more favorable safety profile in the short term.

A 2011 technology assessment from the 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.

National Institute for Health and Care Excellence
The U.K.’s National Institute for Health and Clinical Excellence provided guidance on trabecular stent bypass microsurgery for open angle glaucoma in 2011, which was updated in 2017. The updated guidance stated that "Current evidence on trabecular stent bypass microsurgery for open-angle glaucoma raises no major safety concerns. Evidence of efficacy is adequate in quality and quantity." Therefore, NICE concluded that the procedure should only be used "provided standard arrangements are in place for clinical governance, consent and audit."

European Glaucoma Society
The European Glaucoma Society Terminology and Guidelines for Glaucoma (2014) provided evidence-based guidelines on treatment of primary open-angle glaucoma. The document indicated that, although there are many newer alternatives to trabeculectomy for glaucoma...
treatment, there were no well-controlled, comparative studies supporting superiority among the minimally invasive techniques (including shunts and microstents) or versus trabeculectomy. The guidelines stated that: “These techniques are currently performed in selected glaucoma patients with early to moderate disease and preferably in combination with cataract surgery”; the evidence rating for this statement is II (strength of recommendation: weak), D (quality of evidence: very low).

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

Not applicable.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**

Some currently unpublished trials that might influence this policy are listed in Table 2.

**Table 2. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT02006693</td>
<td>Post Market Multicentric Evaluation of the AqueSys XEN Implant in Moderate Primary Open Angle Glaucoma Subjects</td>
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<td>NCT01444040</td>
<td>A Prospective, Randomized Evaluation of Subjects With Open-angle Glaucoma, Pseudoexfoliative Glaucoma, or Ocular Hypertension Naive to Medical and Surgical Therapy, Treated With Two Trabecular Micro-bypass Stents (iStent Inject) or Travoprost Ophthalmic Solution 0.004%</td>
<td>200</td>
<td>Apr 2017</td>
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<tr>
<td>NCT01456390</td>
<td>A Prospective Evaluation of Open-Angle Glaucoma Subjects With One Prior Trabeculectomy Treated Concurrently With One Suprachoroidal Stent and Two Trabecular Micro-bypass Stents and a Postoperative Prostaglandin</td>
<td>80</td>
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<tr>
<td>NCT02023242</td>
<td>A Prospective, Multicenter, Randomized Comparison of the Hydrus to the iStent® for Lowering Intraocular Pressure in Primary Open Angle Glaucoma</td>
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<td>Jan 2018</td>
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<tr>
<td>NCT01539239</td>
<td>The Safety and Effectiveness of the Hydrus Aqueous Implant for Lowering Intraocular Pressure in Glaucoma Patients Undergoing Cataract Surgery, A Prospective, Multicenter, Randomized, Controlled Clinical Trial</td>
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<td>Jan 2018</td>
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<tr>
<td>NCT02700984</td>
<td>An Observational Multicenter Clinical Study to Assess the Long-Term Safety of the CyPass Micro-Stent in Patients With Primary Open Angle Glaucoma Who Have Completed Participation in the COMPASS Trial</td>
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<td>NCT01461278</td>
<td>A Prospective, Randomized, Single-Masked, Controlled, Parallel Groups, Multicenter Clinical Investigation of the Glaukos® Suprachoroidal Stent Model G3 In Conjunction With Cataract Surgery</td>
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<tr>
<td>NCT02964676</td>
<td>Clinical Efficacy and Safety of Minimally Invasive Glaucoma Surgery on Chinese Primary Angle Closure Glaucoma</td>
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<td>NCT01841450</td>
<td>A Prospective, Randomized, Controlled, Parallel Groups, Multicenter Post-Approval Study Of The Glaukos® iStent® Trabecular Micro-Bypass Stent System In Conjunction With Cataract Surgery</td>
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<td>NCT01282346</td>
<td>Clinical Evaluation of the SOLX Gold Shunt for the Reduction of Intraocular Pressure (IOP) in Refractory Glaucoma</td>
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<td>Dec 2015 (completed)</td>
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Aqueous Shunts and Stents for Glaucoma

<table>
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<td>NCT02024464a</td>
<td>A Prospective, Multicenter, Randomized Comparison of the Hydrus Microstent to the iStent for Lowering Intraocular Pressure in Glaucoma Patients Undergoing Cataract Surgery</td>
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<td>Jan 2017</td>
</tr>
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NCT: national clinical trial.

*a* Denotes industry-sponsored or cosponsored trial.

**CODING**

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

**CPT/HCPCS**

- 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
- 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)
- 0449T Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
- 0450T Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)
- 0474T Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space
- C1783 Ocular implant, aqueous drainage assist device

**ICD-9 Diagnoses**

- 365.00 Unspecified preglaucoma
- 365.01 Borderline glaucoma, open angle with borderline findings, low risk
- 365.02 Borderline glaucoma with anatomical narrow angle
- 365.03 Borderline glaucoma with steroid responders
- 365.04 Borderline glaucoma with ocular hypertension
- 365.05 Open angle with borderline findings, high risk
- 365.06 Primary angle closure without glaucoma damage
- 365.1 Open-angle glaucoma
- 365.10 Unspecified open-angle glaucoma


*Contains Public Information*
365.11  Primary open-angle glaucoma
365.12  Low tension open-angle glaucoma
365.13  Pigmentary open-angle glaucoma
365.14  Open-angle glaucoma of childhood
365.15  Residual stage of open angle glaucoma
365.2   Primary angle-closure glaucoma
365.20  Unspecified primary angle-closure glaucoma
365.21  Intermittent angle-closure glaucoma
365.22  Acute angle-closure glaucoma
365.23  Chronic angle-closure glaucoma
365.24  Residual stage of angle-closure glaucoma
365.3   Corticosteroid-induced glaucoma
365.31  Corticosteroid-induced glaucoma, glaucomatous stage
365.32  Corticosteroid-induced glaucoma, residual stage
365.4   Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes
365.41  Glaucoma associated with chamber angle anomalies
365.42  Glaucoma associated with anomalies of iris
365.43  Glaucoma associated with other anterior segment anomalies
365.44  Glaucoma associated with systemic syndromes
365.5   Glaucoma associated with disorders of the lens
365.51  Phacolytic glaucoma
365.52  Pseudoexfoliation glaucoma
365.59  Glaucoma associated with other lens disorders
365.6   Glaucoma associated with other ocular disorders
365.60  Glaucoma associated with unspecified ocular disorder
365.61  Glaucoma associated with pupillary block
365.62  Glaucoma associated with ocular inflammations
365.63  Glaucoma associated with vascular disorders of eye
365.64  Glaucoma associated with tumors or cysts
365.65  Glaucoma associated with ocular trauma
365.7   Glaucoma stage
365.70  Glaucoma stage, unspecified
365.71  Mild stage glaucoma
365.72  Moderate stage glaucoma
365.73  Severe stage glaucoma
365.74  Indeterminate stage glaucoma
365.8   Other specified forms of glaucoma
365.81  Hypersecretion glaucoma
365.82  Glaucoma with increased episcleral venous pressure
365.83  Aqueous misdirection
365.89  Other specified glaucoma
366.00  Unspecified nonsenile cataract
366.01  Anterior subcapsular polar cataract, nonsenile
366.02  Posterior subcapsular polar cataract, nonsenile
366.03  Cortical, lamellar, or zonular cataract, nonsenile
366.04  Nuclear cataract, nonsenile
366.09  Other and combined forms of nonsenile cataract
366.10  Unspecified senile cataract
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<td>366.50</td>
<td>Unspecified after-cataract</td>
</tr>
<tr>
<td>366.51</td>
<td>Soemmering's ring</td>
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<tr>
<td>366.52</td>
<td>Other after-cataract, not obscuring vision</td>
</tr>
<tr>
<td>366.53</td>
<td>After-cataract, obscuring vision</td>
</tr>
<tr>
<td>366.8</td>
<td>Other cataract</td>
</tr>
<tr>
<td>366.9</td>
<td>Unspecified cataract</td>
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</table>

**ICD-10 Diagnoses**

- E08.36  Diabetes mellitus due to underlying conditions 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 Cortical age-related cataract, right eye
- H25.012 Cortical age-related cataract, left eye
- H25.013 Cortical age-related cataract, bilateral
- H25.031 Anterior subcapsular polar age-related cataract, right eye
- H25.032 Anterior subcapsular polar age-related cataract, left eye
- H25.033 Anterior subcapsular polar age-related cataract, bilateral
- H25.041 Posterior subcapsular polar age-related cataract, right eye
- H25.042 Posterior subcapsular polar age-related cataract, left eye
- H25.043 Posterior subcapsular polar age-related cataract, bilateral
- H25.091 Other age-related incipient cataract, right eye
- H25.092 Other age-related incipient cataract, left eye
H25.093  Other age-related incipient cataract, bilateral
H25.11   Age-related nuclear cataract, right eye
H25.12   Age-related nuclear cataract, left eye
H25.13   Age-related nuclear cataract, bilateral
H25.21   Age-related cataract, morgagnian type, right eye
H25.22   Age-related cataract, morgagnian type, left eye
H25.23   Age-related cataract, morgagnian type, bilateral
H25.811  Combined forms of age-related cataract, right eye
H25.812  Combined forms of age-related cataract, left eye
H25.813  Combined forms of age-related cataract, bilateral
H25.89   Other age-related cataract
H25.9    Unspecified age-related cataract
H26.001  Unspecified infantile and juvenile cataract, right eye
H26.002  Unspecified infantile and juvenile cataract, left eye
H26.003  Unspecified infantile and juvenile cataract, bilateral
H26.011  Infantile and juvenile cortical, lamellar, or zonular cataract, right eye
H26.012  Infantile and juvenile cortical, lamellar, or zonular cataract, left eye
H26.013  Infantile and juvenile cortical, lamellar, or zonular cataract, bilateral
H26.031  Infantile and juvenile nuclear cataract, right eye
H26.032  Infantile and juvenile nuclear cataract, left eye
H26.033  Infantile and juvenile nuclear cataract, bilateral
H26.041  Anterior subcapsular polar infantile and juvenile cataract, right eye
H26.042  Anterior subcapsular polar infantile and juvenile cataract, left eye
H26.043  Anterior subcapsular polar infantile and juvenile cataract, bilateral
H26.051  Posterior subcapsular polar infantile and juvenile cataract, right eye
H26.052  Posterior subcapsular polar infantile and juvenile cataract, left eye
H26.053  Posterior subcapsular polar infantile and juvenile cataract, bilateral
H26.061  Combined forms of infantile and juvenile cataract, right eye
H26.062  Combined forms of infantile and juvenile cataract, left eye
H26.063  Combined forms of infantile and juvenile cataract, bilateral
H26.101  Unspecified traumatic cataract, right eye
H26.102  Unspecified traumatic cataract, left eye
H26.103  Unspecified traumatic cataract, bilateral
H26.111  Localized traumatic opacities, right eye
H26.112  Localized traumatic opacities, left eye
H26.113  Localized traumatic opacities, bilateral
H26.121  Partially resolved traumatic cataract, right eye
H26.122  Partially resolved traumatic cataract, left eye
H26.123  Partially resolved traumatic cataract, bilateral
H26.131  Total traumatic cataract, right eye
H26.132  Total traumatic cataract, left eye
H26.133  Total traumatic cataract, bilateral
H26.211  Cataract with neovascularization, right eye
H26.212  Cataract with neovascularization, left eye
H26.213  Cataract with neovascularization, bilateral
H26.221  Cataract secondary to ocular disorders (degenerative) (inflammatory), right eye
H26.222  Cataract secondary to ocular disorders (degenerative) (inflammatory), left eye
H26.223  Cataract secondary to ocular disorders (degenerative) (inflammatory), bilateral
H26.231  Glaucomatous flecks (subcapsular), right eye
H26.232 Glaucomatous flecks (subcapsular), left eye
H26.233 Glaucomatous flecks (subcapsular), bilateral
H26.31 Drug-induced cataract, right eye
H26.32 Drug-induced cataract, left eye
H26.33 Drug-induced cataract, bilateral
H26.40 Unspecified secondary cataract
H26.411 Soemmering's ring, right eye
H26.412 Soemmering's ring, left eye
H26.413 Soemmering's ring, bilateral
H26.491 Other secondary cataract, right eye
H26.492 Other secondary cataract, left eye
H26.493 Other secondary cataract, bilateral
H26.8 Other specified cataract
H26.9 Unspecified cataract
H40.001 Preglaucoma, unspecified, right eye
H40.002 Preglaucoma, unspecified, left eye
H40.003 Preglaucoma, unspecified, bilateral
H40.011 Open angle with borderline findings, low risk, right eye
H40.012 Open angle with borderline findings, low risk, left eye
H40.013 Open angle with borderline findings, low risk, bilateral
H40.021 Open angle with borderline findings, high risk, right eye
H40.022 Open angle with borderline findings, high risk, left eye
H40.023 Open angle with borderline findings, high risk, bilateral
H40.031 Anatomical narrow angle, right eye
H40.032 Anatomical narrow angle, left eye
H40.033 Anatomical narrow angle, bilateral
H40.041 Steroid responder, right eye
H40.042 Steroid responder, left eye
H40.043 Steroid responder, bilateral
H40.051 Ocular hypertension, right eye
H40.052 Ocular hypertension, left eye
H40.053 Ocular hypertension, bilateral
H40.061 Primary angle closure without glaucoma damage, right eye
H40.062 Primary angle closure without glaucoma damage, left eye
H40.063 Primary angle closure without glaucoma damage, bilateral
H40.10X0 Unspecified open-angle glaucoma, stage unspecified
H40.10X1 Unspecified open-angle glaucoma, mild stage
H40.10X2 Unspecified open-angle glaucoma, moderate stage
H40.10X3 Unspecified open-angle glaucoma, severe stage
H40.10X4 Unspecified open-angle glaucoma, indeterminate stage
H40.1110 Primary open-angle glaucoma, right eye, stage unspecified
H40.1111 Primary open-angle glaucoma, right eye, mild stage
H40.1112 Primary open-angle glaucoma, right eye, moderate stage
H40.1113 Primary open-angle glaucoma, right eye, severe stage
H40.1114 Primary open-angle glaucoma, right eye, indeterminate stage
H40.1120 Primary open-angle glaucoma, left eye, stage unspecified
H40.1121 Primary open-angle glaucoma, left eye, mild stage
H40.1122 Primary open-angle glaucoma, left eye, moderate stage
H40.1123 Primary open-angle glaucoma, left eye, severe stage
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<td>Low-tension glaucoma, right eye, stage unspecified</td>
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<td>Low-tension glaucoma, right eye, mild stage</td>
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<td>Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage</td>
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H40.1433 Capsular glaucoma with pseudoexfoliation of lens, bilateral, severe stage
H40.1434 Capsular glaucoma with pseudoexfoliation of lens, bilateral, indeterminate stage
H40.151 Residual stage of open-angle glaucoma, right eye
H40.152 Residual stage of open-angle glaucoma, left eye
H40.153 Residual stage of open-angle glaucoma, bilateral
H40.20X Unspecified primary angle-closure glaucoma, stage unspecified
H40.20X1 Unspecified primary angle-closure glaucoma, mild stage
H40.20X2 Unspecified primary angle-closure glaucoma, moderate stage
H40.20X3 Unspecified primary angle-closure glaucoma, severe stage
H40.20X4 Unspecified primary angle-closure glaucoma, indeterminate stage
H40.211 Acute angle-closure glaucoma, right eye
H40.212 Acute angle-closure glaucoma, left eye
H40.213 Acute angle-closure glaucoma, bilateral
H40.2210 Chronic angle-closure glaucoma, right eye, stage unspecified
H40.2211 Chronic angle-closure glaucoma, right eye, mild stage
H40.2212 Chronic angle-closure glaucoma, right eye, moderate stage
H40.2213 Chronic angle-closure glaucoma, right eye, severe stage
H40.2214 Chronic angle-closure glaucoma, right eye, indeterminate stage
H40.2220 Chronic angle-closure glaucoma, left eye, stage unspecified
H40.2221 Chronic angle-closure glaucoma, left eye, mild stage
H40.2222 Chronic angle-closure glaucoma, left eye, moderate stage
H40.2223 Chronic angle-closure glaucoma, left eye, severe stage
H40.2224 Chronic angle-closure glaucoma, left eye, indeterminate stage
H40.2230 Chronic angle-closure glaucoma, bilateral, stage unspecified
H40.2231 Chronic angle-closure glaucoma, bilateral, mild stage
H40.2232 Chronic angle-closure glaucoma, bilateral, moderate stage
H40.2233 Chronic angle-closure glaucoma, bilateral, severe stage
H40.2234 Chronic angle-closure glaucoma, bilateral, indeterminate stage
H40.231 Intermittent angle-closure glaucoma, right eye
H40.232 Intermittent angle-closure glaucoma, left eye
H40.233 Intermittent angle-closure glaucoma, bilateral
H40.241 Residual stage of angle-closure glaucoma, right eye
H40.242 Residual stage of angle-closure glaucoma, left eye
H40.243 Residual stage of angle-closure glaucoma, bilateral
H40.31X0 Glaucoma secondary to eye trauma, right eye, stage unspecified
H40.31X1 Glaucoma secondary to eye trauma, right eye, mild stage
H40.31X2 Glaucoma secondary to eye trauma, right eye, moderate stage
H40.31X3 Glaucoma secondary to eye trauma, right eye, severe stage
H40.31X4 Glaucoma secondary to eye trauma, right eye, indeterminate stage
H40.32X0 Glaucoma secondary to eye trauma, left eye, stage unspecified
H40.32X1 Glaucoma secondary to eye trauma, left eye, mild stage
H40.32X2 Glaucoma secondary to eye trauma, left eye, moderate stage
H40.32X3 Glaucoma secondary to eye trauma, left eye, severe stage
H40.32X4 Glaucoma secondary to eye trauma, left eye, indeterminate stage
H40.33X0 Glaucoma secondary to eye trauma, bilateral, stage unspecified
H40.33X1 Glaucoma secondary to eye trauma, bilateral, mild stage
H40.33X2 Glaucoma secondary to eye trauma, bilateral, moderate stage
H40.33X3 Glaucoma secondary to eye trauma, bilateral, severe stage
H40.33X4 Glaucoma secondary to eye trauma, bilateral, indeterminate stage
H40.41X0  Glaucoma secondary to eye inflammation, right eye, stage unspecified  
H40.41X1  Glaucoma secondary to eye inflammation, right eye, mild stage  
H40.41X2  Glaucoma secondary to eye inflammation, right eye, moderate stage  
H40.41X3  Glaucoma secondary to eye inflammation, right eye, severe stage  
H40.41X4  Glaucoma secondary to eye inflammation, right eye, indeterminate stage  
H40.42X0  Glaucoma secondary to eye inflammation, left eye, stage unspecified  
H40.42X1  Glaucoma secondary to eye inflammation, left eye, mild stage  
H40.42X2  Glaucoma secondary to eye inflammation, left eye, moderate stage  
H40.42X3  Glaucoma secondary to eye inflammation, left eye, severe stage  
H40.42X4  Glaucoma secondary to eye inflammation, left eye, indeterminate stage  
H40.43X0  Glaucoma secondary to eye inflammation, bilateral, stage unspecified  
H40.43X1  Glaucoma secondary to eye inflammation, bilateral, mild stage  
H40.43X2  Glaucoma secondary to eye inflammation, bilateral, moderate stage  
H40.43X3  Glaucoma secondary to eye inflammation, bilateral, severe stage  
H40.43X4  Glaucoma secondary to eye inflammation, bilateral, indeterminate stage  
H40.51X0  Glaucoma secondary to other eye disorders, right eye, stage unspecified  
H40.51X1  Glaucoma secondary to other eye disorders, right eye, mild stage  
H40.51X2  Glaucoma secondary to other eye disorders, right eye, moderate stage  
H40.51X3  Glaucoma secondary to other eye disorders, right eye, severe stage  
H40.51X4  Glaucoma secondary to other eye disorders, right eye, indeterminate stage  
H40.52X0  Glaucoma secondary to other eye disorders, left eye, stage unspecified  
H40.52X1  Glaucoma secondary to other eye disorders, left eye, mild stage  
H40.52X2  Glaucoma secondary to other eye disorders, left eye, moderate stage  
H40.52X3  Glaucoma secondary to other eye disorders, left eye, severe stage  
H40.52X4  Glaucoma secondary to other eye disorders, left eye, indeterminate stage  
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H40.53X3  Glaucoma secondary to other eye disorders, bilateral, severe stage  
H40.53X4  Glaucoma secondary to other eye disorders, bilateral, indeterminate stage  
H40.60X0  Glaucoma secondary to drugs, unspecified eye, stage unspecified  
H40.60X1  Glaucoma secondary to drugs, unspecified eye, mild stage  
H40.60X2  Glaucoma secondary to drugs, unspecified eye, moderate stage  
H40.60X3  Glaucoma secondary to drugs, unspecified eye, severe stage  
H40.60X4  Glaucoma secondary to drugs, unspecified eye, indeterminate stage  
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H40.61X1  Glaucoma secondary to drugs, right eye, mild stage  
H40.61X2  Glaucoma secondary to drugs, right eye, moderate stage  
H40.61X3  Glaucoma secondary to drugs, right eye, severe stage  
H40.61X4  Glaucoma secondary to drugs, right eye, indeterminate stage  
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H40.62X2  Glaucoma secondary to drugs, left eye, moderate stage  
H40.62X3  Glaucoma secondary to drugs, left eye, severe stage  
H40.62X4  Glaucoma secondary to drugs, left eye, indeterminate stage  
H40.63X0  Glaucoma secondary to drugs, bilateral, stage unspecified  
H40.63X1  Glaucoma secondary to drugs, bilateral, mild stage  
H40.63X2  Glaucoma secondary to drugs, bilateral, moderate stage  
H40.63X3  Glaucoma secondary to drugs, bilateral, severe stage
Aqueous Shunts and Stents for Glaucoma

H40.63X4  Glaucoma secondary to drugs, bilateral, indeterminate stage
H40.811  Glaucoma with increased episcleral venous pressure, right eye
H40.812  Glaucoma with increased episcleral venous pressure, left eye
H40.813  Glaucoma with increased episcleral venous pressure, bilateral
H40.821  Hypersecretion glaucoma, right eye
H40.822  Hypersecretion glaucoma, left eye
H40.823  Hypersecretion glaucoma, bilateral
H40.831  Aqueous misdirection, right eye
H40.832  Aqueous misdirection, left eye
H40.833  Aqueous misdirection, bilateral
H40.89  Other specified glaucoma
H42  Glaucoma in diseases classified elsewhere
Q15.0  Congenital glaucoma

REVISIONS

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<td>06-07-2013</td>
<td>Policy added to the bcbsks.com website.</td>
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<tr>
<td>01-30-2014</td>
<td>Updated Description section.</td>
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<td>In Policy section:</td>
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<tr>
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<td>• Added new Item B, &quot;Implantation of a single FDA-approved microstent in conjunction with cataract surgery may be considered medically necessary in patients who are intolerant of medications.&quot;</td>
</tr>
<tr>
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<td>• Inserted in new Item D, &quot;for all other conditions, including patients with glaucoma when intraocular pressure is adequately controlled by medication&quot; to read &quot;Use of microstent for all other conditions, including patients with glaucoma when intraocular pressure is adequately controlled by medication, is considered experimental / investigational.&quot;</td>
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<td>01-01-2015</td>
<td>Updated Rationale section.</td>
</tr>
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<td>• Noted CPT code 0192T will be a deleted code, effective December 31, 2013</td>
</tr>
<tr>
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<td>• Added CPT code 66183 (New code, effective January 1, 2014)</td>
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<tr>
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<td>• Added Diagnosis codes: 366.00-366.9</td>
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<tr>
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<td>• Added ICD-10 Diagnosis (Effective October 1, 2014)</td>
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<tr>
<td>12-28-2015</td>
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<td>In Policy section:</td>
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<td>• In Item A, removed &quot;The iStent shunt is FDA approved, only when used in conjunction with cataract surgery.&quot;</td>
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<td>• In Item B, added &quot;with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication&quot; and removed &quot;who are intolerant of medications&quot; to read, &quot;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.&quot;</td>
</tr>
<tr>
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<td>• In Item D, removed &quot;, including patients with glaucoma when intraocular pressure is adequately controlled by medication,&quot; to read, &quot;Use of a microstent for all other...&quot;</td>
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conditions is considered experimental/investigational."

Updated Rationale section.

Updated References section.

04-27-2016

Updated Description section.

Updated Rationale section.

In Coding section:

- Coding bullets removed.

Updated References section.

10-01-2016

In Coding section:

- Removed ICD-10 codes: H40.11x0, H40.11x1, H40.11x2, H40.11x3, H40.11x4

11-09-2016

In Policy section:

- Moved previous Item C to become current Item B.
- In current Item C, removed "treated with ocular hypotensive medication" and added "requiring treatment" to read, "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 requiring treatment."

In Coding section:

- Added CPT codes: 0449T, 0450T (Effective January 1, 2017).

Updated References section.

04-12-2017

Updated Description section.

Updated Rationale section.

Updated References section.

07-01-2017

In Coding section:

- Added CPT code: 0474T (Effective July 1, 2017).

REFERENCES


Contains Public Information

Other References
1. BCBSKS Medical Consultant, Practicing Board Certified Ophthalmologist (538), January 2013.