Name of Policy:  
Aqueous Shunts and Stents for Glaucoma

Policy #: 324       Latest Review Date: March 2017  
Category: Surgery  
Policy Grade: B

Background/Definitions:  
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medication. Due to complications with established surgical approaches such as trabeculectomy, a variety of devices, including aqueous shunts and transluminal dilation procedures, 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.

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**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) and then drains 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.

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**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 (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).

The Trabectome™ is a recently developed electrocautery device with irrigation and aspiration designed to selectively ablate trabecular meshwork and Schlemm’s canal inner wall without external access or creation of a subconjunctival bleb. IOP with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. Canaloplasty involves dilation and tension of Schlemm’s canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack™ illuminated microcatheter (iScience Interventional) to access and dilate the entire length of Schlemm’s canal and to pass the suture loop through the canal (see Medical Policy #505, Viscocanalostomy and Canaloplasty).

Aqueous shunts may also be placed in the anterior or posterior chamber to facilitate drainage of aqueous humor. Examples of shunts cleared by the U.S. Food and Drug Administration include the Ahmed™ (New World Medical), Baerveldt® (Advanced medical optics), Molteno® (IOP), and 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 uses 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. 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; 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., < 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 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.

**Policy:**
**Effective for dates of service on or after December 1, 2013:**
Insertion of aqueous shunts approved by the U.S. Food and Drug Administration (FDA) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage 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, does not meet Blue Cross and Blue Shield of Alabama’s medica criteria for coverage and is considered investigational.

Implantation of a single FDA-approved micro-stent in conjunction with cataract surgery meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.
Use of a micro-stent for all other conditions does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Effective for dates of service prior to December 1, 2013:
Insertion of FDA approved aqueous shunts to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Use of an aqueous shunt for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in is considered investigational.

Use of a micro-stent does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
The most recent literature review was updated through January 25, 2017.

Aqueous Shunts
This section will review the evidence on aqueous shunts that have received FDA-approval. Evidence on non-approved devices in included in a later section.

Systematic Reviews
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 one year. A limitation of this systematic review is that complications were not compared, because 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 agent’s 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 2012 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 versus 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. The study included 212 eyes of 212 patients (18 to 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, 1.2 in the trabeculectomy group) differed significantly from intention. The cumulative probability of failure over the five years was lower in the tube group than the trabeculectomy group (29.8% vs. 46.9%) and the rate of reoperation was lower (9% vs. 29%). The rate of loss of 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 one year and 83% and 79% at 3 years in the EX-PRESS® and trabeculectomy groups, respectively. Visual acuity returned to near baseline levels at one 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-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 (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 did not differ significantly between groups. In the EX-PRESS® group, IOP remained stable from year one (12.0 mm Hg) to year five (11.5 mm Hg), while in the trabeculectomy group, IOP decreased from year 3 (13.5 mm Hg) to year five (11.3 mm Hg). There were more complications after trabeculectomy than after EX-PRESS® implantation.

Two additional small RCTs were published in 2015 and 2016 by Gonzalez-Rodriguez et al (n=63) and Wagschal et al. (n=64). Both of these studies corroborated the results of the earlier RCTs, reporting that there were no differences between the trabeculectomy and Ex-PRESS shunt groups on the outcomes of mean IOP, success rates, number of medications used, or complication rates.

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 needing 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, 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 most of the FDA-approved aqueous shunts. The results of these trials are fairly consistent in reporting that the magnitude of reduction in IOP following aqueous shunt placement is similar, or slightly inferior, to that following trabeculectomy. There are fewer complications from shunts compared to trabeculectomy, and a reduced need for future operations. Overall, the risk/benefit ratio for shunts does not appear to be substantially different than 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 randomized clinical trial were reported to the FDA in 2010, with 1 year results published in 2011 and 2 year results published in 2012. 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 one surgical event. A total of 240 patients (mean age of 73 years) with cataracts and mild to moderate open-angle glaucoma (IOP < 24 mm Hg controlled on 1 to 3 medications) underwent a medication washout period. Patients were randomized to undergo cataract surgery with iStent implantation or cataract surgery only if the unmedicated IOP was 22 mm Hg or higher and 36 mm Hg or lower. 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, the mean IOP was 25 mm Hg and mean visual acuity (logMAR) was 0.36. Follow-up visits were performed at 1, 3, 6, and 12 months. Results were assessed by intent-to-treat analysis with the last observation carried forward and per protocol analysis. Of the 117 subjects randomized to iStent implantation, 111 underwent cataract surgery with stent implantation, and 106 (91%) completed the 12-month postoperative visit. Of the 123 subjects randomized to cataract surgery only, 117 underwent cataract surgery and 3 exited the study because of complications of cataract surgery. Of the remaining 114 subjects, 112 (91%) completed the 12-month visit. The proportion of eyes meeting both the primary (unmedicated IOP <21 mm Hg) and secondary outcomes (IOP reduction >20% without hypotensive medications) was higher in the treatment group than in the control group through 1 year follow up. At one year follow-up, 72% of treatment eyes and 50% of control eyes achieved the primary efficacy endpoint. The proportion of patients achieving the secondary efficacy endpoint 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 one year follow-up (e.g., 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 of 0.4 medications) than in the treatment group (0.2 medications) at 1 year.

At 2 year follow-up, there were 199 of the original patients (83%) remaining in the study. The primary endpoint, (IOP ≤21 mm Hg without use of medication) was reached by 61% of patients in the treatment group compared to 50% of controls (p=0.036). The secondary outcomes of IOP reduction of 20% or more without medication (53% vs. 44%) and mean number of medications used (0.3 vs. 0.5) were no longer significantly different between the groups at 2 years. As noted by 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 indicate that treatment of this specific population with a microstent is likely to improve outcomes at one 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. Inclusion criteria were a previous diagnosis of primary open-angle glaucoma with an IOP above 18 mm Hg at 3 separate visits, and on one or more hypotensive medications. The stent was implanted using the same small
temporal clear corneal incision (approximately 3.0 mm) that had been used for phacoemulsification and intra-ocular lens placement and was guided into Schlemm’s canal by an applicator and ab interno gonioscopy. Follow-up visits with investigators who were masked to the treatment condition were conducted at 24 hours, 1 week, and 1, 2, 3, 6, 9, 12, and 15 months. Prescription of hypotensive medications was performed according to pre-set guidelines. Primary outcomes were IOP and reduction in medication use over 15 months and IOP after a one 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 investigators commented that treatment compliance is an ongoing concern for most ophthalmologists; therefore, a main goal is to keep the patient as free as possible from medications postoperatively. After washout of medications, mean IOP was 16.6 in the stent group and 19.2 in the control group. Two stents were malpositioned, but one of these appeared to be functioning and there were no reported adverse events related to stent implantation. Four year follow-up from this study was published in 2015. A total of 24 of 36 patients were available at four years of follow-up. At this longer time point, the differences between treatment group remained non-significant, with a mean IOP of 15.9mmHg in the stent group and 17mmHg in the control group (p=NS).

**CyPass**

FDA evaluated the clinical performance of the CyPass Micro-Stent system based on the pivotal COMPASS trial. 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. 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. 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 iStents devices 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 one year postoperatively. Target IOP was reached in 77% of eyes, while 59% of patients discontinued use of all medications in the study eye. At one 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 two stent group compared to 72% in the 3 stent group. Stent blockage occurred in the early postoperative period in 15% of eyes and was successfully treated with laser. At least one other prospective case series has also been published. This study enrolled 39 patients with OAG and IOP between 18 and 30 mmHg. Each patient was treated with 2 microstents and medications as needed, and follow-up was for 3 years. At study completion, the mean reduction in IOP was 9.1 mmHg (95% CI 8.0-10.1). There was one postoperative complication, which was a hyphema that resolved without further intervention.

Section Summary: Aqueous Microstents with Cataract Surgery
Two RCTs were identified that compared cataract surgery plus a single iStent to cataract surgery alone. The results of these trials were mixed, with one 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 such as stent malposition and hyphema were reported in all the trials.

Aqueous Shunts Not Approved by the FDA
iStent inject®
A 2014 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 one 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.

**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 when combined with cataract surgery versus 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) when compared to cataract surgery alone. The group with the Hydrus Microstent was using significantly fewer medications (0.5 vs 1.0, p = 0.019) and proportion of patients using no hypotensive medications was higher when the Hydrus Microstent was inserted at the time of cataract surgery (73% vs 38%, p=0.0001).

**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 are treated with 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 leads to slightly less reduction in intraocular pressure (IOP) than standard filtering surgery (trabeculectomy). Reported shunt success rates are as good as trabeculectomy in the long term. FDA-approved shunts have a different adverse effect profile 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 qualitatively 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 other indications for glaucoma treatment 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.
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 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
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 to 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 randomized controlled trials). The assessment indicated that although aqueous shunts have been generally reserved for intractable glaucoma when prior medical or surgical therapy has failed, indications for shunts have broadened (based on Level III evidence; case series, case reports, and poor-quality case-control or cohort studies). The AAO concluded that based on Level I evidence; aqueous shunts offer a valuable alternative to standard filtering surgery or to cyclodestructive therapy for many patients with refractory glaucoma.

The 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 U.S. Food and Drug Administration clearance or were in Phase III clinical trials in the United States 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 if the novel procedures were superior, equal to, or inferior to surgery such as trabeculectomy or to one another.

National Institute for Health and Clinical 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. 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.

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 are no well-controlled, comparative studies supporting superiority among the minimally invasive techniques (including shunts and microstents) nor 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.

Key Words:
Eyepass, Hydrus Microstent, iStent, trabecular shunt, Trabectome, Solx gold shunt, SOLX Gold Shunt, Ex-PRESS®, AquaFlow™, Ahmed™, Baerveldt, Krupin, Molteno®, iStent supra, CyPass, aqueous shunt, trabecular stent, micro-stent, iStent® Trabecular Micro-Bypass Stent, XEN

Approved by Governing Bodies:
The regulatory status of the various aqueous shunts and micro-stents is summarized in Table 1. The first generation Ahmed (New World Medical), Baerveldt (Advanced Medial 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 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 was approved by FDA through the premarket approval process for the maintenance of the sub scleral space following non-penetrating deep sclerectomy.
In 2013, the EX-PRESS® Mini Glaucoma Shunt was cleared for marketing by FDA through the 510(k). The Ex-PRESS shunt is placed under a partial thickness scleral flap and transport 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>
</tr>
<tr>
<td>Baerveldt</td>
<td>Advanced Medical Optics</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt;1993</td>
</tr>
<tr>
<td>Krupin</td>
<td>Eagle Vision</td>
<td>Aqueous glaucoma shunt</td>
<td>510(K)</td>
<td>&lt;1993</td>
</tr>
<tr>
<td>Molteno®</td>
<td>Molento Ophthalmic</td>
<td>Aqueous glaucoma shunt</td>
<td>510(k)</td>
<td>&lt;1993</td>
</tr>
<tr>
<td>Ex-PRESS™</td>
<td>Alco</td>
<td>Mini-glaucoma shunt</td>
<td>510(k)</td>
<td>2003</td>
</tr>
<tr>
<td>iStent®</td>
<td>Glaukos</td>
<td>Microsent</td>
<td>PMA</td>
<td>2012</td>
</tr>
<tr>
<td>Hydrus</td>
<td>Ivantis</td>
<td>Microstent</td>
<td>Not Approved</td>
<td></td>
</tr>
<tr>
<td>iStent inject®</td>
<td>Glaukos</td>
<td>Suprachoroidal stent</td>
<td>Not Approved</td>
<td></td>
</tr>
<tr>
<td>iStent supra®</td>
<td>Glaukos</td>
<td>Suprachoroidal stent</td>
<td>Not Approved</td>
<td></td>
</tr>
<tr>
<td>CyPass®</td>
<td>Transcend Medical</td>
<td>Suprachoroidal stent</td>
<td>PMA</td>
<td>2016</td>
</tr>
<tr>
<td>XEN Gel Stent</td>
<td>AqueSys</td>
<td>Subconjunctival</td>
<td>510(k)</td>
<td>2016</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; PMA: premarket approval

In 2012, the iStent® Trabecular Micro-Bypass Stent (Glaukos Corp) was approved by FDA through the premarket approval process 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 inflammations
   - 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 mmHg
   - In patients with unmedicated IOP less than 22 mmHg or greater than 36 mmHg 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
   - 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 gold shunt and the 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.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Current Coding:**

CPT Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>66183</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach <em>(Effective 01/01/2014)</em></td>
</tr>
<tr>
<td>0191T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; initial insertion</td>
</tr>
<tr>
<td>0253T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the suprachoroidal space</td>
</tr>
<tr>
<td>0376T</td>
<td>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) <em>(Effective 01/01/15)</em></td>
</tr>
<tr>
<td>0449T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device <em>(Effective 01/01/17)</em></td>
</tr>
<tr>
<td>0450T</td>
<td>; each additional device <em>(Effective 01/01/17)</em></td>
</tr>
<tr>
<td>0474T</td>
<td>Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space <em>(new code effective 07/01/17)</em></td>
</tr>
</tbody>
</table>

**Previous Coding:**

CPT Codes:

<table>
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<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>0192T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach <em>(Deleted 01/01/2014)</em></td>
</tr>
</tbody>
</table>

**References:**


Policy History:
Medical Policy Group, July 2008 (2)
Medical Policy Administration Committee, August 2008
Available for comment August 13-September 26, 2008
Medical Policy Group, July 2010 (1): Policy statement updated, Description, Key Points
Medical Policy Administration Committee, June 2010
Available for comment June 18-August 2, 2010
Medical Policy Group, December 2010, Code update
Medical Policy Panel, May 2011
Medical Policy Group, May 2011 (2): Policy change, Key Points and References updated
Medical Policy Administration Committee, June 2011
Available for comment June 8 – July 25, 2011
Medial Policy Panel, September 2011
Medical Policy Group, September 2011 (2): Policy change, Key Points, References updated
Medical Policy Administration Committee, October 2011
Available for comment October 19 through December 5, 2011
Medical Policy Panel, May 2012
Medical Policy Group, June 2012 (2): Name changed from Viscocanaloplasty and Canaloplasty
to Aqueous Shunts for Glaucoma, Updated policy, Key words, Key Points, Approved by
Governing Bodies, References to reflect name of policy
Medical Policy Group, September (2): Removed all references to iTrack
Medical Policy Panel, October 2012
Medical Policy Group, October 2012 (2): Policy updated with literature search through August
2012. Policy statement for use of micro-stent is investigational. Title, Key Words, FDA
approval, Key Points and References updated to support non-coverage statement for use of
micro-stent.
Medical Policy Administration Committee, November 2012
Available of comment November 14 through December 28, 2012
Medical Policy Panel, September 2013
Medical Policy Group, October 2013 (2): Policy updated with literature search through August
2013. Added policy statement that iStent is considered covered in patients intolerant of
medications when implanted in conjunction with cataract surgery. Description, Key Points,
Approved by Governing Bodies, and References updated to reflect findings in literature search
and new policy statement.
Medical Policy Administration Committee, October 2013
Available for comment October 16 through November 30, 2013
Medical Policy Group, December 2013 (1): 2014 Coding Update: added new code 66183,
effective 01/01/2014; moved deleted code 0192T to Previous Coding section, effective
01/01/2014.
Medical Policy Panel September, 2014
Medical Policy Group, September 2014 (1): Update to Description, Key Points and References.
No Policy Statement change
Medical Policy Group, November 2014: 2015 Annual Coding update. Added code 0376T to
current coding; Changed verbiage on 0191T to read ‘initial insertion’, no change to 0253T
Medical Policy Panel, September 2015
Medical Policy Group, September 2015 (6): Updates to Key Points, Key Words, Approved by Governing Bodies and References; no change in policy statement.
Medical Policy Panel, March 2016
Medical Policy Group, March 2016 (6): Updates to Description, Key Points, Approved by Governing Bodies and References: no change to policy statement.
Medical Policy Group, December 2016 (6): Removed Cypass from investigational status in Description of Procedure. FDA approved July 29, 2016, Updated Key Points.
Medical Policy Group, January 2016 (6): Updates to Key Words and Approved by Governing Bodies to include the XEN glaucoma treatment system.
Medical Policy Panel, March 2017
Medical Policy Group, March 2017 (6): Updates to Description, Key Points, Coding, Practice Guidelines, Governing Bodies and References.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.