Name of Policy:  
Aqueous Shunts and Stents for Glaucoma

Policy #: 324   
Category: Surgery

Latest Review Date: October 2013   
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.

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.

Surgical intervention may be indicated in patients with glaucoma when the target IOP can not 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 with a filtering “bleb” on the eye, which can effectively reduce IOP, but is associated with numerous and sometimes sight-threatening complications (e.g., leaks, hypotony, choroidal effusions and hemorrhages, hyphemas or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed in this policy) include trabecular laser ablation, deep sclerectomy, which removes the outer wall of Schlemm’s canal and excises deep sclera and peripheral cornea, and viscocanalostomy, which unroofs and dilates Schlemm’s canal without penetrating the trabecular meshwork or anterior chamber.

More recently the Trabectome™ 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 iTackle™ illuminated microcatheter (iScience Interventional) to access and dilate the entire length of Schlemm’s canal and to pass the suture loop through the canal (see policy #505, Viscocanalostomy and Canaloplasty).

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), Moleeno® (IOP), ExPress® mini-shunt (Alco); and the SOLX® deepLight® Gold Micro-shunt (SOLX), which shunts aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ depending on explant surface areas, shape, plate thickness, the presence or absence of a valve, and details of surgical installation. Generally, the risk of hypotony (low pressure) is reduced with aqueous shunts in comparison with trabeculectomy, but IOP outcomes are higher than after standard guarded filtration surgery.
Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of postoperative infection is less than after trabeculectomy, and failure rates are similar, with about 10% of devices failing each year. The primary indication for aqueous shunts is when prior medical or surgical therapy has failed, although some ophthalmologists have advocated their uses as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

Other aqueous stents are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into Schlemm’s canal or the suprachoroidal space. These include the iStent (Glaukos), which is a 1mm long stent inserted into the end of Schlemm’s canal by-an internal (through the cornea and anterior chamber); the third generation iStent supra, which is designed for ab interno implantation into the suprachoroidal space; 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, e.g., below 15 mm Hg and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma). Health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy if the procedure is unsuccessful, complications, and durability of the procedure.

**Policy:**

Effective for dates of service on 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:
This policy was updated with literature searched through August 2013.

FDA-Approved/Cleared Aqueous Shunts
A 2006 Cochrane review evaluated 15 randomized or pseudo-randomized controlled trials (RCTs), with a total of 1153 participants, on the Ahmed, Baerveldt, Molteno, and Schocket shunts. Trabeculectomy was found to result in a lower mean intraocular pressure (IOP) (by 3.8 mm Hg) than the Ahmed shunt at one year. A limitation of this report is that complications were not compared, as the authors considered them to be too variably reported to allow comparative tabulation. There was no evidence of superiority of one shunt over another.

A literature review on commercially available aqueous shunts, for the American Academy of Ophthalmology (AAO) technology assessment was published in 2008. This review indicated that the IOP will generally settle at higher levels (approximately 18 mm Hg) with aqueous shunts than after standard trabeculectomy (14 to 16 mm Hg) or after trabeculectomy with anti-fibrotic agents 5-fluorouracil or mitomycin C (8 to 10 mm Hg). In one study, mean IOPs with the Baerveld shunt and adjunct medications were found to be equivalent to trabeculectomy with mitomycin C (13 mm Hg). Five-year success rates for the two procedures were found to be similar (50%). The assessment concluded that aqueous shunts were comparable with trabeculectomy for IOP control and duration of benefit. The risk of postoperative infection was less with aqueous shunts than after trabeculectomy. Complications of aqueous shunts were noted to include: immediate hypotony after surgery; excessive capsule fibrosis and clinical failure; erosion of the tube or immediate hypotony after surgery; excessive capsule fibrosis and clinical failure; erosion of the tube or plate edge; strabismus; and very rarely, infection. The most problematic long-term consequence of anterior chamber tube placement was described as accelerated damage to the corneal endothelium over time.
Implantation of the Ex-Press mini shunt under a scleral flap was compared with standard trabeculectomy in a randomized study of 78 patients (80 eyes) with a diagnosis of open-angle glaucoma that could not be controlled with maximal-tolerated medical therapy. The two groups were similar after randomization, with the exception of difference in the mean age (62 years for the Ex-Press group and 69 years for the trabeculectomy group). At an average 12 months’ follow-up, mean IOP had improved from 23 to 12 mm Hg in the Ex-PRESS group and from 22 to 14 mm Hg in the trabeculectomy group. Both groups of patients used fewer antiglaucoma medications postoperatively than before the procedure. Twelve-month Kaplan-Meier success rates were 82% for the Ex-Press shunt and 48% for the trabeculectomy. There was a similar level of postoperative complications in the two groups.

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 were inadequate to draw conclusions on the comparative effectiveness of these treatments in comparison with laser and other surgical treatments.

Baerveldt Glaucoma Shunt
Early results from the open-label multicenter randomized Tube Versus Trabeculectomy (TVT) study were reviewed in the 2008 AAO technology assessment, and in 2012, Gedde et al reported five-year follow-up from this study. 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 one patient who had died, the study had 82% follow-up at five years, with a similar proportion of patients in the tube and trabeculectomy groups. At five-years, neither IOP (14.3 mm Hg in the tube group and 13.6 mm Hg in the trabeculectomy group) were significantly different with intent-to-treat analysis. 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 two or more lines of visual acuity was similar in the two groups (46% in the tube group and 43% in the trabeculectomy group).

Ex_PRESS Mini Shunt
Implantation of the Ex-Press mini shunt under a scleral flap was compared with standard trabeculectomy in a randomized study of 78 patients (80 eyes) with a diagnosis of open-angle glaucomas that could not be controlled with maximal-tolerated medical therapy. The two groups were similar after randomization, with the exception of difference in the mean age (62 years for the Ex-PRESS group and 69 years for the trabeculectomy group). At an average 12 months’ follow-up, mean IOP had improved from 23 to 12 mm Hg in the Ex-PRESS group and from 22 to 14 mm Hg in the trabeculectomy group. Both groups of patients used fewer antiglaucoma medications postoperatively than before the procedure (from 2.8 at baseline to 0.3 in the Ex-PRESS group and from 3.0 at baseline to 0.6 in the trabeculectomy group). Twelve-month Kaplan-Meier success rates (defined as an IOP of &gt;4mm Hg and ≤18 mm Hg without use of antiglaucoma medications) were 82% for the Ex-PRESS shunt and 48% for trabeculectomy. There was a similar level of postoperative complications in the two groups.
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 and published in 2011 and two-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 two 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 one to three medications) were randomized to undergo cataract surgery with iStent implantation or cataract surgery only if the unmedicated IOP was 22 mm Hg or higher and 36 mm Hg or lower. The mean number of medications at baseline was 1.5. The medicated IOP at baseline was 18.7 mm Hg in the stent group and 18.04 in the control group. After washout, the mean IOP was 25 mm Hg and mean visual acuity (logMAR) was 0.36. Follow-up visits were performed at one, three, six, 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 three 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 one-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). The mean reduction in IOP was similar in the two groups, with a higher level of medication used in the control group (mean of 0.4 medications) in comparison with the treatment group (0.2 medications). The overall incidence of adverse events was similar between the groups.

At two-year follow-up, there were 199 of the original 239 patients (83%) remaining in the study. The primary endpoint, IOP of 21 mm Hg or less without use of medication, was reached by 61% of patients in the treatment group compared to 50% of controls (p=0.036). The secondary outcomes of IOP reduction of 20% or more without medication (53% vs. 44%) and mean number of medications used (0.3 vs. 0.5) were no longer significantly different between the groups at two years. Stent-related adverse events were common, with stent obstruction and stent malposition occurring within 30 days postoperatively in all by one eye. The authors reported that all of these stents complications resolved with paracentesis, neodymium: YAG laser, stent repositioning, or stent replacement. As noted by the FDA, this study was conducted in a restricted population of patients who had an unmedicated IOP of 22 mm Hg or higher and 36 mm Hg or lower. The results of this study indicate that treatment of this specific population with a Microstent is likely to improve outcomes at one year compared to cataract surgery alone. However, given the two-year results of the study, it is not possible to conclude with certainty that health outcomes are improved at longer periods of follow-up.
Fea reported a randomized double-blind clinical trial of cataract surgery with or without iStent implantation (2:1 ratio) in 36 patients in 2010. Inclusion criteria were a previous diagnosis of primary open-angle glaucoma with an IOP above 18 mm Hg at three 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 intraocular 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, one week, and one, two, three, six, nine, 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 five in the control group (24% of 21) did not require ocular hypotensive medication. The authors commented that patient compliance is an ongoing concern for most ophthalmologists; therefore, a main goal is to keep the patient as free as possible from medications postoperatively. After washout of medications, mean IOP was 16.6 in the stent group and 19.2 in the control group. Two stents were malpositioned, but one of these appeared to be functioning and there were no reported adverse events related to stent implantation. This small study suggests that without hypotensive medication, the iStent lowers IOP by about 2.5 mm Hg beyond that generated by cataract surgery alone (approximately 25% decrease in the risk of glaucomatous progression).

Use of multiple iStents in combination with cataract surgery was reported in an open-label prospective series of 53 eyes (47 patients) in 2012. Of the 53 eyes, 28 had implantation of two stents and 25 had implantation of three stents, based on the need for greater IOP control, as determined by the operating surgeon. Best-corrected visual acuity (BCVA) improved or remained stable in 89% of eyes. IOP decreased from a mean of 18.0 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 two stent group and 0.4 in the three stent group. Medication use had been stopped in 46% of eyes in the two stent group compared to 72% in the three stent group. Stent blockage occurred in the early postoperative period in 15% of eyes and was successfully treated with laser.

**Aqueous Shunts Not Approved by the FDA**
A small case series has been identified on the EyePass and CyPass micro-stent. The CyPass has not received FDA approval/clearance at this time. The EyePass is no longer being developed.

**Summary**
Randomized controlled trials have shown that the use of large externally placed shunts with extraocular reservoirs results in success rates as good as standard filtering surgery (trabeculectomy). Shunts have a different side effect profile and avoid some of the most
problematic complications of trabeculectomy. Therefore, use of FDA-approved shunts may be considered medically necessary as a method to reduce intraocular pressure in patients with moderate to severe glaucoma in whom medical treatments have failed to adequately control intraocular pressure. Aqueous shunts that are not FDA-approved/cleared, as well as all conditions for the approved devices aside from reducing IOP in patients with glaucoma in whom medical therapy has failed, are considered investigational.

Use of micro-stents has been studied in patients with both cataracts and less advanced glaucoma, where the intraocular pressure (IOP) is at least partially controlled with medication. Results from these studies indicate that IOP may be lowered below baseline with decreased need for medication, although the benefit appears to diminish after the first year. A micro-stent has received FDA approval for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. Based on the documented reduction in the need for medications and the clinical input received on this policy, use of a single FDA-approved micro-stent may be considered medically necessary when implanted concurrently with cataract surgery in patients who are unable to tolerate medication.

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

The American Academy of Ophthalmology (AAO) published a 2008 technology assessment on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices. 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 two procedures, indicating that aqueous shunts are comparable with trabeculectomy for IOP control and duration of benefit. (Based on Level I evidence; well-designed randomized controlled trials). The assessment indicated that although aqueous shunts have been generally reserved for intractable glaucoma when prior medical or surgical therapy has failed, indications for shunts have broadened (based on Level III evidence; case series, case reports, and poor-quality case-control or cohort studies). The AAO concluded that based on Level I evidence; aqueous shunts offer a valuable alternative to standard filtering surgery or to cyclodestructive therapy for many patients with refractory glaucoma.

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

A 2011 technology assessment from the AAO (literature search up to October 2009) reviewed the evidence on novel, or emerging, glaucoma procedures. 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 if the novel procedures were superior, equal to, or inferior to surgery such as trabeculectomy or to one another.

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

**Key Words:**
Eyepass, iStent, trabectome, trabecular shunt, Trabectome, Solx gold shunt, SOLX Gold Shunt, Ex-PRESS, AquaFlow™, Ahmed, Baerveldt, Krupin, Molteno, iStent supra, Cy Pass, aqueous shunt, trabecular stent, micro-stent, iStent, iStent® Trabecular Micro-Bypass Stent
The first generation Ahmed (New World Medical), Baerveldt (Advanced Medial Optics), Krupin (Eagle Vision), and Molteno (Moltenno Ophthalmic) aqueous shunts received marketing clearance from the FDA between 1989 and 1993; modified Ahmed and Molteno devices were most recently cleared in 2006. Their indication for use is “in patients with intractable glaucoma to reduce intraocular pressure where medical and conventional surgical treatments have failed.” The AquaFlow™ Collagen Glaucoma Drainage Device received premarket approval from the FDA in 2001 for the maintenance of sub-scleral space following non-penetrating deep sclerectomy. The Ex-PRESS™ Mini Glaucoma Shunt received 510(k) marketing clearance in 2003. The Ex-PRESS shunt is placed under a partial thickness scleral flap and transport aqueous fluid from the anterior chamber of the eye into a conjunctival filtering bleb.

In 2012, the FDA approved the Glaukos Corporation’s iStent® Trabecular Micro-Bypass Stent. PMA P080030, as indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

### Approved by Governing Bodies:

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<th>Device</th>
<th>Manufacturer</th>
<th>Type</th>
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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

The Solx gold shunt is currently in FDA-regulated trials. The Solx gold shunt has received regulatory approval in Europe. It is 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.
Pre-certification requirements: Not applicable
Current Coding:
CPT Codes:

66183  Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach (Effective 01/01/2014)
0191T  Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork
0253T  Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the suprachoroidal space

Previous Coding:
CPT Codes:

0192T  Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach (Deleted 01/01/2014)

References:
17. Koerber NJ. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. J Glaucoma 2011. [Epub ahead of print]


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.

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.