Aqueous Shunts and Devices for Glaucoma

Description of Procedure or Service

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, a variety of devices, including aqueous shunts are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma.

Stents and tensioning devices are only able to reduce intraocular pressure (IOP) to the mid-teens, and may be inadequate when very low IOP is needed to reduce glaucoma damage. Micro-stents are also being evaluated in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Background

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

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir, which can effectively reduce IOP, but commonly results in filtering “blebs” on the eye, and is associated with numerous complications (e.g., leaks or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed in this policy) include trabecular laser ablation, deep sclerectomy, which removes the outer wall of Schlemm’s canal and excises deep sclera and peripheral cornea, and viscocanalostomy, which unroofs and dilates Schlemm’s canal without penetrating the trabecular meshwork or anterior chamber.

The Trabectome™, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm’s canal without external access or creation of a subconjunctival bleb. IOP with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. Canaloplasty involves dilation and tension of Schlemm’s canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack™ illuminated microcatheter (iScience Interventional) to access and dilate the entire length of Schlemm’s canal and to pass the suture loop through the canal.
Aqueous shunts may also be placed 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 (Alcon); which shunt 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 is reduced with aqueous shunts in comparison with trabeculectomy, but IOP outcomes are higher than after standard guarded filtration surgery. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of postoperative infection is less than after trabeculectomy, and failure rates are similar, with about 10% of devices failing each year. The primary indication for aqueous shunts is when prior medical or surgical therapy has failed, although some ophthalmologists have advocated their use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

Aqueous stents are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into Schlemm’s canal or the suprachoroidal space. They include the iStent® (Glaukos), which is a 1-mm long stent inserted into the end of Schlemm’s canal by an internal approach through the cornea and anterior chamber; the second generation iStent inject®, the third generation iStent supra®, which is designed for ab interno implantation into the suprachoroidal space; and the CyPass® (Transcend Medical) suprachoroidal stent.

Because aqueous humor outflow is pressure dependent, the pressure in the reservoir and venous system are critical for reaching the target IOP. Therefore, some devices may be unable to reduce IOP below the pressure of the distal outflow system used, e.g., below 15 mmHg, and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma). It has been proposed that stents such as the iStent, CyPass and Hydrus Microstent may be useful to lower IOP in patients with early stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is for patients with glaucoma who require cataract surgery. One advantage of ab-interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than one shunt to achieve the desired IOP. Therefore, health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy, complications and durability of the device.

**Regulatory Status**

The Trabectome™ was cleared by the U.S. Food and Drug Administration (FDA) in 2006 for “use with compatible electrosurgical instruments in low power microsurgical applications for the removal, destruction and coagulation of tissue.”

The first generation Ahmed (New World Medical), Baerveldt (Advanced Medical Optics), Krupin (Eagle Vision) and Molteno (Molteno Ophthalmic) aqueous shunts received marketing clearance from the FDA between 1989 and 1993; modified Ahmed and Molteno devices were most recently cleared in 2006. Their indication for use is “in patients with intractable glaucoma to reduce intraocular pressure where medical and conventional surgical treatments have failed.” The AquaFlow™ Collagen Glaucoma Drainage Device received premarket approval from the FDA in 2001 for the maintenance of sub-scleral space following non-penetrating deep sclerectomy. The Ex-PRESS™ Mini Glaucoma Shunt received 510(k) marketing clearance in 2003. The Ex-PRESS shunt is placed under a partial thickness scleral flap and transports aqueous fluid from the anterior chamber of the eye into a conjunctival filtering bleb. In 2016, the Xen® Glaucoma Treatment System (Allergan), which consists of the XEN45 Gel Stent preloaded into the XEN injector, was cleared for marketing by the 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.
Aqueous Shunts and Devices for Glaucoma

The SOLX® DeepLight® Gold Micro-Shunt, Hydrus™ Microstent, are currently in FDA-regulated trials. In 2012, the FDA-approved the Glaukos Corporation iStent® Trabecular Micro-Bypass Stent, PMA P080030, as indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients-with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. The Solx gold shunt has received regulatory approval in Europe. It is not FDA-approved/cleared for use in the U.S. at this time.

The labeling describes the following precautions:

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

2. The safety and effectiveness of the iStent® Trabecular Micro-Bypass Stent has not been established in patients with the following circumstances or conditions which were not studied in the pivotal trial:

   - In children
   - In eyes with significant prior trauma
   - In eyes with abnormal anterior segment
   - In eyes with chronic inflammation
   - In glaucoma associated with vascular disorders
   - In pseudophakic patients with glaucoma
   - In uveitic glaucoma
   - In patients with prior glaucoma surgery of any type including argon laser trabeculoplasty
   - In patients with medicated intraocular pressure greater than 24 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 (intraocular lens)
   - When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract

Note that 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.

Related Policies:
- Glaucoma Evaluation by Ophthalmologic Techniques
- Viscocanaloplasty and Canaloplasty

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will cover aqueous shunts and devices for glaucoma when determined to be medically necessary because the medical criteria and guidelines shown below are met.
**Aqueous Shunts and Devices for Glaucoma**

**Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

**When Aqueous Shunts and Devices for Glaucoma are covered**

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

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

**When Aqueous Shunts and Devices for Glaucoma are not covered**

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

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

**Policy Guidelines**

For individuals who have refractory open-angle glaucoma who receive aqueous shunts, the evidence includes randomized controlled trials (RCTs) and single-arm studies. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. RCTs with 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 IOP compared with standard filtering surgery (trabeculectomy). However, reported 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 quantitatively 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 the reduction of IOP in adult patients 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 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
Aqueous Shunts and Devices for Glaucoma

compared 2 iStents to travoprost. The study did not report statistical comparisons. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input was sought to evaluate the medical necessity of microstents in patients undergoing cataract surgery for whom IOP is not adequately controlled with hypotensive medication and for patients with mild-to-moderate glaucoma undergoing cataract surgery for whom IOP is adequately controlled with hypotensive medications. Input was also sought on the off-label use of more than 1 microstent. Input supported the use of a single microstent in patients with mild-to-moderate glaucoma undergoing cataract surgery to reduce the adverse events of medications and to avoid noncompliance.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0191T, 0253T, 0376T, 0444T, 0445T, 0449T, 0450T, 0474T, 66179, 66180, 66183, 66184, C1783, L8612

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Senior Medical Director –3/2010
Specialty Matched Consultant Advisory Panel review- 6/2012
Specialty Matched Consultant Advisory Panel review- 6/2013
Specialty Matched Consultant Advisory Panel review- 6/2014
Specialty Matched Consultant Advisory Panel review- 6/2015
Aqueous Shunts and Devices for Glaucoma


Specialty Matched Consultant Advisory Panel review- 6/2017

Policy Implementation/Update Information

3/30/10 New policy implemented. Reviewed by Senior Medical Director 3/4/2010. “Insertion of aqueous shunts approved by the U.S. Food and Drug Administration (FDA) may be considered medically necessary as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure.” “Use of an aqueous shunt for all other conditions, including patients with glaucoma when intraocular pressure is controlled by medications, is considered investigational. “Canaloplasty is considered investigational as a method to reduce intraocular pressure in patients with glaucoma.”

6/22/10 Policy Number(s) removed. (amw)

1/4/11 Added new CPT codes 66174, 66175, 0253T to Billing/Coding section. Removed deleted CPT code 0177T. (lpr)

7/19/11 Under Description section: added “Stents and tensioning devices are only able to reduce intraocular pressure (IOP) to the mid-teens, and may be inadequate when very low IOP is needed to reduce glaucoma damage.” Under “When Covered” section added: “Canaloplasty may be considered medically necessary as a method to reduce intraocular pressure in patients with glaucoma under the following conditions: medical therapy has failed to adequately control intraocular pressure, AND the patient is not a candidate for any other intraocular pressure lowering procedure (e.g. trabeculectomy or glaucoma drainage implant).” Under “When Not Covered” section: added “Use of a micro-stent is considered investigational.”

7/10/12 Specialty Matched Consultant Advisory Panel review meeting 6/20/12. Removed CPT codes 66174 and 66175 from Billing/Coding section. Removed canaloplasty references under When Covered section since new Canaloplasty policy addresses. Revised description section and policy guidelines. No changes to policy statement. (lpr)

12/11/12 Revised the description and policy guidelines sections. Under “When Not Covered” section added investigational statement: “Use of a micro-stent is considered investigational.” Notification given 12/11/12 for effective date 3/12/13. (lpr)

7/16/13 Specialty Matched consultant advisory panel review 6/19/2013. No changes to policy statement. (lpr)

10/29/13 Revised Description and Policy Guidelines sections. Under “When Covered” section added the statement “Implantation of a single FDA-approved micro-stent in conjunction with cataract surgery may be considered medically necessary in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.” Reference added. (lpr)
Aqueous Shunts and Devices for Glaucoma

12/31/13  Added CPT code 66183 and deleted 0192T from the Billing/Coding section for 2014 code update. (lpr)

7/15/14  Specialty matched consultant advisory panel meeting 6/24/2014. No change to policy statement. (lpr)

10/28/14  Minor revisions to Description and Policy Guidelines sections. Reference added. No change to policy statement. (lpr)

12/30/14  Added CPT codes 0376T, 66179, 66184 to the Billing/coding section for effective date 1/1/2015. (lpr)

7/28/15  Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)

10/30/15  Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)

4/29/16  Updated Policy Guidelines. Reference added. No change to policy statement. (lpr)

7/26/16  Specialty Matched Consultant Advisory Panel review 6/29/2016. Added CPT codes 0444T and 0445T to the Billing/Coding section for effective date 7/1/2016. No change to policy statement. (lpr)

12/30/16  Added CPT codes 0449T and 0450T to Billing/Coding section for effective date 1/1/2017. (lpr)

3/31/17  Added HCPCS codes C1783 and L8612 to the Billing/Coding section. Updated Description and Policy Guidelines sections. Removed the word “currently” from covered statement #2 beginning with “Implantation of a single FDA approved microstent…” under “When Covered” section. Reference added. (lpr)

7/28/17  Added CPT code 0474T to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.