Corporate Medical Policy

Aqueous Shunts and Devices for Glaucoma

File Name:	aqueous_shunts_and_devices_for_glaucoma
Origination:	3/2010
Last CAP Review:	6/2014
Next CAP Review:	6/2015
Last Review:	6/2014

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.

More recently the Trabectome™, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm's canal without external access or creation of a subconjunctival bleb. IOP with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. 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. Established shunts include the Ahmed™ (New World Medical), Baerveldt® (Advanced Medical Optics), Molteno®, Express® mini-shunt (Alco); and the SOLX® Deep Light® 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 is reduced with aqueous shunts in comparison with trabeculectomy, but IOP outcomes are higher than after standard guarded filtration surgery. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of postoperative infection is less than after trabeculectomy, and failure rates are similar, with about 10% of devices failing each year. The primary indication for aqueous shunts is when prior medical or surgical therapy has failed, although some ophthalmologists have advocated their use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

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

Since aqueous humor outflow is pressure dependent, the pressure in the reservoir and venous system are critical for reaching the target IOP. Therefore, some devices may be unable to reduce IOP below the pressure of the distal outflow system used, 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 shunts may be useful to lower IOP in patients with early stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is for patients with glaucoma who require cataract surgery. An advantage of ab-interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than one shunt to achieve the desired IOP. Therefore, health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy, complications and durability of the device.

Regulatory Status

The 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.

The Solx gold shunt is 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 nor 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

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.

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

Aqueous Shunts and Devices for Glaucoma

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 currently 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 adequately controlled by medications, is considered investigational.

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

Policy Guidelines

Randomized controlled trials have shown that the use of large externally placed shunts results with extraocular reservoirs results in success rates at least as good as standard filtering surgery (trabeculectomy). Therefore, use of FDA-approved shunts may be considered medically necessary as a method to reduce intraocular pressure in patients with glaucoma in whom medical treatments have failed to adequately control intraocular pressure.

Use of micro-stents has been studied in patients with both cataracts and less advanced glaucoma, where the IOP is at least partially controlled with medication. Results from these studies indicate that IOP may be lowered below baseline with decreased need for medication, although the benefit appears to diminish after the first year. A 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.

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, 66180, 66183*

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 12/10/2009

Senior Medical Director –3/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 5/12/2011

Specialty Matched Consultant Advisory Panel Review -6/2011.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 5/10/12

Specialty Matched Consultant Advisory Panel Review- 6/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 10/11/2012

Specialty Matched Consultant Advisory Panel Review- 6/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 9/12/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 3/13/2014

Specialty Matched Consultant Advisory Panel Review- 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 9/11/2014

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." (btw)

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 "under all other conditions, including angle closure glaucoma as a method to reduce intraocular pressure" to investigational statement. Specialty Matched Consultant Advisory Panel review meeting 6/29/2011. Reference added. (lpr)

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)

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 changes to policy statement. (lpr)

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