

Corporate Medical Policy

Aqueous Shunts and Devices for Glaucoma

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Last Review: 6/2011

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 and transluminal dilation procedures, are being evaluated as alternative surgical treatments for patients with 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.

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 between the anterior chamber (or vitreous chamber) and Schlemm's canal to facilitate drainage of aqueous humor. Established shunts include the Ahmed

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(New World Medical), Baerveldt (Advanced Medical Optics), Krupin (Eagle Vision) and Molteno (Molteno Ophthalmic). 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 shunts are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into an ocular reservoir. These include the iStent (Glaukos), which is inserted into the end of Schlemm's canal by either an internal (through the cornea and anterior chamber) or external approach (through the subconjunctiva); the EyePass Bi-Directional Glaucoma Implant (GMP =Companies), which is a Y-shaped shunt in which the 2 arms are placed ab externo into both lumina of Schlemm's canal; and the Solx DeepLight Gold Micro-Shunt (OccuLogix), which shunts aqueous humor between the anterior chamber and the suprachoroidal space.

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 iTrack (iScience Interventional) received 510(k) marketing clearance from the FDA in 2004 as a surgical ophthalmic microcannula that is indicated for the general purpose of “fluid infusion and aspiration, as well as illumination, during surgery.”

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 iStent, EyePass and Solx gold shunt are currently in FDA trials (the iStent trial's FDA investigational device exemption [IDE] designates the iStent as a category B device). In July 2010,

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the FDA's Ophthalmic Devices Panel voted that the benefits outweigh the risks of 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 subjects with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. The Micro-Shunt and Solx gold shunt have received regulatory approval in Europe. These are not FDA-approved/cleared for use in the U.S. at this time.

Related Policies

Glaucoma Testing

*****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

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.

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).

When Aqueous Shunts and Devices for Glaucoma are not covered

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** under all other conditions, including angle closure glaucoma as a method to reduce intraocular pressure.

Policy Guidelines

Randomized controlled trials have shown that the use of shunts results in success rates at least as good as standard filtering surgery, with similar complication rates. 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.

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Other studies have reported use of shunts 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 in some patients, but complications may lead to trabeculectomy within 6 months in a number of eyes. Since it cannot be determined whether trabeculectomy would have been required had these patients remained on medical therapy, randomized controlled trials with longer follow-up are needed to compare clinical outcomes from patients who have undergone cataract surgery combined with device placement or with continued medical management. In addition, the Trabectome study group reports that 3% of patients required subsequent glaucoma surgery following combined Trabectome/cataract surgery in a large series. Therefore, comparative trials with the Trabectome would help to evaluate whether device placement provides a health benefit over an ab interno surgical procedure that does not require permanent device implantation. Aqueous shunts and devices 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. As of April 2011, there are 2 ongoing clinical randomized trials comparing canaloplasty to trabeculectomy. Both studies, NCT01228799 and NCT00854256, are expected to be completed in 2012.

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, 0192T, 0253T, 66174, 66175, 66180

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.

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)

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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)

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.