Medical Coverage Policy | Surgical Treatments for Glaucoma

EFFECTIVE DATE: 04|07|2009
POLICY LAST UPDATED: 00|00|2014

OVERVIEW

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medications. 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.

PRIOR AUTHORIZATION

Prior authorization review is not required.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

Aqueous Shunts

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 in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered **not medically necessary** as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Microstents

Implantation of a single FDA-approved microstent 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.

Use of a microstent for all other conditions is considered **not medically necessary** as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Canaloplasty

Canaloplasty may be considered **medically necessary** as a method to reduce intraocular pressure in patients with chronic primary open-angle glaucoma under the following conditions: ~~when the conditions listed In the description are met.~~

- 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) due to a high risk for complications.

Canaloplasty is considered **not medically necessary** under all other conditions, including angle-closure glaucoma, as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective

~~**Micro-stent, Viscocanalostomy, Transciliary Fistulization:**~~

~~Use of a micro-stent, Viscocanalostomy and Transciliary fistulization for the treatment of glaucoma is considered **not medically necessary** as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.~~

Viscocanalostomy and Transciliary Fistulization

The use of viscocanalostomy and transciliary fistulization for the treatment of glaucoma is considered **not medically necessary** as these is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA

Not applicable.

BACKGROUND

Glaucoma is a disease characterized by degeneration of the optic disc. Elevated intraocular pressure (IOP) has long been thought to be the primary etiology, but the relationship between IOP and optic nerve damage varies among patients, suggesting a multifactorial origin. For example, some patients with clearly elevated IOP will show no damage to the optic nerve, while other patients with marginal or no pressure elevation will, nonetheless, show optic nerve damage. The association between glaucoma and other vascular disorders, such as diabetes or hypertension, suggests vascular factors may play a role in glaucoma. Specifically, it has been hypothesized that reductions in blood flow to the optic nerve may contribute to the visual field defects associated with glaucoma.

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 and deep sclerectomy, which removes the outer wall of Schlemm's canal and excises deep sclera and peripheral cornea. 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.

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. Microstents are also being evaluated in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Alternative nonpenetrating methods that are being evaluated for glaucoma are viscocanalostomy and canaloplasty. Transciliary fistulization for the treatment of glaucoma, also known as transciliary filtration or Singh filtration, is a recent approach to filtering surgery.

Aqueous Shunts

Aqueous shunts may 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® (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 use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

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 (IOP) in patients with moderate to severe glaucoma in whom medical treatments have failed to adequately control IOP. 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.

~~Aqueous shunts may also be placed between the anterior chamber (or vitreous chamber) and Schlemm's canal to facilitate drainage of aqueous humor. 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.~~

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Microstents

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 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, eg, below 15 mm Hg, and are not indicated for patients for whom very low IOP is desired (eg, 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. 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.

Use of microstents 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 microstent 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 microstent may be considered medically necessary when implanted concurrently with cataract surgery in patients who are unable to tolerate medication.

~~Other studies have reported use of micro-stents in a highly selected population of 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 in some patients, but the benefit appears to diminish after the first year. In addition, the need for additional procedures to address obstruction and malposition of the micro-stent is common. Although 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, the label includes a broad range of conditions in which the efficacy and safety of the iStent has not been established. Longer-term study in a broader patient population is needed to permit conclusions concerning the effect of this technology on health outcomes. Therefore, use of a micro-stent is considered not medically necessary as there is no proven efficacy.~~

Canaloplasty

Canaloplasty was developed from viscocanalostomy and 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 length of Schlemm's canal and to pass the suture loop through the canal. An important difference between viscocanalostomy and canaloplasty is that canaloplasty attempts to open the entire length of Schlemm's canal, rather than one section of it.

Positive 2- to 3-year outcomes have been reported for canaloplasty, along with a systematic review that found that Trabectome and canaloplasty provided modest IOP reduction (to about 16 mm Hg) with minimal intraoperative or postoperative complications. When combined with clinical input, the evidence is sufficient for canaloplasty to be considered medically necessary in the subset of patients for whom medical therapy has failed to adequately control intraocular pressure and in whom other surgical procedures are contraindicated ~~when the following conditions have been met:~~

- ~~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) due to a high risk for complications.~~

~~There is insufficient scientific literature to support the use of Canaloplasty for other conditions, including angle-closure glaucoma, therefore, all other indications are considered not medically necessary.~~

Viscocanalostomy

Viscocanalostomy is a variant of deep sclerectomy and unroofs and dilates Schlemm's canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution, such as sodium hyaluronate, is used to open the canal and create a passage from the canal to a scleral reservoir. It has been proposed that viscocanalostomy may lower IOP while avoiding bleb-related complications.

~~A number of small randomized trials have been conducted that compare viscocanalostomy with trabeculectomy. Meta-analysis of these trials indicates that trabeculectomy has a greater intraocular pressure-lowering effect than viscocanalostomy. Although trabeculectomy is associated with greater postoperative risk, most of the adverse events are mild and reversible. Reduction in IOP has also been shown to be greater with canaloplasty than viscocanalostomy in a small within-subject comparison.~~

The clinical input obtained for viscocanalostomy was mixed. Overall, the evidence is insufficient to evaluate health outcomes with this procedure in comparison with currently accepted alternatives. Therefore, viscocanalostomy is considered not medically necessary as there is no proven efficacy.

Transciliary Fistilization

This procedure uses a thermocauterization device called the Fugo blade to create a plasma-ablated pore or filter track from the sclera through the ciliary body to allow aqueous fluid to ooze into the subconjunctival lymphatics from the posterior chamber (behind the iris) of the eye. Plasma ablation with the Fugo blade allows the highly vascular ciliary body to be penetrated with little or no bleeding. Transciliary fistulization allows aqueous fluid to drain from the posterior chamber of the eye and differs from conventional filtering surgeries, such as trabeculoplasty, trabeculectomy, and drainage implant surgery, in which aqueous fluid is filtered from the anterior chamber of the eye.

The limited literature since 2002 suggests poor acceptance of this procedure by the ophthalmologic community; the reasons for this are not clear. While this procedure is similar to other filtration procedures commonly performed for the surgical treatment of glaucoma, further studies with longer term follow-up are needed. Overall, the data are insufficient to determine the long-term health outcomes of transciliary fistulization for the treatment of glaucoma. Therefore, the service is considered not medically necessary.

COVERAGE

~~Benefits may vary between groups/contracts. Please refer to the appropriate member certificate/subscriber agreement for applicable surgery coverage/benefits.~~

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable surgery coverage/benefits and limitations of benefits/coverage when services are not medically necessary.

CODING

BlueCHiP for Medicare and Commercial

Aqueous Shunts and Microstents

The following codes are **medically necessary** when used according to the criteria references in the Policy Statement:

0191T, ~~0192T~~, 0253T, 66180, 66183

There are no specific CPT or HCPCS codes for Microstents, therefore providers should report this service with an unlisted procedure code.

66999

~~**Note:** When these codes are used to report Micro-stents they are considered not medically necessary.~~

Canaloplasty and Viscocanalostomy

The following codes are considered **medically necessary** when used to report Canalostomy:

66174, 66175

~~**Note:** When these codes are used to report Viscocanalostomy they are considered not medically necessary.~~

There are no specific CPT or HCPCS codes to report Viscocanalostomy, therefore providers should report this service with an unlisted procedure code.

66999

Transciliary Fistulization
The following code is **not medically necessary:**

0123T

RELATED POLICIES

~~None~~
Not applicable.

PUBLISHED

Provider Update	Jul	2013
Provider Update	Jul	2011
Provider Update	Jul	2010
Provider Update	Jun	2009

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