Medical Coverage Policy

Surgical Treatments for Glaucoma

☐ Device/Equipment ☐ Drug ☐ Medical ☒ Surgery ☐ Test ☐ Other

Effective Date:	4/7/2009	Policy Last Updated:	5/7/2013

☐ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☒ **Prospective review is not required.**

Description:

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.

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. 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.

Transciliary fistulization for the treatment of glaucoma, also known as transciliary filtration or Singh filtration, is a recent approach to filtering surgery. 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. However, 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.

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.

Randomized controlled trials have shown that the use of shunts 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 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 not medically necessary.

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.

Alternative nonpenetrating methods that are being evaluated for glaucoma are viscocanalostomy and canaloplasty. 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.

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.

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 in 2011 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.

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.

Medical Criteria:
None

Policy:

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.

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

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.

Coverage:

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

Coding:

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

Transciliary Fistulization
0123T Fistulization of sclera for glaucoma, through ciliary body

The following codes are **medically necessary:**
Aqueous Shunts:
0191T Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach
0192T Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach
0253T Insertion of anterior segment aqueous drainage device, without extraocular reservois; internal approach, into the suprachorodial space

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

Canaloplasty:
66174 Transluminal dilation of aqueous outflow canal; without retention of device or stent
66175 Transluminal dilation of aqueous outflow canal;with retention of device or stent

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

Also Known As:
None

Related Topics:
None

Published:
Provider Update, July 2013
Provider Update, July 2011
Provider Update, July 2010
Provider Update,June 2009

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History:

April 2013 - Annual Review

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