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Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With open-angle glaucoma who have failed medical therapy	Interventions of interest are: • Viscocanalostomy	Comparators of interest are: • Intraocular pressure- lowering procedure (e.g., glaucoma drainage implant or trabeculectomy)	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Medication use
Individuals: • With open-angle glaucoma who have failed medical therapy	Interventions of interest are: • Canaloplasty	Comparators of interest are: • Intraocular pressure- lowering procedure (e.g., glaucoma drainage implant or trabeculectomy)	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Medication use

DESCRIPTION

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 (e.g., trabeculectomy), alternative surgical treatments (e.g., transluminal dilation by viscocanalostomy or canaloplasty) are being evaluated for patients with glaucoma.

SUMMARY OF EVIDENCE

For individuals who have open-angle glaucoma who have failed medical therapy who receive viscocanalostomy, the evidence includes small randomized controlled trials (RCTs) comparing viscocanalostomy with trabeculectomy. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. Meta-analysis of these trials has indicated that trabeculectomy has a greater IOP-lowering effect than viscocanalostomy. Reduction in IOP was greater with canaloplasty than viscocanalostomy in a small within-subject comparison. Viscocanalostomy has not been shown to be as good as or better than established alternatives. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

For individuals who have open-angle glaucoma who have failed medical therapy who receive canaloplasty, the evidence includes an RCT, a comparative effectiveness review, and several case series. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. The RCT found not only significantly higher complete success rates with trabeculectomy than with canaloplasty, but also higher complication rates. The qualified

success rate (with medication) was similar between groups. A systematic review found that canaloplasty provided modest IOP reduction (to ≈ 16 mm Hg) with minor intraoperative or postoperative complications. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Viscocanalostomy is considered **not medically necessary**.

Canaloplasty may be considered **medically necessary** as a method to reduce intraocular pressure (IOP) in patients with chronic primary open-angle glaucoma under the following conditions:

- Medical therapy has failed to adequately control IOP, AND
- The patient is not a candidate for any other IOP-lowering procedure (e.g., trabeculectomy or glaucoma drainage implant) due to a high risk for complications.

Canaloplasty is considered **investigational** under all other conditions, including angle-closure glaucoma.

POLICY GUIDELINES

Tensioning devices are only able to reduce IOP to the mid-teens, and may be inadequate when very low IOP is needed to reduce glaucoma damage.

BACKGROUND

IMPAIRED AQUEOUS HUMOR DRAINAGE

In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm 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 canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

Treatment

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 with a filtering “bleb” on the eye, which can effectively reduce IOP, but is associated with numerous and sometimes sight-threatening complications (e.g., leaks, hypotony, choroidal effusions and hemorrhages, hyphemas or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed herein) include trabecular laser ablation and deep sclerectomy, which removes the outer wall of Schlemm 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 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. Aqueous shunts may also be placed to facilitate drainage of aqueous humor (see the Aqueous Shunts and Stents for Glaucoma Protocol). Complications from anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva.

Alternative nonpenetrating methods being evaluated to treat glaucoma are viscocanalostomy and canaloplasty. Visccanalostomy is a variant of deep sclerectomy and unroofs and dilates the Schlemm canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution (e.g., sodium hyaluronate) is used to open the canal and create a passage from the canal to a scleral reservoir. It has been proposed that visccanalostomy may lower IOP while avoiding bleb-related complications.

Canaloplasty, which evolved from visccanalostomy, involves dilation and tension of the Schlemm 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 to access and dilate the length of the Schlemm canal and to pass the suture loop through the canal. An important difference between visccanalostomy and canaloplasty is that canaloplasty attempts to open the entire length of the Schlemm canal, rather than one section of it.

Because aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system is critical for reaching the target IOP. Therefore, some procedures may not reduce IOP below the pressure of the distal outflow system used (e.g., <15 mm Hg), and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma).

Outcome Measures

Health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy if the procedure is unsuccessful, complications, and durability of the procedure.

REGULATORY STATUS

In 2004, iTrack™ (iScience Interventional) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process as a surgical ophthalmic microcannula that is indicated for the general purpose of “fluid infusion and aspiration, as well as illumination, during surgery.” In 2008, iTrack™ was cleared by the Food and Drug Administration for “catheterization and viscodilation of [the] Schlemm canal to reduce intraocular pressure in adult patients with open angle glaucoma.” Food and Drug Administration product code: MPA.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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