Protocol

Viscocanalostomy and Canaloplasty

(90326)

Medical Benefit		**Effective Date**: 04/01/12	**Next Review Date**: 01/15
Preauthorization	No	**Review Dates**: 01/12, 01/13, 01/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *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.*

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 such as trabeculectomy, alternative surgical treatments such as transluminal dilation by viscocanalostomy and canaloplasty are being evaluated for patients with glaucoma.

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 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 in this Protocol) 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. 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. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva.

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.

Since 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 be able to reduce IOP below the pressure of the distal outflow system used, e.g., below 15 mm Hg, and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma). 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

The iTrack (iScience Interventional) received 510(k) marketing clearance from the U.S. Food and Drug Administration (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." In 2008, the iTrack received FDA-clearance for the indication of "catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma."

Related Protocol

Aqueous Shunts and Stents for Glaucoma

Policy (Formerly Corporate Medical Guideline)

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:

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

Viscocanalostomy is considered **investigational**.

Policy Guideline

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.

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.

1. Chai C, Loon SC. Meta-analysis of viscocanalostomy versus trabeculectomy in uncontrolled glaucoma. J Glaucoma 2010; 19(8):519-27.
2. Gilmour DF, Manners TD, Devonport H et al. Viscocanalostomy versus trabeculectomy for primary open angle glaucoma: 4-year prospective randomized clinical trial. Eye (Lond) 2009; 23(9):1802-7.
3. Kobayashi H, Kobayashi K, Okinami S. A comparison of the intraocular pressure-lowering effect and safety of viscocanalostomy and trabeculectomy with mitomycin C in bilateral open-angle glaucoma. Graefes Arch Clin Exp Ophthalmol 2003; 241(5):359-66.
4. Stangos AN, Mavropoulos A, Leuenberger PM et al. The effect of learning curve on the surgical outcome of viscocanalostomy. J Glaucoma 2012; 21(6):408-14.
5. Lewis RA, von Wolff K, Tetz M et al. Canaloplasty: circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults: interim clinical study analysis. J Cataract Refract Surg 2007; 33(7):1217-26.
6. Lewis RA, von Wolff K, Tetz M et al. Canaloplasty: circumferential viscodilation and tensioning of Schlemm canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults: two-year interim clinical study results. J Cataract Refract Surg 2009; 35(5):814-24.
7. Lewis RA, Von Wolff K, Tetz M et al. Canaloplasty: Three-year results of circumferential viscodilation and tensioning of Schlemm canal using a microcatheter to treat open-angle glaucoma. J Cataract Refract Surg 2011; 37(4):682-90.
8. Shingleton B, Tetz M, Korber N. Circumferential viscodilation and tensioning of Schlemm canal (canaloplasty) with temporal clear corneal phacoemulsification cataract surgery for open-angle glaucoma and visually significant cataract: one-year results. J Cataract Refract Surg 2008; 34(3):433-40.
9. Koerber NJ. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. J Glaucoma 2012; 21(2):129-34.
10. Bull H, von Wolff K, Korber N et al. Three-year canaloplasty outcomes for the treatment of open-angle glaucoma: European study results. Graefes Arch Clin Exp Ophthalmol 2011; 249(10):1537-45.
11. Grieshaber MC, Pienaar A, Olivier J et al. Canaloplasty for primary open-angle glaucoma: long-term outcome. Br J Ophthalmol 2010; 94(11):1478-82.
12. Mosaed S, Dustin L, Minckler DS. Comparative outcomes between newer and older surgeries for glaucoma. Trans Am Ophthalmol Soc 2009; 107:127-33.
13. American Academy of Ophthalmology. Preferred practice pattern: Primary open-angle glaucoma 2010. Available online at: http://one.aao.org/ce/default.aspx. Last accessed March, 2011.
14. Francis BA, Singh K, Lin SC et al. Novel glaucoma procedures: a report by the American Academy of Ophthalmology. Ophthalmology 2011; 118(7):1466-80.

15. National Institute for Health and Clinical Evidence (NICE). Canaloplasty for primary open-angle glaucoma. 2008. Available online at: http://www.nice.org.uk/nicemedia/live/11911/40769/40769.pdf. Last accessed March, 2011.
16. National Institute for Health and Clinical Excellence (NICE). Glaucoma: Diagnosis and Management of Chronic Open Angle Glaucoma and Ocular Hypertension. 2009. Available online at: http://www.nice.org.uk/nicemedia/live/12145/43887/43887.pdf. Last accessed August, 2011.