

EFFECTIVE DATE: 08|19|2014
POLICY LAST UPDATED: 09|18|2018

OVERVIEW

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 visco canalostomy and canaloplasty are being evaluated for patients with glaucoma.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

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.

BlueCHiP for Medicare

Canaloplasty is not covered under all other conditions, including angle-closure glaucoma, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Visco canalostomy is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Canaloplasty is considered **not medically necessary** under all other conditions, including angle-closure glaucoma, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Visco canalostomy is considered **not medically necessary** as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery not medically necessary/not covered benefits/coverage.

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. 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 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 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 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 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 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.

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.”

For individuals who have open-angle glaucoma who have failed medical therapy who receive viscocanalostomy, 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 is insufficient to determine the effects of the technology on health outcomes.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are considered medically necessary:

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 Visco canalostomy, they are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products.

RELATED POLICIES

Aqueous Shunts and Stents for Glaucoma

PUBLISHED

Provider Update, November/December 2018

Provider Update, November 2017

Provider Update, July 2016

Provider Update, December 2015

Provider Update, November 2014

REFERENCES

1. Chai C, Loon SC. Meta-analysis of visco canalostomy versus trabeculectomy in uncontrolled glaucoma. *J Glaucoma*. Oct-Nov 2010;19(8):519-527. PMID 20179632
2. Eldaly MA, Bunce C, Elsheikha OZ, et al. Non-penetrating filtration surgery versus trabeculectomy for open-angle glaucoma. *Cochrane Database Syst Rev*. 2014;2:CD007059. PMID 24532137
3. Gilmour DF, Manners TD, Devonport H, et al. Visco canalostomy versus trabeculectomy for primary open angle glaucoma: 4-year prospective randomized clinical trial. *Eye (Lond)*. Sep 2009;23(9):1802-1807. PMID 17293790
4. Kobayashi H, Kobayashi K, Okinami S. A comparison of the intraocular pressure-lowering effect and safety of visco canalostomy and trabeculectomy with mitomycin C in bilateral open-angle glaucoma. *Graefes Arch Clin Exp Ophthalmol*. May 2003;241(5):359-366. PMID 12698257
5. Grieshaber MC, Peckar C, Pienaar A, et al. Long-term results of up to 12 years of over 700 cases of visco canalostomy for open-angle glaucoma. *Acta Ophthalmol*. Jun 2015;93(4):362-367. PMID 25270165
6. Stangos AN, Mavropoulos A, Leuenberger PM, et al. The effect of learning curve on the surgical outcome of visco canalostomy. *J Glaucoma*. Aug 2012;21(6):408-414. PMID 21673593
7. Mosaed S, Dustin L, Minckler DS. Comparative outcomes between newer and older surgeries for glaucoma. *Trans Am Ophthalmol Soc*. Dec 2009;107:127-133. PMID 20126489
8. Matlach J, Dhillon C, Hain J, et al. Trabeculectomy versus canaloplasty (TVC study) in the treatment of patients with open-angle glaucoma: a prospective randomized clinical trial. *Acta Ophthalmol*. Dec 2015;93(8):753-761. PMID 25847610
9. Klink T, Sauer J, Korber NJ, et al. Quality of life following glaucoma surgery: canaloplasty versus trabeculectomy. *Clin Ophthalmol*. 2015;9:7-16. PMID 25565763
10. Ayyala RS, Chaudhry AL, Okogbaa CB, et al. Comparison of surgical outcomes between canaloplasty and trabeculectomy at 12 months' follow-up. *Ophthalmology*. Dec 2011;118(12):2427-2433. PMID 21856008
11. 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*. Jul 2007;33(7):1217-1226. PMID 17586378
12. 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*. May 2009;35(5):814-824. PMID 19393879
13. 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*. Apr 2011;37(4):682-690. PMID 21420593

14. 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*. Mar 2008;34(3):433-440. PMID 18299068
15. Koerber NJ. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. *J Glaucoma*. Feb 2012;21(2):129-134. PMID 21278587
16. 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*. Oct 2011;249(10):1537-1545. PMID 21732110
17. Grieshaber MC, Pienaar A, Olivier J, et al. Canaloplasty for primary open-angle glaucoma: long-term outcome. *Br J Ophthalmol*. Nov 2010;94(11):1478-1482. PMID 20962352
18. Brusini P. Canaloplasty in open-angle glaucoma surgery: a four-year follow-up. *ScientificWorldJournal*. 2014;2014:469609. PMID 24574892
19. Voykov B, Blumenstock G, Leitritz MA, et al. Treatment efficacy and safety of canaloplasty for open-angle glaucoma after 5 years. *Clin Experiment Ophthalmol*. Nov 2015;43(8):768-771. PMID 25952140
20. Francis BA, Singh K, Lin SC, et al. Novel glaucoma procedures: a report by the American Academy of Ophthalmology. *Ophthalmology*. Jul 2011;118(7):1466-1480. PMID 21724045
21. National Institute for Health and Care Evidence (NICE). Canaloplasty for primary open-angle glaucoma [IPG260]. 2008; <https://www.nice.org.uk/guidance/ipg260>. Accessed February 16, 2018.
22. National Institute for Health and Care Evidence (NICE). Ab externo canaloplasty for primary open-angle glaucoma [IPG591]. 2017; <https://www.nice.org.uk/guidance/ipg591>. Accessed February 16, 2018.
23. National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management of chronic open angle glaucoma and ocular hypertension [CG85]. 2009; <https://www.nice.org.uk/guidance/cg85>. Accessed February 18, 2018.
24. National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management [NG81]. 2017; <https://www.nice.org.uk/guidance/NG81>. Accessed February 16, 2018.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

