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POLICY LAST REVIEWED: 03|20|2024

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 individuals with glaucoma.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

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

- Medical therapy has failed to adequately control intraocular pressure, AND
- The individual 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.

Medicare Advantage Plans

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.

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.”

In 2017, the OMNI® Surgical System (Sight Sciences, Inc.) was cleared for marketing by the FDA through the 510(k) process as a manually operated device for the delivery of small amounts of viscoelastic fluid during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculectomy procedures (K173332). In 2020, the OMNI® Plus Surgical System was cleared for the same indications for use as the

predicate OMNI system (K201953). In 2021, the OMNI® Surgical System was cleared for marketing by the FDA through the 510(k) process for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma.

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 intraocular pressure lowering effect than viscocanalostomy. Reduction in intraocular pressure 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 insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have open-angle glaucoma who have failed medical therapy who receive canaloplasty, the evidence includes RCTs, a comparative effectiveness review, and several case series. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. The RCTs found significantly higher complete success rate with trabeculectomy than with canaloplasty in one trial and a significantly lower mean intraocular pressure in another trial. However, higher complication rates were also observed with trabeculectomy. A non-randomized study found both canaloplasty and iStent bypass implantation, when combined with phacoemulsion had similar 1-year post-surgery intraocular pressure and glaucoma medication reductions, but canaloplasty resulted in more early postoperative complications. A systemic review found that canaloplasty provided modest intraocular pressure reduction (to ~16 mmHg) with minor intraoperative or postoperative complications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) for a canaloplasty are considered medically necessary when filed with a covered ICD-10 code, below:

- 66174** Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or Stent
- 66175** Transluminal dilation of aqueous outflow canal (eg, canaloplasty); with retention of device or stent

Covered ICD-10-CM:

H40.10X0 – H42

The following Unlisted CPT code should be filed for a viscocanalostomy, which is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 66999** Unlisted procedure, anterior segment of eye

RELATED POLICIES

Aqueous Shunts and Stents for Glaucoma

PUBLISHED

Provider Update, May 2024
Provider Update, June 2023
Provider Update, July 2022
Provider Update, September 2021
Provider Update, June 2020

REFERENCES

1. Allison K, Patel DG, Greene L. Racial and Ethnic Disparities in Primary Open-Angle Glaucoma Clinical Trials: A Systematic Review and Meta-analysis. *JAMA Netw Open*. May 03 2021; 4(5): e218348. PMID 34003274
2. Chai C, Loon SC. Meta-analysis of viscocanalostomy versus trabeculectomy in uncontrolled glaucoma. *J Glaucoma*. Oct-Nov 2010;19(8):519-527. PMID 20179632
3. 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
4. Gilmour DF, Manners TD, Devonport H, et al. Viscocanalostomy versus trabeculectomy for primary open angle glaucoma: 4-year prospective randomized clinical trial. *Eye (Lond)*. Sep 2009;23(9):1802-1807. PMID 17293790
5. 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*. May 2003;241(5):359-366. PMID 12698257
6. Grieshaber MC, Peckar C, Pienaar A, et al. Long-term results of up to 12 years of over 700 cases of viscocanalostomy for open-angle glaucoma. *Acta Ophthalmol*. Jun 2015;93(4):362-367. PMID 25270165
7. Stangos AN, Mavropoulos A, Leuenberger PM, et al. The effect of learning curve on the surgical outcome of viscocanalostomy. *J Glaucoma*. Aug 2012;21(6):408-414. PMID 21673593
8. 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
9. 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
10. 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
11. Yin P, Li J, Shi Y, et al. Ab interno canaloplasty versus gonioscopy-assisted transluminal trabeculectomy in open-angle glaucoma: a randomised controlled trial. *Br J Ophthalmol*. Jun 13 2023. PMID 37311600
12. Golaszewska K, Obuchowska I, Konopińska J. First-Generation iStent Bypass Implantation versus ab Externo Canaloplasty Combined with Phacoemulsification in Patients with Primary Open Angle Glaucoma-12-Month Follow-Up. *J Clin Med*. Sep 01 2023; 12(17). PMID 37685778
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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

21. Brusini P. Canaloplasty in open-angle glaucoma surgery: a four-year follow-up. *ScientificWorldJournal*. 2014;2014:469609. PMID 24574892
22. 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
23. Gallardo MJ. 36-Month Effectiveness of Ab-Interno Canaloplasty Standalone versus Combined with Cataract Surgery for the Treatment of Open-Angle Glaucoma. *Ophthalmol Glaucoma*. 2022; 5(5): 476-482. PMID 35183815
24. Koerber N, Ondrejka S. Four-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Open-Angle Glaucoma. *Klin Monbl Augenheilkd*. Apr 14 2022. PMID 35426107
25. Khaimi MA, Koerber N, Ondrejka S, et al. Consistency in Standalone Canaloplasty Outcomes Using the iTrack Microcatheter. *Clin Ophthalmol*. 2024; 18: 173-183. PMID 38250597
26. Koerber N, Ondrejka S. 6-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Primary Open-Angle and Pseudoexfoliative Glaucoma. *J Glaucoma*. Sep 12 2023. PMID 37725787
27. Murphy Iii JT, Terveen DC, Aminlari AE, et al. A Multicenter 12-Month Retrospective Evaluation of Canaloplasty and Trabeculotomy in Patients with Open-Angle Glaucoma: The ROMEO 2 Study. *Clin Ophthalmol*. 2022; 16: 3043-3052. PMID 36128338
28. Ondrejka S, Körber N, Dhamdhare K. Long-term effect of canaloplasty on intraocular pressure and use of intraocular pressure-lowering medications in patients with open-angle glaucoma. *J Cataract Refract Surg*. Dec 01 2022; 48(12): 1388-1393. PMID 35796586
29. Gallardo MJ, Pyfer MF, Vold SD, et al. Canaloplasty and Trabeculotomy Combined with Phacoemulsification for Glaucoma: 12-Month Results of the GEMINI Study. *Clin Ophthalmol*. 2022; 16: 1225-1234. PMID 35493971
30. Gallardo MJ, Dhamdhare K, Dickerson JE. Canaloplasty and Trabeculotomy Ab Interno Combined with Cataract Surgery: 12-Month Outcomes in Hispanic Patients with Open-Angle Glaucoma. *Clin Ophthalmol*. 2022; 16: 905-908. PMID 35356700
31. Yadgarov A, Dentice K, Aljabi Q. Real-World Outcomes of Canaloplasty and Trabeculotomy Combined with Cataract Surgery in Eyes with All Stages of Open-Angle Glaucoma. *Clin Ophthalmol*. 2023; 17: 2609-2617. PMID 37674592
32. Greenwood MD, Yadgarov A, Flowers BE, et al. 36-Month Outcomes from the Prospective GEMINI Study: Canaloplasty and Trabeculotomy Combined with Cataract Surgery for Patients with Primary Open-Angle Glaucoma. *Clin Ophthalmol*. 2023; 17: 3817-3824. PMID 38105915
33. Terveen DC, Sarkisian SR, Vold SD, et al. Canaloplasty and trabeculotomy with the OMNI ® surgical system in OAG with prior trabecular microbypass stenting. *Int Ophthalmol*. Oct 13 2022. PMID 36229561
34. 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
35. 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 January 30, 2024.
36. National Institute for Health and Care Evidence (NICE). Canaloplasty for primary open-angle glaucoma [IPG260]. 2008; <https://www.nice.org.uk/guidance/ipg260>. Accessed January 29, 2024.
37. National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management [NG81]. 2022; <https://www.nice.org.uk/guidance/NG81>. Accessed January 28, 2024.
38. National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management [NG81]. 2022; <https://www.nice.org.uk/guidance/NG81>. Accessed January 27, 2024.
39. National Institute for Health and Care Excellence (NICE). Ab interno canaloplasty for open-angle glaucoma [IPG745]. 2022; <https://www.nice.org.uk/guidance/ipg745>. Accessed January 26, 2024.

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