



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:
Viscocanalostomy and Canaloplasty

Policy #: 505
Category: Surgery

Latest Review Date: March 2020
Policy Grade: A

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on and after October 4, 2017:

Blue Advantage will treat canaloplasty as a covered benefit 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.

Blue Advantage will treat canaloplasty as a noncovered benefit and as investigational under all other conditions, including angle-closure glaucoma.

Blue Advantage will treat viscocanalostomy as a noncovered benefit and as investigational.

Blue Advantage will treat trabeculectomy surgery using ab interno (i.e. Trabectome™) as a non-covered benefit and as investigational.

Effective for dates of service on and after January 1, 2011 and prior to October 4, 2017:

Blue Advantage will treat canaloplasty as a covered benefit 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.

Blue Advantage will treat canaloplasty as a non-covered benefit and as investigational under all other conditions, including angle-closure glaucoma.

Blue Advantage will treat viscocanalostomy as a non-covered benefit and as investigational.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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'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.

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 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. 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 MP #324 Aqueous Shunts for Glaucoma*). 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, which evolved from viscocanalostomy, 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 viscocanalostomy 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 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).

KEY POINTS:

The most recent literature review was updated through January 13, 2020.

Summary of Evidence:

For individuals who have open-angle glaucoma who have failed medical therapy who receive viscocanalostomy, the evidence includes small 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 \approx 16 mm Hg) with minor intraoperative or postoperative complications.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

A technology assessment from the American Academy of Ophthalmology (2011) included canaloplasty in its review of novel glaucoma procedures. The Academy concluded that all the techniques and devices reviewed were still in the initial stage (\leq 5 years) of clinical experience and lacked widespread use, with only Level III evidence (cohort studies) supporting the procedures. In addition to describing potential advantages and disadvantages of the procedure, it was noted that the long-term effects of a foreign body in the Schlemm canal are not known.

National Institute for Health and Clinical Excellence

In 2017, the National Institute for Health and Care Excellence (NICE) updated its 2008 guidance on canaloplasty for primary open-angle glaucoma. The current recommendation is that the “evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is inadequate to support the use of this procedure....”

Similarly, in 2017, NICE updated its 2009 guidance on the diagnosis and management of chronic open-angle glaucoma. When comparing penetrating surgery (trabeculectomy) with

nonpenetrating surgery (deep sclerectomy and viscocanalostomy), NICE found moderate-quality evidence that trabeculectomy is more effective than nonpenetrating surgery in reducing the number of eyes with an unacceptable intraocular pressure (IOP), but was more likely to cause cataract formation and persistent hypotony at 12- to 36-month follow-up. There was very low quality evidence that trabeculectomy is more effective than nonpenetrating surgery in reducing IOP from baseline to 6- and 12-month follow-up, but the effect size might have been too small to be clinically significant. The guidance recommended offering information on the risks and benefits associated with surgery and offering surgery (type not specified) with pharmacologic augmentation to people with chronic open-angle glaucoma at risk of progressing to sight loss, despite treatment.

U.S. Preventive Services Task Force Recommendations:
Not applicable.

KEY WORDS:

iTrack, Viscocanalostomy, Canaloplasty, surgical ophthalmic microcannula, Trabectome, Trabeculectomy, Viscocanalostomy, ab interno, Trabeculotomy

APPROVED BY GOVERNING BODIES:

In 2004, the iTrack (iScience Interventional) was cleared for marketing by the U.S. Food and Drug Administration (FDA) 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, the iTrack received FDA clearance for “catheterization and viscodilation of Schlemm canal to reduce intraocular pressure in adult patients with open angle glaucoma.”

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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

REFERENCES:

1. American Academy of Ophthalmology. Preferred practice pattern: Primary open-angle glaucoma 2010. one.aao.org/preferred-practice-pattern/primary-openangle-glaucoma-ppp--october-2010.

2. 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.
3. Brusini P. Canaloplasty in open-angle glaucoma surgery: a four-year follow-up. *ScientificWorldJournal*. 2014; 2014:469609.
4. 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.
5. Chai C, Loon SC. Meta-analysis of viscocanalostomy versus trabeculectomy in uncontrolled glaucoma. *J Glaucoma* 2010; 19(8):519-27.
6. 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.
7. 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.
8. 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.
9. 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.
10. 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.
11. Klink T, Sauer J, Korber NJ, et al. Quality of life following glaucoma surgery: canaloplasty versus trabeculectomy. *Clin Ophthalmol*. 2015; 9:7-16.
12. 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.
13. 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.
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* 2007; 33(7):1217-26.
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* 2009; 35(5):814-24.
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* 2011; (in press).
17. 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*. Apr 3 2015.
18. Mosaed S, Dustin L, Minckler DS. Comparative outcomes between newer and older surgeries for glaucoma. *Trans Am Ophthalmol Soc* 2009; 107:127-33.

19. 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.
20. National Institute for Health and Clinical Evidence (NICE). Canaloplasty for primary open-angle glaucoma. 2008. Available online at: www.nice.org.uk/nicemedia/live/11911/40769/40769.pdf. Accessed February 16, 2018.
21. National Institute for Health and Clinical Excellence (NICE). Glaucoma: Diagnosis and Management of Chronic Open Angle Glaucoma and Ocular Hypertension. 2009. Available online at: www.nice.org.uk/nicemedia/live/12145/43887/43887.pdf. Accessed February 18, 2019.
22. 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.
23. 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.
24. 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.
25. 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.

POLICY HISTORY:

Adopted for Blue Advantage, January 1, 2011

Medical Policy Group, October 2012

Medical Policy Group, September 2013

Medical Policy Group, September 2014

Medical Policy Group, September 2015

Medical Policy Group, March 2016

Medical Policy Group, March 2017

Medical Policy Group, October 2017

Medical Policy Group, March 2018

Medical Policy Group, April 2019

Medical Policy Group, March 2020

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.