



## Medical Policy

### Viscocanalostomy and Canaloplasty

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#### Policy Number: 372

BCBSA Reference Number: 9.03.26 (For Plan internal use only)  
 NCD/LCD: N/A

#### Related Policies

None

#### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Canaloplasty may be considered **MEDICALLY NECESSARY** as a method to reduce intraocular pressure (IOP) in individuals 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 (eg, 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**.

#### Prior Authorization Information

##### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

##### Outpatient

- For services described in this policy, see below for situations where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .
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## CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

### CPT Codes

CPT Codes:	Description
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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if **medical necessity criteria** are met:

### ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
H40.1110	Primary open-angle glaucoma, right eye, stage unspecified
H40.1111	Primary open-angle glaucoma, right eye, mild stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1113	Primary open-angle glaucoma, right eye, severe stage
H40.1114	Primary open-angle glaucoma, right eye, indeterminate stage
H40.1120	Primary open-angle glaucoma, left eye, stage unspecified
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1124	Primary open-angle glaucoma, left eye, indeterminate stage
H40.1130	Primary open-angle glaucoma, bilateral, stage unspecified
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1133	Primary open-angle glaucoma, bilateral, severe stage
H40.1134	Primary open-angle glaucoma, bilateral, indeterminate stage
H40.1190	Primary open-angle glaucoma, unspecified eye, stage unspecified
H40.1191	Primary open-angle glaucoma, unspecified eye, mild stage
H40.1192	Primary open-angle glaucoma, unspecified eye, moderate stage
H40.1193	Primary open-angle glaucoma, unspecified eye, severe stage
H40.1194	Primary open-angle glaucoma, unspecified eye, indeterminate stage

### Description

## **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 intraocular pressure and glaucoma risk.

### **Treatment**

Surgical intervention may be indicated in individuals with glaucoma when the target intraocular pressure 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 intraocular pressure, but is associated with numerous and sometimes sight-threatening complications (eg, 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. Intraocular pressure 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 evidence review 9.03.21). 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. Viscocanalostomy 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 (eg, 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 intraocular pressure 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.

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

## **Summary**

Glaucoma surgery is intended to reduce intraocular pressure when the target intraocular pressure cannot be reached with medications. Due to complications with established surgical approaches (eg, trabeculectomy), alternative surgical treatments (eg, transluminal dilation by viscocanalostomy or canaloplasty) are being evaluated for individuals 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

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 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 intraocular pressure reduction (to ~16 mm Hg) with minor intraoperative or postoperative complications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Policy History

Date	Action
5/2022	Annual policy review. Not medically necessary policy statement changed to Investigational for policy standardization purposes. Policy intent unchanged.
5/2021	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2018	New references added from BCBSA National medical policy. Background and summary clarified. Prior Authorization Information reformatted.
5/2017	BCBSA National medical policy review. Policy statement on viscocanalostomy clarified to state that it is not medically necessary.
10/2016	Clarified coding information.
4/2016	New references added from BCBSA National medical policy.
11/2015	New references added from BCBSA National medical policy.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
11/2013	Removed CPT code 66180 as it does not meet the intent of the policy.
9/1/12	New policy describing ongoing coverage and non-coverage.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Chai C, Loon SC. Meta-analysis of viscocanalostomy versus trabeculectomy in uncontrolled glaucoma. *J Glaucoma*. Oct-Nov 2010; 19(8): 519-27. 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*. Feb 15 2014; (2): CD007059. PMID 24532137
3. 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): 1802-7. PMID 17293790

4. 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): 359-66. PMID 12698257
5. 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): 362-7. PMID 25270165
6. 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): 408-14. 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: 127-33. 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): 753-61. 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): 2427-33. 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): 1217-26. 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): 814-24. 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): 682-90. 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): 433-40. 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): 129-34. 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): 1537-45. 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): 1478-82. 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 Exp Ophthalmol*. Nov 2015; 43(8): 768-71. 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): 1466-80. PMID 21724045
21. 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 25, 2022.
22. 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 23, 2022.
23. National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management [NG81]. 2017; <https://www.nice.org.uk/guidance/NG81>. Accessed February 24, 2022.
24. 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 26, 2022.

