

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

# Medical Policy Viscocanalostomy and Canaloplasty

#### **Table of Contents**

- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- <u>Description</u>
- Policy History
- Information Pertaining to All Policies
- References

#### 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 <u>MEDICALLY NECESSARY</u> 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 individual 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 <u>IS REQUIRED</u> if the procedure is performed inpatient.

Outpatient

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

	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> .
---------------------------------	--

## 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 <u>medical necessity criteria MUST</u> 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 <u>medical necessity criteria</u> are met:

ICD-10	Diagno	sis	Codes	
100 40	014			

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

#### Glaucoma

Glaucoma is the leading cause of irreversible blindness worldwide and is characterized by elevated intraocular pressure (IOP). In 2020, glaucoma affected approximately 52.7 million individuals globally, with a projected increase to 79.8 million in 2040.1, Glaucoma has been reported to be 7 times more likely to cause blindness and 15 times more likely to cause visual impairment in Black individuals as compared to White individuals. In the U.S. in 2010, Black individuals had the highest prevalence rate of primary open angle glaucoma at 3.4% compared to 1.7% among White individuals.

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 the Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in intraocular pressure and glaucoma risk.

#### **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 patients 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<sup>™</sup>, 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. 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 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 patients 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 two RCTs, a comparative effectiveness review, and several case series. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. The RCTs found a 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 systematic review found that canaloplasty provided modest intraocular pressure reduction (to approximately 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.

Date	Action
5/2025	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2023	Annual policy review. Minor editorial refinements made to policy statements; intent unchanged.
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.

#### **Policy History**

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

- 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. Gedde SJ, Vinod K, Bowden EC, et al. Special Commentary: Reporting Clinical Endpoints in Studies of Minimally Invasive Glaucoma Surgery. Ophthalmology. Aug 08 2024. PMID 39127407
- 3. Chai C, Loon SC. Meta-analysis of viscocanalostomy versus trabeculectomy in uncontrolled glaucoma. J Glaucoma. 2010; 19(8): 519-27. PMID 20179632
- 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; 2014(2): CD007059. PMID 24532137
- 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
- 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
- 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
- 8. 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
- 9. 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
- 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
- 11. Klink T, Sauer J, Körber NJ, et al. Quality of life following glaucoma surgery: canaloplasty versus trabeculectomy. Clin Ophthalmol. 2015; 9: 7-16. PMID 25565763
- Yin P, Li J, Shi Y, et al. Ab interno canaloplasty versus gonioscopy-assisted transluminal trabeculotomy in open-angle glaucoma: a randomised controlled trial. Br J Ophthalmol. May 21 2024; 108(5): 687-694. PMID 37311600
- Gołaszewska 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
- 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
- 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

- 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
- 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
- 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
- 19. 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
- Bull H, von Wolff K, Körber N, et al. Three-year canaloplasty outcomes for the treatment of openangle glaucoma: European study results. Graefes Arch Clin Exp Ophthalmol. Oct 2011; 249(10): 1537-45. PMID 21732110
- 21. 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
- 22. Brusini P. Canaloplasty in open-angle glaucoma surgery: a four-year follow-up. ScientificWorldJournal. 2014; 2014: 469609. PMID 24574892
- 23. Voykov B, Blumenstock G, Leitritz MA, et al. Treatment efficacy and safety of canaloplasty for openangle glaucoma after 5 years. Clin Exp Ophthalmol. Nov 2015; 43(8): 768-71. PMID 25952140
- 24. Ennerst CD, Fischinger IR, Tetz MR. Long-Term Outcome After Canaloplasty and Phacocanaloplasty in Primary Open Angle Glaucoma. J Glaucoma. Nov 01 2024; 33(11): 867-873. PMID 39093018
- 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
- 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. Dec 2023; 240(12): 1394-1404. PMID 35426107
- 27. 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
- Koerber N, Ondrejka S. 6-Year Efficacy and Safety of iTrack Ab-Interno Canaloplasty as a Stand-Alone Procedure and Combined With Cataract Surgery in Primary Open Angle and Pseudoexfoliative Glaucoma. J Glaucoma. Mar 01 2024; 33(3): 176-182. PMID 37725787
- 29. Murphy lii 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
- Ondrejka S, Körber N, Dhamdhere 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
- 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
- Gallardo MJ, Dhamdhere 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
- 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
- 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
- Terveen DC, Sarkisian SR, Vold SD, et al. Canaloplasty and trabeculotomy with the OMNI 
  <sup>®</sup> surgical system in OAG with prior trabecular microbypass stenting. Int Ophthalmol. May 2023; 43(5): 1647-1656. PMID 36229561

- 36. 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
- 37. Richter GM, Takusagawa HL, Sit AJ, et al. Trabecular Procedures Combined with Cataract Surgery for Open-Angle Glaucoma: A Report by the American Academy of Ophthalmology. Ophthalmology. Mar 2024; 131(3): 370-382. PMID 38054909
- National Institute for Health and Care Evidence (NICE). Ab externo canaloplasty for primary openangle glaucoma [IPG591]. 2017; https://www.nice.org.uk/guidance/ipg591. Accessed January 15, 2025.
- 39. National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management [NG81]. 2022; https://www.nice.org.uk/guidance/NG81. Accessed January 12, 2025.
- 40. National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management [NG81]. 2022; https://www.nice.org.uk/guidance/NG81. Accessed January 13, 2025.
- 41. 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 14, 2025.