



## Canaloplasty

---

<b>State(s):</b> <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:	<b>LOB(s):</b> <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid
---	--

## Enterprise Policy

---

*Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.*

## Background

---

Glaucoma is an irreversible group of conditions/diseases involving damage to the optic nerve and loss of peripheral vision. Glaucoma was previously defined by high eye pressure (IOP); however, the condition is also found in individuals with normal or low eye pressure. Primary open-angle glaucoma (POAG) is the most common form, and other types include, but may not be limited to, angle-closure and congenital glaucoma; all of which will result in blindness if left untreated. Prescription medication, in the form of eye drops, pills or both, is the most common early treatment for glaucoma.

Current standard surgical treatments for glaucoma include trabeculectomy or trabeculoplasty (incisional or laser). Iridotomy, iridectomy or iridoplasty may be necessary for angle-closure glaucoma.

Alternative procedures such as canaloplasty may be indicated where medical therapy has failed to adequately control the IOP, and previous laser trabeculoplasty or trabeculectomy procedures have failed. See definitions section for further information.

## Criteria

---

### Commercial

#### **Prior Authorization is Required.**

Ab externo Canaloplasty may be considered medically necessary as a method to reduce intraocular pressure when **ALL** of the following conditions are met:

- The member has a diagnosis of chronic primary open-angle glaucoma (POAG), including normal-tension glaucoma
- Pharmacologic and trabeculectomy or trabeculoplasty has been tried and failed to adequately control intraocular pressure,

- The patient is not a candidate for any other intraocular pressure lowering procedure (e.g. repeat trabeculectomy or glaucoma drainage implant) due to a high risk for complications (e.g., high risk of infection, bleeding or history of complications from trabeculectomy).

## Medicaid

PacificSource Medicaid follows Guideline Note 173 of the OHP Prioritized List of Health Services and considers Canaloplasty as insufficient evidence of benefit.

## Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of internal policy guidelines, CMS criteria, and evidence-based criteria, requests are reviewed on an individual basis for determination of coverage and medical necessity.

## Coding Information

---

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

## Definitions

---

- Ab interno: Procedure approach from inside the eye. This is a newer approach which accesses Schlemm's canal via a small corneal incision rather than conjunctival dissection. See experimental/investigational/unproven section
- Ab externo: Procedure approach from outside the eye.
- Canaloplasty is a minimally invasive surgical technique for glaucoma which attempts to widen the eye's natural drainage canal, and reestablish normal eye pressure. Canaloplasty is a surgical procedure in which tissue flaps are cut in the conjunctiva and the sclera (ab externo) to expose Schlemm's canal (the drainage area). Canaloplasty attempts to open the entire drainage area surrounding the anterior chamber (360°) instead of just a portion of it, as in viscocanalostomy below. Canaloplasty involves viscodilation and tension of the Schlemm's canal with an illuminated tipped microcatheter (iTrack™). The microcatheter is used to place an intracanalicular suture that cinches and stretches the trabecular meshwork inwards while permanently opening the entire length of Schlemm's canal. The canal is expanded by the injection to promote better fluid drainage. This procedure is done under local anesthesia on an outpatient basis.
- Trabeculectomy is a surgical procedure either done with laser or incision used to create a new channel, or "bleb" through which fluid can drain from the eye.
- Viscocanalostomy is a surgical procedure similar to canaloplasty in which tissue flaps are cut in the conjunctiva and the sclera. The creation of these flaps exposes a portion of Schlemm's canal into which a high-viscosity elastic gel is injected. The injected material opens and enlarges the canal purportedly enhancing fluid flow out of the anterior chamber. The tissue flaps are then closed.

## References

---

American Academy of Ophthalmology Glaucoma Panel. Primary Open Angle Glaucoma. PPP- 2010. Accessed 3/5/2018, 2/8/2019, 2/27/2020, 12/23/2020

<http://one.aao.org/preferred-practice-pattern/primary-openangle-glaucoma-ppp--october-2010>

Brusini P. Canaloplasty in open-angle glaucoma surgery: A four-year follow-up. *ScientificWorldJournal*. 2014;2014:469609. Accessed July 14, 2017, March 5, 2018, February 8, 2019, January 27, 2020, December 23, 2020

<http://www.hindawi.com/journals/tswj/2014/469609/>

Bull H et al. Three-year canaloplasty outcomes for the treatment of open-angle glaucoma: European study results. *Graefes Arch Clin Exp Ophthalmol*. 2011 Oct;249(10):1537-45. Accessed July 14, 2017, March 5, 2018, February 8, 2019, January 27, 2020, December 23, 2020

<http://www.ncbi.nlm.nih.gov/pubmed/21732110>

Bulent Cankaya, A., & Elgin, U. (2011, November 22). *Comparison of the Outcome of Repeat Trabeculectomy with Adjunctive Mitomycin C and Initial Trabeculectomy*. National Center for Biotechnology Information. PubMed Central. US National Library of Medicine (Ncbi.Nlm.Nih.Gov).

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3223707/>

*Canaloplasty for Open-Angle Glaucoma*. (2020, January 13). Hayes, a TractManager Company.

<https://evidence.hayesinc.com/report/dir.canaloplasty2002>

Gandolfi, SA. et al (2016) Comparison of Surgical Outcomes between Canaloplasty and Schlemm's Canal Scaffold at 24 Months' Follow-Up. *J Ophthalmol*. 2016; 2016: 3410469. Accessed July 14, 2017, March 5, 2018, February 8, 2019, January 27, 2020, December 23, 2020

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4771907/>

*Glaucoma Surgery*. (n.d.). Glaucoma Research Foundation. Retrieved November 25, 2020, from

<https://www.glaucoma.org/treatment/surgery-overview.php>

Gunenc, U., Ozturk, T., Arikan, G., & Kocak, N. (2015, December 18). *Long-term results of viscocanalostomy and phacoviscocanalostomy: a twelve-year follow-up study*. National Center for Biotechnology Information. PubMed Central. US National Library of Medicine (Ncbi.Nlm.Nih.Gov)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4651882/>

Hayes Health Technology Brief: Canaloplasty (iTrack 250A Canaloplasty Microcatheter; iScience Interventional Inc.) for Primary Open-Angle Glaucoma. Hayes Inc. September 16, 2011. Annual review September 27, 2013. Archived October 16, 2014.

Heersink, M., & Dovich, J. (2019, August 12). *Ab interno canaloplasty combined with trabecular bypass stenting in eyes with primary open-angle glaucoma*. National Center for Biotechnology Information. PubMed Central. US National Library of Medicine (Ncbi.Nlm.Nih.Gov)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6697664/>

*Incisional Surgery*. (2017, January 6). Glaucoma Research Foundation.

<https://www.glaucoma.org/treatment/conventional->

[surgery.php#:~:text=When%20medicines%20and%20laser%20surgeries,a%20trabeculectomy%20or%20a%20sclerostomy.](https://www.glaucoma.org/treatment/conventional-surgery.php#:~:text=When%20medicines%20and%20laser%20surgeries,a%20trabeculectomy%20or%20a%20sclerostomy.)

Khaimi MA. Canaloplasty: A Minimally Invasive and Maximally Effective Glaucoma Treatment. J Ophthalmol. 2015; 2015: 485065. Accessed July 14, 2017, March 5, 2018, February 8, 2019, January 27, 2020, 11/23/20

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4606093/>

Koerber NJ et al. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. J Glaucoma. 2012 Feb;21(2):129-34. Accessed July 14, 2017, March 5, 2018, February 8, 2019, January 27, 2020

<http://www.ncbi.nlm.nih.gov/pubmed/21278587>

Lewis RA, 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; 37(4):682-90. Accessed July 14, 2017, March 5, 2018, February 8, 2019, January 27, 2020

<https://www.ncbi.nlm.nih.gov/pubmed/?term=Canaloplasty%3A+three-year+results+of+circumferential+viscodilation+and+tensioning+of+Schlemm+canal+using+a+microcatheter+to+treat+open-angle+glaucoma>

Tian B, Kaufman PL. A potential application of canaloplasty in glaucoma gene therapy. Transl Vis Sci Technol. 2013;2(1). pii: 2. Accessed July 14, 2017, March 5, 2018, February 8, 2019, January 27, 2020

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3718561/pdf/i2164-2591-2-1-2.pdf>.

## Appendix

---

Policy Number: [Policy Number]

Effective: 1/1/2021

Next review: 1/1/2022

Policy Type: Enterprise

Author(s): PD: 1/7/2021

Depts: Health Services

Applicable regulation(s):

