Canaloplasty and viscocanalostomy for glaucoma

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Policy contains: Canaloplasty; glaucoma; Schlemm's canal surgery; viscocanalostomy.

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Sandhills Center when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Sandhills Center clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Sandhills Center’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

Coverage policy

Canaloplasty and viscocanalostomy (i.e., Ab externo Schlemm's canal surgery) are clinically proven and, therefore, medically necessary for treatment of chronic, primary open-angle glaucoma when all of the following criteria are met (Eldaly, 2014; National Institute for Health and Care Excellence, 2017; Zhang, 2017):

- Member is at least 18 years of age.
- There is failure, intolerance, or contraindication to maximal medical therapy needed to adequately control intraocular pressure.

Limitations

All other uses of canaloplasty and viscocanalostomy are not medically necessary.

Contraindications to canaloplasty and viscocanalostomy include, but are not limited to (National Institute for Health and Care Excellence, 2017; Riva, 2019):

- Previous penetrating or non-penetrating surgeries in the index eye.
- Angle closure glaucoma.
- Post-traumatic glaucoma with angle recession.
- Elevated episcleral venous pressure.
• Congenital or other secondary types or glaucoma (uveitic, neovascular, or traumatic).

Alternative covered services

• Approved pharmacotherapy as ordered by primary care provider and/or specialist.
• Approved conventional treatments (e.g., trabeculectomy).

**Background**

Glaucoma describes a complex group of eye diseases characterized by damage to the optic nerve, leading to irreversible vision loss and blindness (Boyd, 2021). It usually begins with subtle loss of peripheral vision and, if left undiagnosed and untreated, will eventually progress to complete blindness. Therefore, early detection of the disease is critically important.

There are several types of glaucoma (Boyd, 2021). Secondary glaucoma occurs as a complication of other visual disorders, but the vast majority occur without a known cause (i.e., primary). The most common type in adults is primary open-angle glaucoma in which there is no physical obstruction of the drainage angle of the eye, but there is characteristic damage to the optic nerve and the presence of visual field loss. The early stages of primary open-angle glaucoma are often asymptomatic. Both eyes are usually affected, though typically asymmetrically.

Increased intraocular pressure is one of the main risk factors, although it is not a requirement for diagnosis, as primary open-angle glaucoma may occur in patients with intraocular pressures within the normal range (Boyd, 2021). Other risk factors for primary open-angle glaucoma include older age, family history, African or Latino ancestry, and Type 2 diabetes.

Treatment for glaucoma aims at reducing intraocular pressure either by reducing the amount of aqueous humor produced by the eye or by improving the flow of aqueous humor through the open angle between the cornea and the iris, through the trabecular meshwork, and into a collector channel known as Schlemm's canal. Treatment options include medications (prostaglandin analogs, alpha-adrenergic agonists, beta-blockers, carbonic anhydrase inhibitors, and mitotics), laser therapy, and surgery (Boyd, 2021). Medical therapies, alone or in combination, require a high level of adherence to prescribed therapy, and often this is not achieved (Prum, 2016). Laser procedures, such as trabeculoplasty, that open clogged channels in the trabecular network have variable efficacy and durability (Chen, 2019).

Trabeculectomy is the most common incisional surgical treatment for primary open-angle glaucoma, but it is associated with a high complication rate (Boyd, 2021). The filtering procedure involves full thickness penetration of sclera to remove a small portion of the trabecular meshwork or surrounding tissue; it bypasses the natural outflow system by diverting aqueous humor from the anterior chamber into a subconjunctival reservoir with a filtering “bleb” on the eye. Antifibrotic agents, such as mitomycin-C and 5-fluorouracil, may be used intraoperatively and postoperatively to reduce scarring and prevent closure of the new channel. Other surgical options for primary open-angle glaucoma include trabeculotomy, insertion of trabecular meshwork stents, and insertion of aqueous shunts.

To avoid the complications of a full thickness filtering procedure, non-penetrating surgical techniques have emerged that target the abnormally high resistance to aqueous outflow in the trabecular meshwork and inner wall of Schlemm’s canal without producing an external filtration bleb (Grieshaber, 2017). Two procedures are viscocanalostomy and canaloplasty. Both procedures require examination of the integrity of the distal outflow system by either provocative gonioscopy with blood reflux or fluorescein channelography to determine candidacy. While these procedures are more technically demanding than trabeculectomy and require special equipment, postoperative care and follow up tend to be simpler and less demanding and with faster visual recovery.
Viscocanalostomy is a variation of a deep sclerectomy procedure that involves unroofing and dilation of the Schlemm’s canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution is injected to dilate the canal and create a passage from the canal to a scleral reservoir, thereby reducing intraocular pressure.

Canaloplasty is a modification of viscocanalostomy, in which an additional intracanalicular stent is inserted to maintain canal patency and enhance the circumferential flow. In 2004, the U.S. Food and Drug Administration issued 510(k) approval to the iTrack™ 250A Canaloplasty Microcatheter (iScience Interventional Inc., Redwood City, California) for the catheterization and viscodilation of Schlemm’s canal to reduce intraocular pressure in adult patients with open angle glaucoma (U.S. Food and Drug Administration, 2004). The procedure can be done under local or general anesthetic.

Findings

Several guidelines have been published on the efficacy of various procedures for open-angle glaucoma. An updated guideline from the National Institute for Health and Care Excellence (2017) states that “current evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent, and audit.”

A 2015 American Academy of Ophthalmology guideline provided nine references given for viscocanalostomy, eight of which were published from 2001 to 2006; the other was from 2009 (Prum, 2016). Only two references were given for canaloplasty. In one, reductions in average intraocular pressure for canaloplasty in 157 eyes was significant (23.8 to 15.2 mm Hg) three years postoperative (Lewis, 2011). In the other, the 46 eyes undergoing trabeculectomy had an intraocular pressure reduction of 46%, close to significantly higher than the 32% reduction in the 33 eyes undergoing canaloplasty (Ayyala, 2011). The guideline also stated that “no randomized clinical trial comparing trabeculectomy and canaloplasty exists.”

A systematic review for the U.S. Preventive Services Task Force concluded that, compared with viscocanalostomy or deep sclerectomy, trabeculectomy “produces more hypotony, hyphema, shallow anterior chambers, cataract, and choroidal detachment,” and that intraocular glaucoma surgery presents an increased risk for cataract and a rare but serious intraocular infection, compared with laser trabeculoplasty and medical treatment (Boland, 2013). No studies were found that compared visual impairment or patient-reported outcomes among glaucoma treatments.

Additional meta-analyses and/or systematic reviews examining the efficacy of canaloplasty and/or viscocanalostomy found that trabeculectomy was more effective in reducing intraocular pressure than non-penetrating surgery with a higher incidence of complications (Eldaly, 2014; Lin, 2016; Rulli, 2013; Zhang, 2017). Both canaloplasty and viscocanlostomy are relatively safe procedures when performed by highly trained surgeons, but their impact on quality of life has not been systematically assessed.

In 2016 and 2017: The policy references were updated with no policy changes warranted.

In 2018, we updated the policy references. The policy ID changed from 10.03.03 to CCP.1140.

In 2019, we updated the policy references.

In 2020, we updated the policy references, and added coverage criteria and contraindications to the coverage section.

In 2021, we updated the policy references. We found no new systematic reviews or meta-analyses. Newly published research consists of nonrandomized, single-arm, retrospective analyses of the safety and efficacy of ab interno canaloplasty in patients with primary open angle glaucoma of varying severity. The studies
employed either the iTrack system (Gallardo, 2021) or Omni® surgical system (Sight Sciences, Menlo Park, California; Hirsh, 2021; Hughes, 2020; Vold, 2021) performed as stand-alone procedures or with cataract surgery. The results suggest canaloplasty has a low risk profile and can effectively lower intraocular pressure and medication requirements for up to 24 months in patients with primary open angle glaucoma. No policy changes are warranted.

On July 20, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “glaucoma,” “canaloplasty,” and “viscocanalostomy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.


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**Policy updates**

10/2014: initial review date and clinical policy effective date: 4/2014

9/2016: Policy references updated.

9/2017: Policy references updated.


7/2019: Policy references updated.