KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Canaloplasty

- Circumferential Viscodilation and Tensioning of Schlemm's Canal for Primary Open-Angle Glaucoma

Criteria

For Medicare Members

No review required for Medicare members

For Non-Medicare Members

Canaloplasty is covered when all of the following criteria have been met:

1. Diagnosis of glaucoma with eye pressures inadequately controlled on maximum tolerated topical medications and laser treatment
2. Documented risk for greater problems with standard glaucoma surgery (trabeculectomy or valve implant) as defined by one of the following:
   - Myopic diopters greater than 5
   - Hyperoptic diopters greater than 3
   - Moderate to severe dry eye
   - Blepharitis
   - Preservative allergy
   - Has allergy or side effects preventing the use of one or more of the standard glaucoma eye drops
   - Had problems with trabeculectomy or glaucoma valve implant surgery in the contralateral eye (such as bleb dysesthesia (chronic eye pain) or need for re-operation)

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Glaucoma is a common eye disease caused by elevated intraocular pressure (IOP) that leads to optic nerve damage and visual field loss. Glaucoma is frequently referred to as the "silent thief of sight" because it is not usually associated with ocular or systemic symptoms but can cause irreversible blindness if left undiagnosed and untreated. It is estimated that over 2 million people in the United States have glaucoma, 80,000 of whom are legally blind as the result of the disease (Lee 2005).

Glaucoma has been classically categorized into primary or secondary angle-closure glaucoma (closure of the anterior chamber angle), and primary or secondary open-angle glaucoma (where the anterior chamber angle of the eye remains open). The condition is considered primary if the eye has no pre-existing disease and secondary in an eye with a pre-existing disease. Primary open-angle glaucoma is the most common type in the US. It occurs insidiously and is usually asymptomatic in its early stages. In the later stages, when the optic nerve is damaged,

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the patient experiences progressive worsening of vision, and eventually peripheral followed by central visual loss (Lee 2005, Rotchford 2005).

The treatment goal for patients with glaucoma is preventing functional vision loss by lowering the IOP to a level where progressive glaucomatous optic neuropathy is stopped, or at least slowed. Conventional treatment usually begins with the use of topical IOP-lowering agents. These include beta-blockers, alpha-adrenergic agonists, carbonic anhydrase inhibitors, cholinergic, and prostaglandin analogs. Laser trabeculoplasty has also been used to further lower the IOP to decrease or eliminate the need for antiglaucoma medications. Incisional filtering surgery is considered if the patient's IOP cannot be reduced with the maximal tolerated medical therapy, laser trabeculoplasty or a combination of both. Trabeculectomy is a filtration surgical procedure commonly used to lower the IOP. The procedure involves creating an opening in the anterior chamber angle to allow the aqueous humor flow from the anterior chamber into a space beneath the conjunctiva under the surface of the eye. A successful trabeculectomy procedure is marked by an elevated conjunctival zone, the bleb, where the aqueous gathers in pockets prior to absorption into the surrounding blood vessels and lymphatics. Trabeculectomy with or without antimetabolites can successfully control IOP, but not without risks. It may be associated with numerous intraoperative or postoperative complications including hypotony, bleb leaks, bleb infections /endophthalmitis, hyphaema, loss of visual acuity, increased risk of cataract formation, scar tissue which causes obstruction of the channel created and in turn blocking the drainage of the aqueous humor, and several other complications (Lee 2005, Rotchford 2005, Lewis 2007).

Nonpenetrating glaucoma procedures were first introduced in the late 1950s and early 1960s, and revived in the 1980s and 1990s, as alternatives to standard filtration surgeries for controlling IOP in open-angle glaucoma without penetration of the intraocular space. These procedures include deep sclerectomy with and without an implant, and viscocanalostomy. The latter is performed by several techniques that basically involve the production of superficial and deep scleral flaps, excision of the deep scleral flap to create a scleral reservoir, and unroofing of Schlemm's canal. An ophthalmic viscoelastic device is then injected into the deep scleral lake and toward the cut ends of Schlemm's canal to open it and create a passage from the scleral reservoir to the canal. The superficial scleral flap is then sutured water tight trapping the viscoelastic until healing takes place (Filippopoulos 2008, Green 2007, Noureddin 2006).

Recent advances in technology, ocular ultrasound, and viscoelastics have led to the development of canaloplasty as a promising nonpenetrating surgical technique for lowering the IOP in patients with open-angle glaucoma. The procedure aims at increasing the flow of aqueous humor from the anterior chamber through the trabecular meshwork and Descemet's window into and around the Schlemm's canal and out through the collector channels, thus reducing the IOP by restoring the trabeculocanalicular outflow pathway. The procedure utilizes the full 360 degrees of the canal and outflow system without creating a fistula or need for a bleb. Unlike viscocanalostomy, canaloplasty aims at opening the entire length of the canal rather than opening only a section of it. Canaloplasty uses viscoelastic and specialized flexible microcatheter with an illuminated tip (iScience surgical Ophthalmic Microcannula) to forcibly open the Schlemm's canal (Lewis 2006, 2007, Godfrey 2009).

Similar to viscocanalostomy, canaloplasty is completed under a scleral flap. A one-half thickness parabolic shaped scleral flap is dissected. A deep flap is then dissected down to a depth very close to the ciliary body/choroid and carefully carried forward anteriorly until the Schlemm's canal is unroofed. The canal is identified and intubated with a cannula which has a lighted tip to identify its location as it passes through the canal. The cannula has a lumen to allow for the passage of viscoelastic for dilatation of the canal. Once it has passed the full length of Schlemm's, a 10-0 Prolene suture is tied to the cannula which is then withdrawn leaving the suture in its place. Tying off the suture provides tension that holds the canal open. The scleral flap is then tightly closed as well as the conjunctiva. The procedure is usually performed under special ultrasound imaging to help identify the canal and its instrumentation (Lewis 2006, 2007).

Canaloplasty has a steep learning curve. Identifying and entering the Schlemm's canal, inserting the catheter, placing the tension suture, and providing the right tension in the suture depend on the surgeon's skill and experience. The outcome of the surgery also depends on the selection of the patients; those who had previous trabeculectomies with scarring in the canal are not good candidates. According to the authors of a review article, the ideal candidates would be patients who cannot have a bleb because they wear contact lenses, have a dry eye, or for cosmetic reasons. The procedure is contraindicated in patients with angle recession, neovascular glaucoma, chronic angle closure, narrow-angle glaucoma, narrow inlets with plateau iris, and in patients with previous surgery which would prevent 360o catheterization of Schlemm's canal (Lewis 2006, Godfrey 2009).

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In June 2008 The FDA cleared the iScience Interventional Canaloplasty Microcatheter for marketing for catheterization and vasodilatation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

Medical Technology Assessment Committee (MTAC)

Canaloplasty

10/06/2008: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the safety and efficacy of canaloplasty in the management of open angle glaucoma among adults. There are no published controlled trials that compared the outcomes of canaloplasty to other established medical therapies, laser trabeculoplasty, or filtration surgeries as trabeculectomy. The only published studies were 2 relatively small case series, conducted in the same centers with the same group of investigators, and possibly with a population overlap. None had a control or comparison group. Three of the principal authors had consulting agreement with iScience Interventional, the manufacturer of the microcatheter used. The interim analysis of one-year results of a multicenter case series (Lewis 2007) that included 94 patients from the 14 centers in US and Germany, showed that IOP dropped significantly after the procedure among all patients (from 24.7 + 4.8 mmHg at baseline to 15.3 +3.9 mmHg at 12 months), and among the sutured subgroup (from 23.9 + 4.3 mmHg at baseline to 15.3 + 3.8 mmHg at 12 months). The medication uses also dropped from a mean of 1.9 +1 per patient to 0.6 + 0.9 per patient at 12 months. The most common adverse events observed were hyphaema and increased IOP which occurred at a rate of 3% each. The other published series that included 54 patients with open-angle glaucoma and cataract reported similar outcomes. None of the two studies compared the procedure to any other established surgical or nonsurgical intervention. Conclusion: There is insufficient evidence to determine that canaloplasty has the same or better effect than medical treatment in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty has the same or better effect than filtration surgical procedures as trabeculectomy in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is safer for the patient than filtration surgical interventions as trabeculectomy.

Articles: The search yielded only two studies on canaloplasty: Lewis 2007, and Shingleton 2008. Both were prospective case series with no comparison or control groups. Lewis and colleagues reported the interim results of canaloplasty performed on 94 patients with open-angle glaucoma. Shingleton et al reported one-year results of canaloplasty combined with cataract surgery performed on 54 patients with open-angle glaucoma and cataract. The authors of the latter study were co-authors in the first study. Both studies involved the same 14 clinical sites and same group of ophthalmologists. It appears also that there could be an overlap of the patients participating in the two studies. Both reported on one-year results. The published case series with the larger population size was selected for critical appraisal. Lewis R A, 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 Refrat Surg 2007; 33:1217-1226. See Evidence Table.

The use of canaloplasty in the treatment of primary open-angle glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/05/2009: MTAC REVIEW

Canaloplasty

Evidence Conclusion*:* The available literature does not provide sufficient evidence to determine the safety and efficacy of canaloplasty in the management of open angle glaucoma among adults. There are no published controlled trials that compared the outcomes of canaloplasty to other established medical therapies, laser trabeculoplasty, or filtration surgeries as trabeculectomy. The only published studies were 2 relatively small case series, conducted in the same centers by the same study group, and possibly with a population overlap. Lewis and colleagues, reported on the one- and two-year interim results of canaloplasty with or without corneal phacoemulsification cataract surgery, and Shingleton et al (2008) reported on the results of a subgroup that underwent the two procedures. Neither of the two series had a control or comparison group. iScience Interventional, the manufacturer of the microcatheter used in the studies, supported the studies and had consulting agreement with three of the principal authors. In their first publication, Lewis and colleagues (2007) reported the one-year interim results of canaloplasty performed on 94 patients with open-angle glaucoma, and in their 2009 publication they reported on the results of the procedure among 127 patients. No explanation was provided why there were more patients in the 2-year follow-up. The interim analysis of one-year results showed that IOP dropped significantly after the procedure among all patients from 24.7 + 4.8 mmHg at baseline to 15.3 +3.9 mmHg at 12 months. The medication uses also dropped from a mean of 1.9 +1 per patient at baseline to 0.6 + 0.9 at 12 months. Eyes that underwent a combined canaloplasty and posterior chamber intraocular lens (IOL) implantation had lower IOP and medication use than those undergoing canaloplasty alone. The two-year

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postoperative data were similar to those observed at the end of the first-year follow-up with a minimal increase in the mean IOP and medication use. Overall 32% reduction in IOP and 74% reduction on medication use were achieved in 24 months. Surgical complications were reported in 15 patients (16%) in the first publication and in 10 patients in the second report, with hyphaema and increased IOP >30mmHg being the most common. Conclusion: There is insufficient evidence to determine that canaloplasty is better than or equivalent to medical treatment in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is better than or equivalent to filtration surgical procedures as trabeculectomy in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is safer than filtration surgical interventions as trabeculectomy.
Articles: The search yielded only one more recent report (Lewis et al 2009) on the 2-year results of the same case series on canaloplasty that was published earlier in 2007 and reviewed by MTAC in 2008. No randomized or nonrandomized controlled trials comparing canaloplasty to another treatment or intervention were identified. The new report by Lewis and colleagues (2009) was critically appraised. Lewis R A, 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. Two-year interim clinical study results. J Cataract Refrat Surg 2009; 35:814-824 See Evidence Table.

The use of canaloplasty in the treatment of primary open-angle glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Medicare – Medical Necessity Review not required

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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
11/12/2008	01/05/2010 MDCRPC, 11/02/2010 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	07/26/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
07/26/2017	Added no review required for Medicare members

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