# Medical Policy

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***Current Policy Effective Date: 3/1/25**
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# Title: Viscocanalostomy and Canaloplasty

## Description/Background

### 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 IOP 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 (IOP) and glaucoma risk.

### Treatment

Surgical intervention may be indicated in patients with glaucoma when the target IOP 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 IOP, but is associated with numerous and sometimes sight-threatening complications (e.g., leaks, hypotony, choroidal effusions and hemorrhages, hyphemas or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed in this policy) include trabecular laser ablation and deep sclerectomy, which removes the outer wall of Schlemm’s 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. IOP 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 of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva.

Alternative nonpenetrating methods that are being evaluated for glaucoma are viscocanalostomy and canaloplasty. Viscocanalostomy is a variant of deep sclerectomy and unroofs and dilates Schlemm’s canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution, such as 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 IOP while avoiding bleb-related complications.

Canaloplasty was developed from viscocanalostomy and involves dilation and tension of Schlemm’s 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 (iScience Interventional) to access and dilate the length of Schlemm’s 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 Schlemm canal, rather than one section of it.

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

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## Regulatory Status:

The iTrack (iScience Interventional) received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2004 as a surgical ophthalmic microcannula that is indicated for the general purpose of “fluid infusion and aspiration, as well as illumination, during surgery.” In 2008, the iTrack received FDA-clearance for the indication of “catheterization and viscodilation of Schlemm’s canal to reduce intraocular pressure in adult patients with open angle glaucoma.” FDA product code: MPA

In 2017, the OMNI® Surgical System (Sight Sciences, Inc.) was cleared for marketing by the FDA through the 510(k) process as a manually operated device for the delivery of small amounts of viscoelastic fluid during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures (K173332). In 2020, the OMNI® Plus

Surgical System was cleared for the same indications for use as the predicate OMNI system (K201953). In 2021, the OMNI® Surgical System was cleared for marketing by the FDA through the 510(k) process for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma (K202678). FDA product code: MRH.

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## Medical Policy Statement

The safety and effectiveness of canaloplasty have been established. It is a useful therapeutic procedure for patients meeting selection criteria.

Viscocanalostomy is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes.

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## Inclusionary and Exclusionary Guidelines

**Canaloplasty:**
Inclusions:
Canaloplasty may be considered established as a method to reduce intraocular pressure in individuals with chronic primary open-angle glaucoma when both conditions are met:

- Medical therapy has failed to adequately control intraocular pressure, AND
- The individual is not a candidate for any other intraocular pressure lowering procedure (e.g. trabeculectomy or glaucoma drainage implant) due to a high risk for complications.

Exclusions:
Canaloplasty for all other conditions, including angle-closure glaucoma.

**Viscocanalostomy:**
Procedure is experimental/investigational.

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## CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

### *Established codes:*

66174 66175

### *Other codes (investigational, not medically necessary, etc.):*

66999

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## Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

## VISCOCANALOSTOMY

### Clinical Context and Therapy Purpose

The purpose of viscocanalostomy for individuals who have open-angle glaucoma that has failed medical therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

### Populations

The relevant population of interest is individuals with open-angle glaucoma that has failed medical therapy.

### Interventions

The treatment being considered is viscocanalostomy.

### Comparators

The comparators of interest are intraocular pressure-lowering procedures such as glaucoma drainage implant or trabeculectomy.

### Outcomes

The general outcomes of interest are symptoms, morbid events, quality of life, and medication use. Other health outcomes of interest are the intraocular pressure (IOP) achieved, ability to convert to trabeculectomy if procedure is unsuccessful, and durability of procedure.

Follow-up of 15 years or longer is desirable to assess outcomes and duration of results; glaucoma is generally managed by ophthalmologists for the duration of a patient’s life.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

**Systematic Reviews**
A 2010 meta-analysis by Chai and Loon compared the safety and efficacy of viscocanalostomy with the gold standard of trabeculectomy.[2] Ten randomized controlled trials with a total of 458 eyes (397 patients) with medically uncontrolled glaucoma were included in the analysis. The number of eyes in each study ranged from 20 to 60, with follow-up ranging from 6 months to 4 years. The majority of eyes (81%) had primary open angle glaucoma, while 16.4% had secondary open angle glaucoma, and 1.7% had primary angle closure glaucoma. Meta-analysis found that trabeculectomy had a significantly better pressure-lowering outcome. The difference in intraocular pressure between the treatments was 2.25 mm Hg at 6 months, 3.64 mm Hg at 12 months, and 3.42 mm Hg at 24 months. Viscocanalostomy had a significantly higher relative risk (RR) of perforation of Descemet's membrane (RR: 7.72). In contrast, viscocanalostomy had significantly fewer postoperative events compared with trabeculectomy (hypotony RR: 0.29, hyphema RR: 0.50, shallow anterior chamber RR: 0.19, and cataract formation RR: 0.31). Although viscocanalostomy had a better risk profile, most of the adverse events associated with trabeculectomy were considered to be mild and reversible. Similar results were obtained in a 2014 Cochrane review and meta-analysis by Edaly et al that included 2 small randomized trials (50 eyes).[3]

**Randomized Controlled Trials**
One of the studies included in the systematic review by Chai and Loon was a randomized trial by Gilmour et al from 2009 with 4-year follow-up.[4] Patients (n=43) with open angle glaucoma were randomized to viscocanalostomy (25 eyes) or trabeculectomy (25 eyes) and prospectively followed at regular intervals for up to 60 months. A successful outcome was defined as intraocular pressure (IOP) less than 18 mm Hg with no medications; a qualified success was defined as IOP less than 18 mm Hg with or without topical treatment. One patient in each group was lost to follow-up. At baseline, patients had a mean IOP of 25 mm Hg and were using an average of 1.4 medications. At mean follow-up of 40 months (range, 6 to 60 months), 10 patients (42%) in the trabeculectomy group had achieved success compared to 5 patients (21%) in the viscocanalostomy group. Although 19 patients (79%) in both groups achieved qualified success, fewer trabeculectomy patients required additional topical treatment (50% vs. 83%, respectively) to achieve qualified success. There were more early postoperative complications in the trabeculectomy group (e.g., hypotony, wound leak, choroidal detachment), but these did not affect the outcome. At 1 month, conjunctival blebs were observed in 19 (79%) of the trabeculectomy group and 16 (64%) of the viscocanalostomy group. At 12 months, blebs were observed in 19 (79%) of the trabeculectomy group and 14 (56%) of the viscocanalostomy group. The proportion of patients with conjunctival blebs at final follow-up and the statistical significance of these differences were not reported. It was reported that more bleb manipulations (7 vs.1) and antimetabolites (5 vs.1) were needed in the trabeculectomy group. The 3 patients who required cataract surgery were all in the viscocanalostomy group.

**Case Series**

In 2003, Kobayashi et al reported a within-subject safety and efficacy comparison of trabeculectomy (with mitomycin C) and viscocanalostomy in 25 patients with bilateral primary open-angle glaucoma who had IOP greater than 22 mm Hg under medical therapy.[5] Patients were randomly assigned to receive trabeculectomy in one eye and viscocanalostomy (with removal of the internal wall of Schlemm's canal) in the other eye. Follow-up was performed at 1 and 3 days, 1 and 2 weeks, and 1, 2, 3, 4, 5, 6, 9, and 12 months after surgery. Throughout follow-up, the mean IOP decreased significantly more in trabeculectomy-treated eyes (e.g., from 24.8 to 12.6 mm Hg at 12 months) than in viscocanalostomy-treated eyes (from 25.0 to 17.1 mm Hg). At 12 months, significantly more trabeculectomy-treated eyes achieved an intraocular pressure less than 20 mm Hg without medication (88% vs. 64%, respectively). The mean IOP reduction was 48.9% in trabeculectomy-treated eyes and 30.5% in viscocanalostomy-treated eyes. Overall success, defined as IOP less than 20 mm Hg and IOP reduction greater than 30% with or without glaucoma medication, was not significantly different between the 2 groups (96% for trabeculectomy and 92% for viscocanalostomy). Although trabeculectomy had a greater IOP-lowering effect, there were fewer complications with viscocanalostomy (1 microperforation of Descemet's membrane compared with 4 cases of shallow anterior chamber and 5 cases of hypotony with IOP <4 mm Hg).

Grieshaber et al (2015) reported long-term results of viscocanalostomy in a series of 726 patients.[6] Mean IOP before surgery was 42.6 mm Hg. Mean IOP was 15.4 at 5 years, 15.5 at 10 years, and 16.8 at 15 years. Qualified success (with or without medications) at 10 years of 18 mm Hg or less was 40% in the European population and 59% in the African population. Laser goniopuncture was performed postoperatively on 127 eyes (17.7%). Fifty-three eyes (7.3%) were considered failures and required reoperation. There were no significant complications.

Stangos et al (2012) reported the effect of the learning curve on the surgical outcome of viscocanalostomy from a retrospective series of 180 consecutive cases performed by 2 surgeons at a single center in Europe.[7] Overall success, defined as no visual field deterioration with an IOP of 20 mm Hg or less and IOP reduction of 30% or greater compared to baseline values, improved from 64% to 91% when comparing the first 45 to the last 45 cases of the series. Complete success, defined as no medications required, improved from 38% to 73%. Surgical complications were not significantly different between the first and last 45 cases (16 vs. 10, respectively).

**Section Summary: Viscocanalostomy**

Two meta-analyses and 1 systematic review have evaluated RCTs comparing viscocanalostomy with trabeculectomy and reported that trabeculectomy was significantly better than viscocanalostomy at lowering IOP in patients with open-angle glaucoma. Similarly, a randomized, within-subject comparative trial reported that trabeculectomy was significantly better than viscocanalostomy at lowering IOP. However, results of other outcome measures did not differ significantly between trabeculectomy and viscocanalostomy. Viscocanalostomy was associated with fewer complications than trabeculectomy. A nonrandomized uncontrolled study suggested that results of viscocanalostomy were sustained over the long term (up to 15 years) with no significant complications. However, about 7% of treated eyes required reoperation.

## CANALOPLASTY

### Clinical Context and Therapy Purpose
The purpose of canaloplasty for individuals who have open-angle glaucoma that has failed medical therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

### Populations
The relevant population of interest is individuals with open-angle glaucoma that has failed medical therapy.

### Interventions
The treatment being considered is canaloplasty.

### Comparators
The comparators of interest are intraocular pressure-lowering procedures such as glaucoma drainage implant or trabeculectomy.

### Outcomes
The general outcomes of interest are symptoms, morbid events, quality of life, and medication use. Other health outcomes of interest are the intraocular pressure (IOP) achieved, ability to convert to trabeculectomy if procedure is unsuccessful, and durability of procedure.

Follow-up of 5 years was reported in the available studies, but to assess outcomes and duration of results, longer follow-up is needed; glaucoma is generally managed by ophthalmologists for the duration of a patient's life.

### Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

### Systematic Reviews
A comparative effectiveness review of newer (Trabectome and canaloplasty) and older (trabeculectomy and Baerveldt shunt) surgeries for glaucoma was published in 2009.[8] Twelve-month outcomes (IOP adjunctive medications and complications) were compared after glaucoma-only and combined glaucoma-phacoemulsification surgeries. The review found that Trabectome and canaloplasty provided modest IOP reduction (to about 16 mm Hg) with minimal intraoperative or postoperative complications. Results of Baerveldt glaucoma implant IOP reduction were comparable with trabeculectomy (≈12 mm Hg), but typically, this shunt required more postoperative IOP-lowering medication (average, 1.3 vs. 0.5 medications, respectively) to achieve a success rate comparable with trabeculectomy. Patients treated with Trabectome required more medications (average, 1.5) to control IOP than patients treated with canaloplasty (average, 0.6). The study concluded that Trabectome and canaloplasty are reasonable surgical therapy choices for patients in which IOPs in the mid-teens seem adequate; although trabeculectomy remains the most effective IOP-lowering procedure, it also has the highest serious complication rates.

**Randomized Controlled Trials**

In 2015, Matlach et al reported an RCT with 62 patients that compared canaloplasty with trabeculectomy for the treatment of open-angle glaucoma.[9] Patients were included who had medically uncontrolled or not sufficiently lowered IOP and progression of visual field defects or structural changes to the optic disc over time. The primary end point was an IOP of 18 mm or less or an IOP reduction of at least 20% and less than 21 mm Hg without medication. Complete success at 2 years was achieved in 74.2% of patients after trabeculectomy and 39.1% of patients after canaloplasty (p=0.01). The qualified success rate (with medication) did not differ significantly between the 2 groups, although more patients in the canaloplasty group needed IOP-lowering medication (52.2% vs 25.8%). Mean absolute IOP reduction was similar for the 2 interventions. There was a trend (p=0.08) for visual acuity to be lower in the canaloplasty group during follow-up. Trabeculectomy was associated with more frequent postoperative complications, including hypotony (37.5%), choroidal detachment (12.5%), and corneal erosion (43.8%). Scarring of the filtering bleb was a late complication in 25% of trabeculectomy patients. One limitation of this study is the unequal rate of dropouts, with 7 of 30 (23.3%) canaloplasty patients and 1 of 32 (3.1%) trabeculectomy patients lost to follow-up over the 2 years of the study. Another study by this group found higher quality of life (QOL) at 24 months following canaloplasty than trabeculectomy in a questionnaire survey of 327 patients.[10] Canaloplasty patients had a higher positive postoperative mood, satisfaction with results of surgery, and lower rates of visual and nonvisual symptoms and stress caused by surgery or postsurgical treatment. Difficulties with activities of daily living, such as reading, and complaints like eye burning were significantly lower in the canaloplasty group. Some, but not all, questions were from validated QOL questionnaires.

Yin et al. (2023) reported on an RCT with ab interno canaloplasty (n=38) versus gonioscopy-assisted transluminal trabeculectomy (n=39) in open-angle glaucoma.[11] Participants had medically uncontrolled or not sufficiently lowered intraocular pressure but no prior history of incisional ocular surgery. Demographic and clinical characteristics were balanced between canaloplasty and trabeculectomy groups, including age (mean ± standard deviation [SD], 41±3 vs. 41±15 years), % severe glaucoma (35.1% vs. 50%), mean preoperative IOP (24.9±10 vs 25.6±10.1 mm Hg), and mean number of IOP lowering medications (3.2±0.9; vs 3.3±0.9). The primary endpoint was the difference in mean IOP and the number of medications used with a secondary outcome of complete surgical success, defined as no additional glaucoma surgery, IOP between 6 and 21mmHg, and no IOP lowering medication usage at 12 months follow-up. Outcome data at the 12-month follow-up was available for 71 participants (92.2%). The study met its primary efficacy endpoint, which showed a superior IOP in the trabeculectomy group (16.0±3.1 mm Hg) over canaloplasty (19.0±5.2; p=.003). No significant between-group differences were observed in the rate of freedom from IOP-lowering medications (57.2% in the canaloplasty group vs. 77.8% in the trabeculectomy group; p=.06)or mean glaucoma medication usage (0.9±1.3 in the canaloplasty group vs. 0.6±1.2 in the trabeculectomy group; p=.27) at 1-year follow-up. The 12-month rate of complete surgical success was 56% in the canaloplasty group, and 75% in the trabeculectomy group (p=.09). Three eyes in the canaloplasty group and 1 eye in the trabeculectomy group required additional glaucoma surgeries. Hyphema (87% vs. 47%) and supraciliary effusion (92% vs. 71%) were noted more often in the trabeculectomy group than in the canaloplasty group. No intention-to-treat analysis was performed, and the number of recruited participants was lower than the power calculations recommended. A follow-up of one year limits the assessment of the durability of the treatment

effect, and the study took place at a single center in China, which may limit the generalizability of these findings.

**Nonrandomized Comparative Study**

Golaszewska et al. (2023) reported on a prospective, non-randomized study that compared the safety and efficacy of iStent bypass implantation (n=69) versus ab externo canaloplasty (n=69) in patients with primary open-angle glaucoma.[12] Both procedures were combined with phacoemulsification. All patients were indicated for surgery despite receiving the maximum tolerated pharmacological treatment and in whom glaucoma progression was detected on multiple examinations within the same year. Demographic and clinical characteristics were generally balanced between iStent and canaloplasty groups, including age (mean ± SD, 71.5±9.4 vs. 70.2±6.9 years) and preoperative IOP (18.4±3.9 vs 17.2±4.0 mm Hg). The mean number of antiglaucoma drugs before surgery was significantly higher in the canaloplasty group (2.4±1) than in the iStent group (1.9±0.9;p=.036). No significant differences in IOP (15.5 ± 2.5 vs. 15.0 ± 2.4; p=.48) or the proportion of patients with >20% reduction in IOP (37% in both groups; p>.999) were observed between the iStent and canaloplasty groups. The mean number of antiglaucoma drugs (0.2 ± 0.6 vs. 0.6 ± 1.2) and the rate of medication discontinuation (86% vs. 71.4%) did not vary at 1 year between the iStent and canaloplasty groups. Complications of microhyphema (2.9% vs. 42.3%; p<.001) and elevated IOP (21.7% vs. 50.0%; p=.015) were significantly less common in the iStent group intra-operatively through 14 days post-operatively, but no differences were observed in the rate of late complications.

**Case Series**

The primary literature on canaloplasty consists mainly of case series that compare posttreatment IOP with pretreatment IOP. One retrospective comparative study evaluated outcomes from 33 eyes (33 patients) that underwent canaloplasty and 46 eyes (46 patients) that underwent trabeculectomy during a 2-year period and had a minimum of 12 month of follow-up.[13] This study group was drawn from a larger group of 243 patients who underwent surgery during the same 2-year period (87 canaloplasty procedures and 156 trabeculectomy procedures). The specific procedure was determined by the ability to obtain insurance coverage for canaloplasty, and the groups were comparable in demographics, previous surgery, and visual acuity at baseline. At 12 months after surgery, the mean reduction in IOP from preoperative values was 32% for canaloplasty and 43% for trabeculectomy (p=0.072). IOP was slightly lower in the trabeculectomy group (11.6 vs. 13.8 mm Hg; p=0.03), and fewer patients needed postoperative glaucoma medications. There was no significant difference in surgical reoperation rates between the 2 procedures (15% canaloplasty and 11% trabeculectomy). This study is limited by the potential for bias in the selection of patients for the study. Only a minority of all surgical patients had 12-month follow-up data and were included in the study, and selection into treatment groups was dependent on insurance status.

In 2007, Lewis et al. reported interim data analysis from a company-sponsored multicenter (15 centers) safety/efficacy study on canaloplasty using the iTrack microcatheter[14] with 2- and 3-year results reported in 2009 and 2011.[15,16] The study included 157 patients with a diagnosis of primary open-angle glaucoma, pigmentary glaucoma, exfoliative glaucoma, and a baseline IOP of 16 mm Hg or higher before surgery, with a historical IOP of 21 mm Hg or higher. Exclusion criteria were neovascular disease, uveitis, peripheral anterior synechiae, angle recession, and developmental or secondary glaucoma (except for pigmentary and exfoliative glaucoma). At baseline, the mean IOP was 23.8, and patients were on an average 1.8

medications. Canaloplasty was successful in 133 eyes (85%). Eyes that did not have placement of a tensioning suture were viscodilated to the extent possible by catheterizing the canal from both ostia. Early surgical/postoperative complications included microhyphema (12%), hyphema (10%), elevated IOP (6%), Descemet membrane detachment (3%), suture extrusion (1%), and hypotony (1%). Late postoperative complications included cataract (12.7%), transient IOP elevation (6.4%), and partial suture extrusion through the trabecular meshwork (0.6%). At 3 years postoperatively, 134 study eyes (85% follow-up) had a mean IOP of 15.2 mm Hg and mean glaucoma medication use of 0.8 medications; 66 eyes (49.3%) were on no medications. Another 7 patients (4.4%) had additional glaucoma surgery. With qualified success defined as achieving IOP of 18 mm Hg or lower (with 0 to 2 medications), success was achieved in 69 of the 89 eyes (77.5%) that had successful suture implantation alone and 24 of the 27 eyes (89%) with successful suture placement combined with phacoemulsification.

Additional reports from this group of investigators included interim 1-year results for 40 patients who had combined canaloplasty and cataract surgery (potential overlap in patients from the study described earlier)[17] and a within subject comparison in 15 of the patients who participated in the trial described earlier who had bilateral primary open-angle glaucoma (POAG) and received canaloplasty in 1 eye and viscocanalostomy in the contralateral eye.[18] For the canaloplasty eye, IOP decreased from 26.5 mm Hg on 2.1 medications to 14.5 on 0.3 medications. For the viscocanalostomy eye, IOP decreased from 24.3 mm Hg on 1.9 medications to 16.1 on 0.4 medications. The reduction in IOP from baseline was significantly greater with canaloplasty than with viscocanalostomy (12.0 vs. 8.2 mm Hg, p=0.02). There was no loss in visual acuity and no adverse events from either procedure. The authors noted that this study evaluates the effects of 2 additional maneuvers associated with canaloplasty: first, 360 degrees viscodilation of Schlemm canal, as opposed to partial dilation achieved with viscocanalostomy, and second, prolonged opening and tensioning of Schlemm canal with suture placement.[18]

The same investigators reported an industry-sponsored 3-year prospective, multicenter study of 109 open-angle glaucoma patients (109 eyes) who underwent canaloplasty or combined cataract-canaloplasty surgery.[19] All patients had documented visual field loss and met criteria for the diagnosis of glaucoma and failure of prior medical or laser therapy. A tensioning suture was successfully placed in 98 eyes (89.9%) and 96 eyes (88.1%) completed the 3-year follow-up. Of the 13 patients who did not complete follow-up, 4 (3.7%) had undergone additional glaucoma surgery; these patients were not included in the analysis. In eyes treated with canaloplasty with a successful tensioning suture, IOP decreased from 23 mm Hg on 1.9 medications to 15.1 mm Hg on 0.9 medications. In eyes treated with combined cataract-canaloplasty surgery with a successful tensioning suture, IOP decreased from 24.3 mm Hg on 1.5 medications to 13.8 mm Hg on 0.5 medications. For the 11 eyes that had canaloplasty without suture placement, IOP decreased from 24.4 on 1.9 medications to 15.6 on 1.2 medications. Late postoperative complications included cataracts (19.1%) and transient IOP elevation (1.8%).

A prospective series with 60 consecutive South African patients with POAG who underwent canaloplasty was reported by Grieshaber et al in 2010.[20] The mean preoperative IOP was 45 mm Hg. At 12-month follow-up, the IOP was 15 mm Hg (n=54), and at 36 months, the IOP was 13.3 mm Hg (n=49). Eleven patients (18%) were lost to follow-up at 3 years. With qualified success defined as achieving IOP of 21 mm Hg or lower (with or without medications), success was achieved in 40 of 49 patients (82%). When defined as an IOP of 16 mm Hg or less without

medications, 47% of eyes met criteria for complete success. There were no severe complications in this series.

Three-year follow-up from an independent series of 214 patients treated with canaloplasty in Europe was reported by Brusini in 2014.[21] Mean IOP was reduced from 29.4 mm Hg at baseline to 17.0 mm Hg, after excluding 17 patients (7.9%) who later underwent trabeculectomy. IOP was 21 mm Hg or lower in 86.2% of patients, 18 mm Hg or lower in 58.6%, and 16 mm Hg or lower in 37.9%. There was a decrease in mean medication use, from 3.3 at baseline to 1.3 at follow-up. Complications, which included hyphema, Descemet membrane detachment, IOP spikes, and hypotony, were fewer than is typically seen with trabeculectomy. Several disadvantages of the procedure were noted, including the inability to complete the procedure in 16.4% of eyes.

In 2015, Voykov et al reported on a 5-year follow-up on patients (20 eyes) with open-angle glaucoma who underwent canaloplasty at a single center in Germany.[22] Mean IOP decreased from 25.7 mm Hg at baseline (n=33) to 15.5 mm Hg (n=19) at one year, 15.1 mm Hg (n=18) at three years, and 14.2 mm Hg (n=18) at five years. At each time point, reductions in mean IOP were statistically significant versus baseline ($p<0.001$). Mean number of medications used was 3.4 at baseline, 1.5 at one year, 1.6 at three years and 1.7 at five years. At each time point, medication use was significantly lower than baseline ($p<0.001$). Thirteen (65%) of 20 eyes underwent another surgical procedure due to inadequate IOP control. Median length of time before additional surgery was 24 months (95% confidence interval, 1 to 51 months). The complication rate was low, the most common being hyphema (7/20 [35%] eyes). No sight-threatening complications were reported.

Other case series have evaluated ab interno canaloplasty via the use of the iTrack[23-26] or OMNI surgical systems[27-31] in patients with mild-to-moderate primary open-angle glaucoma as a standalone procedure or in combination with cataract surgery. Two studies of the OMNI system evaluating a total of 267 eyes with uncontrolled baseline intraocular pressure (IOP) reported mean reductions in IOP and medication use ranging between 5.5 to 6.4 mmHg and 0.6 to 1.1 medications, respectively, over 12-36 months of follow-up.[27,28,31] Results from the smaller GEMINI study of 120 patients treated with the OMNI system reported an IOP reduction of 8.2 mmHg and a mean decrease of 1.4 medications over 12 months, with 75% of participants achieving a mean IOP ≤18 mmHg; however, analysis was based on mean diurnal ocular pressure following medication washout at baseline, and it is unclear what proportion of patients initially had uncontrolled IOP on medication.[29] In a GEMINI extension study, 66 participants demonstrated a mean diurnal ocular pressure reduction of 6.9 mm Hg from baseline, with 71% maintaining an IOP between 6 and 16 mm Hg and a reduction in mean number of IOP-lowering medications from 1.7 to 0.3 over three years of follow-up.[32] A subgroup analysis of 39 Hispanic participants in the GEMINI study, a demographic disproportionally affected by primary open-angle glaucoma in the U.S., showed comparable results, with a mean IOP decrease of 7.9 and no need for continued medication use in 87%.[30] One small study utilizing the OMNI system in 27 patients previously treated with the iStent trabecular microbypass stent reported a mean IOP reduction of 5.1 mmHg and a mean decrease of 0.4 medications.[33] Four studies of the iTrack system evaluated a total of 162 eyes treated with canaloplasty alone or in combination with cataract surgery and reported 36 to 72 month outcomes.[23-26] Mean IOP reductions ranged from 5.2 to 7.2 mmHg and medication use decreased between 1 to 1.5 medications. Overall, 40% to 77.2% of participants were using ≤1

medication at final follow-up. No serious complications were reported across studies utilizing the iTrack or OMNI systems.

**Section Summary: Canaloplasty**
Findings from two small RCT and one comparative effectiveness review have indicated that trabeculectomy is generally superior to canaloplasty for lowering IOP; however, the procedure has been associated with more serious complication rates. Another study has reported that canaloplasty resulted in improved QOL outcomes at 2 years relative to trabeculectomy, although not all QOL measures derived from validated questionnaires. Additionally, several, small, industry-sponsored case series comparing pre- and post-treatment results of canaloplasty alone or in combination with cataract surgery have shown that most patients achieved sufficient IOP lowering with reduced need for continued medication and relatively few complications.

## 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 comparing Viscocanalostomy with Trabeculectomy. Relevant outcomes include symptoms, morbid events, quality of life, and medication use. Meta-analysis of these trials indicates that trabeculectomy has a greater intraocular pressure–lowering effect than viscocanalostomy. Reduction in IOP has also been shown to be greater with canaloplasty than viscocanalostomy in a small within-subject comparison. This evidence is not sufficient to determine whether viscocanalostomy is at least as good as established alternatives. Therefore, the evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have open-angle glaucoma who have failed medical therapy who receive canaloplasty, the evidence includes one RCT, one comparative effectiveness review, and several case series. Relevant outcomes include symptoms, morbid events, quality of life, and medication use. The RCTs found significantly higher complete success rates 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 ~16 mm Hg) with minor intraoperative or postoperative complications. The evidence is insufficient to determine the effects of the technology on health outcomes.

## SUPPLEMENTAL INFORMATION

**Clinical Input Obtained From Specialty Medical Societies and Academic Medical Centers**
In response to requests regarding viscocanalostomy, BCBSA received input from 1 specialty medical society and 3 academic medical centers while this policy was under review in 2011. Although some considered viscocanalostomy to be medically necessary in a select group of patients who would be at risk for suffering a blinding complication with trabeculectomy, the input was mixed. Notably, one reviewer considered outcomes with viscocanalostomy to be inferior to other currently used non-penetrating techniques.

In response to requests regarding canaloplasty, input was received from 1 specialty medical society and 2 academic medical centers while this policy was under review in 2011. The American Academy of Ophthalmology provided a statement indicating that the case series cited are sufficient to show efficacy of canaloplasty to lower IOP to treat open angle glaucoma. Other reviewers considered canaloplasty investigational but medically necessary for a select group of patients (e.g., patients who are at risk for infection or hypotony, who have surface disease that would preclude the creation of good trabeculectomy bleb, or that would not be able to cover a glaucoma drainage device implant).

## PRACTICE GUIDELINES AND POSITION STATEMENTS

### American Academy of Ophthalmology (AAO)

A 2011 Technology Assessment from the AAO included canaloplasty in its review of novel glaucoma procedures.[34] The AAO concluded that all of the techniques and devices reviewed were still in the initial stage (≤5 years) of clinical experience and lacking widespread use, with only level III evidence (cohort studies) in support of the procedures. In addition to describing potential advantages and disadvantages of the procedure, it was noted that the long-term effects of a foreign body in Schlemm's canal are not known.

### National Institute for Health and Clinical Excellence (NICE)

In 2017, the National Institute for Health and Care Excellence (NICE) updated its 2008 guidance on canaloplasty for primary open-angle glaucoma.[35,36] The current recommendation is that the "evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is adequate is support the use of this procedure.…"

Similarly, in 2017, amended in 2022, guidance on the diagnosis and management of chronic open-angle glaucoma.[37,38] When comparing penetrating surgery (trabeculectomy) with nonpenetrating surgery (deep sclerectomy and viscocanalostomy), NICE found moderate-quality evidence that trabeculectomy is more effective than nonpenetrating surgery in reducing the number of eyes with an unacceptable intraocular pressure, but was more likely to cause cataract formation and persistent hypotony at 12- to 36-month follow-up. There was very low-quality evidence that trabeculectomy is more effective than nonpenetrating surgery in reducing intraocular pressure from baseline to 6- and 12-month follow-up, but the effect size might have been too small to be clinically significant. The guidance recommended offering information on the risks and benefits associated with surgery and offering surgery (type not specified) with pharmacologic augmentation to people with chronic open-angle glaucoma at risk of progressing to sight loss, despite treatment.

In 2022, NICE published an interventional procedures guidance on ab interno canaloplasty for open-angle glaucoma.[39] The current recommendation states that "evidence on the safety of ab interno canaloplasty for open-angle glaucoma shows no major safety concerns. Evidence on the efficacy is limited in quality and quantity, particularly in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov did not identify any ongoing or unpublished trials that would likely influence this review.

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## Government Regulations
## National/Local:

No NCD or LCD on canaloplasty and/or viscocanalostomy.
Codes 66174 & 66175 are payable.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

- Ophthalmologic Techniques for Evaluating Glaucoma

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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2024, the date the research was completed.*

## Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|---|---|---|---|
| 1/1/09 | 12/1/08 | 12/14/08 | Joint policy, **"**Insertion of Anterior Segment Aqueous Drainage Device for Glaucoma" established |
| 5/1/10 | 3/16/10 | 2/16/10 | Policy title changed from "Insertion of Anterior Segment Aqueous Drainage Device for Glaucoma" to "Glaucoma Surgery using Aqueous Shunts and Transluminal Dilation Devices." Combined the previous "Canaloplasty and Viscocanalostomy" policy into this policy. |
| 9/1/11 | 6/21/11 | 6/21/11 | Title changed from "Glaucoma Surgery using Aqueous Shunts and Transluminal Dilation Devices" to "Glaucoma Surgery." Updated codes, added 0192T as established and 0191T as experimental and investigational. NOTE: the EyePass shunt, coded as 0192T, is still experimental and investigational, as it has not received FDA approval.<br><br>0176T and 0177T were replaced by 66174 and 66175, respectively, 66175 is still considered experimental/ investigational. Canaloplasty (66174) status changed to "established." 0253T added as experimental and investigational. Updated references and rationale. Added code 66999 to be used for Trabectome. |
| 9/1/11 | 8/16/11 | 8/16/11 | Correction made to coding; 66175 changed to "established" as it is a form of canaloplasty. Code 66999 still considered experimental and investigational, may be used for coding viscocanalostomy as well as Trabectome. Effective date remains 9/1/11. |
| 9/1/13 | 6/19/13 | 6/26/13 | This policy was split out from the combined policy on Glaucoma Surgery in order to mirror the BCBSA policy. Code status unchanged. Viscocanalostomy remains experimental/investigational. |
| 3/1/15 | 12/12/14 | 12/29/14 | Routine maintenance. No change in policy status. |
| 3/1/16 | 12/10/15 | 12/10/15 | Routine maintenance, no changes in policy status. Updated references. |
| 3/1/17 | 12/13/16 | 12/13/16 | Updated references and rationale, deleted Blue Cross Complete from coverage section. No change in policy status. |
| 3/1/18 | 12/12/17 | 12/12/17 | Routine policy maintenance, no change in policy status. |

| | | | |
|---|---|---|---|
| 3/1/19 | 12/11/18 | | Routine policy maintenance, no change in policy status. |
| 3/1/20 | 12/17/19 | | Routine policy maintenance. No change in policy status. |
| 3/1/21 | 12/15/20 | | Routine policy maintenance. No change in policy status. |
| 3/1/22 | 12/14/21 | | Routine policy maintenance. No change in policy status. |
| 3/1/23 | 12/20/22 | | Routine policy maintenance, no change in policy status. |
| 3/1/24 | 12/19/23 | | Updated rationale, added references 1, 21-27 and 33. No change in policy status. Vendor managed: N/A (ds) |
| 3/1/25 | 12/17/24 | | Routine policy maintenance, updated rational adding references. No change in status. Vendor managed: N/A (ds) |

Next Review Date: 4th Qtr. 2025

# BLUE CARE NETWORK BENEFIT COVERAGE
# POLICY: VISCOCANALOSTOMY AND CANALOPLASTY

## I. Coverage Determination:

| | |
|---|---|
| **Commercial HMO (includes Self-Funded groups unless otherwise specified)** | Per policy |
| **BCNA (Medicare Advantage)** | See government section |
| **BCN65 (Medicare Complementary)** | Coinsurance covered if primary Medicare covers the service. |

## II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.