

<b>Policy Number</b>	<b>SUR713.032</b>
<b>Policy Effective Date</b>	<b>07/15/2025</b>

## Viscocanalostomy and Canaloplasty

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### Disclaimer

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### Coverage

Canaloplasty **may be considered medically necessary** 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 (e.g., trabeculectomy or glaucoma drainage implant) due to a high risk for complications.

Canaloplasty is **considered experimental, investigational and/or unproven** under all other conditions, including angle-closure glaucoma.

Viscocanalostomy is **considered experimental, investigational and/or unproven**.

### Policy Guidelines

Tensioning devices are only able to reduce intraocular pressure (IOP) to the mid-teens and may be inadequate when very low IOP is needed to reduce glaucoma damage.

## Description

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 (e.g., trabeculectomy), alternative surgical treatments (e.g., transluminal dilation by viscocanalostomy or canaloplasty) are being evaluated for individuals with glaucoma.

### **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.

### 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 the 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 (e.g., 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™, 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 (e.g., 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 (e.g., <15 mm Hg), and are not indicated for patients for whom very low intraocular pressure is desired (e.g., those with advanced glaucoma).

### **Regulatory Status**

In 2004, iTrack™ (iScience Interventional) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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, iTrack™ was cleared by the FDA for “catheterization and viscodilation of [the] Schlemm 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.

### **Rationale**

Medical policies 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. Randomized controlled trials 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 have 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 policy.

#### *Populations*

The relevant population of interest is individuals with open-angle glaucoma that have 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 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.

In 2024, the American Academy of Ophthalmology's Glaucoma Preferred Practice Pattern® Committee published a special commentary outlining guidelines for reporting clinical endpoints in studies of Minimally Invasive Glaucoma Surgery (MIGS), emphasizing standardized methodologies, meaningful patient-centered outcomes, and defining success criteria for various MIGS procedures. (2) The Committee made the following recommendations: "The Committee recommends that the cumulative probability of surgical success at 2 years with Kaplan–Meier survival analysis be used as the primary efficacy endpoint in MIGS studies. The Committee suggests that surgical success for standalone MIGS be defined as intraocular pressure of 21 mm Hg or less and reduced by 20% or more from baseline without an increase in glaucoma medications, additional laser or incisional glaucoma surgery, loss of light perception vision, or hypotony. The proposed MCID [minimal clinically important difference] for the cumulative probability of success of standalone MIGS at 2 years is 50%. The panel recommends that surgical success for MIGS combined with cataract extraction with intraocular lens implantation (CE-IOL) be defined as a decrease in glaucoma medical therapy of 1 medication or more from baseline without an increase in IOP [intraocular pressure] or IOP of 21 mm Hg or less and reduced by 20% or more from baseline without an increase in glaucoma medications, additional laser or incisional glaucoma surgery, loss of light perception vision, or hypotony. The suggested MCID for the cumulative probability of success for MIGS combined with CE-IOL at 2 years is 65%."

### 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 meta-analysis by Chai and Loon (2010) compared the safety and efficacy of viscocanalostomy with the criterion standard of trabeculectomy. (3) Ten RCTs with a total of 458 eyes (397 patients) with medically uncontrolled glaucoma were analyzed. The number of eyes in each study ranged from 20 to 60, with follow-up ranging from 6 months to 4 years. Most 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 viscocanalostomy and trabeculectomy 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 the Descemet membrane (RR=7.72). In contrast, viscocanalostomy had significantly fewer postoperative events than trabeculectomy (hypotony RR=0.29, hyphema

RR=0.50, shallow anterior chamber RR=0.19, cataract formation RR=0.31). Although viscocanalostomy had a better risk profile, most adverse events associated with trabeculectomy were considered to be mild and reversible. Similar results were obtained in a Cochrane review and meta-analysis by Eldaly et al. (2014) that included 2 small, randomized trials (total 50 eyes). (4)

#### Randomized Controlled Trial

A study included in the Chai and Loon systematic review is the RCT by Gilmour et al. (2009), which reported 4-year follow-up. (5) 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 an intraocular pressure less than 18 mm Hg with no medications; a qualified success was defined as an intraocular pressure 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 intraocular pressure of 25 mm Hg and were using an average of 1.4 medications. At mean follow-up of 40 months (range, 6-60 months), 10 (42%) patients in the trabeculectomy group had achieved success compared with 5 (21%) patients in the viscocanalostomy group. Although 19 (79%) patients 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 they did not affect outcomes. 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 in the viscocanalostomy group.

#### Case Series

Kobayashi et al. (2003) reported on 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 intraocular pressure greater than 22 mm Hg under medical therapy. (6) Patients were randomized to trabeculectomy in 1 eye and viscocanalostomy (with removal of the internal wall of the Schlemm canal) in the other. Follow-up was performed on certain days, weeks, and months up to 12 months after surgery. Throughout follow-up, mean intraocular pressure 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). At 12 months, significantly more trabeculectomy-treated eyes achieved an intraocular pressure less than 20 mm Hg without medication (88% vs. 64%, respectively). Mean intraocular pressure reduction was 48.9% in trabeculectomy-treated eyes and 30.5% in viscocanalostomy-treated eyes. Overall success (intraocular pressure <20 mm Hg) and intraocular pressure reduction greater than 30% with or without glaucoma medication did not differ significantly between the groups (96% for trabeculectomy vs. 92% for viscocanalostomy).

Although trabeculectomy had a greater intraocular pressure-lowering effect, viscocanalostomy had fewer complications (1 microperforation of the Descemet membrane vs. 4 cases of shallow anterior chamber, and 5 cases of hypotony with intraocular pressure <4 mm Hg).

Grieshaber et al. (2015) reported on long-term results of viscocanalostomy for a series of 726 patients. (7) Mean intraocular pressure before surgery was 42.6 mm Hg. Mean intraocular pressure postsurgery was 15.4 mm Hg at 5 years, 15.5 mm Hg at 10 years, and 16.8 mm Hg at 15 years. Qualified success (with or without medications) at 10 years ( $\leq 18$  mm Hg) was 40% in the European population and 59% in the African population. Laser goniopuncture was performed postoperatively on 127 (17.7%) eyes. Fifty-three (7.3%) eyes were considered failures and required reoperation. There were no significant complications.

Stangos et al. (2012) reported on the effect of the learning curve on surgical outcomes from viscocanalostomy for a retrospective series of 180 consecutive cases performed by 2 surgeons at a single center in Europe. (8) Overall success (no visual field deterioration with an intraocular pressure  $\leq 20$  mm Hg) and intraocular pressure reduction of 30% or more compared with baseline values improved from 64% for the first 45 and to 91% for the last 45 cases of the series. Complete success (no medications required) improved from 38% to 73%. Surgical complications did not differ significantly between the first (16) and last 45 cases (10).

#### Section Summary: Viscocanalostomy

Two meta-analyses and a systematic review have evaluated RCTs comparing viscocanalostomy with trabeculectomy and reported that trabeculectomy was significantly better than viscocanalostomy at lowering intraocular pressure in patients with open-angle glaucoma. Similarly, a randomized, within-subject comparative trial reported that trabeculectomy was significantly better than viscocanalostomy at lowering intraocular pressure. 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 policy.

##### *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 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.

In 2024, the American Academy of Ophthalmology's Glaucoma Preferred Practice Pattern® Committee published a special commentary outlining guidelines for reporting clinical endpoints in studies of MIGS, emphasizing standardized methodologies, meaningful patient-centered outcomes, and defining success criteria for various MIGS procedures. (2) The Committee made the following recommendations: "The Committee recommends that the cumulative probability of surgical success at 2 years with Kaplan–Meier survival analysis be used as the primary efficacy endpoint in MIGS studies. The Committee suggests that surgical success for standalone MIGS be defined as intraocular pressure of 21 mmHg or less and reduced by 20% or more from baseline without an increase in glaucoma medications, additional laser or incisional glaucoma surgery, loss of light perception vision, or hypotony. The proposed MCID [minimal clinically important difference] for the cumulative probability of success of standalone MIGS at 2 years is 50%. The panel recommends that surgical success for MIGS combined with cataract extraction with intraocular lens implantation (CE-IOL) be defined as a decrease in glaucoma medical therapy of 1 medication or more from baseline without an increase in IOP [intraocular pressure] or IOP of 21 mmHg or less and reduced by 20% or more from baseline without an increase in glaucoma medications, additional laser or incisional glaucoma surgery, loss of light perception vision, or hypotony. The suggested MCID for the cumulative probability of success for MIGS combined with CE-IOL at 2 years is 65%."

### 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 comparative effectiveness review of newer (Trabectome and canaloplasty) and older (trabeculectomy and Baerveldt shunt) surgeries for glaucoma was published in 2009. (9) Twelve-month outcomes (intraocular pressure adjunctive medications, complications) were compared after glaucoma-only and combined glaucoma-phacoemulsification surgeries. Reviewers found that Trabectome and canaloplasty provided modest intraocular pressure reduction (to approximately 16 mm Hg) with minor intraoperative or postoperative complications. Reductions for Baerveldt glaucoma implant intraocular pressure were comparable to those for trabeculectomy (approximately 12 mm Hg), but the Baerveldt shunt required more postoperative intraocular pressure lowering medication (average, 1.3 medications vs. 0.5 medications, respectively) to produce a success rate comparable to trabeculectomy. Patients treated with Trabectome required more medications (average, 1.5 medications) to control intraocular pressure than patients treated with canaloplasty (average, 0.6 medications). Reviewers concluded that Trabectome and canaloplasty were reasonable surgical choices for patients in whom intraocular pressures in the mid-teens seemed adequate; although trabeculectomy was the most effective intraocular pressure lowering procedure, it also had the most serious complication rates.

#### Randomized Controlled Trials

Matlach et al. (2015) reported on an RCT with 62 patients that compared canaloplasty (n=31) with trabeculectomy (n=31) for the treatment of open-angle glaucoma. (10) Patients included had medically uncontrolled or not sufficiently lowered intraocular pressure and progression of visual field defects or structural changes to the optic disc over time. The primary end point was an intraocular pressure of 18 mm Hg or less or an intraocular pressure 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 intraocular pressure lowering medication (52.2% vs. 25.8%, respectively). Mean absolute intraocular pressure reduction was similar for both 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 study flaw was the unequal rate of dropouts (23.3% [7/30] for canaloplasty vs. 3.1% [1/32] for trabeculectomy) over the 2 years of study. Another study (2015) by this group found higher quality of life at 24 months following canaloplasty than trabeculectomy in a questionnaire survey of 327 patients. (11) Canaloplasty patients had a higher positive postoperative mood, higher satisfaction with surgical results, and lower rates of visual and nonvisual symptoms and stress caused by surgery or postsurgical treatment. Difficulties with activities of daily living (e.g., reading) and complaints (e.g., eye burning) were significantly lower in the canaloplasty group. Some questions used were not from validated quality of life 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. (12) 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 trabeculotomy groups, including age (mean  $\pm$  standard deviation [SD], 41 $\pm$ 3 vs. 41 $\pm$ 15 years), % severe glaucoma (35.1% vs. 50%), mean preoperative IOP (24.9 $\pm$ 10 vs. 25.6 $\pm$ 10.1 mm Hg), and mean number of IOP lowering medications (3.2 $\pm$ 0.9 vs. 3.3 $\pm$ 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 21 mm Hg, 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 $\pm$ 3.1 mm Hg) over canaloplasty (19.0 $\pm$ 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 $\pm$ 1.3 in the canaloplasty group vs. 0.6 $\pm$ 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. (13) 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  $\pm$  SD, 71.5 $\pm$ 9.4 vs. 70.2 $\pm$ 6.9 years) and preoperative IOP (18.4  $\pm$  3.9 vs. 17.2  $\pm$  4.0 mm Hg). The mean number of antiglaucoma drugs before surgery was significantly higher in the canaloplasty group (2.4 $\pm$ 1) than in the iStent group (1.9 $\pm$ 0.9;  $p=.036$ ). No significant differences in IOP (15.5 $\pm$ 2.5 vs. 15.0 $\pm$ 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  $\pm$  0.6 vs. 0.6  $\pm$  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

Most of the primary literature on canaloplasty consists of case series that have compared posttreatment with pretreatment intraocular pressure. For example, a retrospective comparative study by Ayyala et al. (2011) 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 follow-up of 12 months. (14) This study group was drawn from 243 patients who underwent surgery during the same 2-year period (87 canaloplasty procedures, 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 postsurgery, mean reduction in intraocular pressure from preoperative values was 32% for canaloplasty and 43% for trabeculectomy ( $p=0.072$ ). Intraocular pressure was slightly lower in the trabeculectomy group (11.6 mm Hg vs. 13.8 mm Hg;  $p=0.03$ ), and fewer patients in that group needed postoperative glaucoma medications. There was no significant difference in surgical reoperation rates between the 2 procedures (15% canaloplasty vs. 11% trabeculectomy). This study had a potential for patient selection bias. Only a minority of surgical patients had 12-month follow-up data, and treatment group assignment depended on insurance status.

Lewis et al. (2007) reported on interim data analysis from a manufacturer-sponsored multicenter (15 centers) safety and efficacy study on canaloplasty using the iTrack microcatheter (15) with 2- and 3-year results reported in 2009 and 2011. (16, 17) The 2011 study included 157 patients with a diagnosis of primary open-angle glaucoma, pigmentary glaucoma, exfoliative glaucoma, and a baseline intraocular pressure of 16 mm Hg or higher before surgery, with a history of intraocular pressure 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, mean intraocular pressure was 23.8 mm Hg, and patients were on an average of 1.8 medications. Canaloplasty was successful in 133 (85%) eyes. Eyes that did not have placement of a tensioning suture were viscodilated to the extent possible by catheterizing the canal from both ostia. Some of the more common early surgical and postoperative complications included microhyphema (12%), hyphema (10%), elevated intraocular pressure (6%), and Descemet membrane detachment (3%). More common late postoperative complications included cataracts (12.7%) and transient intraocular pressure elevation (6.4%). At 3 years postoperatively, 134 study eyes (85% follow-up) had a mean intraocular pressure of 15.2 mm Hg and mean glaucoma medication use of 0.8 medications; 66 (49.3%) eyes were on no medications. Another 7 (4.4%) patients had additional glaucoma surgery. With qualified success defined as achieving an intraocular pressure of 18 mm Hg or lower (with 0-2 medications), success was achieved in 69 (77.5%) of the 89 eyes that had successful suture implantation alone and in 24 (89%) of the 27 eyes with successful suture placement combined with phacoemulsification.

Additional reports from this group of investigators included interim 1-year results (2008) for 40 patients who had combined canaloplasty and cataracts surgery (potential overlap in patients from the study described earlier) (18) and a within-subject comparison (2012) in 15 patients who participated in the trial described earlier who had bilateral primary open-angle glaucoma

and received canaloplasty in 1 eye and viscocanalostomy in the contralateral eye. (19) For the canaloplasty eye, intraocular pressure decreased from 26.5 mm Hg on 2.1 medications to 14.5 mm Hg on 0.3 medications. For the viscocanalostomy eye, intraocular pressure decreased from 24.3 mm Hg on 1.9 medications to 16.1 mm Hg on 0.4 medications. Reduction in intraocular pressure from baseline was significantly greater with canaloplasty (12.0 mm Hg) than with viscocanalostomy (8.2 mm Hg;  $p=0.02$ ). No losses in visual acuity or adverse events were reported for either procedure. The investigators noted that this study evaluated the effects of 2 other maneuvers associated with canaloplasty: 1) 360° viscodilation of Schlemm canal, as opposed to partial dilation achieved with viscocanalostomy, and 2) prolonged opening and tensioning of Schlemm canal with suture placement. (19)

The same investigators also reported on an industry-sponsored, 3-year prospective, multicenter study (2011) of 109 open-angle glaucoma patients (109 eyes) who underwent canaloplasty or combined cataract-canaloplasty surgery. (20) All patients had documented visual field loss and met criteria for diagnosis of glaucoma and failure of prior medical or laser therapy. A tensioning suture was successfully placed in 98 (89.9%) eyes, and 96 (88.1%) eyes completed the 3-year follow-up. Of the 13 patients who did not complete follow-up, 4 (3.7%) had additional glaucoma surgery; they were not included in the analysis. In eyes treated with canaloplasty with a successful tensioning suture, intraocular pressure 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, intraocular pressure 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, intraocular pressure decreased from 24.4 mm Hg on 1.9 medications to 15.6 mm Hg on 1.2 medications. Late postoperative complications included cataracts (19.1%) and transient intraocular pressure elevation (1.8%).

A prospective series with 60 consecutive Black South African patients with primary open-angle glaucoma who underwent canaloplasty was reported by Grieshaber et al. (2010). (21) Mean preoperative intraocular pressure was 45 mm Hg. At 12-month follow-up, intraocular pressure was 15 mm Hg (n=54); at 36 months, intraocular pressure was 13 mm Hg (n=49). Eleven (18%) patients were lost to follow-up at 3 years. With qualified success defined as achieving an intraocular pressure of 21 mm Hg or lower (with or without medications), success was achieved in 40 (82%; 95% CI not reported) of 49 patients. When defined as an intraocular pressure of 16 mm Hg or less without medications, 47% (95% CI, 36% to 62%) of eyes met criteria for complete success at 36 months. 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 (2014). (22) Mean intraocular pressure was reduced from 29.4 mm Hg at baseline to 17.0 mm Hg, after excluding 17 (7.9%) patients who later underwent trabeculectomy. At 3 years, intraocular pressure 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, intraocular pressure spikes, and hypotony, were

fewer than typically seen with trabeculectomy. Several disadvantages of the procedure were noted, including the inability to complete the procedure in 16.4% of eyes.

Voykov et al. (2015) reported on 5-year follow-up on patients (20 eyes) with open-angle glaucoma who underwent canaloplasty at a single center in Germany. (23) Mean intraocular pressure decreased from 25.7 mm Hg at baseline (n=33) to 15.5 mm Hg (n=19) at 1 year, 15.1 mm Hg (n=18) at 3 years, and 14.2 mm Hg (n=18) at 5 years. At each time point, reductions in mean intraocular pressure were statistically significant versus baseline ( $p<0.001$ ). Mean number of medications used was 3.4 at baseline, 1.5 at 1 year, 1.6 at 3 years, and 1.7 at 5 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 intraocular pressure control. Median length of time before additional surgery was 24 months (95% CI, 1 to 51 months). The complication rate was low, with the most common being hyphema (7/20 [35%] eyes). No sight-threatening complications were reported.

Ennerst et al. (2024) reported on a retrospective study comparing long-term outcomes of canaloplasty in patients with primary open-angle glaucoma. (24) A total of 48 eyes (34 patients) underwent canaloplasty alone (28 eyes) or combined with phacoemulsification (20 eyes). In the canaloplasty group, mean intraocular pressure decreased from  $22.0\pm3.8$  mmHg at baseline to  $16.5\pm1.2$  mmHg at 10 years, with medication count reduced from  $1.5\pm1.0$  to  $0.9\pm1.1$ . In the group that received canaloplasty combined with phacoemulsification, mean intraocular pressure decreased from  $24.5\pm6.0$  mmHg to  $14.8\pm2.0$  mmHg at 10 years, and medication count decreased from  $2.2\pm1.2$  to  $0.5\pm0.9$ . Most reported postoperative complications in both groups were self-limiting.

Other case series have evaluated ab interno canaloplasty via the use of the iTrack (25-28) or OMNI surgical systems (29-33) in patients with mild-to-moderate primary open-angle glaucoma as a standalone procedure or in combination with cataract surgery. Three studies of the OMNI system evaluating a total of 438 eyes with uncontrolled baseline intraocular pressure (IOP) reported mean reductions in IOP and medication use ranging between 3.2 to 6.4 mmHg and 0.4 to 1.1 medications, respectively, over 12-36 months of follow-up. (29, 30, 33) 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  $\leq 18$  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. (31) 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. (34) A subgroup analysis of 39 Hispanic participants in the GEMINI study, a demographic disproportionately 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%. (32) 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. (35) 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. (25-28) Mean IOP reductions ranged from 5.2 to 7.2 mmHg and medication use decreased between 0.9 to 1.5 medications. Overall, 40% to 77.2% of participants were using  $\leq 1$  medication at final follow-up. No serious complications were reported across studies utilizing the iTrack or OMNI systems.

### Section Summary: Canaloplasty

Findings from two RCTs and a comparative effectiveness review have indicated that trabeculectomy is generally superior to canaloplasty for lowering intraocular pressure; however, the procedure has been associated with more serious complication rates. Another study has reported that canaloplasty resulted in improved quality of life outcomes at 2 years relative to trabeculectomy, although not all quality-of-life measures derived from validated questionnaires. A non-randomized, comparative study found that when combined with phacoemulsion, both canaloplasty and iStent bypass implantation had similar 1-year post-surgery intraocular pressure and glaucoma medication reductions, but a greater number of early postoperative complications were observed in the canaloplasty group. Additionally, several, small, industry-sponsored case series comparing pre- with posttreatment results of canaloplasty alone or in combination with cataract surgery have shown that most patients achieved sufficient intraocular pressure 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 (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, a non-randomized comparative study, 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 for 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.

### **Clinical Input from Physician Specialty Societies and Academic Medical Centers**

In 2011, one ophthalmology association provided a statement indicating that the case series cited are sufficient to show efficacy of canaloplasty to lower intraocular pressure to treat open-angle glaucoma. Other reviewers considered canaloplasty to be investigational but medically necessary for a select group of patients (e.g., patients at risk for infection or hypotony, who have surface disease precluding the creation of good trabeculectomy bleb, or for whom a patch would not cover a glaucoma drainage device implant).

### **Practice Guidelines and Position Statements**

#### American Academy of Ophthalmology

A technology assessment from the American Academy of Ophthalmology (AAO; 2011) included canaloplasty in its review of novel glaucoma procedures. (36) The Academy concluded that all the techniques and devices reviewed were still in the initial stage ( $\leq 5$  years) of clinical experience and lacked widespread use, with only level III evidence (cohort studies) supporting 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 the Schlemm canal are not known.

Another technology assessment from the AAO (2024) evaluated intraocular pressure reduction with various trabecular procedures combined with cataract surgery vs cataract surgery alone. (37) The following results were reported: "Based on studies that performed a medication washout, adding a trabecular procedure to cataract surgery provided an additional 1.6 to 2.3 mmHg of IOP [intraocular pressure] reduction in subjects with hypertensive, mild to moderate open-angle glaucoma (OAG) at 2 years over cataract surgery alone, which itself provided approximately 5.4 to 7.6 mmHg IOP reduction. In other words, adding a trabecular procedure provided an additional 3.8% to 8.9% IOP reduction over cataract surgery alone, which itself provided 21% to 28% IOP reduction. There was no clear benefit of one trabecular procedure over another. Patient-specific considerations that can guide procedure selection include uveitis predisposition, bleeding risk, metal allergy, and narrowing of Schlemm's canal. There are no level I data on the efficacy of trabecular procedures in subjects with pretreatment IOP of 21 mmHg or less."

#### National Institute for Health and Care Excellence

In 2017, the National Institute for Health and Care Excellence (NICE) updated its 2008 guidance on ab externo canaloplasty for primary open-angle glaucoma. (38) The current recommendation is that the "evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is adequate to support the use of this procedure..."

Similarly, in 2017 (amended in 2022), NICE updated its 2009 guidance on the diagnosis and management of chronic open-angle glaucoma. (39) 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 (recommendation 1.4.21).

In 2022, NICE published an interventional procedures guidance on ab interno canaloplasty for open-angle glaucoma. (40) 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**

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT Number	Trial Name	Planned Enrollment	Completion Date
<b><i>Ongoing</i></b>			
NCT05564091 <sup>a</sup>	Cataract Surgery in Conjunction With Ab-interno Canaloplasty Compared to Cataract Surgery Only in Patients With Mild to Moderate Primary Open-Angle Glaucoma (CATALYST)	78	Jul 2027
NCT05786196 <sup>a</sup>	Multicenter Glaucoma Study Investigating Standalone Canaloplasty, Randomized Controlled Trial: iTrack Advance (Nova Eye, Inc.) Compared to OMNI (Sight Sciences)	86	Dec 2026
NCT05696561 <sup>a</sup>	Clinical Trial to Evaluate the Safety and Effectiveness of a Canaloplasty Device in Subjects With Open-Angle Glaucoma	100	Sep 2026

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

### **Coding**

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<b>CPT Codes</b>	66174, 66175
<b>HCPCS Codes</b>	None

\*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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## Centers for Medicare and Medicaid Services (CMS)

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

### Policy History/Revision

Date	Description of Change
07/15/2025	Document updated with literature review. Coverage unchanged. Added references 2, 24, and 37; one removed.
01/01/2025	Document updated with literature review. Coverage unchanged. Added/updated the following references: 1, 11, 12, 23-33, and 38.
11/15/2023	Reviewed. No changes.
01/15/2023	Document updated with literature review. The following change was made to Coverage: Not medically necessary policy statement on viscocanalostomy changed to experimental, investigational and/or unproven per current policy language standards; intent unchanged. No new references added.
07/15/2021	Document updated with literature review. Coverage unchanged. References updated, none added/deleted.
06/15/2020	Reviewed. No changes.
07/01/2019	Document updated with literature review. Coverage unchanged. Added references 22 and 24.
06/15/2018	Reviewed. No changes.
10/01/2017	Document updated with literature review. Coverage changed for viscocanalostomy from experimental, investigational and/or unproven to not medically necessary.
08/01/2016	Document updated with literature review. Coverage unchanged.
10/15/2015	Reviewed. No changes.
04/15/2014	Document updated with literature review. Coverage unchanged.
08/15/2012	New medical policy split out from SUR713.030, Surgical Treatments for Glaucoma policy SUR713.030 will be deleted when these new policies 713.032, 713.033, and 713.034 are effective