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Viscocanalostomy and Canaloplasty

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Related Policies (if applicable)
None.

Disclaimer

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Coverage

Canaloplasty **may be considered medically necessary** as a method to reduce intraocular pressure (IOP) in patients with chronic primary open-angle glaucoma under the following conditions:

- Medical therapy has failed to adequately control IOP; AND
- The patient 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 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 (IOP) when the target IOP 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 patients with glaucoma.

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 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 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. 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 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 IOP 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 ab externo 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 IOP. Therefore, some procedures may not reduce IOP below the pressure of the distal outflow system used (e.g., <15 mm Hg), and are not indicated for patients for whom very low IOP 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.

Rationale

This medical policy was originally created in 2012 and has been updated regularly with searches of the PubMed database. The most recent literature review was performed through December 20, 2021.

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. 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 patients 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 question addressed in this medical policy is: Does the use of viscocanalostomy for patients who have open-angle glaucoma that has failed medical therapy improve net health outcomes?

The following PICO was used to select literature to inform this policy.

Populations

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

Interventions

The treatment being considered is viscocanalostomy.

Comparators

The comparators of interest are intraocular pressure (IOP)-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 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.

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. (1) 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 IOP 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 2014 Cochrane review and meta-analysis by Eldaly et al. that included 2 small randomized trials (total 50 eyes). (2)

Randomized Controlled Trials

A study included in the Chai and Loon systematic review is the RCT by Gilmour et al. (2009), which reported 4-year follow-up. (3) 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 IOP less than 18 mm Hg with no medications; a qualified success was defined as an 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, 6-60 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 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. (4) 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 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 (e.g., from 25.0 to 17.1 mm Hg at 12 months). At 12 months, significantly more trabeculectomy-treated eyes achieved an IOP less than 20 mm Hg without medication (88% vs 64%, respectively). Mean IOP reduction was 48.9% in trabeculectomy-treated eyes and 30.5% in viscocanalostomy-treated eyes. Overall success (IOP <20 mm Hg) and IOP 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 IOP-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 IOP <4 mm Hg).

Grieshaber et al. (2015) reported long-term results of viscocanalostomy for a series of 726 patients. (5) Mean IOP before surgery was 42.6 mm Hg. Mean IOP 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 (< of 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 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. (6) Overall success (no visual field deterioration with an IOP ≤20 mm Hg) and IOP 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 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 patients 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 question addressed in this medical policy is: Does the use of canaloplasty for patients who have open-angle glaucoma that has failed medical therapy improve net health outcomes?

The following PICO was used to select literature to inform this policy.

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

Interventions
The treatment being considered is canaloplasty.

Comparators
The comparators of interest are IOP-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 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.

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. (7) Twelve-month outcomes (IOP adjunctive medications, complications) were compared after glaucoma-only and combined glaucoma-phacoemulsification surgeries. Reviewers found that Trabectome and canaloplasty provided modest IOP reduction (to ≈16 mm Hg) with minor intraoperative or postoperative complications. Reductions for Baerveldt glaucoma implant IOP

were comparable to those for trabeculectomy (≈12 mm Hg), but the Baerveldt shunt required more postoperative IOP 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) to control IOP than patients treated with canaloplasty (average, 0.6). Reviewers concluded that Trabectome and canaloplasty were reasonable surgical choices for patients in whom IOP in the mid-teens seemed adequate; although trabeculectomy was the most effective IOP 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. (8) Patients included 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 Hg 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%, respectively). Mean absolute IOP 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 (QOL) at 24 months following canaloplasty than trabeculectomy in a questionnaire survey of 327 patients. (9) 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 QOL questionnaires.

Case Series

Most of the primary literature on canaloplasty consists of case series that have compared posttreatment and pretreatment IOP. 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. (10) 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 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 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 interim data analysis from a manufacturer-sponsored multicenter (15 centers) safety and efficacy study on canaloplasty using the iTrack microcatheter (11) with 2- and 3-year results reported in 2009 and 2011. (12, 13) The 2011 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 history of 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, mean IOP 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 IOP (6%), and Descemet membrane detachment (3%). More common late postoperative complications included cataracts (12.7%) and transient IOP elevation (6.4%). 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 (49.3%) eyes were on no medications. Another 7 (4.4%) patients had additional glaucoma surgery. With qualified success defined as achieving an IOP 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) (14) and a within-subjects 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. (15) For the canaloplasty eye, IOP decreased from 26.5 mm Hg on 2.1 medications to 14.5 mm Hg on 0.3 medications. For the viscocanalostomy eye, IOP decreased from 24.3 mm Hg on 1.9 medications to 16.1 mm Hg on 0.4 medications. Reduction in IOP 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. (15)

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. (16) 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, 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 mm Hg on 1.9 medications to 15.6 mm Hg on 1.2 medications. Late postoperative complications included cataracts (19.1%) and transient IOP 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). (17) Mean preoperative IOP was 45 mm Hg. At 12-month follow-up, IOP was 15 mm Hg (n=54); at 36 months, IOP was 13 mm Hg (n=49). Eleven (18%) patients were lost to follow-up at 3 years. With qualified success defined as achieving an IOP 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 IOP 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). (18) Mean IOP 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, 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 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 5-year follow-up on patients (20 eyes) with open-angle glaucoma who underwent canaloplasty at a single center in Germany. (19) Mean IOP 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 IOP 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 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.

Section Summary: Canaloplasty

Findings from a small RCT and a 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 posttreatment results of canaloplasty 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 (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 (IOP) lowering effect than viscocanalostomy. Reduction in IOP 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 an RCT, a comparative effectiveness review, and several case series. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. The RCT found not only significantly higher complete success rates with trabeculectomy than with canaloplasty, but also higher complication rates. The qualified success rate (with medication) was similar between groups. A systematic review found that canaloplasty provided modest IOP reduction (to ~ 16 mm Hg) with minor intraoperative or postoperative complications. Further evidence from RCTs is required to corroborate results of this single trial. 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 (eg, 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 (2011) included canaloplasty in its review of novel glaucoma procedures. (20) The Academy concluded that all the techniques and devices reviewed were still in the initial stage (≤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.

National Institute for Health and Care Excellence

In 2017, the National Institute for Health and Care Excellence (NICE) updated its 2008 guidance on canaloplasty for primary open-angle glaucoma. (21, 22) 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), NICE updated its 2009 guidance on the diagnosis and management of chronic open-angle glaucoma. (23, 24) 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 IOP, 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 IOP 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).

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in February 2022 did not identify any ongoing or unpublished trials that would likely influence this policy.

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.

CPT Codes	66174, 66175
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

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

Policy History/Revision	
Date	**Description of Change**
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