Anthem

# Medical Policy

**Subject:** Viscocanalostomy and Canaloplasty
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## Description/Scope

This document addresses viscocanalostomy and canaloplasty. Viscocanalostomy and canaloplasty are forms of non-penetrating glaucoma surgery. They are proposed as alternatives to trabeculectomy, the traditional surgical treatment of primary open-angle glaucoma (POAG).

## Position Statement

**Medically Necessary:**

Canaloplasty is considered **medically necessary** for the treatment of mild to moderate primary open-angle glaucoma (POAG).

**Investigational and Not Medically Necessary:**

Viscocanalostomy is considered **investigational and not medically necessary** for all indications, including but not limited to the treatment of primary open-angle glaucoma (POAG).

Canaloplasty is considered **investigational and not medically necessary** for all other indications.

## Rationale

Surgical intervention is indicated in the management of glaucoma when medication therapies have failed to adequately reduce intraocular pressure (IOP). The established surgical procedure to which alternatives have been compared is trabeculectomy. A trabeculectomy procedure creates a conjunctival reservoir or "filtering bleb" which reduces IOP by allowing aqueous humor to enter the subconjunctival space. Alternative surgical methods under evaluation include viscocanalostomy and canaloplasty. Viscocanalostomy unroofs and dilates a portion of Schlemm's canal, and a high viscosity (viscoelastic) solution is used to open the canal and create a passage from Schlemm's canal to a scleral reservoir. A related procedure, canaloplasty, requires the dilation of the entire length of Schlemm's canal with a suture loop between the canal and the trabecular meshwork using a specialized microcatheter (iTrack™) device.

*Viscocanalostomy*

Chai and Loon (2010) performed a meta-analysis comparing the safety and efficacy of viscocanalostomy with the gold standard of trabeculectomy. A total of 10 randomized controlled trials comprised of 458 eyes from 397 subjects 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 POAG, 16.4% had secondary open-angle glaucoma (OAG), 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 (IOP) 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 membrane (RR=7.72). In contrast, viscocanalostomy had significantly fewer postoperative events compared to 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.

A study by Gilmour and colleagues (2009), included in the previously noted meta-analysis, consisted of 50 eyes of 43 individuals with open angle glaucoma randomized to have either a viscocanalostomy (25 eyes) or trabeculectomy (25 eyes) and prospectively followed at regular intervals for up to 60 months. A successful outcome was defined as 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 person from each group was lost to follow-up. At baseline, subjects 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 subjects (42%) in the trabeculectomy group had achieved success compared to 5 (21%) in the viscocanalostomy group. Although 19 individuals (79%) in both groups achieved qualified success, fewer from the trabeculectomy group required additional topical treatment (50% vs. 83%) to achieve qualified success. There were more early postoperative complications in the trabeculectomy group (e.g., hypotony, wound leak, choroidal detachment), but these had no long-term effect on IOP control or cataract formation. The authors concluded that trabeculectomy was more effective than viscocanalostomy at lowering IOP and maintaining long-term control of IOP in those with POAG.

A Cochrane review (Edaly, 2014) compared the effectiveness of non-penetrating trabecular surgery with conventional trabeculectomy in persons with glaucoma and reached similar conclusions. Five studies (Cillino, 2005; El Sayyad, 2000; Kobayashi, 2003; Russo, 2008; Yalvac, 2004) were included in the review for a total of 311 eyes (247 participants). A total of 160 eyes in the trabeculectomy group were compared to 151 eyes that had non-penetrating glaucoma surgery. The odds of success in viscocanalostomy participants was lower than in trabeculectomy participants (odds ratio [OR], 0.33; 95% confidence interval [CI], 0.13 to 0.81). The authors reported that some limited evidence was provided that control of IOP is better with trabeculectomy than viscocanalostomy.

In a retrospective multicenter study, Grieshaber and colleagues (2015) assessed the safety and efficacy of viscocanalostomy performed for OAG in subjects in Europe and South Africa. A total of 726 eyes of 726 subjects with primary OAG (POAG) and pseudoexfoliative glaucoma (PXFG) were included. The mean IOP before surgery was 42.6 ± 14.2 mm Hg for all cases, 29.6 ± 6.6 mm Hg for Europeans and 48.1 ± 12.9 mm Hg for South Africans. The follow-up time was 86.2 ± 43.1 months. Mean IOP was 15.4 ± 3.6 mm Hg at 5 years, 15.5 ± 4.4 mm Hg at 10 years and 16.8 ± 4.2 mm Hg at 15 years. The qualified success rate for an IOP of 21, 18 or 16 mm Hg or less after 5 years was 92% (95% CI, 0.88-0.96), 70% (95% CI, 0.63-0.77) and 43% (95% CI, 0.36-0.51) in Europeans, and 90% (95% CI, 0.87-0.93), 77% (95% CI, 0.74-0.81) and 67% (95% CI, 0.63-0.72) in South Africans, respectively. No difference was reported in the POAG and PXFG success rates with an IOP of 21, 18 or 16 mm Hg or below at 5 years (p=0.64, p=0.20, p=0.22, respectively). Postoperatively, laser goniopuncture was performed on 127 eyes (17.7%), lowering the pressure from 23.1 ± 1.9 mm Hg to 15.0 ± 2.2 mm Hg. No significant complications were noted. The authors concluded that viscocanalostomy is "a procedure to consider in patients in whom trabeculectomy is not advisable." This study contained numerous limitations including a

potential for “patient selection bias due to data availability and follow-up losses.”

*Canaloplasty*

Lewis and colleagues (2007) performed a nonrandomized, uncontrolled study of 94 individuals who underwent a canaloplasty for POAG with an IOP of at least 16 mm Hg or higher. A total of 74 individuals had successful tension suture placement with a resulting mean IOP of 15.3 ± 3.8 mm Hg at 1 year postop compared to a mean IOP of 24.7 ± 4.8 mm Hg at baseline. However, at 1 year, only 48 of the 74 individuals had follow-up. Many uncontrolled variables were noted such as suture placement versus no suture placement, and cataract surgery with canaloplasty versus canaloplasty alone, which could influence the results. It is unclear how the uncontrolled variables and those lost to follow-up affected study results. In addition to the uncontrolled variables, this study was limited by lack of randomization.

In an international, multicenter, prospective study, Shingleton and colleagues (2008) evaluated the safety and efficacy of canaloplasty to treat open-angle glaucoma combined with clear corneal phacoemulsification and posterior chamber intraocular lens implantation. Data from 54 eyes that had combined glaucoma and cataract surgery performed by 11 surgeons at nine study sites were examined. The Schlemm canal and anterior segment angle morphology were assessed by intraoperative and postoperative high-resolution ultrasound imaging. Upon comparison of baseline with postoperative data, it was found that postoperatively the mean baseline IOP had decreased at 1 month, 3 months, 6 months, and 12 months. Medication usage had also decreased at 12 months postoperatively. Surgical complications occurred in 5 eyes and included hyphema, Descemet tear, and iris prolapse. Limitations of this study include lack of randomization and lack of a control group. The authors noted that “additional studies to evaluate this new technique in relation to existing treatments as well as other types of glaucoma are recommended.”

In an ongoing international, multi-center, prospective, open-label study, Lewis and colleagues (2009) evaluated the 2-year post-surgical safety and efficacy of canaloplasty performed for the treatment of OAG. The study group consisted of 127 individuals (127 eyes) of which 97 eyes (76%) had canaloplasty alone and 30 eyes (24%) with significant cataracts had a combined glaucoma-cataract surgery (phacocanaloplasty). Primary outcome measures included IOP and glaucoma medication use. The authors reported that at 24 months, all 127 eyes had a mean IOP of 16.0 mm Hg ± 4.2 standard deviation (SD) and mean glaucoma medication use of 0.5 ± 0.8 (baseline values 23.6 ± 4.8 mm Hg and 1.9 ± 0.8 medications). Eyes with canaloplasty alone had a mean IOP of 16.3 ± 3.7 mm Hg and 0.6 ± 0.8 medications (baseline values 23.2 ± 4.0 mm Hg and 2.0 ± 0.8 medications). Eyes with a combined glaucoma-cataract surgery had a mean IOP of 13.4 ± 4.0 mm Hg and 0.2 ± 0.4 medications (baseline values 23.1 ± 5.5 mm Hg and 1.7 ± 1.0 medication). Also at 24 months, 3 eyes (3%) had lost visual acuity. Of these eyes, 1 had posterior capsule opacification, 1 had a dense cataract, and 1 had an unspecified reason for the visual acuity decrease. A total of 20 (15.7%) of 127 individuals did not meet study analysis criteria due to missed visits. There were 13 post-surgical complications reported in 10 eyes and also 3 complications noted during surgery. Complications reported included suture extrusion, hyphema, and IOP elevation. Limitations of this study included lack of randomization. There was flexibility in individual selection and treatment according to each investigator’s current practice. The authors noted “the study design includes additional follow-up and reporting with more extensive subgroup analysis anticipated during the continuing study.”

Mosaed and colleagues (2009) performed a literature review comparing traditional (trabeculectomy) and novel glaucoma surgical techniques which included canaloplasty. The authors concluded that trabeculectomy remains the most effective IOP lowering procedure to date; however, it has the highest risk of severe complications. In addition, the authors indicated that canaloplasty may not be able to regularly achieve the lower IOP required in advanced glaucoma.

Grieshaber and colleagues (2010) reported on a prospective, single-center study evaluating canaloplasty in 60 randomly selected eyes of 60 consecutive African individuals with POAG. The mean preoperative IOP was 45.0 ± 12.1 mm Hg. The mean follow-up time was 30.6 ± 8.4 months. The mean IOP at 12 months was 15.4 ± 5.2 mm Hg (n=54), at 24 months 16.3 ± 4.2 mm Hg (n=51) and at 36 months 13.3 ± 1.7 mm Hg (n=49). For IOP ≤ 21 mm Hg, the complete success rate (without medications) was 77.5% and qualified success rate (with or without medications) was 81.6% at 36 months.

Grieshaber and colleagues (2011) reported on an additional prospective, single-center study which aimed to assess the safety and efficacy of canaloplasty. This procedure was performed in 32 eyes of 32 consecutive individuals with medically uncontrolled OAG and a follow-up time of over 1 year. The mean preoperative IOP dropped from 27.3 ± 5.6 mm Hg to 12.8 ± 1.5 mm Hg at 12 months and was 13.1 ± 1.2 mm Hg at 18 months ($p<0.001$). The complete success rate of an IOP ≤ 21, 18, and 16 mm Hg was 93.8% (95% CI, 0.86-1.0), 84.4% (95% CI, 0.73-0.98), and 74.9% (95% CI, 0.61-0.92), respectively, at 12 months. The authors concluded that canaloplasty was an efficient method in lowering IOP in OAG in this series, but the procedure had its own distinct risk profile, and comparative, randomized, long-term studies are needed to draw final conclusions.

Lewis and colleagues (2011) followed up on their 2007 and 2009 nonrandomized, multicenter studies and reported 3-year results addressing the safety and efficacy of canaloplasty. The study cohort consisted of adults with OAG having had canaloplasty or combined cataract-canaloplasty surgery. At 3 years after surgery, all eyes studied (n=157) had a mean IOP of 15.2 mm Hg ± 3.5 (SD) and mean glaucoma medication use of 0.8 ± 0.9 compared with a baseline IOP of 23.8 ± 5.0 mm Hg on 1.8 ± 0.9 medications. Eyes having undergone combined cataract-canaloplasty surgery had a mean IOP of 13.6 ± 3.6 mm Hg while on 0.3 ± 0.5 medications compared with a baseline IOP of 23.5 ± 5.2 mm Hg on 1.5 ± 1.0 medications. IOP and medication use results in all eyes were decreased from baseline at every time point ($p<0.001$). Late postoperative complications included cataracts (12.7%), transient IOP elevation (6.4%), and partial suture extrusion through the trabecular meshwork (0.6%).

Bull and colleagues (2011) reported 3-year results of a European, prospective, multi-center, interventional study consisting of 109 eyes of 109 adults with open-angle glaucoma undergoing canaloplasty or combined cataract-canaloplasty surgery. Primary outcome measures included IOP, glaucoma medication usage, and adverse events. Eyes with canaloplasty showed a mean baseline IOP of 23.0 ± 4.3 mm Hg and mean glaucoma medication usage of 1.9 ± 0.7 medications, which decreased to a mean IOP of 15.1 ± 3.1 mm Hg on 0.9 ± 0.9 medications at 3 years postoperatively. Eyes with combined cataract-canaloplasty surgery showed a mean baseline IOP of 24.3 ± 6.0 mm Hg on 1.5 ± 1.2 medications, which decreased to a mean IOP of 13.8 ± 3.2 mm Hg on 0.5 ± 0.7 medications at 3 years. Intraocular pressure and medication use results for all study eyes were significantly decreased from baseline at all intervals ($p<0.00001$). Late postoperative complications included transient IOP elevation (1.8%) and cataracts (19.1%). The authors concluded that predictive factors for successful canaloplasty outcomes and reasons for later failure remain unclear and should be explored in future studies.

In a retrospective case series, Ayyala and colleagues (2011) compared individual outcomes through 12 months of follow-up post canaloplasty and trabeculectomy procedures. Individuals with open-angle glaucoma who underwent either canaloplasty (33 eyes of 33 subjects) or trabeculectomy with mitomycin C (46 eyes of 46 subjects) to control IOP between January 2007 and December 2008 were included. A single surgeon performed all surgeries. Primary outcome measures were: change in IOP, visual acuity, postoperative medications, failure based on IOP (> 18 or < 4 mm Hg at 1 year) or second operative procedure (any eye requiring reoperation) and complication rates at 12 months. There were no differences in demographics, previous surgery, or preoperative and postoperative visual acuity between the groups. The mean percentage of reduction in IOP from preoperative values at 12 months after surgery was 32% (± 22%) for the canaloplasty group compared with 43% (± 28%) for the trabeculectomy group. The median

reduction in the number of medications at 12 months follow-up was 2 in the canaloplasty group and 3 in the trabeculectomy group. A higher percentage of those treated with canaloplasty than trabeculectomy (36% vs. 20%) required postoperative medications. Failure based on IOP (IOP > 18 or < 4 mm Hg at 12 months) was 12.1% (4/33 subjects) for the canaloplasty group and 4.3% (2/46 subjects) for the trabeculectomy group. Surgical failure rates for the canaloplasty group (n=5, 15%) and trabeculectomy group (n=5, 11%) were comparable. The authors concluded that these results need to be confirmed by a prospective, randomized, longitudinal study. Limitations of this study included small size and limited duration of follow-up.

Rulli and colleagues (2013) conducted a systematic review and meta-analysis of comparative studies of two or more surgical techniques (one of which had to be Trabeculectomy [TE]), including individuals with open-angle glaucoma. Comparisons were made between TE and the main types of nonpenetrating surgery (NPS) (deep sclerectomy, viscocanalostomy, and canaloplasty). The primary outcome was the mean between-group difference in the reduction in diurnal IOP from baseline to the 6- or 12-month follow-up evaluation. A total of 18 articles, consisting of 20 comparisons, were analyzed. The 6-month follow-up data demonstrated that the pooled estimate of the mean between-group difference was –2.15 mm Hg (95% CI, –2.85 to –1.44) in favor of TE. There was no difference between the NPS subgroups. The absolute risk of hypotony, choroidal effusion, cataract, and flat or shallow anterior chamber was higher in the TE group than in the NPS group. The authors concluded that trabeculectomy seemed to be the most effective surgical procedure for reducing IOP in individuals with open-angle glaucoma. However, it was associated with a higher incidence of complications when compared with NPS.

Brusini and colleagues (2014) performed a 3-year follow-up from an independent series of 214 individuals treated with canaloplasty in Europe. Mean IOP was reduced from 29.4 mm Hg at baseline to 17.0 mm Hg after excluding 17 subjects (7.9%) who later underwent trabeculectomy. IOP was 21 mm Hg or lower in 86.2% of subjects, 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 usually seen with trabeculectomy. Disadvantages of canaloplasty that were reported included the inability to complete the procedure in 16.4% of eyes, a long and rather steep surgical learning curve, the need for specific instruments, and an average postoperative IOP level that tended to not be very low.

A small, prospective clinical trial by Matlach and colleagues (2015) consisted of 62 eyes of 62 Caucasian subjects with uncontrolled, open-angle glaucoma randomized to either a trabeculectomy (n=32) or canaloplasty (n=30). Both surgeries were performed by a single glaucoma surgeon at a single European center, and all subjects were followed for 2 years postoperatively. A significant reduction of intraocular pressure (IOP) occurred in both groups. Mean absolute IOP reduction was 10.8 ± 6.9 mm Hg in the trabeculectomy and 9.3 ± 5.7 mm Hg in the canaloplasty group after 2 years. Mean IOP was 11.5 ± 3.4 mm Hg in the trabeculectomy and 14.4 ± 4.2 mm Hg in the canaloplasty group after 2 years. Complications were more common in the trabeculectomy group and included choroidal detachment (12.5%), hypotony (37.5%), and elevated IOP (25.0%). The authors concluded that trabeculectomy allowed for a stronger decrease of IOP with less need for medication, and canaloplasty had a lower complication rate. Limitations of this study included a small sample size.

Zhang and colleagues (2017) published a systematic review and meta-analysis on the efficacy and safety of canaloplasty compared to trabeculectomy. Using a baseline of 28 studies published before April 1, 2016, the researchers compared 1-year, post-procedure outcomes for 1498 eyes. Trabeculectomy was more efficient in IOP reduction than canaloplasty (MeD 3.61 mm Hg; 95% CI, 1.69 to 5.53). For both procedures, there was a similar reduction in the need for glaucoma medications (MeD –0.37 mm Hg; 95% CI, –0.83 to 0.08). Adverse events included hyphema (≥ 1 mm), which was higher in the canaloplasty group (OR 9.24; 95% CI, 3.09 to 27.60), and hypotony, which was higher in the trabeculectomy group (OR 0.32; 95% CI, 0.13 to 0.80). In addition, trabeculectomy had higher incidences of choroidal effusion or detachment (OR 0.25; 95% CI, 0.06 to 0.97). Some adverse events were specific to the procedure, with incidences of Descemet membrane attachment in the canaloplasty group only (3%), and incidences of suprachoroidal hemorrhage and bleb needling in the trabeculectomy group only (2.3% and 10.9%, respectively). The researchers concluded that trabeculectomy was more effective than canaloplasty in reducing IOP, but trabeculectomy had more complications. The researchers concluded that high-quality, randomized controlled trials are needed to verify the findings.

Liu and colleagues (2017) analyzed the safety and efficacy of canaloplasty versus trabeculectomy for the treatment of glaucoma. The researchers pooled data from 8 included studies published between 2010 and 2015, focusing on complications and intraocular pressure at 6 and 12 months post-procedure. The researchers did not find a difference in intraocular pressure at 6 months; however, at 12 months, the intraocular pressure was higher in the canaloplasty group (weighted mean difference [WMD] 1.90; 95% CI, 0.12 to 3.69; p<0.05). The canaloplasty group was more likely to have hyphema (RR 2.96; 95% CI, 1.51 to 5.83), but less likely to have hypotony (RR 0.30; 95% CI, 0.11 to 0.83) and postoperative choroid abnormalities (RR 0.24; 95% CI, 0.09 to 0.66). The researchers concluded that trabeculectomy “can significantly reduce the intraocular pressure better than canaloplasty method in glaucoma patients after operation,” and “trabeculectomy leads a more marked IOP decrease than canaloplasty at the cost of a higher complication rate.”

Khaimi and colleagues (2017) published 3-year outcomes following canaloplasty for the treatment of open-angle glaucoma. The researchers retrospectively reviewed charts at a single center to gather a cohort of 277 eyes treated by canaloplasty. Primary endpoints were the mean IOP and mean number of glaucoma medications at each follow-up visit and secondary endpoints were surgical and post-surgical complications. The overall baseline IOP of 19.7 mmHg was reduced to 15.2 mmHg at 3 years (p<0.001). Average medication usage was reduced from a baseline of 2.1 to 0.6 at 3 years (p<0.001). Hyphema was present postoperatively in 144 eyes (52.8%) but was resolved in 125 of those eyes in 3 months. Baseline mean visual acuity was 0.31 ± 0.35 with a mean Snellen fraction of 20/41.1. At 3 years (n=65), mean visual acuity was 0.20 ± 0.24 with a Snellen fraction of 20/31.5 (p=0.29). The authors noted that visual acuity “worsens significantly after surgery but may return to preoperative values by around 3-12 months postoperatively.” The researchers concluded “the risk profile of canaloplasty was favorable and consistent with the well-documented, lower risks associated with other nonpenetrating procedures.” The study was limited by a retrospective design and loss to follow-up.

Gabai and colleagues (2019) analyzed the efficacy and safety of trabeculectomy versus nonpenetrating glaucoma surgery, including deep sclerectomy, viscocanalostomy, and canaloplasty. The researchers searched for published peer-reviewed data until January 10, 2018. A total of 21 studies were included in the analysis. Combined weighted mean difference (WMD) between initial and final IOP, favored trabeculectomy compared with nonpenetrating glaucoma surgery at 6 months (WMD=2.12 mm HG; 95% CI, 1.62 to 2.63; $I^2$=0%; P=0.510), at 12 months (WMD=2.53 mm Hg; 95% CI, 1.72 to 3.34;$I^2$=58.5%; P=0), and 24 months (WMD=2.13 mm Hg; 95% CI, 0.89 to 3.36; $I^2$=5.72%; P=0.01). The researchers noted the results might indicate trabeculectomy as the best choice for individuals where lower postsurgical IOP is desirable and who have a higher risk for glaucoma progression requiring a more IOP reduction. In regard to safety, more complications were observed with trabeculectomy than nonpenetrating glaucoma surgery. The researchers concluded that further studies with larger samples and longer follow-up are needed to evaluate long-term efficacy and safety of trabeculectomy and nonpenetrating glaucoma surgery.

Vastardis and colleagues (2021) conducted a 12-month follow-up, retrospective, single-surgeon, single-center study to compare the efficacy of trabeculectomy with mitomycin and ab externo canaloplasty. The study excluded individuals with previous glaucoma surgery, intraoperative conversion of surgery or failure to complete, glaucoma surgery with phacoemulsification, cataracts, age-related macular degeneration, retinal pathology, prior pars plana vitrectomy surgery, and corneal pathologies. This yielded 104 eyes that

underwent ab externo canaloplasty (group A) and 136 eyes that underwent trabeculectomy with mitomycin (group B). The IOP was reduced from 20.45 ± 7.76 to 13.87 ± 3.34 mm HG (32.17% IOP reduction) in group A and from 23.44 ± 7.56 to 10.54 ± 3.98 mm Hg (55.04% IOP reduction) in group B. Hyphema (30.76%) was the most common complication in group A. Choroidal detachment due to hypotony was the most common post-operative complication (12.5%). The authors concluded both surgeries provided good results in reducing IOP.

*Canaloplasty versus Viscocanalostomy*

Wagdy (2017) completed a study comparing the efficacy and safety of canaloplasty versus viscocanalostomy. In group A, canaloplasty was performed on 30 participants with POAG and in group B, viscocanalostomy was performed on 30 participants with POAG. In group A, the mean IOP was 27.2 ± 1.9, it was reduced to 15.8 ± 3.4 in the first postoperative day, then further reduced to 15.5 ± 1.2 in the first month, and then after 1 year, the mean IOP = 15.6 ± 1.2. In group B, the mean IOP was 26.4 ± 2.95, it was reduced to 17.4 ± 1.38 in the first postoperative day, then further reduced to 16.9 ± 1.32 in the first month, and then after 1 year, the mean IOP = 16.8 ± 1.49. One line drop of visual acuity was noted in 1 case in group A (3%) and 3 cases in group B (10%). Visual field deterioration was noted in 2 cases in group A (6%) and 4 cases in group B (13%). Less postoperative complications were noted in group A than in group B: Descemet's membrane detachment (3% in group A and 8% in group B); ocular hypotony (2% in group A and 4% in group B); and hyphema (3% in group A and 5% in group B). The researcher concluded that canaloplasty appears to be more effective and safer than viscocanalostomy.

*Other Considerations*

The American Academy of Ophthalmology (AAO) Preferred Practice Pattern for POAG (2020) states:

> The goals of managing patients with POAG are as follows:
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> - Control of IOP in the target range
> - Stable optic nerve/RNFL status
> - Stable visual fields
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> The effects of treatment, as well as, the patient's quality of life, comorbidities, and life expectancy are to be considered in the decision-making process about therapy.
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> The rationale for nonpenetrating glaucoma surgery is that by avoiding a continuous passageway from the anterior chamber to the subconjunctival space, the incidence of complications such as bleb-related problems and hypotony can be reduced. The nonpenetrating procedures have a higher degree of surgical difficulty compared with trabeculectomy and they require special instrumentation.
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> *Viscocanalostomy*: Viscocanalostomy includes deep sclerectomy along with expansion of Schlemm's canal using an ophthalmic viscoelastic device. The procedure is intended to allow passage of aqueous humor through the trabeculodescemetic membrane window and into the physiologic outflow pathway through Schlemm's canal. Randomized clinical trials comparing viscocanalostomy with trabeculectomy suggest greater IOP reduction with trabeculectomy but fewer complications with viscocanalostomy. A 2014 Cochrane Systematic Review found some limited evidence that control of IOP was better with trabeculectomy than with viscocanaloplasty, but conclusions could not be drawn for deep sclerectomy, and quality of life outcomes may be needed to differentiate among procedures. Thus, the selection of viscocanalostomy and deep sclerectomy over trabeculectomy should be left to the discretion of the treating ophthalmologist, in consultation with the individual patient. (*I-, Insufficient Quality, Strong Recommendation*)
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> *Canaloplasty*: In canaloplasty, circumferential viscodilation of Schlemm's canal using a flexible microcatheter is performed in combination with deep sclerectomy. Dilating the entire canal aims to give aqueous humor access to a greater number of collector channels. A 10-0 polypropylene (Prolene) suture is placed with appropriate tension within Schlemm's canal when possible to apply inward directed tension on the trabecular meshwork. The safety and efficacy of canaloplasty alone and combined with phacoemulsification was described in a nonrandomized, multicenter clinical trial through 3 years of follow-up. A retrospective case series found lower postoperative IOP with trabeculectomy compared with canaloplasty. In a randomized clinical trial comparing trabeculectomy and canaloplasty, patients in the trabeculectomy group achieved higher success rates and required fewer medications than those in the canaloplasty group, but they also experienced a higher rate of late hypotony.
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> The severity of glaucoma damage can be estimated according to the following categories:
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> - Mild: Definite optic disc, RNFL, or macular imaging abnormalities consistent with glaucoma as detailed above and a normal visual field as tested with standard automated perimetry (SAP)
> - Moderate: Definite optic disc, RNFL, or macular imaging abnormalities consistent with glaucoma as detailed above, and visual field abnormalities in one hemifield that are not within 5 degrees of fixation
> - Severe: Definite optic disc, RNFL, or macular imaging abnormalities consistent with glaucoma as detailed above, and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with SAP
> - Indeterminate: Definite optic disc, RNFL, or macular imaging abnormalities consistent with glaucoma as detailed above, inability of patient to perform visual field testing, unreliable/uninterpretable visual field test results, or visual fields not yet performed

*Conclusion*

Although initial studies show potential promise, there is a need for large, well-designed, randomized controlled comparative trials to clearly determine the safety and efficacy of viscocanalostomy.

The AAO Preferred Practice Pattern for POAG stated, "The effects of treatment, as well as, the patient's quality of life, comorbidities, and life expectancy are to be considered in the decision-making process about therapy." Several trials have noted fewer complications with canaloplasty than trabeculectomy; however, trabeculectomy is superior in lowering IOP compared to canaloplasty. The results in a 2019 review noted that trabeculectomy might be the best choice for individuals where lower postsurgical IOP is desirable and who have a higher risk for glaucoma progression requiring a more IOP reduction. A study in 2017 comparing viscocanalostomy to canaloplasty concluded that canaloplasty appears to be more effective and safer than viscocanalostomy.

## Background/Overview

Glaucoma is a group of diseases which can damage the eye's optic nerve and result in vision loss or blindness. According to the AAO

(2020), glaucoma (both open-angle and angle-closure) is the second leading cause of blindness worldwide. In the United States, it is estimated that 2% of people over 40 have POAG, the most common type of glaucoma. POAG is associated with a buildup of aqueous fluid pressure within the eye and can lead to visual field loss and optic nerve damage, usually without any associated pain or discomfort. There is no visible abnormality in the anterior chamber angle; however, the aqueous fluid is unable to flow correctly.

In the management of POAG, the goal is to reduce the IOP to slow the development of optic nerve damage. The IOP can be reduced by medical treatment or surgery (alone or in combination). Surgical procedures may be indicated in individuals with glaucoma when the target IOP cannot be reached pharmacologically. The traditional surgery is a trabeculectomy, a filtering surgery in which a surgical excision of a small portion of the trabecular tissue, sclera, and, in some cases, cornea, is made in order to facilitate drainage of aqueous humor. Another option is laser trabeculoplasty, a procedure that can lead to tissue remodeling and improved aqueous humor outflow to reduce IOP.

Viscocanalostomy and canaloplasty have been proposed as non-penetrating surgical alternatives to trabeculectomy. The viscocanalostomy procedure involves deroofing the Schlemm's canal and injecting viscoelastic sodium hyaluronate into the canal. The canaloplasty has been described as an extension of viscocanalostomy with the addition of a flexible microcatheter to dilate the full circumference of Schlemm's canal, the placement of a permanent suture under tension in the canal, and the creation of an intrascleral reservoir. A significant difference between viscocanalostomy and canaloplasty is that canaloplasty attempts to open the entire length of the Schlemm's canal rather than one section of it.

The iTrack™ (iScience Interventional Corp., Menlo Park, CA) received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2004 as a surgical ophthalmic microcannula indicated for the general purpose of "fluid infusion and aspiration, as well as illumination, during surgery." In 2008, the iTrack canaloplasty microcatheter 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."

## Definitions

Hyphema: Bleeding in the eye.

Schlemm's canal: A circular canal in the eye that drains aqueous humor from the anterior chamber of the eye into the anterior ciliary veins.

Trabecular tissue: A mesh-like structure inside the eye at the iris-scleral junction of the anterior chamber angle; filters aqueous fluid and controls its flow into the canal of Schlemm, prior to its leaving the anterior chamber.

## Coding

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

**When services are Medically Necessary for canaloplasty:**

**CPT**

| | |
|---|---|
| | For the following codes **when specified as canaloplasty**: |
| 66174 | Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent [*when specified as canaloplasty*] |
| 66175 | Transluminal dilation of aqueous outflow canal (eg, canaloplasty); with retention of device or stent [*when specified as canaloplasty*] |

**ICD-10 Procedure**

| | |
|---|---|
| | For the following codes **when specified as canaloplasty**: |
| 08123J4 | Bypass right anterior chamber to sclera with synthetic substitute, percutaneous approach |
| 08123Z4 | Bypass right anterior chamber to sclera, percutaneous approach |
| 08133J4 | Bypass left anterior chamber to sclera with synthetic substitute, percutaneous approach |
| 08133Z4 | Bypass left anterior chamber to sclera, percutaneous approach |

**ICD-10 Diagnosis**

| | |
|---|---|
| H40.1111-H40.1112 | Primary open-angle glaucoma, right eye, mild/moderate stage |
| H40.1121-H40.1122 | Primary open-angle glaucoma, left eye, mild/moderate stage |
| H40.1131-H40.1132 | Primary open-angle glaucoma, bilateral, mild/moderate stage |
| H40.1191-H40.1192 | Primary open-angle glaucoma, unspecified eye, mild/moderate stage |

**When services are Investigational and Not Medically Necessary:**
For the procedure codes listed above for canaloplasty for all other diagnoses not listed.

**When services are also Investigational and Not Medically Necessary:**
For the procedure codes listed below when specified as viscocanalostomy or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

**CPT**

| | |
|---|---|
| | For the following codes **when specified as viscocanalostomy** |
| 66174 | Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent [*when specified as viscocanalostomy*] |
| 66999 | Unlisted procedure, anterior segment of eye [*when specified as viscocanalostomy*] |

**ICD-10 Procedure**

| | |
|---|---|
| | For the following codes **when specified as viscocanalostomy**: |
| 08123J4 | Bypass right anterior chamber to sclera with synthetic substitute, percutaneous approach |
| 08123Z4 | Bypass right anterior chamber to sclera, percutaneous approach |
| 08133J4 | Bypass left anterior chamber to sclera with synthetic substitute, percutaneous approach |
| 08133Z4 | Bypass left anterior chamber to sclera, percutaneous approach |

**ICD-10 Diagnosis**

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## Websites for Additional Information

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## Index

Canaloplasty
iTrack™ Microcatheter
Viscocanalostomy

**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

## Document History

| Status | Date | Action |
|---|---|---|
| Reviewed | 05/11/2023 | Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References and Websites sections. |
| | 12/28/2022 | Updated Coding section with 01/01/2023 CPT changes; revised descriptors for 66174, 66175. |
| Reviewed | 05/12/2022 | MPTAC review. Updated Rationale, References, and Websites sections. |
| Revised | 05/13/2021 | MPTAC review. Added MN statement for canaloplasty in the treatment of mild to moderate primary open-angle glaucoma. Update INV & NMN statement for canaloplasty to all other indications. Background/Overview, Rationale, Coding, References, and Websites sections updated. |
| Reviewed | 08/13/2020 | MPTAC review. References and Websites sections updated. |
| Reviewed | 08/22/2019 | MPTAC review. Rationale and References sections updated. |
| Reviewed | 09/13/2018 | MPTAC review. Rationale and References sections updated. |
| Reviewed | 11/02/2017 | MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Rationale, Background and References sections updated. |
| Reviewed | 11/03/2016 | MPTAC review. Rationale, Background and References sections updated. |
| Reviewed | 11/05/2015 | MPTAC review. Rationale and Reference sections updated. Removed ICD-9 codes from Coding section. |
| Reviewed | 11/13/2014 | MPTAC review. Description, Rationale and Reference sections updated. |
| Reviewed | 11/14/2013 | MPTAC review. Rationale and Reference sections updated. |
| Reviewed | 11/08/2012 | MPTAC review. Rationale and Reference sections updated. |
| Revised | 11/17/2011 | MPTAC review. Title and position statement revised to include Viscocanalostomy. Description, Rationale, Background and Reference sections updated. |
| Reviewed | 02/17/2011 | MPTAC review. Note in Description added. Rationale, Background, and References updated. |
| | 01/01/2011 | Updated Coding section with 01/01/2011 CPT changes; removed CPT 0176T, 0177T deleted 12/31/2010. |
| Reviewed | 02/25/2010 | MPTAC review. Description, rationale, background, definitions, and references updated. |
| Reviewed | 02/26/2009 | MPTAC review. Rationale and references updated. |
| Reviewed | 02/21/2008 | MPTAC review. Rationale and references updated. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.” This change was approved at the November 29, 2007 MPTAC meeting. |
| New | 03/08/2007 | MPTAC review. Initial document development. |

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.