I. POLICY

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

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

Canaloplasty is considered **investigational** for all other indications, including angle closure glaucoma. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Viscocanalostomy is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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.

**Cross-references:**

- MP-2.149 Aqueous Shunts and Stents for Glaucoma
- MP-2.056 Ophthalmologic Techniques for Evaluating Glaucoma

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below
III. DESCRIPTION/BACKGROUND

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 such as trabeculectomy, alternative surgical treatments such as transluminal dilation by viscocanalostomy and canaloplasty are being evaluated for patients with glaucoma.

Surgical procedures for glaucoma aim to reduce intraocular pressure (IOP) resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm’s canal. In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm’s 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’s canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir with a filtering “bleb” on the eye, which can effectively reduce IOP, but is associated with numerous and sometimes sight-threatening complications (e.g., leaks, hypotony, choroidal effusions and hemorrhages, hyphemas or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed in this policy) include trabecular laser ablation and deep sclerectomy, which removes the outer wall of Schlemm’s canal and excises deep sclera and peripheral cornea.

More recently the Trabectome™, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm’s 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 (see policy number 2.149). Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva.

Alternative nonpenetrating methods that are being evaluated for glaucoma are viscocanalostomy and canaloplasty. Viscocanalostomy is a variant of deep sclerectomy and unroofs and dilates Schlemm’s canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution, such as sodium hyaluronate, is used to open the canal and create a passage from the canal to a scleral reservoir. It has been proposed that viscocanalostomy may lower IOP while avoiding bleb-related complications.

Canaloplasty was developed from viscocanalostomy and involves dilation and tension of Schlemm’s canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack™ illuminated microcatheter (iScience Interventional) to access and dilate the length of Schlemm’s canal and to pass the suture loop through the canal. An important difference between viscocanalostomy and canaloplasty is that canaloplasty attempts to open the entire length of Schlemm’s canal, rather than one section of it.

Because aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system is critical for reaching the target IOP. Therefore, some procedures may not be able to reduce IOP below the pressure of the distal outflow system used, e.g., below 15 mm Hg, and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma). Health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy if the procedure is unsuccessful, complications, and durability of the procedure.

Regulatory Status

In 2004, the 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, the iTrack received FDA clearance for the indication of “catheterization and viscodilation of Schlemm canal to reduce intraocular pressure in adult patients with open angle glaucoma.” FDA product code: MPA.

IV. RATIONALE

This evidence review was created in 2011 and has been updated periodically using the MEDLINE database. The most recent literature review was performed through February 8, 2016.
Viscocanalostomy

A 2010 meta-analysis by Chai and Loon compared the safety and efficacy of viscocanalostomy with the criterion standard of trabeculectomy.\(^1\) Ten randomized controlled trials (RCTs) with a total of 458 eyes (397 patients) with medically uncontrolled glaucoma were included in the analysis. The number of eyes in each study ranged from 20 to 60, with follow-up ranging from 6 months to 4 years. Most eyes (81%) had primary open-angle glaucoma (POAG), 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 (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 (50 eyes).\(^2\)

One study included in the systematic review by Chai and Loon is a 2009 randomized trial by Gilmour et al with 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 outcome. At 1 month, conjunctival blebs were observed in 19 (79%) of the trabeculectomy group and 16 (64%) of the viscocanalostomy group. At 12 months, blebs were observed in 19 (79%) of the trabeculectomy group and 14 (56%) of the viscocanalostomy group. The proportion of patients with conjunctival blebs at final follow-up and the statistical significance of these differences were not reported. It was reported that more bleb manipulations (7 vs 1) and antimetabolites (5 vs 1) were needed in the trabeculectomy group. The 3 patients who required cataract surgery were in the viscocanalostomy group.

In 2003, Kobayashi et al reported a within-subject safety and efficacy comparison of trabeculectomy (with mitomycin C) and viscocanalostomy in 25 patients with bilateral POAG who had IOP greater than 22 mm Hg under medical therapy.\(^4\) Patients were randomly assigned to receive trabeculectomy in 1 eye and viscocanalostomy (with removal of the internal wall of Schlemm canal) in the other eye. 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 (eg, 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 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, there were fewer complications with viscocanalostomy (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 reported long-term results of viscocanalostomy in a series of 726 patients. 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 reported the effect of the learning curve on the surgical outcome of viscocanalostomy from a retrospective series of 180 consecutive cases performed by 2 surgeons at a single center in Europe. 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% to 91% when comparing the first and 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 and last 45 cases (16 vs 10, respectively).

Canaloplasty

A comparative effectiveness review of newer (Trabectome and canaloplasty) and older (trabeculectomy and Baerveldt shunt) surgeries for glaucoma was published in 2009. Twelve-month outcomes (IOP adjunctive medications, complications) were compared after glaucoma-only and combined glaucoma-phacoemulsification surgeries. The review 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 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). The review concluded that Trabectome and canaloplasty are reasonable surgical therapy choices for patients in whom IOPs in the mid-teens seem adequate; although trabeculectomy was the most effective IOP-lowering procedure, it also had the most serious complication rates.

In 2015, Matlach et al reported on an RCT with 62 patients that compared canaloplasty (n=31) with trabeculectomy (n=31) for the treatment of open-angle glaucoma. 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 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 results of surgery, and lower rates of visual and nonvisual symptoms and stress caused by surgery or postsurgical treatment. Difficulties with activities of daily living (eg, reading) and complaints (eg, eye burning) were significantly lower in the canaloplasty group. Some questions used were not from validated QOL questionnaires.

Most of the primary literature on canaloplasty consists of case series that compare posttreatment and pretreatment IOP. For example, a retrospective comparative study evaluated outcomes from 33 eyes (33 patients) that underwent canaloplasty and 46 eyes (46 patients) that underwent trabeculectomy during a 2-year period and had a minimum follow-up of 12 months.10 This study group was drawn from a larger group of 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 were analyzed, and treatment group assignment depended on insurance status.

In 2007, Lewis et al reported interim data analysis from a manufacturer-sponsored multicenter (15 centers) safety and efficacy study on canaloplasty using the iTrack microcatheter11 with 2- and 3-year results reported in 2009 and 2011.12,13 The 2011 study included 157 patients with a diagnosis of POAG, 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 cataract (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 24 (89%) of the 27 eyes with successful suture placement combined with phacoemulsification.

Additional reports from this group of investigators interim 1-year results for 40 patients who had combined canaloplasty and cataract surgery (potential overlap in patients from the study described earlier) and a within-subjects comparison in 15 patients who participated in the trial described earlier who had bilateral POAG and received canaloplasty in 1 eye and viscocanalostomy in the contralateral eye. For the canaloplasty eye, IOP decreased from 26.5 mm Hg on 2.1 medications to 14.5 on 0.3 medications. For the viscocanalostomy eye, IOP decreased from 24.3 mm Hg on 1.9 medications to 16.1 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.

The same investigators reported an industry-sponsored 3-year prospective, multicenter study of 109 open-angle glaucoma patients (109 eyes) who underwent canaloplasty or combined cataract-canaloplasty surgery. All patients had documented visual field loss and met criteria for the diagnosis of glaucoma and failure of prior medical or laser therapy. A tensioning suture was successfully placed in 98 (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 South African patients with POAG who underwent canaloplasty was reported by Grieshaber et al in 2010. 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%) of 49 patients. When defined as an IOP of 16 mm Hg or less without medications, 47% of eyes met criteria for complete success. There were no severe complications in this series.

Three-year follow-up from an independent series of 214 patients treated with canaloplasty in Europe was reported by Brusini in 2014.\(^1\) 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.

In 2015, Voykov et al reported 5-year follow-up on patients (20 eyes) with open-angle glaucoma who underwent canaloplasty at a single center in Germany.\(^2\) 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.

### Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in February 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

### Summary of Evidence
The evidence for viscocanalostomy in individuals who have open-angle glaucoma and have failed medical therapy includes small randomized controlled trials (RCTs) that compare 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 the effects of the technology on health outcomes.

The evidence for canaloplasty in individuals who have open-angle glaucoma and have failed medical therapy includes an RCT and case series. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. The RCT found a significantly higher complete success rate with trabeculectomy than with canaloplasty, but a higher complication rate as well. The qualified success rate (with medication) was similar between the 2 groups. A systematic review found that canaloplasty provided modest IOP reduction (to 16 mm Hg) with minor
intraoperative or postoperative complications. Further RCT evidence is required to corroborate results of this single trial. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Clinical Input Received From Physician Specialty Societies and Academic Medical Centers**
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests regarding viscocanalostomy, input was received from 1 specialty medical society and 3 academic medical centers while this policy was under review in 2011. Although some considered viscocanalostomy to be medically necessary in a select group of patients who would be at risk for suffering a blinding complication with trabeculectomy, the input was mixed. For example, 1 reviewer considered outcomes with viscocanalostomy to be inferior to other currently used nonpenetrating techniques.

In response to requests regarding canaloplasty, input was received from 1 specialty medical society and 2 academic medical centers while this policy was under review in 2011. One ophthalmology association provided a statement indicating that the case series cited are sufficient to show efficacy of canaloplasty to lower IOP to treat open-angle glaucoma. Other reviewers considered canaloplasty 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 that would not be able to cover a glaucoma drainage device implant).

**Practice Guidelines and Position Statements**

**American Academy of Ophthalmology**
A 2011 Technology Assessment from the American Academy of Ophthalmology (AAO) included canaloplasty in its review of novel glaucoma procedures.20 AAO concluded that all the techniques and devices reviewed were still in the initial stage (≤5 years) of clinical experience and lacking widespread use, with only level III evidence (cohort studies) 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 Schlemm canal are not known.

**National Institute for Health and Clinical Excellence**
The 2008 guidance from U.K.’s National Institute for Health and Clinical Excellence (NICE) stated that the current evidence on the safety and efficacy of canaloplasty for primary open-angle glaucoma is inadequate in both quality and quantity, and that this procedure should only be used for research or formal prospective data collection.21

In 2009, NICE published guidance on the diagnosis and management of chronic open-angle glaucoma and ocular hypertension.22 When comparing penetrating surgery (trabeculectomy) with nonpenetrating surgery (deep sclerectomy and viscocanalostomy), the reviewers 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 at 6- and 12-month follow-up, but the effect size may have been too small to be clinically significant. The guidance recommended offering information on the risks and benefits associated with surgery and offering surgery (type not specified) with pharmacologic augmentation to people with chronic open-angle glaucoma at risk of progressing to sight loss, despite treatment. In November 2015, NICE determined this guideline should be updated; the expected completion date is May 2017.

U.S. Preventive Services Task Force Recommendations

Not applicable.

V. DEFINITIONS

NA

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION
MEDICAL POLICY

**POLICY TITLE**

VISCOCANALOSTOMY AND CANALOPLASTY

**POLICY NUMBER**

MP-2.177

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015:

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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES

15. Koerber NJ. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. J Glaucoma. Feb 2012;21(2):129-134. PMID 21278587

Other Sources
X. POLICY HISTORY

| MP 2.177 | CAC 6/4/13 New Policy. Information related to Viscocanalostomy and Canaloplasty was extracted from MP 2.149 Aqueous Shunts and Stents for Glaucoma (previously Aqueous Shunts and Devices for Glaucoma). BCBSA adopted. Type of glaucoma specified in policy statement. Canaloplasty is considered medically necessary for patients with chronic primary open-angle glaucoma under specific conditions as a method to reduce intraocular pressure. No change to viscocanalostomy – remains investigational. Rationale section added. Policy coded. |
| MP 2.177 | CAC 3/25/14 Consensus. No change to policy statements. References updated. |
| MP 2.177 | 11/10/2014- Administrative code review |
| MP 2.177 | CAC 3/24/15 Consensus review. No changes to policy statements. Reference and rationale update. Coding reviewed. |
| MP 2.177 | CAC 5/31/16 Consensus review. Added Medicare variation to reference LCD L35087 Glaucoma Treatment With Aqueous Drainage Device. No change to policy statements. References and rationale updated. Policy presented for retirement and approved. Policy will be retired effective 9/1/2016. |