Viscocanalostomy and Canaloplasty

Policy # 00280
Original Effective Date: 11/16/2010
Current Effective Date: 06/20/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of canaloplasty as a method to reduce intraocular pressure (IOP) in patients with chronic primary open-angle glaucoma to be **eligible for coverage** under the following conditions:

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

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers canaloplasty under all other conditions, including angle-closure glaucoma, to be **investigational.***

Based on review of available data, the Company considers viscocanalostomy to be **investigational.***

Background/Overview

Surgical procedures for glaucoma aim to reduce IOP resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm 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 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.

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 (eg, leaks, hypotony, choroidal effusions and hemorrhages, hyphemas or bleb-related endophthalmitis) and long-term failure. Other

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

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 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 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 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 canal and to pass the suture loop through the canal. An important difference between viscocanalostomy and canaloplasty is that canaloplasty attempts to open the entire length of Schlemm canal, rather than 1 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 (eg, below 15 mm Hg), and are not indicated for patients for whom very low IOP is desired (eg, 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.

FDA or Other Governmental Regulatory Approval

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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Viscocanalostomy and Canaloplasty

Policy # 00280
Original Effective Date: 11/16/2010
Current Effective Date: 06/20/2018

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Viscocanalostomy

Systematic Reviews

A 2010 meta-analysis by Chai and Loon compared the safety and efficacy of viscocanalostomy with the criterion standard of trabeculectomy. 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 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 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).

Randomized Controlled Trials

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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Case Series
In 2003, Kobayashi et al reported a within-subject safety and efficacy comparison of trabeculectomy (with mitomycin C) and viscocanalostomy in 25 patients with bilateral POAG who had IOP greater than 22 mm Hg under medical therapy. 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 at 1 and 3 days, 1 and 2 weeks, and 1, 2, 3, 4, 5, 6, 9, and 12 months after surgery. Throughout follow-up, the mean IOP decreased significantly more in trabeculectomy-treated eyes (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, 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, defined as IOP less than 20 mm Hg, and IOP reduction greater than 30% with or without glaucoma medication, did not differ significantly between the 2 groups (96% for trabeculectomy, 92% for viscocanalostomy). Although trabeculectomy had a greater IOP-lowering effect, there were fewer complications with viscocanalostomy (1 microperforation of Descemet membrane vs 4 cases of shallow anterior chamber, 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 at 5 years, 15.5 at 10 years, and 16.8 at 15 years. Qualified success (with or without medications) at 10 years of 18 mm Hg or less was 40% in the European population and 59% in the African population. Laser goniopuncture was performed postoperatively on 127 eyes (17.7%). Fifty-three eyes (7.3%) were considered failures and required reoperation. There were no significant complications.

Stangos et al 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, defined as no visual field deterioration with an IOP of 20 mm Hg or less and IOP reduction of 30% or greater compared with baseline values, improved from 64% to 91% when comparing the first 45 to the last 45 cases of the series. Complete success, defined as no medications required, improved from 38% to 73%. Surgical complications did not differ significantly between the first and last 45 cases (16 vs 10, respectively).

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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Canaloplasty
Systematic Reviews
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 and 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 minimal intraoperative or postoperative complications. Results of Baerveldt glaucoma implant IOP reduction were comparable with trabeculectomy (≈12 mm Hg), but typically, this shunt required more postoperative IOP-lowering medication (average, 1.3 vs 0.5 medications, respectively) to achieve a success rate comparable with trabeculectomy. Patients treated with Trabectome required more medications (average, 1.5) to control IOP than patients treated with canaloplasty (average, 0.6). The review concluded that Trabectome and canaloplasty are reasonable surgical therapy choices for patients in which IOPs in the mid-teens seem adequate; although trabeculectomy remains the most effective IOP-lowering procedure, it also has the highest serious complication rates.

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

Case Series
Most of the primary literature on canaloplasty consists of case series that compare posttreatment IOP with pretreatment IOP. One retrospective comparative study evaluated outcomes from 33 eyes (33 patients) that underwent canaloplasty and 46 eyes (46 patients) that underwent trabeculectomy during a 2-year period and had a minimum of 12 month of follow-up. This study group was drawn from a larger group of 243

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

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 after surgery, 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 needed postoperative glaucoma medications. There was no significant difference in surgical reoperation rates between the 2 procedures (15% canaloplasty, 11% trabeculectomy). This study is limited by the potential for bias in the selection of patients for the study. Only a minority of all surgical patients had 12-month follow-up data and were included in the study, and selection into treatment groups was dependent on insurance status.

In 2007, Lewis et al reported interim data analysis from a company-sponsored multicenter (15 centers) safety/efficacy study on canaloplasty using the iTrack microcatheter with 2- and 3-year results reported in 2009 and 2011. The 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 historical IOP of 21 mm Hg or higher. Exclusion criteria were neovascular disease, uveitis, peripheral anterior synechiae, angle recession, and developmental or secondary glaucoma (except for pigmentary and exfoliative glaucoma). At baseline, mean IOP was 23.8, and patients were on an average 1.8 medications. Canaloplasty was successful in 133 eyes (85%). Eyes that did not have placement of a tensioning suture were viscodilated to the extent possible by catheterizing the canal from both ostia. Early surgical/postoperative complications included microhyphema (12%), hyphema (10%), elevated IOP (6%), Descemet membrane detachment (3%), suture extrusion (1%), and hypotony (1%). Late postoperative complications included cataract (12.7%), transient IOP elevation (6.4%), and partial suture extrusion through the trabecular meshwork (0.6%). At 3 years postoperatively, 134 study eyes (85% follow-up) had a mean IOP of 15.2 mm Hg and mean glaucoma medication use of 0.8 medications; 66 eyes (49.3%) were on no medications. Another 7 patients (4.4%) had additional glaucoma surgery. With qualified success defined as achieving IOP of 18 mm Hg or lower (with 0 to 2 medications), success was achieved in 69 of the 89 eyes (77.5%) that had successful suture implantation alone and 24 of the 27 eyes (89%) with successful suture placement combined with phacoemulsification.

Additional reports from this group of investigators included interim 1-year results for 40 patients who had combined canaloplasty and cataract surgery (potential overlap in patients from the study described earlier) and a within subject comparison in 15 of the 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 on 0.4 medications. The reduction in IOP from baseline was significantly greater with canaloplasty than with viscocanalostomy (12.0 mm Hg vs 8.2 mm Hg, p=0.02). There was no loss in visual acuity and no adverse events from either procedure. The investigators noted that this study evaluated the effects of 2 additional maneuvers associated with canaloplasty: first, 360° viscodilation of Schlemm canal, as opposed to partial dilation

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

achieved with viscocanalostomy, and, second, 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 eyes (89.9%), and 96 eyes (88.1%) completed the 3-year follow-up. Of the 13 patients who did not complete follow-up, 4 (3.7%) had undergone additional glaucoma surgery; these patients were not included in the analysis. In eyes treated with canaloplasty with a successful tensioning suture, IOP decreased from 23 mm Hg on 1.9 medications to 15.1 mm Hg on 0.9 medications. In eyes treated with combined cataract-canaloplasty surgery with a successful tensioning suture, IOP decreased from 24.3 mm Hg on 1.5 medications to 13.8 mm Hg on 0.5 medications. For the 11 eyes that had canaloplasty without suture placement, IOP decreased from 24.4 on 1.9 medications to 15.6 on 1.2 medications. Late postoperative complications included cataracts (19.1%) and transient IOP elevation (1.8%).

A prospective series with 60 consecutive South African patients with POAG who underwent canaloplasty was reported by Grieshaber et al in 2010. Mean preoperative IOP was 45 mm Hg. At 12-month follow-up, IOP was 15 mm Hg (n=54), and at 36 months, IOP was 13.3 mm Hg (n=49). Eleven patients (18%) were lost to follow-up at 3 years. With qualified success defined as achieving IOP of 21 mm Hg or lower (with or without medications), success was achieved in 40 of 49 patients (82%). When defined as an IOP of 16 mm Hg or less without medications, 47% of eyes met criteria for complete success. There were no severe complications in this series.

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

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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

low, the most common being hyphema (7/20 [35%] eyes). No sight-threatening complications were reported.

Section Summary: Canaloplasty
Findings from 1 small RCT and 1 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 showed 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 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 sufficient to determine that the technology is unlikely to improve the net health outcome.

For individuals who have open-angle glaucoma who have failed medical therapy who receive canaloplasty, the evidence includes 1 RCT, 1 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 the effects of the technology on health outcomes.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Viscocanalostomy and Canaloplasty”. 9.03.26. 03:2018.
2. Chai C, Loon SC. Meta-analysis of viscocanalostomy versus trabeculectomy in uncontrolled glaucoma. J Glaucoma. Oct-Nov 2010;19(8):519-527. PMID 20179632
3. Eldaly MA, Bunce C, Elsheikha OZ, et al. Non-penetrating filtration surgery versus trabeculectomy for open-angle glaucoma. Cochrane Database Syst Rev. 2014;2:CD007059. PMID 24532137
4. Gilmour DF, Manners TD, Devonport H, et al. Viscocanalostomy versus trabeculectomy for primary open angle glaucoma: 4-year prospective randomized clinical trial. Eye (Lond). Sep 2009;23(9):1802-1807. PMID 17293790
5. Kobayashi H, Kobayashi K, Okinami S. A comparison of the intraocular pressure-lowering effect and safety of viscocanalostomy and trabeculectomy with mitomycin C in bilateral open-angle glaucoma. Graefes Arch Clin Exp Ophthalmol. May 2003;241(5):359-366. PMID 12698257

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

6. Grieshaber MC, Peckar C, Pienaar A, et al. Long-term results of up to 12 years of over 700 cases of viscocanalostomy for open-angle glaucoma. Acta Ophthalmol. Jun 2015;93(4):362-367. PMID 25270165
7. Stangos AN, Mavropoulos A, Leuenberger PM, et al. The effect of learning curve on the surgical outcome of viscocanalostomy. J Glaucoma. Aug 2012;21(6):408-414. PMID 21673593
8. Mosaed S, Dustin L, Minckler DS. Comparative outcomes between newer and older surgeries for glaucoma. Trans Am Ophthalmol Soc. Dec 2009;107:127-133. PMID 20126489
9. Matlach J, Dhillon C, Hain J, et al. Trabeculectomy versus canaloplasty (TVC study) in the treatment of patients with open-angle glaucoma: a prospective randomized clinical trial. Acta Ophthalmol. Apr 3 2015. PMID 25847610
10. Klink T, Sauer J, Korber NJ, et al. Quality of life following glaucoma surgery: canaloplasty versus trabeculectomy. Clin Ophthalmol. 2015;9:7-16. PMID 25565763
11. Ayyala RS, Chaudhry AL, Okogbaa CB, et al. Comparison of surgical outcomes between canaloplasty and trabeculectomy at 12 months' follow-up. Ophthalmology. Dec 2011;118(12):2427-2433. PMID 21856008
12. Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults: interim clinical study analysis. J Cataract Refract Surg. Jul 2007;33(7):1217-1226. PMID 17586378
13. Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: circumferential viscodilation and tensioning of Schlemm canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults: two-year interim clinical study results. J Cataract Refract Surg. May 2009;35(5):814-824. PMID 19393879
14. Lewis RA, Von Wolff K, Tetz M, et al. Canaloplasty: Three-year results of circumferential viscodilation and tensioning of Schlemm canal using a microcatheter to treat open-angle glaucoma. J Cataract Refract Surg. 2011;37(4):682-690.
15. Shingleton B, Tetz M, Korber N. Circumferential viscodilation and tensioning of Schlemm canal (canaloplasty) with temporal clear corneal phacoemulsification cataract surgery for open-angle glaucoma and visually significant cataract: one-year results. J Cataract Refract Surg. Mar 2008;34(3):433-440. PMID 18299068
16. 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
17. Bull H, von Wolff K, Korber N, et al. Three-year canaloplasty outcomes for the treatment of open-angle glaucoma: European study results. Graefes Arch Clin Exp Ophthalmol. Oct 2011;249(10):1537-1545. PMID 21732110
18. Grieshaber MC, Pienaar A, Olivier J, et al. Canaloplasty for primary open-angle glaucoma: long-term outcome. Br J Ophthalmol. Nov 2010;94(11):1478-1482. PMID 20962352
19. Brusini P. Canaloplasty in open-angle glaucoma surgery: a four-year follow-up. Scientific World Journal. 2014;2014:469609. PMID 24574892
20. American Academy of Ophthalmology. Preferred practice pattern: Primary open-angle glaucoma 2010; http://www.aao.org/preferred-practice-pattern/primary-openangle-glaucoma-suspect-ppp--october-20. Accessed June 4, 2015.
21. Francis BA, Singh K, Lin SC, et al. Novel glaucoma procedures: a report by the American Academy of Ophthalmology. Ophthalmology. Jul 2011;118(7):1466-1480. PMID 21724045
22. National Institute for Health and Clinical Evidence (NICE). Canaloplasty for primary open-angle glaucoma (IPG260). 2008; http://www.nice.org.uk/guidance/ipg260. Accessed June 4, 2015.
23. National Institute for Health and Clinical Excellence (NICE). Glaucoma: Diagnosis and Management of Chronic Open Angle Glaucoma and Ocular Hypertension (CG85). 2009; http://www.nice.org.uk/guidance/cg85. Accessed June 4, 2015.

Policy History

Original Effective Date: 11/16/2010
Current Effective Date: 06/20/2018

11/04/2010	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. New policy.
12/31/2010	Coding Updated
09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee approval. Title changed from “Canaloplasty for Primary Open Angel Glaucoma” to “Viscocanalostomy and Canaloplasty”. Coverage for canaloplasty revised to be eligible under specified conditions. Viscocanalostomy added as investigational.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Viscocanalostomy and Canaloplasty

Policy # 00280
Original Effective Date: 11/16/2010
Current Effective Date: 06/20/2018

11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. No change to coverage.
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. No change to coverage.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 06/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	66174, 66175
HCPCS	No codes
ICD-10 Diagnosis	A00.0, H40.10X0-H40.10X4, H40.111, H40.1110-H40.1114, H40.1120-H40.1124, H40.1130-H40.1134, H40.1190-H40.1194, H40.1210-H40.1214, H40.1220-H40.1224, H40.1230-H40.1234, H40.1290-H40.1294, H40.1310-H40.1314, H40.1320-H40.1324,

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

	H40.1330-H40.1334, H40.1390-H40.1394, H40.151-H40.159, H40.20X0-H40.20X4, H40.211-H40.219, H40.2210-H40.2214, H40.2220-H40.2224, H40.2230-H40.2234, H40.2290-H40.2294, H40.231-H40.239, H40.241-H40.249, Q15.0

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.