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Subject: Viscocanalostomy and Canaloplasty

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Glaucoma surgery is intended to reduce intraocular pressure when the target intraocular pressure cannot be reached with medications. Due to complications with established surgical approaches (eg, trabeculectomy), alternative surgical treatments (eg, transluminal dilation by viscocanalostomy or canaloplasty) are being evaluated for those with glaucoma.

Viscocanalostomy is a variant of deep sclerectomy and unroofs and dilates the Schlemm canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution (eg, sodium hyaluronate) is used to open the canal and create a passage from the canal to a scleral reservoir. It has been proposed that viscocanalostomy may lower intraocular pressure while avoiding bleb-related complications.

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

Summary and Analysis of Evidence: Gilmour et al (2009) conducted a randomized controlled trial that compared the effectiveness and safety of viscocanalostomy (visco) with trabeculectomy (trab) in the management of primary open angle glaucoma (POAG). Fifty eyes were studied, with mean follow-up of 40 months and a range from 6 to 60 months. The authors stated “in this study, we found trabeculectomy to be more effective at lowering IOP than viscocanalostomy in POAG patients.”

A meta-analysis by Chai and Loon (2010) compared the safety and efficacy of viscocanalostomy with the criterion standard of trabeculectomy. Ten RCTs with a total of 458 eyes (397 patients) with medically uncontrolled glaucoma were analyzed. Most eyes (81%) had primary open-angle glaucoma, while 16.4% had secondary open-angle glaucoma, and 1.7% had primary angle-closure glaucoma. Meta-analysis found that trabeculectomy had a significantly better pressure-lowering outcome. Viscocanalostomy had a significantly higher relative risk (RR) of perforation of the Descemet membrane. Viscocanalostomy had significantly fewer postoperative events than trabeculectomy. Although viscocanalostomy had a better risk profile, most adverse events associated with trabeculectomy were considered to be mild and reversible.

Similar results were obtained in a Cochrane review and meta-analysis by Eldaly et al (2014) that included 2 small randomized trials (total 50 eyes), with the authors stating, "(t)his review provides some limited evidence that control of IOP is better with trabeculectomy than viscocanalostomy."

Grieshaber et al (2015) reported on long-term results of viscocanalostomy for a series of 726 patients. Mean intraocular pressure before surgery was 42.6 mm Hg. Mean intraocular pressure post-surgery 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 (£ 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. Limitations of this study included a potential for "patient selection bias due to data availability and follow-up losses."Matlach et al (2015) compared the outcomes of canaloplasty and trabeculectomy in open-angle glaucoma. This prospective, randomized clinical trial included 62 patients who randomly received trabeculectomy (n = 32) or canaloplasty (n = 30) and were followed up prospectively for 2 years. Surgical treatment significantly reduced IOP in both groups. Complete success was achieved in 74.2% and 39.1%, and 67.7% and 39.1% after 2 years in the trabeculectomy and canaloplasty group, respectively. The authors concluded "(t)rabeculectomy is associated with a stronger IOP reduction and less need for medication at the cost of a higher rate of complications. If target pressure is attainable by moderate IOP reduction, canaloplasty may be considered for its relative ease of postoperative care and lack of complications."

National Institute for Health and Care Excellence (NICE) interventional procedure guidance "Ab interno canaloplasty for open-angle glaucoma" (NICE, 2022) states, "evidence on the safety of ab interno canaloplasty for open-angle glaucoma shows no major safety concerns. Evidence on the efficacy is limited in quality and quantity, particularly in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research." The guidance further states, "treatment <for glaucoma> usually involves eye drops containing medicines that either reduce the production of aqueous humor or increase its drainage. Surgical procedures such as trabeculectomy, deep sclerectomy, trabeculotomy, stenting, canaloplasty or laser trabeculoplasty may be used. Ab interno canaloplasty aims to reduce IOP by improving the drainage of aqueous fluid from the eye in people with open-angle glaucoma. It is usually done under local anaesthesia, but general anaesthesia can be used. Unlike traditional (ab externo) canaloplasty, which is done by cutting through the conjunctiva and sclera, ab interno canaloplasty uses an internal approach through a clear corneal or limbal incision. A microcatheter is introduced into the canal through a small opening in the trabecular meshwork and advanced around its entire circumference. As the catheter tip is withdrawn, viscoelastic fluid is injected into the canal to dilate it. The microcatheter is then removed. The viscoelastic fluid

disperses down the collector channels of the eye within 2 to 3 days. The aim is to permanently dilate the canal to allow increased drainage of aqueous humor from the eye and thereby lower IOP. Some devices allow canaloplasty to be done sequentially with trabeculotomy as part of a single operation. Canaloplasty is often done concurrently with phacoemulsification (cataract surgery)."

Yin et al (2023) reported on an RCT with ab interno canaloplasty versus gonioscopy-assisted transluminal trabeculectomy in 77 participants with open-angle glaucoma. Participants had medically uncontrolled or not sufficiently lowered intraocular pressure but no prior history of incisional ocular surgery. Outcome data at the 12-month follow up was available for 71 participants. The 12-month rate of complete surgical success was 56% in the canaloplasty group, and 75% in the trabeculectomy group. Three eyes in the canaloplasty group and 1 eye in the trabeculectomy group required additional glaucoma surgeries.

Khaimi et al (2024) investigated the clinical outcomes of canaloplasty performed with the iTrack microcatheter (Nova Eye Medical, Fremont, USA) as a standalone procedure and in combination with phacoemulsification in patients with primary angle-closure glaucoma (PACG). Sixty eyes (9 canaloplasty-standalone, pseudophakic, and 51 canaloplasty + phaco) were eligible. OP reduction was statistically significant when canaloplasty was performed as a standalone procedure or combined with phacoemulsification, or if canaloplasty was performed in mild, moderate, or severe glaucoma eyes, with no difference between the groups postoperatively. Medication reduction was significant when canaloplasty was performed in combination with phacoemulsification and in mild glaucoma eyes. The authors concluded "canaloplasty via an ab-interno surgical technique, performed as standalone or combined with phacoemulsification, is a safe and clinically effective treatment in primary angle closure glaucoma patients up to 2 years." The authors noted several study limitations, including small sample size, loss at follow-up, and the retrospective nature of the study. They stated, "a prospective study with a larger sample size and the inclusion of wider range of ethnic groups (especially Asian PACG patients) would further underline the usefulness of this canaloplasty via an ab-interno surgical technique in PACG patients."

Beres et al (2025) evaluated the long-term efficacy and safety of canaloplasty and phacocanaloplasty in patients with primary open-angle glaucoma (POAG) and pseudoexfoliation glaucoma (PEXG). This retrospective observational study included 85 patients with POAG and PEXG who underwent canaloplasty (group 1) or phacocanaloplasty (group 2). In both groups, the mean baseline intraocular pressure (IOP) and mean medication use dropped at 1, 5, and 10 years. Goniopuncture was performed postoperatively in nine cases (13.9%) within the initial 3 months due to IOP spikes. Patients with PEXG had a significantly higher likelihood of requiring re-operation. No serious complications were observed. The authors concluded, "canaloplasty is a safe and effective procedure for lowering IOP in eyes with POAG and PEXG, achieving approximately a 30% reduction in IOP. PEXG patients are likelier to have IOP spikes in the late postoperative period therefore careful monitoring and management is required." The authors noted several study limitations, including lack of randomization, small sample size, and its retrospective nature, unequal sample sizes,and some patients lost to follow-up or mortality before study completion, thereby impacting data integrity and completeness.

POSITION STATEMENT:

Canaloplasty **meets the definition of medical necessity** as a method to reduce intraocular pressure in individuals with chronic primary open-angle glaucoma (POAG) under the following conditions:

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

Canaloplasty is considered **experimental or investigational** for all other conditions, including angle-closure glaucoma. There is a lack of clinical data to permit conclusions regarding net health outcomes.

Viscocanalostomy is considered **experimental or investigational** for any condition. There is a lack of clinical data to permit conclusions regarding net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

66174	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); with retention of device or stent

ICD-10 Diagnosis Codes That Support Medical Necessity:

H40.10X0 – H40.10X4	Unspecified open-angle glaucoma
H40.1110 – H40.1194	Primary open-angle glaucoma, staged
H40.1210 – H40.1294	Low-tension glaucoma
H40.1310 – H40.1394	Pigmentary glaucoma
H40.151 – H40.159	Residual stage of open-angle glaucoma

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

01-92000-24, Aqueous Shunts and Stents for Glaucoma

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/26/25.

GUIDELINE UPDATE INFORMATION:

07/15/14	New Medical Coverage Guideline.
06/15/15	Scheduled review. Position Statement maintained. Revised ICD9/ICD10 coding and updated references.
11/01/15	Revision: ICD-9 Codes deleted.
07/15/16	Scheduled review. Maintained Position statement section. Updated references.
10/01/16	ICD-10 coding update: deleted codes H40.11X0 – H40.11X4; added codes H40.1110 – H40.1194.
07/15/17	Scheduled review. Maintained Position Statement section. Updated references. Reformatted guideleine.
06/15/18	Scheduled review. Maintained Position Statement section. Updated references.
06/15/19	Scheduled review. Position statement maintained. Updated references.
06/15/20	Scheduled review. Revised description, Maintained position statement and updated references.
07/15/21	Scheduled review. Revised description, maintained position statement, and updated references.
01/01/23	Annual CPT/HCPCS coding update. Revised 66174, 66175.
07/15/23	Scheduled review. Maintained position statement and updated references.
08/21/23	Update to Program Exceptions section.
07/15/24	Scheduled review. Revised description. Maintained position statement and updated references.
07/15/25	Scheduled review. Revised description. maintained position statement and updated references.