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Subject: Visco canalostomy and Canaloplasty

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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 visco canalostomy or canaloplasty) are being evaluated for those with glaucoma.

Visco canalostomy 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 visco canalostomy may lower intraocular pressure while avoiding bleb-related complications.

Canaloplasty, which evolved from visco canalostomy, 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 visco canalostomy and canaloplasty is that canaloplasty attempts to open the entire length of the Schlemm canal, rather than one section.

Summary and Analysis of Evidence: A meta-analysis by Chai and Loon (2010) compared the safety and efficacy of visco canalostomy 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. Visco canalostomy had a significantly higher relative risk (RR) of perforation of the Descemet membrane. Visco canalostomy had significantly fewer postoperative events than trabeculectomy. Although visco canalostomy 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." 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." 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 (\leq 18 mm Hg) was 40% in the European population and 59% in the African population. Laser goniotomy 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."

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. 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."

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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5. American Academy of Ophthalmology. Primary Open-Angle Glaucoma Summary Benchmarks for Preferred Practice Pattern® Guidelines; 2013. Accessed at: www.aao.org/ppp on 04/22/14.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/27/24.

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 guideline.
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.