

Policy: MP260

Section: Medical Benefit Policy

Subject: Canaloplasty and Viscocanalostomy

Applicable Lines of Business

Commercial	X	СНІР	X
Medicare	Х	ACA	Х
Medicaid	Х		

I. Policy: Canaloplasty and Viscocanalostomy

II. Purpose/Objective:

To provide a policy of coverage regarding Canaloplasty and Viscocanalostomy

III. Responsibility:

- A. Medical Directors
- **B.** Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

• Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Canaloplasty and Viscocanalostomy have been proposed as treatments for open angle glaucoma. Viscocanalostomy involves creation of superficial and deep scleral flaps, excision of the deep scleral flap to create a scleral reservoir, and unroofing of Schlemm's canal. A high-viscosity viscoelastic, such as sodium hyaluronate, is used to open the canal and create a passage from a scleral reservoir to the canal. The injected material opens and enlarges the canal to allow increased fluid flow out of the anterior chamber. The superficial scleral flap is then sutured water tight, trapping the viscoelastic until healing takes place. Canaloplasty (also called 360° viscocanalostomy) is similar to viscocanalostomy and also begins by creating tissue flaps to expose the drainage area. However, canaloplasty attempts to open the entire drainage area surrounding the anterior chamber (360°) instead of just a portion of it. The canal is identified then intubated with a flexible microcatheter which has a lighted tip to identify its location as it passes through the Schlemm's canal. The microcatheter also has a lumen to allow for the passage of high viscosity sodium hyaluronate for dilation of the canal. Once the cannula has passed the full length (360° through) of the Schlemm's canal, a suture is tied to the cannula and as the cannula is withdrawn the suture is tied off and left in place. The intracanalicular suture cinches and stretches the trabecular meshwork inwards and permanently opening the Schlemm's canal. The scleral flap is tightly closed as well as the conjunctiva. Before, during and after the surgery, a special ultrasound imaging system is used to help identify the canal and the instrumentation in the canal. An important difference between viscocanalostomy and canaloplasty is that canaloplasty aims at opening the entire length of the Schlemm's canal, not just one section of it. Canaloplasty and viscocanalostomy are both referred to as nonpenetrating procedures

INDICATIONS:

Canaloplasty is considered to be medically necessary for the treatment of primary open-angle glaucoma only when the following criteria are met:

- Maximized medical therapy including medication and laser therapy has failed to control intraocular pressure; and
- The member is not a candidate for trabeculectomy or aqueous shunt due to a high risk for complications

EXCLUSIONS:

The Plan does **NOT** provide coverage for canaloplasty for any other indication because it is considered **experimental**, **investigational or unproven**.

The Plan does **NOT** provide coverage for viscocanalostomy or combined phacoemulsification and viscocanalostomy for any indication because it is considered **experimental**, **investigational or unproven**. The Geisinger Technology Assessment Committee determined there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these treatments on health outcomes when compared to established treatments or technologies.

The Plan does **NOT** provide coverage for canaloplasty and trabeculotomy ab interno with the OMNI System combined with cataract surgery **experimental**, **investigational or unproven** for the treatment of POAG because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

<u>Note:</u> A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven experimental, investigational, and unproven services is outlined in **MP 15 -Experimental Investigational or Unproven Services or Treatment**

CODING ASSOCIATED WITH: Canaloplasty and Viscocanalostomy

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

HCPCS/CPT Codes:

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

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Technology Assessment Committee Triage Group. October 2011.

Chai, C, Loon, SC. Meta-analysis of viscocanalostomy versus trabeculectomy in uncontrolled glaucoma. *J Glaucoma*. 2010;19(8):519-527.

Cheng, JW, Xi, GL, Wei, RL, Cai, JP, and Li, Y. Efficacy and tolerability of nonpenetrating filtering surgery in the treatment of open-angle glaucoma: a meta-analysis. *Ophthalmologica*. 2010;224(3):138-146.

Mosaed, S, Dustin, L, and Minckler, DS. Comparative outcomes between newer and older surgeries for glaucoma. *Trans Am Ophthalmol Soc.* 2009;107:127-133.

Hondur, A, Onol, M, and Hasanreisoglu, B. Nonpenetrating glaucoma surgery: meta-analysis of recent results. *J Glaucoma*. 2008;17(2):139-146.

Ang, GS, Varga, Z, and Shaarawy, T. Postoperative infection in penetrating versus non-penetrating glaucoma surgery. *Br J Ophthalmol.* 2010;94(12):1571-1576.

Grieshaber, MC, Pienaar, A, Olivier, J, and Stegmann, R. Comparing two tensioning suture sizes for 360 degrees viscocanalostomy (canaloplasty): a randomised controlled trial. *Eye (Lond)*. 2010;24(7):1220-1226.

Gilmour, DF, Manners, TD, Devonport, H, Varga, Z, Solebo, AL, and Miles, J. Viscocanalostomy versus trabeculectomy for primary open angle glaucoma: 4-year prospective randomized clinical trial. *Eye (Lond)*. 2009;23(9):1802-1807.

Kobayashi, H, Kobayashi, K. Randomized comparison of the intraocular pressure-lowering effect of phacoviscocanalostomy and phacotrabeculectomy. *Ophthalmology*. 2007;114(5):909-914.

Yuan, ZL, Yang, Q, Chen, Q, Zhang, WZ, and Sun, H. [Modified viscocanalostomy for the surgical treatment with primary open angle glaucoma]. *Zhonghua Yan Ke Za Zhi*. 2007;43(5):421-425.

Noureddin, BN, El-Haibi, CP, Cheikha, A, and Bashshur, ZF. Viscocanalostomy versus trabeculotomy ab externo in primary congenital glaucoma: 1-year follow-up of a prospective controlled pilot study. *Br J Ophthalmol.* 2006;90(10):1281-1285.

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 2007; 33(7):1217-26.

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 2009; 35(5):814-24.

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):682-90.

Jacob DS. Open-angle glaucoma: Treatment. UpToDate Inc., Waltham, MA. Last reviewed February 2016-

Gedde SJ, et al. Three-year follow-up of the tube versus trabeculectomy study. Am J Ophthal, 2009;148(5):670-84.

Chakib A, Ouarranch N, et al. Viscocanalostomy: preliminary clinical results. J Fr Ophthalmol. 2010;33(6):403-407.

Winifred S. Hayes, Hayes Inc. Online, <u>iStent Trabecular Micro-Bypass Stent (Glaukos Corp.) for Treatment of Primary</u> <u>Open-Angle Glaucoma</u>, March, 2013.

Grieshaber MC. Ab extern Schlemm's canal surgery: viscocanalostomy and canaloplasty. Dev Ophthalmol. 2012;50:109-24.

Brusini P, Tosoni C, Zeppieri M (2014) The Role of Canaloplasty in the Surgical Treatment of Open-Angle Glaucoma. Surgery Curr Res 4:169

Tian B, Kaufman PL. A potential application of canaloplasty in glaucoma gene therapy. Transl Vis Sci Technol. 2013;2(1). pii: 2.

Brusini P, Tosoni C. Canaloplasty after failed trabeculectomy: A possible option. J Glaucoma. 2014;23(1):33-34.

Matlach J, Klink T. Trabeculectomy versus canaloplasty. Ophthalmologe. 2015;112(4):325-331.

Brusini P. Canaloplasty in open-angle glaucoma surgery: A four-year follow-up. ScientificWorldJournal. 2014;2014;469609

Liu H, Zhang H, Li Y, Yu H. Safety and efficacy of canaloplasty versus trabeculectomy in treatment of glaucoma. Oncotarget. 2017 Jan 19

Wagdy FM. Canaloplasty versus viscocanalostomy in primary open angle glaucoma. Electron Physician. 2017;9(1):3665-3671.

Lin ZJ, Xu S, Huang SY, et al. Comparison of canaloplasty and trabeculectomy for open angle glaucoma: A metaanalysis. Int J Ophthalmol. 2016;9(12):1814-1819.

Jacob DS. Open-angle glaucoma: Treatment. UpToDate Inc., Waltham, MA. Last reviewed February 2016.

Liu H, Zhang H, Li Y, Yu H. Safety and efficacy of canaloplasty versus trabeculectomy in treatment of glaucoma. Oncotarget. 2017;8(27):44811-44818

Zhang B, Kang J, Chen X. A system review and meta-analysis of canaloplasty outcomes in glaucoma treatment in comparison with trabeculectomy. J Ophthalmol. 2017;2017:2723761

Gad AAM, Abdulhalim BH, Lotfy A, et al. Combined phacoemulsification and viscocanalostomy with Ologen implant versus combined phacoemulsification and viscocanalostomy. BMC Ophthalmol. 2019 Feb 6;19(1):45

Gabai A, Cimarosti R, Isola M, Battistella C, Lanzetta P. Efficacy and safety of trabeculectomy versus nonpenetrating surgeries in open-angle glaucoma: a meta-analysis. J Glaucoma. 2019

Hirsch L, Cotliar J, Vold S, et al. Canaloplasty and trabeculotomy ab interno with the OMNI System combined with cataract surgery in open-angle glaucoma: 12-month outcomes from the ROMEO Study. J Cataract Refract Surg. 2020 Dec 9

Vastardis I, Fili S, Perdikakis G, et al. Estimation of risk-benefit ratio and comparison of post-operative efficacy results between trabeculectomy and canaloplasty. Eur J Ophthalmol. 2021 May; 31(3):1405-1412.

Gallardo MJ. 36-Month Effectiveness of Ab-Interno Canaloplasty Standalone versus Combined with Cataract Surgery for the Treatment of Open-Angle Glaucoma. Ophthalmol Glaucoma. 2022; 5(5): 476-482.

Murphy Iii JT, Terveen DC, Aminlari AE, et al. A Multicenter 12-Month Retrospective Evaluation of Canaloplasty and Trabeculotomy in Patients with Open-Angle Glaucoma: The ROMEO 2 Study. Clin Ophthalmol. 2022; 16: 3043-3052

Gallardo MJ, Pyfer MF, Vold SD, et al. Canaloplasty and Trabeculotomy Combined with Phacoemulsification for Glaucoma: 12-Month Results of the GEMINI Study. Clin Ophthalmol. 2022; 16: 1225-1234.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/21/2011

Revised: 2/15, 10/19(refine exclusion); 10/21 (add OMNI exclusion)

Reviewed: 11/12, 11/13, 11/14, 11/15. 11/16, 10/17, 10/18, 10/20, 10/22, 10/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

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