Policy: MP260
Section: Medical Benefit Policy
Subject: Canaloplasty and Viscocanalostomy

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

   (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
   (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
   (iii) The service or benefit 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 intracanicular 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:

- Maximised 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.

Note: 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](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

HCPCS/CPT Codes:
66174 transluminal dilation of aqueous outflow canal; without retention of device or stent
66175 transluminal dilation of aqueous outflow canal; with retention of device or stent


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 supersede this policy. For PA Medicaid Business segment, this policy applies as written.
REFERENCES:


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.


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.


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


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

Devised: 11/21/2011

Revised: 2/15, 10/19(refine exclusion)

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