

Policy: MP260

Section: Medical Benefit Policy

Subject: Canaloplasty and Viscoanalostomy

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Canaloplasty and Viscoanalostomy

II. Purpose/Objective:

To provide a policy of coverage regarding Canaloplasty and Viscoanalostomy

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 Visco canalostomy have been proposed as treatments for open angle glaucoma. Visco canalostomy 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° visco canalostomy) is similar to visco canalostomy 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 visco canalostomy and canaloplasty is that canaloplasty aims at opening the entire length of the Schlemm's canal, not just one section of it. Canaloplasty and visco canalostomy 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 visco canalostomy or combined phacoemulsification and visco canalostomy 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 trabeculectomy 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

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 Visco canalostomy

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:

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

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

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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); 10/21 (add OMNI exclusion)

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

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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