Geisinger Health Plan Policies and Procedure Manual

Policy: MP261

Section: Medical Benefit Policy

Subject: Aqueous Drainage Shunt

Applicable line of business:

Commercial	**x**	**Medicaid**	**x**
Medicare	**x**	**ACA**	**x**
CHIP	**x**		

I. Policy: Aqueous Drainage Shunt

II. Purpose/Objective:

To provide a policy of coverage regarding Aqueous Drainage Shunt

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.

Commercial

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.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

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:
Aqueous drainage shunts are implantable devices that are intended to reduce intra-ocular pressure (IOP) in the anterior chamber of the eye in individuals with neovascular glaucoma or with glaucoma that has not responded to medical and conventional surgical treatments. Tube-shunt surgery is also frequently used to treat glaucoma when a person has:

- Failure of previous trabeculectomy.
- Neovascular glaucoma
- Corneal transplant

There are several devices that have been approved by the US Food and Drug Administration to facilitate the inflow/outflow balance of aqueous humor in the eye. Examples of devices that are FDA-approved for insertion by an external approach are Ex-PRESS™ Mini Glaucoma Shunt, Baerveldt glaucoma drainage devices, Krupin eye valves, Molteno implants, Schocket shunt Ahmed Glaucoma Valve and AquaFlow collagen shunt. The basic design of these devices is similar -- a silicone tube shunts aqueous humor from the anterior chamber to a fibrous capsule surrounding a synthetic plate or band positioned at the equatorial region of the globe. The capsule serves as a reservoir for aqueous drainage.

Minimally invasive glaucoma surgery (MIGS) devices, or micro-stents, such as iStent, iStent inject, Hydras are FDA-approved for use in the treatment of mild to moderate open-angle glaucoma in conjunction with cataract surgery where optimal intraocular pressure has not been achieved with medication. XEN micro stent is FDA-approved for use in the treatment of mild to moderate open-angle glaucoma either with or without cataract surgery when optimal intraocular pressure has not been achieved with medication.

INDICATIONS:
FDA-approved ab externo or ab interno aqueous drainage/shunt implants are considered to be medically necessary for the treatment of refractory primary open-angle glaucoma when first and second - line pharmacologic therapies such as, but not limited to latanoprost, timolol, brimonidine or dorzolamide have failed to control intra-ocular pressure. Aqueous drainage/shunt implants may be utilized as an alternative to laser trabeculectomy or as an alternative to a failed previous trabeculectomy.

The use of FDA-approved ab interno stents in conjunction with cataract surgery is considered to be medically necessary in members diagnosed with mild to moderate open angle glaucoma being treated with ocular hypotensive medication.

MEDICARE BUSINESS SEGMENT: See also Novitas Local Carrier Determination L38223 and A56633

LIMITATIONS:
This service is covered only for services using FDA-approved devices.

EXCLUSIONS:
The Plan does **NOT** provide coverage for any aqueous drainage/shunt implants device not currently FDA- approved. These devices are considered **experimental or investigational.** The Geisinger Technology Assessment Committee determined there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these devices on health outcomes when compared to established treatments or technologies.

Novartis International AG / Alcon has withdrawn the CyPass Micro-Stent from the global market, effective August 29, 2018. Based on this recall, Novitas considers this procedure/device to be unsafe and therefore **NOT COVERED.**

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: Aqueous Drainage Shunt
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.***

0191T Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion

0253T Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoiroidal space.

0376T Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion (list separately in addition to code for primary procedure)

0449T Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device

0450T Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device each additional device (list separately in addition to code for primary procedure)

0474T Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space

0730T Trabeculotomy by laser, including optical coherence tomography (OCT) guidance

66179 Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft

66180 Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft

66183 Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach

66184 Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft

66185 Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft

66989 Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

66991 Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular

meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

C1783 ocular implant, aqueous drainage assist device

L8612 aqueous shunt

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.

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

Devised: 11/21/2011

Revised: 2/14 (Limitation added), 2/18; 10/18 (Added CyPass Micro-Stent exclusion); 10/19 (add approved devices); 10/24 (clarify Indication)

Reviewed: 11/12, 11/13, 2/15, 2/16, 2/17, 10/20, 10/21, 10/22, 10/23

CMS UM Oversight Committee Approval: 12/23, 12/24