

BENEFIT COVERAGE POLICY



Title: BCP-68 Glaucoma Surgery: iStent Trabecular Micro-Bypass Stent

Effective Date: 7/1/2018

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

- The terms of the applicable benefit document in effect on the date of service.
- Any applicable laws and regulations.
- Any relevant collateral source materials including coverage policies.
- The specific facts of the situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

Health Plan covers insertion of a single FDA-approved microstent (ie., Glaukos iStent Trabecular Micro-Bypass Stent) procedure as medically necessary.

For all non-network covered services to be paid at the network benefit level except for emergency/urgent services, prior approval is required.

Refer to member's benefit coverage document for specific benefit description, guidelines, coverage, and exclusions.

2.0 Background

Glaucoma is a chronic disorder involving increased pressure in the eye due to fluid buildup. There are several forms of glaucoma with open angle glaucoma (OAG) being the most common. The increased pressure associated with OAG can lead to optic neuropathies characterized by visual field loss and structural damage to the optic nerve fiber. If left untreated, glaucoma can result in partial or complete visual impairment. Currently, intraocular pressure (IOP) is the only treatable risk factor for glaucoma, and lowering IOP has proven beneficial in reducing the progression of loss of vision.

In most cases, topical or oral medication is the first treatment of choice. For patients who are unwilling or unable to use medications or are unresponsive to medications, laser therapy or trabeculectomy, may be an option. Although laser therapy reduces IOP initially, its effects diminish over the course of a few years, and repetition of the procedure may not be beneficial. Trabeculectomy (CPT® 66170 and 66172), an invasive procedure, is the current standard surgical technique for reduction of IOP, but it can result in extremely low IOP, causing ocular damage. Over time, the surgery may fail due to scar formation at the drainage site. Aqueous shunts have been developed as alternative surgical treatment for patients with inadequately controlled glaucoma. Microstents have also been evaluated in the treatment of mild to moderate glaucoma in patients who are receiving treatment with ocular hypotensive medication.

The iStent Trabecular Micro-Bypass Stent is a heparin-coated titanium L-shaped implant that was developed as a treatment option for patients with mild or moderate open-angle glaucoma. It is

intended to improve aqueous outflow and decrease IOP by creating an opening in the trabecular meshwork and allow aqueous humor to drain into Schlemm's canal and exit the eye. The iStent is a one-piece, heparin-coated, titanium L-shaped implant that can be inserted by either an internal or external approach. The iStent is an ab interno device (entirely within the eye with no communication to the outside). It is used in patients with mild-to-moderate chronic open-angle glaucoma who are also candidates for cataract surgery.

- A. Insertion of a single FDA-approved microstent (i.e., Glaukos iStent Trabecular Micro-Bypass Stent) is considered medically necessary when:
 - 1. It is inserted in conjunction with cataract surgery; and
 - 2. It is done to reduce intraocular pressure in an individual with mild to moderate open-angle glaucoma when treatments have failed to control IOP. Failure is defined as:
 - a. Refractory primary open-angle glaucoma when first-line drugs (e.g., latanoprost or timolol) or second-line drugs (e.g., brimonidine or dorzolamide) have failed to maintain an IOP of less than 21 mm Hg; or
 - b. Need for additional IOP-lowering surgery.
- B. Coverage for an aqueous shunt/aqueous drainage device for any other indication is not covered because it is considered experimental, investigational or unproven.
- C. Procedures that are covered as FDA-approved external approach insertion:
 - 1. Ahmed glaucoma implant.
 - 2. Baerveldt seton.
 - 3. Ex-PRESS mini glaucoma shunt.
 - 4. Glaucoma pressure regulator.
 - 5. Krupin-Denver valve implant.
 - 6. Molteno implant.
 - 7. Shocket shunt (e.g., Ex-PRESS Ophthalmic Glaucoma Device).
- D. Procedures and devices that are not covered because each is considered experimental, investigational or unproven:
 - 1. Ab interno gel stent (i.e., XEN Glaucoma Treatment System); CPT codes 0449T, 0450T.
 - 2. Drug-eluting ocular devices; CPT codes 0356T, 0444T, 0445T.
 - 3. Ab interno trabeculectomy (trabectome); CPT code 66999.
 - 4. Canaloplasty; CPT codes 66174, 66175.
 - 5. Transciliary fistulization (transciliary filtration, Singh filtration); CPT code 66999.
 - 6. Visco canalostomy (including phacovisco canalostomy); CPT code 66999.

3.0 Clinical Determination Guidelines:

None.

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = PPO; 3 = ASO group L0000264; 4 = ASO group L0001269 Non-Union; 5 = ASO group L0001269; 6 = ASO group L0002011; 7 = ASO group L0001269 Union.

COVERED CODES			
Code	Description	Prior Approval	COC Reference

COVERED CODES			
Code	Description	Prior Approval	COC Reference
66170	Fistulization of sclera for glaucoma; trephination with iridectomy trabeculectomy ab externo in absence of previous surgery	N	Benefits and Coverage: Outpatient Surgery Services
66172	Fistulization of sclera for glaucoma; trephination with iridectomy trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents)	N	Benefits and Coverage: Outpatient Surgery Services
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft	N	Benefits and Coverage: Outpatient Surgery Services
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft	N	Benefits and Coverage: Outpatient Surgery Services
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach	N	Benefits and Coverage: Outpatient Surgery Services
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft	N	Benefits and Coverage: Outpatient Surgery Services
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft	N	Benefits and Coverage: Outpatient Surgery Services
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)	N	Benefits and Coverage: Outpatient Surgery Services
66999	Unlisted procedure, anterior segment of eye	Y	Benefits and Coverage: Outpatient Surgery Services, unless determined to be Experimental, Investigational or Unproven
67255	Scleral reinforcement (separate procedure; with graft	N	Benefits and Coverage: Outpatient Surgery Services
92020	Gonioscopy (separate procedure)	N	Benefits and Coverage: Outpatient Surgery Services
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion	N	Benefits and Coverage: Outpatient Surgery Services
0376T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; each additional device insertion (when specified as the iStent Trabecular Micro-Bypass Stent)	N	Benefits and Coverage: Outpatient Surgery Services

COVERED CODES			
Code	Description	Prior Approval	COC Reference
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space (CyPass system)	N	Benefits and Coverage: Outpatient Surgery Services
C1783	Ocular implant, aqueous drainage assist device	N	Benefits and Coverage: Outpatient Surgery Services
L8612	Aqueous shunt	N	Benefits and Coverage: Outpatient Surgery Services

NON-COVERED CODES		
Code	Description	COC Reference/Reason
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent	What's Not Covered; Experimental, Investigational or Unproven Services
66175	Transluminal dilation of aqueous outflow canal; with retention of device or stent	What's Not Covered; Experimental, Investigational or Unproven Services
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space. (There are no FDA approved devices that fit into this category, at this time.)	What's Not Covered; Experimental, Investigational or Unproven Services
0356T	Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each	What's Not Covered; Experimental, Investigational or Unproven Services
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral	What's Not Covered; Experimental, Investigational or Unproven Services
0445T	Subsequent placement of a drug-eluting ocular insertion under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral	What's Not Covered; Experimental, Investigational or Unproven Services
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device (XEN Gel Stent)	What's Not Covered; Experimental, Investigational or Unproven Services
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (XEN Gel Stent)	What's Not Covered; Experimental, Investigational or Unproven Services

ICD-10 DIAGNOSIS CODES

Code	Description
H25.011 – H26.9	Cataract
H40.1110-H40.1194	Primary open-angle glaucoma
H40.50X0 – H40.53X4	Glaucoma secondary to other eye disorders
Q12.0 – Q12.9	Congenital cataract and lens malformations

5.0 Unique Configuration/Prior Approval/Coverage Details:

None.

6.0 Terms & Definitions:

Aqueous humor (vitreous humor/fluid) – Clear aqueous gel that fills the space between the lens and the retina in the anterior chamber of the eye where it flows continuously in and out of the chamber and nourishes nearby tissues; this aqueous fluid leaves the chamber at the open angle where the cornea and the iris meet and flows through a spongy meshwork drain.

Glaucoma – a disease of the major nerve of vision, called the optic nerve. The optic nerve receives light-generated nerve impulses from the retina and transmits these to the brain, where we recognize those electrical signals as vision. Glaucoma is characterized by a pattern of progressive damage to the optic nerve that generally begins with a subtle loss of side vision (peripheral vision). If glaucoma is not diagnosed and treated, it can progress to loss of central vision and blindness.

Glaucoma is usually, but not always, associated with elevated pressure in the eye (intraocular pressure). Generally, it is this elevated eye pressure that leads to damage of the eye (optic) nerve. In some cases, glaucoma may occur in the presence of normal eye pressure. This form of glaucoma is believed to be caused by poor regulation of blood flow to the optic nerve.

Types of glaucoma include:

- Open-angle (OAG) – most common, also called primary or chronic glaucoma.
- Angle-closure (ACG) – less common, also called acute glaucoma or narrow-angle glaucoma.
- Normal-tension (NTG) – also called low-tension or normal-pressure glaucoma.
- Congenital glaucoma – occurs in babies when there is incorrect or incomplete development of the eye's drainage canals during the prenatal period.

Hypotony – Condition refers to abnormally low intraocular pressure of the intraocular fluid; this condition usually occurs as a complication of an underlying ocular disorder, such as glaucoma.

Intraocular pressure (IOP) – The pressure within the chambers of the eye which is maintained by a balance between aqueous fluid secretion and fluid outflow; in glaucoma, defects that interfere with aqueous humor outflow lead to a rise in intraocular pressure resulting in degenerative compromise of optic nerve function known as progressive optic nerve atrophy and vision loss. IOP normally ranges between 10 millimeters (mm) and 21 mm of mercury.

Trabeculectomy – A surgical filtration procedure in which a portion of the trabecular meshwork is surgically removed through a superficial flap of sclera to lower the IOP by creating an alternate pathway for the aqueous fluid to flow from the anterior chamber to a bleb created in the subconjunctival space; this is currently considered the gold standard treatment for glaucoma that is refractory to medical management.

7.0 References, Citations & Resources:

1. CyPass Micro-Stent, July 26, 2016. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150037d.pdf.

2. Glaucoma Research Foundation, Types of Glaucoma. 09/15/15. Available at: <http://www.glaucoma.org/glaucoma/types-of-glaucoma.php>.
3. Hayes, Health Technology Brief, iStent Trabecular Micro-Bypass (Glaukos Corp.) in Combination with Cataract Surgery for Treatment of Open-Angle Glaucoma. 02/28/2017.
4. National Institutes of Health, Factors correlating with failure to control intraocular pressure in primary angle-closure glaucoma eyes with coexisting cataract treated by phacoemulsification or combined phacotrabeculectomy. <https://www.ncbi.nlm.nih.gov/pubmed/26068613>.
5. Ophthalmology Management. Coding & Compliance 2015 ASC Coding Update for Glaucoma Surgery, Volume: 19, Issue February 2015. Available at: <http://www.ophthalmologymanagement.com/articleviewer.aspx?articleID=112305>.
6. U. S. Food & Drug Administration, Premarket Approval of Glaukos iStent Trabecular Bypass Stent Model GTS 100R/L, 4/9/2018. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080030>.

8.0 Associated Documents [For internal use only]:

Business Process Flow (BPF) – None.
 Standard Operating Procedure (SOP) – None
 Desk Level Procedure (DLP) – None.
 Sample Letter – None
 Form – None
 Other – None.

9.0 Revision History:

Original Effective Date: 06/01/2016
 Last Approval Date: 06/07/2018
 Next Review Date: 06/07/2019

Revision Date	Reason for Revision
May 2016	Policy created
May 2017	Annual review; converted from Medical Policy 031 to Benefit Coverage Policy (BCP)-68. Added 3.0, 2.a and b – clarification of “failed control of IOP.” CPT codes added: 0356T, new codes as of 1/1/17 0444T, 0445T, 0449T, 0450T.
March 2018	Annual review by QI/MRM June 2018. Initial review by BCC. No changes to clinical criteria or codes. References updated. Recommendation to remove PA requirement due to low utilization and billed charges <\$50,000 in one year.