Medical Affairs Policy

**Service:** Glaucoma Surgical Treatments [Micro-bypass stents (iStent), filtration devices, and shunts]

*PUM 250-0036*

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<th>Arise/WPS Policy Committee Approval</th>
<th>09/16/16</th>
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<td>Effective Date</td>
<td>10/01/16</td>
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<td>Prior Authorization Needed</td>
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**Description:**

Glaucoma is a group of eye diseases characterized by optic neuropathy involving atrophy of the optic nerve head, which may or may not be accompanied by elevated intra-ocular pressure (IOP). There are two general types of glaucoma: open angle glaucoma (OAG) and angle closure glaucoma. OAG comprises approximately 90% of all cases. In OAG, optic nerve damage results in a progressive loss of retinal ganglion cell axons, which is manifested initially as visual field loss and, ultimately, irreversible blindness if left untreated. OAG is considered a lifelong condition and is often asymptomatic. OAG and cataract often occur together and the risk of both increases with increasing age. The goal of treatment is to prevent progressive vision loss.

OAG is associated with partial blockage of flow of the ocular fluid (aqueous humor) inside the eye through the drainage system of trabecular network and Schlemm’s canal. This results in increase IOP and damage to eye structures. The primary treatment is to attempt to lower IOP with ophthalmic drops and/or oral medications including prostaglandins, beta blockers, alpha adrenergic agonists, oral acetazolomide (Diamox), and combination products. Prescription compliance is an issue due to the need for frequent dosing, multiple drugs, and the high cost of newer drugs. Trabeculectomy and laser trabeculoplasty and trabeculectomy have been the primary surgical treatments for patients with medication failure or advancing symptoms. Insertion of mechanical valves or shunts are being used more frequently as they may have fewer complications than...
traditional surgical procedures. Microstents have been developed which show promise for improved IOP control and decreased need for medication.

Angle-closure glaucoma (ACG) is a form of glaucoma characterized by narrowing or closure of the anterior chamber angle. ACG can be acute or chronic and requires surgical treatment such as iridotomy.

**Indications of Coverage:**

A. One iStent (Glaukos) trabecular Micro-bypass Stent per eye is considered medically necessary in adults when all of the following FDA indications are met:

1. Diagnosed mild to moderate OAG **and**
2. Currently treated with ocular hypotensive medication therapy **and**
3. Procedure performed in conjunction with cataract surgery

B. FDA approved Aqueous shunts and Drainage devices (ExPRESS glaucoma filtration device (mini-shunt), Krupin eye valve, Molteno implant) are considered medically necessary when all of the following indications are met:

1. Diagnosed Glaucoma **and**
2. Failure of ocular hypotensive medication therapy **and**
3. Failure of or contraindication to at least one of the following surgical techniques:
   a. Laser trabeculoplasty
   b. Trabeculectomy

➢ **Note:** Any device used must be FDA approved. It is the responsibility of the surgeon to insure that a FDA approved device is used.

**Limitations of Coverage:**

A. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental, investigational, and unproven to affect health outcomes.

B. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

C. iStent in eyes with primary or secondary ACG (as opposed to OAG) is considered experimental, investigational, and unproven to affect health outcomes.
D. More than one iStent per eye is considered experimental, investigational, and unproven to affect health outcomes.

E. iStent G3Supra, iStent inject, or any other bypass stent or shunt not approved by the FDA is considered experimental, investigational, and unproven to affect health outcomes.

F. CyPass Microstent is considered experimental, investigational, and unproven to affect health outcomes.

G. Canaloplasty is considered experimental, investigational, and unproven to affect health outcomes.

H. Drug eluting punctual plugs (not yet FDA approved) are considered experimental, investigational, and unproven to affect health outcomes.

I. Transciliary fistulization (transciliary filtration, Singh filtration) is considered experimental, investigational, and unproven to affect health outcomes.

**Documentation Required:**

- Office notes including history, physical, ophthalmic medication and surgical history

**References:**


3. MCG 20th ed. ACG:A-0196: Trabeculoplasty and Trabeculectomy, Laser

4. Center for Medicare Services LCD Glaucoma Treatment with Aqueous Drainage Device (L35087) Novitas. Effective Date for services performed on or after 10/01/2015 Updated 04/08/2016 available at: https://www.cms.gov/medicare-coverage-database/


**Review History:**

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<tr>
<td>Medical Policy Committee Approval</td>
<td>Interim Policy (Medical Director approval 08/24/2016), 09/16/16</td>
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*Approved by the Medical Director*