Medical Policy:
Glaucoma (Commercial)

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<tr>
<th>POLICY NUMBER</th>
<th>EFFECTIVE DATE</th>
<th>APPROVED BY</th>
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<tbody>
<tr>
<td>MG.MM.SU.63d</td>
<td>01/10/2020</td>
<td>MPC (Medical Policy Committee)</td>
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**IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:**

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**Related Guidelines**
Canaloplasty and Viscocanalostomy

**Definitions**

| Aqueous Humor | Clear aqueous fluid, which fills the space between the lens and retina in the anterior chamber of the eye where it flows continuously in and out of the chamber nourishing nearby tissues. The fluid exits the chamber at the open angle, where the cornea and iris meet, and flows through a spongy meshwork drain. |
| Schlemm's Canal | Circular canal in the eye that drains aqueous humor from the anterior chamber of the eye into the anterior ciliary veins. |
| Intraocular pressure (IOP) | The pressure within the eye, which is maintained by a balance between aqueous fluid secretion and fluid outflow; in glaucoma, |
## Medical Policy:
### Glaucoma (Commercial)

<table>
<thead>
<tr>
<th>Glaucoma</th>
<th>A group of eye diseases characterized by increased IOP, which causes pathological changes in the optic disk and defects in the field of vision.</th>
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<tbody>
<tr>
<td>• <strong>Open-angle glaucoma (OAG)</strong> — progressive form of glaucoma in which the drainage channel for the aqueous humor, composed of the attachment at the edge of the iris and the junction of the sclera and cornea, remains open, and in which serious vision-reduction occurs (advanced stages of the disease) due to tissue changes along the drainage channel.</td>
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<td>• <strong>Primary open-angle glaucoma</strong> (POAG; aka chronic glaucoma) — most common type of glaucoma, which is associated with a build-up of aqueous fluid pressure within the eye that can lead to visual field loss and optic nerve damage (usually without any associated pain or discomfort). There is no abnormality in the anterior chamber angle; however, the aqueous fluid is unable to flow correctly.</td>
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<td>• <strong>Secondary open-angle glaucoma</strong> (SOAG) — open angle glaucoma resulting from other medical conditions (e.g. pseudoexfoliative glaucoma, pigmentary glaucoma) or trauma.</td>
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<td>The severity of glaucoma damage can be estimated using the following:</td>
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<td>• <strong>Mild</strong> — optic nerve abnormalities consistent with glaucoma and a normal visual field as tested with standard automated perimetry</td>
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<tr>
<td>• <strong>Moderate</strong> — optic nerve abnormalities consistent with glaucoma and visual field abnormalities in one hemifield that are not within 5 degrees of fixation as tested with standard automated perimetry</td>
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<tr>
<td>• <strong>Severe</strong> — optic nerve abnormalities consistent with glaucoma and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with standard automated perimetry</td>
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| Hypotony | Abnormally low IOP of intraocular fluid; typically occurs as a complication of an underlying ocular disorder (such as uveitis or following a glaucoma surgery). |

| Aqueous shunts (Aka aqueous drainage devices or glaucoma drainage devices, setons, tube implants and tube shunts) | Devices implanted into the eye to create an alternate pathway for aqueous humor drainage from the anterior or posterior eye-chamber to a space between the conjunctiva and the sclera where it is absorbed into the blood, thereby lowering IOP. These devices differ depending on explanst surface areas, shape, plate thickness, the presence or absence of a valve and details of surgical installation. Generally, the risk of hypotony is reduced with aqueous shunts in comparison with trabeculectomy, but IOP outcomes are higher than after standard guarded filtration surgery. |
Other aqueous stents (e.g., microstents) are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into Schlemm’s canal or the suprachoroidal space. These include the iStent® (Glaukos), which is a 1-mm long stent inserted into the end of Schlemm’s canal by an internal approach through the cornea and anterior chamber; the third generation iStent supra®, which is designed for ab interno implantation into the suprachoroidal space; and the CyPass® (Transcend Medical) suprachoroidal stent. An advantage of ab interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than one shunt to achieve the desired IOP. (See Limitations/Exclusions)

| 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. |

**Guideline**

A. Laser trabeculoplasty or FDA-approved aqueous drainage/shunt implants* are considered medically necessary for the treatment of refractory open-angle glaucoma when there is intolerance, contraindication or failure of topical/oral medication** to control IOP. (Note: Goniotomy requests will be case-by-case reviewed)

- First line examples include latanoprost or timolol; second line, brimonidine or dorzolamide, etc.
- Currently available FDA-approved implants include: Ahmed glaucoma implant, Baerveldt seton, Ex-PRESS mini glaucoma shunt, Glaucoma pressure regulator, Krupin-Denver valve implant, Molteno implant, Schococket shunt

B. One iStent®, iStent inject or Hydrus® Microstent per eye is considered medically necessary when used in combination with cataract surgery for mild to moderate open-angle glaucoma, and a cataract, in adult members being treated with ocular hypotensive medication.

C. One XEN45 device per eye is covered for the management of refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP ≥20 mm Hg) on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues). XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

D. Adjunctive use of anti-fibrotic agents (e.g., mitomycin C) is considered medically necessary for use with the Ex-PRESS mini glaucoma shunt
Limitation/Exclusion

The following treatments/procedures are not considered medically necessary due to insufficient evidence of therapeutic value:

1. Transciliary filtration for glaucoma or other indications (e.g., Fugo Blade transciliary filtration, Singh filtration)
2. Ab interno trabeculectomy (trabectome)
4. Glaucoma drainage devices without FDA approval (e.g., Eyepass, DeepLight SOLX ® Gold Shunt, which are inserted internally)
5. Adjunctive use of anti-fibrotic agents (e.g., mitomycin C) or systemic corticosteroids with shunt implants other than the Ex-Press mini
6. Drug-eluting implants inserted into the lacrimal canaliculus (including punctal dilation and implant removal when performed) for glaucoma or ocular hypertension (CPT 0356T, 0444T and 0445T)

Coding Criteria
To access the codes, please download the policy to your computer, and click on the paperclip icon within the policy

Applicable CPT and Diagnosis Codes

References

Augustinus CJ, Zeyen T. The effect of phacoemulsification and combined phaco/glucoma


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Specialty matched clinical peer review.


Zhou J, Smedley GT. Trabecular bypass: Effect of schlemm canal and collector channel

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/RecentlyApprovedDevices/ucm620440.htm?utm_campaign=Recently%20Approved%20Devices&utm_medium=email&utm_source=Eloqua&elqTrackId=708D50160915A726A00765F2B7C00E3&elq=e3267e4e1fe3401c964c28d46452968c&elqaid=5071&elqat=1&elqCampaignId=4044. January 24, 2012.


Revision history

<table>
<thead>
<tr>
<th>DATE</th>
<th>REVISION</th>
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<tr>
<td>04/24/2020</td>
<td>Added CPT codes 0356T, 0444T and 0445T to Limitations/Exclusion section #6-drug-eluting implants</td>
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<tr>
<td>01/10/2020</td>
<td>Added iStent inject coverage and case-by-case language for goniotomy</td>
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<tr>
<td>12/09/2019</td>
<td>Reformatted and reorganized policy, transferred content to new template</td>
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<tr>
<td>12/14/2018</td>
<td>Added coverage for Hydrus</td>
</tr>
<tr>
<td>09/14/2018</td>
<td>Removed CyPass as a covered device due to Alcon recall Aug. 8, 2018</td>
</tr>
<tr>
<td>03/09/2018</td>
<td>Added coverage for CyPass and XEN45 devices</td>
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