Glaucoma Treatment with Aqueous Drainage Device
Policy Number: PG0327
Last Review: 03/02/2022

GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE
X Professional
✓ Facility

DESCRIPTION
Glaucoma refers to a disease of the optic nerve characterized by elevated intraocular pressure (IOP), which results in visual field loss and irreversible blindness if left untreated. There are several types of glaucoma; the two main types are open-angle glaucoma (OAG) and angle-closure glaucoma. It is the second leading cause of blindness in the world. Therapy for glaucoma mainly consists of reducing the intraocular pressure by medical or surgical means. Historically, trabeculectomy (penetrating) has been considered the gold standard for surgical intervention. More recently a minimally penetrating glaucoma surgery has developed with the use of an aqueous drainage device. It is indicated in patients who are refractory to medical intervention (first line and second line drugs).

The term aqueous drainage device refers to a broad class of tools used to facilitate aqueous flow out of the anterior chamber to control IOP. They may also be referred to as glaucoma drainage devices, tubes or shunts, and may be valved or nonvalved. Such drainage devices may be placed in individuals with advanced disease in whom medical and laser therapies are inadequate and who have an underlying diagnosis that increases the risk of failure of conventional surgery.

Insertion of shunts from outside the eye (ab externo) is a surgical option to lower IOP. Examples of ab externo devices cleared by the U.S. Food and Drug Administration (FDA) include the Ahmed, Baerveldt, Molteno, and EX-PRESS mini-shunt, which shunt aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ by explant surface areas, shape, plate thickness, presence or absence of a valve, and details of surgical installation. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of Post-operative infection is lower with shunts than with trabeculectomy, and failure rates are similar (≈10% of devices fail annually). The primary indication for aqueous shunts is for failed medical or surgical therapy.

Minimally invasive glaucoma surgeries (MIGS) are alternative, less invasive techniques that are being developed and evaluated. MIGS, which use microscopic-sized equipment and smaller incisions, involves less surgical manipulation of the sclera and the conjunctiva compared with other surgical techniques. There are several categories of MIGS: miniaturized trabeculectomy, trabecular bypass, milder laser photocoagulation, and totally internal or suprachoroidal stents (ab interno). This policy evaluates the placement of ab interno stents. Examples of ab interno devices either approved or given marketing clearance by FDA include the iStent, which is a 1-mm long stent inserted into the end of the Schlemm canal through the cornea and anterior chamber and XEN ADVANTAGE | ELITE | HMO INDIVIDUAL MARKETPLACE | PROMEDICA MEDICARE PLAN | PPO

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gelatin stent.

It has been proposed that stents such as the iStent and Hydrus Microstent may be useful in patients with early-stage glaucoma to reduce the burden of medications and problems with compliance. This is being researched/investigated.

Drug-eluting devices are in development to combat low patient adherence with medications since many eye drops require multiple doses daily. These types of devices are implanted or inserted into the eye temporarily and purportedly release a steady dose of medication until they are removed, dissolve or are washed out via the tear duct. Methods of delivery include, but may not be limited to:

- Anterior segment intraocular nonbiodegradable drug-eluting system
- Biodegradable collagen matrix scaffold impregnated with medication, formed into a wafer and implanted in the sclera
- Contact lens-like clear plastic flexible polymer infused with medication that rests on the sclera and may be worn for up to 120 days
- Injections into the anterior chamber or subconjunctival space that deliver a medication-laden dissolvable medium

**POLICY**

<table>
<thead>
<tr>
<th>HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Covered Glaucoma Treatment with FDA approved Aqueous Drainage Devices do not require a prior authorization when the coverage criteria is met.</strong></td>
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</table>

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<tr>
<th>HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage</th>
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<tbody>
<tr>
<td><strong>Procedures 0253T, 0444T, 0445T, 0474T, 0660T, 0661T, 0671T are non-covered</strong></td>
</tr>
</tbody>
</table>

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

**COVERAGE CRITERIA**

HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage

Insertion of Food and Drug Administration (FDA) approved glaucoma aqueous drainage devices/aqueous shunts are considered medically necessary for the treatment of refractory open-angle glaucoma when there is:

- Failure, intolerance or contraindication to conventional medical (i.e., topical or oral medication); and
- Failure, intolerance or contraindication to surgical (i.e., laser therapy, trabeculectomy) treatment.

Implantation of FDA-approved interno stents in conjunction with cataract surgery may be considered medically necessary:

- Patient has definitive diagnoses of cataract and mild to moderate open angle glaucoma; and
- Implant used to relieve IOP; and
- Implantation is in conjunction with cataract surgery; and
- Insertion of 1 or 2 FDA approved device per medically necessary eye; and
- One of the following medical criteria are met:
  - Patient is currently being treated with ocular hypotensive medication; or
  - Ocular hypotensive medications have failed to adequately control IOP

➤ For IStent Device and Hydrus - eyes do NOT have the following*
  - Prior significant trauma
  - In eyes with abnormal anterior segment
  - In eyes with chronic inflammation
  - In glaucoma associated with vascular disorders
  - In pseudophakic patients with glaucoma
  - In uveitic glaucoma
  - In eyes with prior incisional glaucoma surgery or cilioablative procedures
In eyes with prior laser trabeculoplasty (LT) with selective LT within 90 days prior to screening or prior argon laser trabeculoplasty (ALT) at any time
In patients with unmedicated IOP greater than 36 mmHg after “washout” of medications
Plan for implantation of more than two stents
After complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitrectomy my required, corneal injuries, or complications requiring the placement of an anterior chamber IOL
When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract

For Xen Gel Implant should NOT be used if any of the following are met:
- Angle-closure glaucoma where the drainage angle of the eye has not been surgically open
- Glaucoma drainage device previously implanted
- Presence of conjunctival scarring, prior conjunctival surgery or other conjunctival pathologies (e.g., pterygium) in the target quadrant
- Pathologies of the conjunctiva (clear membrane covering the white outer layer of the eye) in the area needed for this implant Active iris neovascularization or neovascularization of the iris within six months of the surgical date (abnormal formation of new blood vessels on the iris)
- Eye inflammation (e.g., conjunctivitis, keratitis, uveitis)
- Artificial lens implanted in the anterior chamber (intraocular lens)
- Presence of intraocular silicone oil
- Vitreous present in the anterior chamber

The following are considered covered, FDA approved, glaucoma aqueous drainage devices/aqueous shunts (this list is not all-inclusive):
- Ahmed glaucoma valve implant
- Baerveldt glaucoma implant
- ExPRESS mini glaucoma shunt
- Krupin-Denver Valve Implant
- Molteno Implant
- Schickett shunt
- XEN® Glaucoma Treatment System
- iStent® Trabecular Micro-Bypass Stent*
- iStent inject®*
- Hydrus® Microstent*
- *iStent® Trabecular Micro-Bypass Stent, iStent inject® and Hydrus® Microstent must be performed in conjunction with cataract surgery on the same date of service and documented in the medical record.

The following devices have not demonstrated equivalence or superiority to currently accepted standard means of treatment. The following devices are considered investigational and not eligible for reimbursement (this list is not all-inclusive):
- CyPass Micro-Stent (manufacturer voluntary recall on 8/29/2018 due to safety concerns)
- iStent G3 Supra
- Implantation of multiple iStent Trabecular Micro-Bypass Stents
- Trabectome (ab interno trabeculectomy)
- Drug-eluting ocular devices

Limitations:
Glaucoma drainage devices for all other clinical conditions, including for indications outside of the FDA approval/clearance, not medically necessary and not eligible for reimbursement because it is considered experimental, investigational or unproven.

Use of an ab externo aqueous shunt in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered investigational.
More than 2 iStents per eye is considered experimental and investigational because their safety and effectiveness has not been established.

Glaucoma drainage devices that do not have FDA approval/clearance, as well as devices that have been recalled, not medically necessary and not eligible for reimbursement

Shunts and stents are only able to reduce intraocular pressure to the mid-teens and may be inadequate when very low intraocular pressure is needed to reduce glaucoma damage.

A drug-eluting implant into lacrimal canaliculus during routine cataract removal is considered experimental and investigational because the effectiveness of this approach has not been established.

**CODING/BILLING INFORMATION**

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODES</th>
<th>Description</th>
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<tbody>
<tr>
<td>0253T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space</td>
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<tr>
<td>0444T</td>
<td>Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral</td>
</tr>
<tr>
<td>0445T</td>
<td>Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral</td>
</tr>
<tr>
<td>0449T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device (New code effective 01/01/2017) (Xen Gel)</td>
</tr>
<tr>
<td>0450T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure) (New code effective 01/01/2017)</td>
</tr>
<tr>
<td>0474T</td>
<td>Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space (Effective 07/01/2017) (Cypass)</td>
</tr>
<tr>
<td>0660T</td>
<td>Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach</td>
</tr>
<tr>
<td>0661T</td>
<td>Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant</td>
</tr>
<tr>
<td>0671T</td>
<td>Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one of more</td>
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<tr>
<td>66179</td>
<td>Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft</td>
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<tr>
<td>66180</td>
<td>Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft</td>
</tr>
<tr>
<td>66183</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach (Xen Gel)</td>
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<tr>
<td>66184</td>
<td>Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft</td>
</tr>
<tr>
<td>66185</td>
<td>Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft</td>
</tr>
<tr>
<td>66989</td>
<td>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 capsulorrhesis) 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 (iStent and Hydrus)</td>
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<tr>
<td>66991</td>
<td>Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion</td>
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of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more (iStent and Hydrus)

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<tr>
<td><strong>0191T</strong></td>
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<tr>
<td><strong>0356T</strong></td>
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<td><strong>0376T</strong></td>
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Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/services/providers/medical-policies/.

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### REVISION HISTORY EXPLANATION

**ORIGINAL EFFECTIVE DATE: 04/23/2015**

<table>
<thead>
<tr>
<th>Date</th>
<th>Explanation &amp; Changes</th>
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| 04/23/15   | • Glaucoma Treatment with Aqueous Drainage Device (L32733) reviewed  
• Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)                                           |
| 01/27/17   | • Added code 0356T as non-covered for all product lines  
• Added codes 0444T, 0445T effective 07/01/2016 as non-covered for all product lines  
• Added codes 0449T, 0450T effective 01/01/2017 as non-covered for all product lines  
• Code 0253T is now non-covered for all product lines  
• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG) |
| 09/22/17   | • Added effective 07/01/2017 new code 0474T as covered without prior authorization for HMO, PPO, Individual Marketplace, & Elite per CMS guidelines  
• Procedure 0474T is non-covered for Advantage per ODM guidelines  
• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG) |
| 03/22/18   | • XEN Glaucoma Treatment System (XEN45 Gel Stent and XEN Injector) (0449T, 0450T) is now covered without prior authorization for HMO, PPO, Individual Marketplace, & Elite per CMS guidelines  
• Implantation of multiple iStent Trabecular Micro-Bypass Stents (0376T) is now non-covered for all product lines per CMS guidelines  
• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG) |
| 12/21/2020 | • Medical policy placed on the new Paramount Medical Policy Format                                                                                                                                                   |
| 03/02/2022 | • Policy reviewed and updated to reflect most current clinical evidence  
• CODING/BILLING INFORMATION section updated to add new codes 0660T, 0661T, 0671T and document end-dated codes 0191T, 0356T, 0376T |

### REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid


Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets


Industry Standard Review

Hayes, Inc.

Industry Standard Review