GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Glaucoma consists of a group of disease, frequently characterized by raised intraocular pressure (IOP) which affects the optic nerve. 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).

Although there are a limited number of published, well-designed clinical trials evaluating the safety and efficacy of aqueous shunts/aqueous drainage devices implantation of these devices (e.g., Ahmed™ Glaucoma Valve, Baerveldt® glaucoma implants, ExPRESS™ Mini Glaucoma Shunt, Krupin eye valve, Molteno® implant) has become a well-established surgical intervention for patients with refractory glaucoma who are unresponsive to medical and standard surgical intervention or in whom medical and surgical treatment is not tolerated or is contraindicated. Implantation of a microstent (e.g., iStent Trabecular Micro Bypass Stent) may be a reasonable treatment option when performed in conjunction with cataract surgery in an individual with mild to moderate glaucoma being treated with ocular hypotensive medication.

POLICY
Does not require prior authorization for all product lines:
- FDA-approved Aqueous Drainage Devices (66183)

Does not require prior authorization for HMO, PPO, Individual Marketplace, & Elite:
- CyPass Stent (0474T)
- Implantation of a single iStent Trabecular Micro-Bypass Stent (0191T)
- XEN Glaucoma Treatment System (XEN45 Gel Stent and XEN Injector) (0449T, 0450T)

Non-covered for Advantage:
- CyPass Stent (0474T)
- Implantation of a single iStent Trabecular Micro-Bypass Stent (0191T)
- XEN Glaucoma Treatment System (XEN45 Gel Stent and XEN Injector) (0449T, 0450T)

Non-covered for all product lines:
- iStent G3 Supra (0253T)
- Drug-eluting ocular devices (0356T, 0444T, 0445T)
- Implantation of multiple iStent Trabecular Micro-Bypass Stents (0376T)

Insertion of Food and Drug Administration (FDA) approved aqueous drainage devices/aqueous shunts (66183) are considered medically necessary for the treatment of refractory glaucoma when there is failure, intolerance or contraindication to conventional medical (i.e., topical or oral medication) and surgical (i.e., laser therapy, trabeculectomy) treatment (this list may not be all inclusive):

1. Ahmed glaucoma implant
2. Baerveldt seton glaucoma implant
3. Ex-PRESS mini glaucoma shunt
4. Glaucoma pressure regulator
5. Krupin-Denver valve implant
6. Molteno implant
7. Schocket shunt
Paramount does not cover an aqueous shunt/aqueous drainage device for ANY other indication because it is considered experimental, investigational or unproven.

Paramount does not cover ANY of the following devices for any indication because each is considered experimental, investigational or unproven:

- iStent G3 Supra (0253T)
- Drug-eluting ocular devices (0356T, 0444T, 0445T)
- Implantation of multiple iStent Trabecular Micro-Bypass Stents (0376T)

HMO, PPO, Individual Marketplace, Elite

Paramount considers one iStent (0191T) or CyPass (0474T) device per eye medically reasonable and necessary for the treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication and the procedure is being performed in conjunction with cataract surgery.

Paramount considers one XEN device per eye medically reasonable and necessary for the management of refractory glaucoma, defined (based on the pivotal trial criteria) 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).

Paramount does not cover a microstent for ANY other indication because it is considered experimental, investigational or unproven.

Advantage

Procedures 0191T, 0474T, 0449T, 0450T are non-covered.

CODING/BILLING INFORMATION

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

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TAWG REVIEW DATES: 04/23/2015, 01/27/2017, 09/22/2017, 03/22/2018

REVISION HISTORY EXPLANATION

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).

**REFERENCES/RESOURCES**
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.