Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Glaucoma Treatment with Aqueous Drainage Device

Policy Number: PG0327
Last Review: 10/01/2024

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
X 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. The goal in primary open-angle glaucoma is to reduce the IOP to slow the development of optic nerve damage. Therapy for glaucoma mainly consists of reducing the intraocular pressure by medical or surgical means. Prescription medication, in the form of eye drops, pills or both, is the most common early treatment for glaucoma. The medication helps to lower IOP by improving aqueous humor (fluid) drainage from the eye or by decreasing the amount of fluid produced by the eye and must be taken regularly. If medication fails, other interventions may be suggested. Current standard surgical treatments for open-angle glaucoma include trabeculectomy or trabeculoplasty (incisional or laser). Iridotomy, iridectomy or iridoplasty may be necessary for angle-closure glaucoma.

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 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:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Glaucoma Treatment with FDA approved Aqueous Drainage Devices do not require a prior authorization when the coverage criteria below are met.**

- **Procedures 0253T, 0444T, 0445T, 0474T, 0660T, 0661T are non-covered.**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

The specific model of the implanted device must be FDA-approved and be used according to FDA-approved indications. FDA-approved aqueous tube/shunt drainage devices are considered medically necessary for moderate to severe glaucoma when all three indications below are met:

1. Primary open-angle glaucoma, active neovascular glaucoma, congenital glaucoma, or secondary glaucoma; and
2. Uncontrolled IOP on documented maximally tolerated medical treatment, including laser. trabeculoplasty; and
3. Patient is a poor candidate for trabeculectomy for any of the following (list is not all inclusive):
    a. Failed trabeculectomy or history of failed trabeculectomy in the fellow eye
    b. Patient on anticoagulant therapy which cannot be stopped.
    c. History of poor wound healing
    d. History of cataract surgery within two years
    e. Anticipated need for cataract extraction
    f. Patient with corneal transplant
    g. Monocular vision
    h. Requires or chooses daily contact lens wear.
    i. Ocular surface pathology, including presence of scarring or ulceration.
    j. Uveitic or neovascular glaucoma with need for quick IOP decrease.
    k. Patient has any other condition, including medical or psychiatric illness, or circumstances likely to compromise the patient's ability to comply with postprocedural follow-up.

Insertion of FDA approved Ex-PRESS Glaucoma Filtration Device is considered medically necessary for the treatment of refractory open-angle glaucoma (primary and secondary) when there is:

- Failure, intolerance, or contraindication, to conventional medical therapies to control intraocular pressure.

Implantation of FDA approved glaucoma aqueous drainage devices/aqueous shunts (i.e., XEN Glaucoma Treatment System) are considered medically necessary for the treatment of refractory open-angle glaucoma when there is:

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

Implantation of FDA approved glaucoma aqueous drainage devices/aqueous shunts (i.e., Hydrus Microstent, iStent Trabecular Micro-Bypass Stent system and the iStent inject Trabecular Micro-Bypass System) in conjunction with cataract surgery may be considered medically necessary:

- Patient has definitive diagnoses of cataract and mild to moderate open angle glaucoma; and
- Medical therapies have failed to adequately control intraocular pressure; and
    - Patient is currently being treated with ocular hypotensive medication; or
    - Ocular hypotensive medications have failed to adequately control IOP
- Implantation is in conjunction with cataract surgery.

Implantation of FDA approved glaucoma aqueous drainage devices/aqueous shunts (i.e., iStent infinite Trabecular Micro-Bypass Stent System, model iS3) is considered medically necessary in patients with primary open-angle glaucoma when:

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

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 glaucoma filtration device
- ExPRESS mini glaucoma shunt
- Hydrus microstent
- iStent infinite Trabecular Micro-Bypass System, Model iS3
- iStent inject Trabecular Micro-Bypass System
- iStent Trabecular Micro-Bypass Stent
- Krupin-Denver Valve Implant
- Molteno Implant
- Schocket shunt
- XEN Glaucoma Treatment System
- 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):

- ab interno suprachoroidal microstent (i.e., ab interno suprachoroidal microstent (i.e., Micro-Stent) (CPT codes 0253T, 0474T)

- iStent G3 Supra (CPT code 0253T)
- Implantation of multiple iStent Trabecular Micro-Bypass Stents
- Trabectome (ab interno trabeculectomy)
- Drug-eluting ocular devices (i.e., CPT codes 0444T, 0445T, 0660T, 0661T)

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

Glaucoma drainage devices that do not have FDA approval are experimental/investigational because they lack the needed regulatory affirmation in addition to lacking sufficient high-quality evidence to establish their safety and efficacy for clinical use, therefore are not eligible for reimbursement.

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.

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/investigational because the effectiveness of this approach has not been established.

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.

CPT CODES	
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space **Not Covered**
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral **Not Covered**
0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral **Not Covered**
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device (New code effective 01/01/2017)
0450T	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) **~~Not Covered~~ Covered Effective 10/01/2023**
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space (Effective 07/01/2017) **Not Covered - Cypass removed from market and no longer available**
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach New Code Effective 07/01/2021 **Not Covered**
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant **Not Covered**
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one of more **New Code Effective 1/1/2022 ~~Not Covered~~ Covered Effective 10/01/2023**

66174	Transluminal dilation of aqueous outflow canal (e.g., canaloplasty); without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal (egg, canaloplasty); with retention of device or stent
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft
66989	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 capsulorrhexis) 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
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
HCPCS CODES	
C1783	Ocular implant, aqueous drainage assist device
L8612	Aqueous shunt

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 04/23/2015

Date	Explanation & Changes
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

02/22/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
09/06/2023	• Policy reviewed and updated to reflect most current clinical evidence • U.S. Food and Drug Administration (FDA): The iStent infinite Trabecular Micro-Bypass System, Model iS3 was 510(k) (K220032) approved on August 2, 2022 "for use in adult patients with primary open-angle glaucoma in whom previous medical and surgical treatment has failed". It was approved as a stand alone procedure. • Added coverage for procedure 0450T and 0671T effective 10/01/2023
04/08/2024	• Updated/Clarified documentation: added procedure 0449T also covered effective 10/01/2023 within the box above
10/01/2024	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Add covered CPT codes 66174 and 66175 • Add covered HCPCS codes C1783 and L8612 • Add notation CyPass Micro-Stent as has been removed from the market and no longer available • Removed deleted codes 0191T, 0356T, 0376T

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/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting https://www.cms.gov/medicare/coding/icd10

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review