Health Plans

Manual: IU Health Plans
Department: Utilization Management
Policy # MP034
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Medicare Advantage **X Commercial**

Glaucoma, Invasive Procedures Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Glaucoma, Invasive Procedures.

II. Scope

This policy applies to all Utilization Management (UM) staff having decision making responsibilities where authorization is required for Fully insured commercial plan.

III. Exceptions

None

IV. Definitions

Glaucoma- According to the National Eye Institute glaucoma is a group of eye diseases characterized by increased intraocular pressure (IOP) which damages the optic nerve and can lead to vision loss and blindness. There is a higher risk for development of glaucoma in people over the age of 60, African American or Hispanic/Latino over the age of 40, or if there is a family history of glaucoma.

Primary Open Angle Glaucoma (POAG) as a progressive, chronic, optic neuropathy in adults in which is characterized by an increased intraocular pressure (IOP) with progression of the optic nerve.

EX-PRESS Glaucoma Filtration Device was developed as an alternative to trabeculectomy. It was designed to regulate intraocular pressure in the eyes suffering from glaucoma. The device works by diverting aqueous humor through the implant from the anterior chamber to the intrascleral space, the bleb.

iStent Inject Trabecular Micro-Bypass Stent inject consists of 2 heparin-coated titanium multidirectional stent creates a permanent opening from the anterior chamber and the head to reside in

Schlemm's canal, with the thorax of the stent retained by the trabecular meshwork, allowing aqueous humor to drain directly from the anterior chamber of the eye and reducing intraocular pressure (IOP).

XEN Glaucoma Treatment System is comprised of the XEN45 Gel Stent and a preloaded XEN Injector. The Food and Drug Administration (FDA) has approved the XEN system for management of OAG that is refractory to maximum-tolerated medical therapy, including cases where previous surgical treatment has failed. The XEN Gel Stent is composed of gelatin derived from porcine skin that has been formed into a tube and cross-linked with glutaraldehyde to retain its shape. In its dry state, the stent is 6 millimeters long and has inner and outer diameters of 45 and 150 micrometers, respectively. The stent enlarges and becomes flexible when hydrated. After implantation, the stent becomes a permanent channel through the sclera, allowing aqueous humor to flow from the anterior chamber of the eye into the subconjunctival space, thereby reducing intraocular pressure (IOP)

V. Policy Statements

IU Health Plans considers Invasive Procedures for Glaucoma medically necessary for **one or more of the following** indications:

1. Ex-PRESS™ Mini Glaucoma Shunt and FDA-Approved Aqueous Drainage Devices is considered medically necessary for **all of the following:**
   a. Refractory open-angle glaucoma to reduce intraocular pressure (IOP) in patients where documented medical and conventional surgical treatments have failed.
   b. The specific model of the implanted device must be FDA-approved and be used according to FDA-approved indications.
2. iSTENT® Trabecular Micro-Bypass Stent is considered medically necessary for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.
3. Canaloplasty is considered medically necessary when ALL **of the following** are met:
   a. An intraocular pressure (IOP) of 21 mm Hg or higher
   b. A diagnosis of **one or more of the following:**
      1. Primary open-angle glaucoma (POAG)
      2. Pigmentary glaucoma
      3. Exfoliation glaucoma
      4. POAG mixed with another mechanism under **one of the following** circumstances:
         a. Failed trabeculectomy in opposite eye
         b. Failed laser trabeculoplasty without scarring
         c. Documented case with medical reason why target IOP is unlikely to be achieved on maximum doses of ophthalmic medications
         d. IOP has not been achieved over 6 months on maximum dose of ophthalmic medications alone
         e. Keloid formers
         £ Patients with significant ocular surface disease
         g. Patients with ocular pemphigoid
         h. Concern about further loss of vision in patients with **one or more of the following:**
            1. High myopia (-6 diopters or higher)
            2. Advanced previous glaucoma damage = visual field lost & visual fixation is split
            3. Ocular hypotony in opposite eye 2° to trabeculectomy

4. Immuno-suppressed
5. Anti-coagulation
6. Diabetes mellitus with documented early retinopathy or diabetic macular edema

c. Procedure must be completed with an FDA-approved device or system.
d. Providers must have evidence of credentialing and privileges for performing canaloplasty at the surgical facility/center where the procedure is performed.
e. Ophthalmic surgeon must be formally trained with documentation of training to perform the canaloplasty procedure.

CODES

HCPCS	Description
65855	Trabeculoplasty by laser surgery
66170	Creation of eye fluid drainage tract
66174	Canaloplasty
66175	Transluminal dilation of aqueous outflow canal; with retention device or stent
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion
0253T	Insertion of anterior segment aqueous drainage, device without extraocular reservoir, internal approach, into the suprachoroidal space
ICD CODES	
H40.1	Open angle glaucoma
H40.11	Primary Angle Glaucoma
H40.12	Low-tension glaucoma, unspecified eye, stage unspecified
H40.139	Pigmentary open angle glaucoma
H40.159	Residual state of open angle glaucoma
H40.50	Glaucoma secondary to other eye disorders/drugs
Q15.0	Congenital glaucoma

VI. Procedures

None

VII. References

1. American Society of Cataract & Refractive Surgery, Eyeworld. September *2021.Examining Trabeculectomy.* Examining trabeculectomy - EyeWorld
2. Lam, D., & Wechsler, D. Z. (2021). Five-Year Outcomes of Trabeculectomy and Phacotrabeculectomy. *Cureus*, *13*(1), e12950. https://doi.org/10.7759/cureus.12950
3. National Institute of Health; National Eye Institute. Glaucoma. Last Updated April 21, 2022. Glaucoma | National Eye Institute (nih.gov)
4. Rao, A., & Cruz, R. D. (2022). Trabeculectomy: Does It Have a Future?. *Cureus*, *14*(8), e27834. https://doi.org/10.7759/cureus.27834

VIII. Forms/Appendices

None

IX. Responsibility

Medical Director