Medica Coverage Policy

Policy Name: Glaucoma Surgical Treatments

Effective Date: 04/22/2024

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Aqueous Shunts and Microstents Implants for Glaucoma

- **Aqueous Shunt/Aqueous Drainage Devices (Ab externo approach)**
  Insertion of aqueous shunts is not investigative when used according to U.S. Food and Drug Administration (FDA)-approved labeled indications and when ALL of the following criteria are met:
  1. Treatment to reduce intraocular pressure (IOP) in adults with mild to moderate open-angle glaucoma (OAG).
  2. Medical therapies have failed or are inappropriate to adequately control IOP.
  3. At least one of the conventional surgical techniques has failed or are inappropriate (e.g., trabeculectomy, argon laser therapy or selective traculoplasty).

  Aqueous shunt devices are investigative for all other indications not listed above, including but not limited to:
  1. Patients with glaucoma when IOP is adequately controlled by medications.
  2. Ab externo shunts devices not approved by the FDA.
  3. Reliable evidence does not permit conclusions concerning its effectiveness.

- **Microstent/Micro Bypass Stent (ab interno approach): Also known as Minimally Invasive Glaucoma Surgery (MIGS)**
  Microstent implantation of the Glaukos iStent® Trabecular Micro-Bypass Stent system, Glaukos iStent inject®, or Hydrus®. Microstent is not investigative when used according to FDA labeled indications and when ALL of the following criteria are met:
  1. Treatment to reduce IOP in adults with mild to moderate OAG.
  2. Medical therapies have failed or are inappropriate to adequately control IOP.
  3. The procedure is being performed in conjunction with cataract surgery.

Microstent implantation of XEN Glaucoma Treatment System is not investigative in individuals with refractory open-angle glaucoma when used according to FDA labeled indications and both medical therapies and previous surgical treatment have failed to control intraocular pressure.

Aqueous stent devices listed above are investigative for all other indications not listed above, including implantation of more than two microstents per eye. Reliable evidence does not permit conclusions concerning its effectiveness.

Canaloplasty and Viscocanalostomy (Schlemm Canal Dilation)

- **Canaloplasty (ab externo) is not investigative when ALL of the following criteria are met:**
  1. Treatment to reduce IOP in adults with chronic OAG.
  2. Medical therapies have failed or are inappropriate to adequately control IOP.
  3. The patient is not a candidate for any other IOP-lowering procedure (e.g., trabeculectomy or glaucoma drainage implant).

  Canaloplasty (ab externo) is investigative for all other indications not listed above. Reliable evidence does not permit conclusions concerning its effectiveness.

  Ab interno canaloplasty (ABiC) is investigative for all indications. Reliable evidence does not permit conclusions concerning its effectiveness.

- Viscocanalostomy is investigative for all indications, including angle-closure glaucoma. Reliable evidence does not permit conclusions concerning its effectiveness.

NOTE: Trabeculectomy, trabeculoplasty, iridotomy, iridectomy, iridoplasty and/or similar surgeries are not subject to the criteria within this medical coverage policy.

Description

Glaucoma is a chronic disorder involving increased pressure in the eye due to fluid buildup. There are several forms of glaucoma with open angle glaucoma (OAG) being the most common. The increased pressure associated with OAG can lead to optic neuropathies characterized by visual field loss and structural damage to the optic nerve. If left untreated, glaucoma can result in partial or complete visual impairment. Currently, IOP is the only treatable risk factor for glaucoma, and lowering IOP has proven beneficial in reducing the progression of loss of vision.

The American Academy of Ophthalmology defines the severity of OAG as follows:

- Mild: definite optic disc or retinal nerve fiber layer (RNFL) abnormalities consistent with glaucoma and a normal visual field as tested with standard automated perimetry (SAP).
- Moderate: definite optic disc or RNFL abnormalities consistent with glaucoma and visual field abnormalities in one hemifield that are not within 5 degrees of fixation as tested with SAP.
- Severe: definite optic disc or RNFL 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 SAP.

- Indeterminate: definite optic disc or RNFL abnormalities consistent with glaucoma, inability of patient to perform visual field testing, unreliable/uninterpretable visual field test results, or visual fields not performed yet.

Aqueous Shunts (also known as tube shunts, glaucoma drainage devices, and setons) refers to devices that are implanted from outside the eye and are used to facilitate aqueous flow out of the anterior chamber to control IOP. Aqueous shunts have traditionally been used to manage medically uncontrolled glaucoma when trabeculectomy has failed to control IOP or is deemed unlikely to succeed. These devices are implanted under local or general anesthetic.

Micro-invasive or minimally invasive glaucoma surgery (MIGS) refers to a group of surgical procedures that are performed by using an ab interno (from inside the eye) approach. In contrast to external filtration surgeries such as trabeculectomy and aqueous tube shunt, these procedures are categorized as internal filtration surgeries. MIGS has been proposed to provide a medication-sparing, conjunctival-sparing approach to lower IOP for patients with mild-to-moderate glaucoma. MIGS is proposed to be safer than traditional incisional glaucoma surgery. Internal filtration procedures include, but may not be limited to:

- The XEN Glaucoma Treatment System (Allergan, Inc. Aliso Viejo, CA) consists of XEN Gel Stent preloaded into the XEN Injector. The Stent is composed of a gelatin derived from porcine dermis, formed into a tube, that is implanted to create a permanent channel through the sclera allowing an outflow of aqueous humor from the anterior chamber to the subconjunctival space resulting in a conjunctival bleb. The goal of the XEN is too lower IOP.
- Glaukos iStent® Trabecular Micro-Bypass Stent system is a small heparin-coated, titanium implant, placed into Schlemm's canal, intended to restore more normal fluid drainage and reduce IOP in individuals who are also undergoing cataract surgery.
- Glaukos iStent inject is a second-generation stent device which includes two multidirectional titanium stents that are preloaded in a single use injector system. The stent is designed for placement in either eye, with the head positioned in the anterior chamber and the rear extending into Schlemm's canal, creating a bypass for the outflow of aqueous humor.
- The Hydrus Microstent is a flexible crescent-shaped scaffold designed to reduce IOP by increasing trabecular outflow. The device is permanently implanted in Schlemm's canal, where it helps to open the trabecular meshwork and dilate the canal, thereby augmenting aqueous humor outflow from the anterior chamber to the fluid collector channel. It is usually implanted in conjunction with cataract surgery.

Ab externo canaloplasty is a surgical technique to reduce IOP by drainage of aqueous fluid from the eye and is performed from outside the eye. It is done under local or general anesthetic. A superficial hinged flap of sclera is excised, exposing the Schlemm's canal. An ultrasound imaging system is used to identify the canal and to visualize the surgical instruments when they are in the canal. A microcatheter is introduced into the canal and advanced around its entire circumference. As the catheter tip advances, viscoelastic fluid is injected into the canal to dilate it. The tip of the microcatheter is withdrawn and the superficial flap is sutured. This widens the canal. The Omni Surgical System is an example of device that combines the functions of cutting the trabecular meshwork and delivering viscoelastic.

Ab interno canaloplasty (ABiC) is a surgical technique performed using the iTrack microcatheter system (Ellex iScience, Fremont, CA), with a fiber optic light allowing for visualization of the catheter while in Schlemm's canal. It is performed through a direct opening in the trabecular meshwork from within the anterior chamber. After making a nasal goniotomy, the catheter is advanced 360 degrees into Schlemm's canal and slowly withdrawn while performing circumferentially viscodilation of the canal and the distal outflow system with cohesive viscoelastic.

Viscocanalostomy, the precursor to canalostomy, involves cutting tissue flaps in the conjunctiva and the sclera. The creation of these flaps exposes a portion of Schlemm's canal into which viscoelastic (a high-viscosity elastic gel) is injected. The viscoelastic opens and enlarges the canal purportedly enhancing fluid flow out of the anterior chamber. The tissue flaps are then closed. The amount of angle treated in this procedure is minor in comparison to a canaloplasty (generally less than 90 degrees).

FDA Approval

- **Microstent/Micro Bypass Stent (Ab Interno approach): Also known as Minimally Invasive Glaucoma Surgery (MIGS)**

  On November 21, 2016 the XEN Glaucoma Treatment System (consisting of the XEN45 Gel Stent and the XEN Injector) was granted FDA clearance for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open-angle glaucoma (POAG), and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

  On June 2012, the Glaukos iStent Trabecular Micro-Bypass Stent (Glaukos Corp., Laguna Hills, CA) received FDA premarket approval (PMA) for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

  On June 25, 2018, Glaukos Corporation received PMA approval for the iStent inject Trabecular Micro-Bypass System (model G2-M-IS), indicated for use in conjunction with cataract surgery for the reduction of IOP in adults with mild-to-moderate POAG.

  On August 2018, the Hydrus Microstent was granted FDA clearance for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild-to-moderate POAG.

- **Aqueous Shunt/Aqueous Drainage Devices (Ab externo approach):**

  The ExPRESS™ Mini Glaucoma Shunt (K030350), indicated for use in reduction of IOP in patients with glaucoma where medical and conventional surgical treatments have failed, received 501(k) approval on March 26, 2002.

  Predicate Devices include the Molteno Implant (K890598 and K902489), the Baerveldt Glaucoma Implant (K905129 and K955455), the Krupin Eye Valve (K885125 and K905703), and the Ahmed Glaucoma Valve Implant (K925636).

- **Canaloplasty and Viscocanalostomy (Schlemm Canal Dilation):**

  Omni Surgical System received the original FDA 510(k) marketing clearance in December 2017 (K173332). In August 2020, FDA granted 510(k) marketing clearance for the next-generation Omni Plus Surgical System (K201953) with the Omni Surgical System as the predicate device. In March 2021, FDA granted additional 510(k) approval (K202678). In August 2023, the device received another 501(k)-marketing clearance (K232214). The most recent labeled indication reads: "The OMNI® Surgical System is indicated for canaloplasty (microcatheterization and transluminal vasodilation of Schlemm's canal) followed by trabeculotomy (cutting of the trabecular meshwork) to reduce [IOP] in adult patients with primary [OAG]."
  According to the FDA 510(k) document, the primary functional difference between the two Omni surgical devices is the volume of viscoelastic fluid that can be delivered.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

- **0499T -** Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
- **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)
- **0671T -** Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more
- **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
- **C1783 -** Ocular implant, aqueous drainage assist device

HCPC Codes:

- **L8612 –** Ocular Implant, aqueous drainage assist device

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