Medical Policy

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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Title

Glaucoma Surgeries Policy

Indication/Usage: Glaucoma is a disease of the optic nerve characterized by elevated intraocular pressure (IOP) and progressive, irreversible loss of vision. There are several types of glaucoma, all associated with optic nerve damage, leading to visual impairment. Primary open-angle glaucoma (OAG) is the most common type. OAG is associated with partial blockage of the flow of aqueous humor. Patients with OAG develop thickening of the trabecular meshwork, which may result in partial blockage of Schlemm's canal. First-line treatment of OAG employs medications that lower IOP with the aim of preventing loss of vision. However, many patients require more than 1 medication to adequately lower IOP. Adherence may be suboptimal because medications for glaucoma are sometimes time-consuming or difficult to administer, produce side effects, and are costly. Surgical approaches are used if medical treatment does not lower IOP adequately. Surgical procedures are designed to either increase the exit of aqueous humor from the eye or decrease its

production. Many surgical procedures are associated with pain, infection, hypotony (extremely low IOP), hemorrhage, corneal edema, and visual disturbances. For these reasons, minimally invasive approaches are preferred in Combination with Cataract Surgery for the Treatment of Open-Angle Glaucoma, 2016)

Medical Indications for Authorization

SummaCare considers the following treatments medically necessary for the treatment of glaucoma. [HD1]

1. **Aqueous Drainage/Shunt Implants**
   - Considered medically necessary for the treatment of members with refractory primary open-angle glaucoma when first-line and second-line drugs or surgical treatments have failed to control intra-ocular pressure (IOP) using only FDA approved products. Current FDA approved implants include:
     - Ahmed glaucoma implant
     - Baerveldt seton
     - Ex-PRESS mini glaucoma shunt
     - Glaucoma pressure regulator
     - Krupin-Denver valve implant
     - Molteno implant
     - Schocket shunt

2. **iStent Trabecular Micro-Bypass**
   - Considered medically 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.
     - 1 or 2 stents per eye covered when above criteria is met, more than 2 stents per eye is considered experimental and investigational.

3. **Hydrus Microstent**
   - Considered medically 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.
     - 1 stent per eye covered when above criteria is met, more than 1stents per eye is considered experimental and investigational

4. **XEN Glaucoma Treatment System** [HD2]
   - Considered medically necessary for the management of refractory glaucoma, including ANY of the following:
     - primary open angle glaucoma
     - failiure of previous surgical treatment

- pseudoexfoliative or pigmentary glaucoma with open angles that is unresponsive to maximum tolerated medical therapy

- 1 stent per eye covered when above criteria is met, more than 1stents per eye is considered experimental and investigational

5. **Canaloplasty** [HD3]
   - Considered medically necessary for the treatment of primary open-angle glaucoma (POAG), including normal-tension glaucoma, and for pseudoexfoliation glaucoma.

Limitations

Any additional treatments not listed above are unproven and not medically necessary for treating any type of glaucoma due to insufficient evidence of efficacy and/or safety.

Coverage Decisions

No CMS National Coverage Determination (NCD) was identified. In the absence of an NCD, coverage decisions are left to the discretion of Medicare carriers

No Hayes rating found for Glaucoma Surgeries

Micro-Invasive Glaucoma Surgery (MIGS)
LCD ID
L38301

Coverage Indications, Limitations, and/or Medical Necessity

This LCD addresses use of a group of surgical procedures for glaucoma referred to as MicroInvasive Glaucoma surgery (MIGS). Noridian considers up to two iStent aqueous drainage devices, or one Hydrus 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. According to CPT®, in this setting a 'device' is a 'stent'. Therefore, 'two iStent aqueous drainage devices' means two (initial generation) iStents or one pair of stents that are contained in iStent Inject.
One XEN45 device per eye is covered for the management of refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled Intraocular Pressure (IOP) on maximally tolerated medical therapy. XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

Micro-Invasive Glaucoma Surgery (MIGS)
LCD ID
L38223

Covered Indications

Glaucoma surgical aqueous drainage devices will be considered medically reasonable and necessary when approved by the FDA and used within accordance of the FDA-approved/cleared indications.

1. A single insertion per eye of an anterior segment aqueous drainage device(s), without extraocular reservoir, via internal approach into the trabecular meshwork or with creation of intraocular reservoir into the supraciliary space is considered medically reasonable and necessary in conjunction with cataract surgery 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.
2. A single insertion per eye of an aqueous drainage device(s) without extraocular reservoir, via internal approach into the subconjunctival space is considered medically reasonable and necessary as a standalone treatment for refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and/or mean diurnal medicated IOP greater than or equal to 20 mmHg) on maximally tolerated medical therapy (i.e., greater than or equal to 4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues).

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

http://www.aetna.com/cpb/medical/data/400_499/0484.html#:~:text=Aetna%20considers%20combined%20glaucoma%20and,therapy%20and%2For%20laser%20trabeculoplasty.

https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medicaldrug/glaucoma-surgical-treatments.pdf

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