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

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)

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Medical Indications for Authorization

Medical Indications for Authorization Commercial Members

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

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:
        a. Ahmed glaucoma implant
        b. Baerveldt seton
        c. Ex-PRESS mini glaucoma shunt
        d. Glaucoma pressure regulator
        e. Krupin-Denver valve implant
        f. Molteno implant
        g. 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

- Considered medically necessary for the management of refractory glaucoma, including ANY of the following:
  a. primary open angle glaucoma
  b. failure of previous surgical treatment
  c. 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

- Considered medically necessary for the treatment of primary open-angle glaucoma (POAG), including normal-tension glaucoma, and for pseudoexfoliation glaucoma.

Medicare Members CGS LCD ID 37578 Micro-Invasive Glaucoma Surgery (MIGS) Coverage Guidance Coverage Indications, Limitations, and/or Medical Necessity

Indications of Coverage

The following are considered reasonable and necessary and covered:

1. One trabecular aqueous stent device per eye which is approved for the treatment of adults with mild or moderate open-angle glaucoma (OAG) 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.
2. One supraconjunctival space stent or trabecular aqueous stent device is approved for use as a standalone procedure device per eye for the management of refractory glaucoma, defined as prior failure of a filtering/cilioablative procedure **OR** uncontrolled intraocular pressure (IOP) defined a progressive damage or mean diurnal medicated IOP ≥20 mmHg on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues).

Limitations of Coverage

1. Minimally invasive glaucoma surgery (MIGS) is not considered a first line treatment for mild-moderate glaucoma.
2. A combination of surgical MIGs procedure and aqueous shunts cannot be performed at the same time of service in the same patient.
3. Phacoemulsification can be performed with a single MIGS procedure, but multiple procedures (e.g., stent and MIGS surgical procedure) cannot be performed in the same eye at the same time.

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.

1. Minimally invasive glaucoma surgery (MIGS) is not considered a first line treatment for mildmoderate glaucoma.
2. A combination of a surgical MIGS procedure and an aqueous shunt cannot be performed at the same time of service in the same eye.
3. Phacoemulsification/intraocular lens placement performed with a combination of a MIGS procedure, (e.g., cataract + stent + canaloplasty or goniotomy) at the same time of service in the same eye is non-covered.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

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

Sources Reviewed

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