

## ***Transciliary Fistulization for the Treatment of Glaucoma***

**Effective:** November 1, 2018

**Next Review:** October 2019

**Last Review:** October 2018

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Glaucoma is a disease characterized by degeneration of the optic disc. Transciliary fistulization for the treatment of glaucoma is an approach to filtering surgery.

### **MEDICAL POLICY CRITERIA**

Transciliary fistulization for the treatment of glaucoma is considered **investigational**.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

None

### **BACKGROUND**

#### **GLAUCOMA**

Glaucoma is a disease characterized by degeneration of the optic disc. Elevated intraocular pressure (IOP) has long been thought to be the primary etiology. However, the relationship between IOP and optic nerve damage varies among patients, suggesting a multifactorial origin.

For primary-open angle glaucoma (POAG) associated with elevated IOP, a decrease in aqueous outflow through the trabecular meshwork is believed to cause the increase in pressure. Many theories exist on what causes the decrease in aqueous outflow, such as foreign body obstruction, trabecular endothelial cell loss, reduced trabecular pore density, disturbances in neurofeedback mechanisms, or normal phagocytic activity, etc.

## **STANDARD POAG TREATMENTS**

### **Drug Therapy to Control IOP**

Examples of drugs that may be prescribed include, but are not limited to, alpha-agonist, beta blockers, carbonic-anhydrase inhibitors, miotic agents and prostaglandin analogs.

### **Surgical Care**

#### Laser Trabeculoplasty

A laser is used to burn small areas of the trabecular meshwork (where normal drainage of the eye occurs) to increase aqueous fluid outflow, thereby lowering IOP.

#### Incisional or Filtering Surgery (trabeculectomy or drainage implants)

Trabeculectomy (or glaucoma filtration procedure) involves a surgical removal of a portion of trabecular meshwork through a superficial flap of sclera. This lowers IOP by creating an alternate pathway for the aqueous fluid to flow from the anterior chamber to a bleb created in the subconjunctival space.

Drainage implant surgery involves a placement of the tube in the anterior chamber to shunt aqueous fluid to the subconjunctival space and lower IOP. Drainage implant surgery may be considered if trabeculectomy has failed or a patient is considered high risk for trabeculectomy.

Both trabeculectomy and drainage implant surgery often result in flat or collapsed anterior chambers and usually require that an iridectomy (placement of a hole in the iris) also be performed.

#### Cycloablation

This technique is also known as ablation of the ciliary body but is usually considered a last resort option due to the permanent destruction of the ciliary body.

## **TRANSCILIARY FISTULIZATION (TRANSCILIARY FILTRATION, SINGH FILTRATION)**

Transciliary fistulization for the treatment of glaucoma is an approach to filtering surgery. A thermocauterization device called the Fugo Blade is used to create a plasma-ablated pore or filter track from the sclera through the ciliary body to allow aqueous fluid to ooze into the subconjunctival lymphatics from the posterior chamber (behind the iris) of the eye. Plasma ablation with the Fugo Blade allows the highly vascular ciliary body to be penetrated with little or no bleeding. Aqueous fluid drains from the posterior chamber of the eye (in contrast to conventional filtering surgeries in which aqueous fluid is filtered from the anterior chamber).

The Fugo Blade (Medisurg Ltd.) received the U.S. Food and Drug Administration (FDA) 510(k) approval in October 2004 for sclerostomy for the treatment of primary open-angle glaucoma where maximum tolerated medical therapy and trabeculoplasty have failed.

## EVIDENCE SUMMARY

To reliably establish the safety and effectiveness of transciliary fistulization, the procedure should be compared to trabeculectomy (the current standard of care) in large, well-designed, well-executed, prospective randomized clinical trials.

### SYSTEMATIC REVIEWS

Lavia (2017)<sup>[1]</sup> published a systematic review (SR) on nine randomized controlled trials (RCTs) and 21 case series evaluating minimally invasive glaucoma surgeries (MIGSs) for open-angle glaucoma. The authors concluded that although MIGSs appear to reduce intraocular pressure and the need for glaucoma medication, the evidence is mostly from non-comparative studies and more RCTs are needed. No RCTs evaluated the Fugo Blade and because the SR did not include studies with follow-up < 12 months or those that lost greater than or equal to 15% at follow-up, none of the case studies on the Fugo Blade met inclusion criteria.

### RANDOMIZED CONTROLLED TRIALS

No RCTs were identified on transciliary fistulization for the treatment of glaucoma.

### NONRANDOMIZED STUDIES

Data concerning transciliary fistulization consists of case series and nonrandomized comparative studies. The nonrandomized studies have limitations including a nonrandomized design, lack of appropriate comparator groups, small sample sizes, short term follow-up, and/or significant loss of patients at follow-up.<sup>[2-4]</sup>

## PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of transciliary fistulization for the treatment of glaucoma.

## SUMMARY

There is not enough research to show that transciliary fistulization improves health outcomes for people with glaucoma. No clinical practice guidelines recommend transciliary fistulization for the treatment of glaucoma. Therefore, transciliary fistulization for the treatment of glaucoma is considered investigational.

## REFERENCES

1. Lavia, C, Dallorto, L, Maule, M, Ceccarelli, M, Fea, AM. Minimally-invasive glaucoma surgeries (MIGS) for open angle glaucoma: A systematic review and meta-analysis. *PloS one*. 2017;12(8):e0183142. PMID: 28850575
2. Dow, CT, deVenecia, G. Transciliary filtration (Singh filtration) with the Fugo plasma blade. *Ann Ophthalmol (Skokie)*. 2008 Spring;40(1):8-14. PMID: 18556974
3. Singh, D, Singh, K. Transciliary filtration using the Fugo Blade. *Ann Ophthalmol*. 2002;34(3):183-7. PMID: No PMID Entry
4. Sinha, R, Bali, SJ, Kumar, C, et al. Results of cataract surgery and plasma ablation posterior capsulotomy in anterior persistent hyperplastic primary vitreous. *Middle East African journal of ophthalmology*. 2013 Jul-Sep;20(3):217-20. PMID: 24014984

## CODES

<b>Codes</b>	<b>Number</b>	<b>Description</b>
CPT	66999	Unlisted procedure, anterior segment of eye
HCPCS	None	

*Date of Origin: December 2005*