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Medical Policy Manual

Topic: Transciliary Fistulization for the Treatment of Glaucoma

Date of Origin: December 6, 2005

Section: Surgery

Last Reviewed Date: October 2013

Policy No: 150

Effective Date: January 1, 2014

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

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 treatment involves:

- 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.

  - *Ablation of the ciliary body.*
    Usually considered a last resort option

Transciliary Fistulization (Transciliary Filtration, Singh Filtration)

Transciliary fistulization for the treatment of glaucoma is a recent 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.

MEDICAL POLICY CRITERIA

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

SCIENTIFIC EVIDENCE

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.

Literature Appraisal

Randomized Controlled Trials (RCT)

A literature search failed to identify any randomized controlled trials of transciliary fistulization for the treatment of glaucoma.

Other Comparative Studies and Case Series

Preliminary data concerning transciliary fistulation consists of two case series (n=147; n=10)[1,2] and one non-randomized comparative study (n=36)[3]. However, these non-randomized studies are unreliable for at least one of the following reasons:

- Overall evidence from the non-randomized comparative studies and case series is unreliable due to inherent methodological limitations, such as non-random allocation of treatment and lack of appropriate comparison groups.
- Small study populations limit the ability to rule out the role of chance as an explanation of the findings.
- Short-term follow-up limits conclusions regarding long-term treatment effectiveness and safety.

The study had significant loss to follow-up suggesting that there might be differences affecting the outcomes.

Clinical Practice Guidelines and Position Statements

There are currently no evidence-based clinical practice guidelines from U.S. professional associations that recommend the use of transciliary fistulization for the treatment of glaucoma.

Summary

The published evidence on transciliary fistulization is limited to three small nonrandomized studies with short follow-up. There are no published prospective, randomized controlled trials comparing transciliary fistulization with other standard treatments of glaucoma. It is not known from this limited data whether transciliary fistulization offers any additional benefit in the treatment of glaucoma compared with standard medical and surgical treatments; therefore, this procedure is considered investigational.

REFERENCES

1. Singh, D, Singh, K. Transciliary filtration using the Fugo Blade. *Ann Ophthalmol*. 2002;34(3):183-7. PMID: No PMID Entry

2. 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
3. Dow, CT, deVenecia, G. Transciliary filtration (Singh filtration) with the Fugo plasma blade. *Ann Ophthalmol (Skokie)*. 2008 Spring;40(1):8-14. PMID: 18556974

CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	0123T	Fistulization of sclera for glaucoma, through ciliary body
HCPCS	None	