Transciliary Fistulization for the Treatment of Glaucoma

Archived Medical Policy

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Policy # 00183
Original Effective Date: 02/23/2006
Archived Date: 03/21/2012

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Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers transciliary fistulization for the treatment of glaucoma to be investigational.*

Background/Overview
Glaucoma is a disease characterized by degeneration of the optic disc. Elevated intraocular pressure (IOP) has long been thought to be the primary etiology, but the relationship between IOP and optic nerve damage varies among patients, suggesting a multifactorial origin. For example, some patients with clearly elevated IOP will show no damage to the optic nerve, while other patients with marginal or no pressure elevation will, nonetheless, show optic nerve damage. The association between glaucoma and other vascular disorders such as diabetes or hypertension suggests vascular factors may play a role in glaucoma. Specifically, it has been hypothesized that reductions in blood flow to the optic nerve may contribute to the visual field defects associated with glaucoma.

For primary-open angle glaucoma (POAG) associated with IOP, a decrease in aqueous outflow through the trabecular meshwork is believed to cause the IOP. However, there are many theories 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.

Intraocular pressures above 21 mm Hg have been shown to increase rates of visual field loss, and conventional management of the patient principally involves drug therapy to control elevated intraocular pressures to prevent or delay glaucomatous loss of vision. For POAG, drug therapy may include alpha-agonist, beta-blockers, carbonic-anhydrase inhibitors, miotic agents and prostaglandin analogs. When the maximum tolerated medical therapy fails to control optic neuropathy, surgical care is considered the next treatment option. Surgical procedures include laser trabeculoplasty, incisional or filtering surgery, such as trabeculectomy or drainage implants, and as a last resort, ablation of the ciliary body.

Transciliary fistulization for the treatment of glaucoma, also known as transciliary filtration or Singh filtration, is a recent approach to filtering surgery. This procedure uses a thermocauterization device called the Fugo Blade™ 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
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Transciliary fistulization allows aqueous fluid to drain from the posterior chamber of the eye and differs from conventional filtering surgeries, such as trabeculoplasty, trabeculectomy and drainage implant surgery, in which aqueous fluid is filtered from the anterior chamber of the eye. In the trabeculoplasty procedure, 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. In trabeculectomy (or glaucoma filtration procedure), a portion of trabecular meshwork is surgically removed through a superficial flap of sclera to lower IOP by creating an alternate pathway for the aqueous fluid to flow from the anterior chamber to a bleb created in the subconjunctival space. If trabeculectomy has failed to reduce IOP sufficiently or a patient is considered to be at high risk for trabeculectomy failure, drainage implant surgery may be considered in which a tube is placed in the anterior chamber to shunt aqueous fluid to the subconjunctival space and lower IOP. 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. Transciliary fistulization rarely requires an iridectomy and is thought to reduce tissue damage and risk of scarring and other complications associated with trabeculectomy and drainage implant surgery.

FDA or Other Governmental Regulatory Approval

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

Rationale/Source

A literature search conducted through July 2005 identified only one case series study by Singh and Singh of 147 patients treated with transciliary filtration (or fistulization) for the treatment of glaucoma followed up for up to six months. The authors reported at six months that intraocular pressures (IOPs) were reduced to 21 mm Hg or below without medication in 132 eyes. The decrease in IOP was statistically significant (p<0.02), and no cases of anterior chamber flattening occurred. Adverse events included the need for surgical revision in seven patients three months after surgery, and choroidal effusion in two patients, which resolved within one month after surgery. No data on changes in vision or optic neuropathy were reported.

Periodic literature updates, most recently performed through December 2010, have identified little additional evidence on this procedure. No clinical trials were identified that were performed in the United States. In 2008, Dow and deVenecia reported use of transectional (Singh) filtration with the Fugo plasma blade in 60 eyes of 36 patients at a Philippine mission for indigent patients. The authors propose that this procedure may be a possible answer for patients who do not have access to more complicated glaucoma procedures and/or medications. Filtration was performed on consecutive patients requiring surgical filtration surgery; 15
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of the patients had pain due to high IOP and 24 had IOP greater than 50 mmHg. The average time required to perform the procedure was about three minutes. Postoperative IOP was compared with results from a published study on trabeculectomy versus thermosclerotomy with follow-up at one day, 1–3 months, and 6–12 months postoperatively. The results appeared similar to trabeculectomy, although the patients treated with transciliary filtration and lost to follow-up at 6–12 months was greater than 50%. It was noted in the discussion that 14 eyes (23%) failed the procedure by six months, including all five eyes with neovascular glaucoma. This study is limited by the absence of a concurrent control, lack of detail in the reporting, and the loss to follow-up.

Summary

The limited literature since 2002 suggests poor acceptance of this procedure by the ophthalmologic community; the reasons for this are not clear. While this procedure is similar to other filtration procedures commonly performed for the surgical treatment of glaucoma, further studies with longer term follow-up are needed. Overall, the data are insufficient to determine the long-term health outcomes of transciliary fistulization for the treatment of glaucoma.

References


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**Policy History**

Original Effective Date: 02/23/2006

- 01/04/2006 Medical Director review
- 01/17/2006 Medical Policy Committee review
- 02/23/2006 Quality Care Advisory Council approval
- 07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
- 01/10/2007 Medical Director review
- 01/17/2007 Medical Policy Committee approval
- 01/07/2009 Medical Director review
- 01/14/2009 Medical Policy Committee approval. No change to coverage.
- 01/07/2010 Medical Policy Committee approval
- 01/06/2011 Medical Policy Committee review
- 01/19/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 03/01/2012 Medical Policy Committee review. Recommend archiving.
- 03/21/2012 Medical Policy Implementation Committee approval. Archived policy.

Next Scheduled Review Date: Archived Medical policy.

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A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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