



BlueCross BlueShield  
of Alabama

---

**Name of Policy:**

**Transciliary Fistulization for the Treatment of Glaucoma**

Policy #: 255  
Category: Ophthalmology

Latest Review Date: February 2010  
Policy Grade: **Active Policy but no  
longer scheduled for  
regular literature  
reviews and updates.**

---

**Background/Definitions:**

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

### **Description of Procedure or Service:**

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 eye. Plasma ablation with the Fugo Blade allows the highly vascular ciliary body to be penetrated with little or no bleeding. 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 intraocular pressure (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 complication associated with trabeculectomy and drainage implant surgery.

### **Policy:**

**Transciliary fistulization for the treatment of glaucoma does not** meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

### **Key Points:**

Glaucoma is a disease characterized by degeneration of the optic disc. Elevated IOP has long been thought to be the primary etiology, but the relationship between IOP and optic nerve damage varies among patient, 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 neuro feedback mechanisms or normal phagocytic activity, etc.

IOPs 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 as 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.

A literature search conducted through July 2005 identified only one case series study by Singh and Singh of 147 patients treated with transcliliary filtration (or fistulization) for the treatment of glaucoma followed for up to six months. The authors reported, at six months, 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 that resolved within one month after surgery. No data on changes in vision or optic neuropathy were reported.

While this procedure is similar to other filtration procedures commonly performed for the surgical treatment of glaucoma and initial results appear promising, further studies with longer-term follow-up are needed. The data are insufficient to determine the long-term health outcomes of transcliliary fistulization for the treatment of glaucoma.

#### **October 2007 Update**

A literature search was done and no new publications were identified that report results for transcliliary fistulization. The policy statement remains unchanged.

#### **February 2009 Update**

Additional search of the literature failed to reveal any new publication concerning transcliliary fistulization. The Fugo Blade (Medisurg, Ltd) continues to have FDA 510K approval. Therefore, the policy coverage statement remains unchanged.

#### **February 2010 Update**

The most recent literature search identified little additional evidence on this procedure. No clinical trials were identified that were performed in the U.S. In 2008, Dow and Devencia reported use of transcliliary (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 procedure and/or medications. Filtration was performed on consecutive patients requiring surgical filtration surgery; 15 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 3 minutes. Postoperative IOP was compared with results from a published study on trabeculectomy versus thermosclerotomy with follow-up at 1 day, 1-3 month, and 6-12 months postoperatively. The results appeared similar to trabeculectomy, although the patients in the discussion that 14 eyes (23% failed the procedure by 6 months, including all of the 5 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.

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 and initial results appear promising, further studies with longer term follow-up are needed. Overall, the data are insufficient to determine the long-term health outcomes of transcliliary fistulization for the treatment of glaucoma.

**Key Words:**

Transcliliary fistulization, transcliliary filtration, fistulization of sclera, glaucoma, increased intraocular pressure, fugo blade

**Approved by Governing Bodies:**

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

**Benefit Application:**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

Pre-certification requirements: Not applicable

**Coding:**

CPT Codes:

**Effective for dates of service on or after January 1, 2006:**

<b>0123T</b>	Fistulization of sclera for glaucoma, through ciliary body
--------------	--

## **References:**

1. Blue Cross Blue Shield Association. *Transciliary fistulization for the treatment of glaucoma*. Medical Policy Reference Manual, January 2010.
2. Dow CT and deVenecia G. *Transciliary filtration (Singh filtration) with the Fugo plasma blade*. Ann Ophthalmol (Skokie), Spring 2008; 40(1): 8-14.
3. Singh D and Singh K. Transciliary filtration using the Fugo Blade. Ann Ophthalmol 2002; 34(3): 183-7.

## **Policy History:**

Medical Policy Group, October 2005 (2)

Medical Policy Administration Committee, October 2005

Available for comment October 24-December 7, 2005

Medical Policy Group, October 2006 (1) (Literature search (i.e., Pubmed, Medscape) performed with no new information found)

Medical Policy Group, October 2007 (1)

Medical Policy Group, February 2009 (4)

Medical Policy Group, February 2010 (1)

**Medical Policy Group, June 14, 2011; Active Policy but no longer scheduled for regular literature reviews and updates.**

---

*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*