



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:
Transciliary Fistulization for the Treatment of Glaucoma

Policy #: 255
Category: Ophthalmology

Latest Review Date: November 2019
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after December 14, 2005:

Blue Advantage will treat transciliary fistulization for the treatment of glaucoma as a non-covered benefit and as investigational.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

DESCRIPTION OF PROCEDURE OR SERVICE:

Glaucoma is the second-leading cause of blindness in the United States (U.S.) and is the most prominent in individuals over age 40. Specific individuals have an increased risk to develop glaucoma which may include: family history of glaucoma, individuals over the age of 40, individuals with thinner corneas, chronic eye inflammation and taking medications that increases ocular pressure.

Transciliary fistulization is being investigated for the treatment of glaucoma (e.g., primary open-angle glaucoma) when conventional management by drug therapy fails to control elevated intraocular pressures. Transciliary fistulization, 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. This is done to allow aqueous fluid to ooze into the subconjunctival lymphatics from the posterior chamber (behind the iris) of the eye. Transciliary fistulization rarely requires an iridectomy.

This technique differs from conventional filtering surgeries in which aqueous fluid is filtered from the anterior chamber of the eye. Transciliary fistulization allows aqueous fluid to drain from the posterior chamber of the eye.

KEY POINTS:

Literature review through November 2019.

Summary of Evidence

Published literature is limited to small case series and review articles; No published randomized controlled trials (RCTs) were identified. It is unknown whether transciliary fistulization offers any benefit in the treatment of glaucoma compared to standard medical and surgical treatments. Additional large, well-designed, RCTs comparing transciliary fistulization to trabeculectomy (the current standard of care) is needed to establish the safety and effectiveness of this procedure.

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

KEY WORDS:

Transciliary fistulization, transciliary filtration, fistulization of sclera, glaucoma, increased intraocular pressure, fugo blade, Singh filtration

Practice Guidelines and Position Statements

American Academy of Ophthalmology (AAO)

In 2015, AAO published benchmarks for primary open-angle glaucoma which state: “medical therapy is presently the most common initial intervention to lower IOP. Laser trabeculoplasty can be considered as initial therapy in select patients or an alternative for patients at high risk for non-adherence to medical therapy who cannot or will not use medications reliably.”

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.

CURRENT CODING:

CPT Codes:

66999 Unlisted procedure, anterior segment of eye

REFERENCES:

1. American Academy of Ophthalmology. (2005). Preferred practice patterns in primary open-angle glaucoma. Retrieved June 15, 2006 from www.aao.org/education/library/ppp/upload/Primary_Open-Angle_Glaucoma.pdf.
2. American Academy of Ophthalmology. Primary Open-Angle Glaucoma Summary Benchmarks for Preferred Practice Guidelines (2015 November). Available at: aao.org
3. Blue Cross Blue Shield Association. Transciliary fistulization for the treatment of glaucoma. Medical Policy Reference Manual, January 2010.
4. Dow CT and deVenecia G. Transciliary filtration (Singh filtration) with the Fugo plasma blade. *Ann Ophthalmol (Skokie)*, Spring 2008; 40(1): 8-14.
5. FDA-510(k) premarket notification. Fugo Blade. (October 2004). Available at www.accessdata.fda.gov

6. Jacobs, Deborah. Open-Angle Glaucoma: UpToDate Post TW (Ed), UpToDate, Waltham, MA. Topic last updated: December 22, 2015. Available at: www.uptodate.com
7. Singh D and Singh K. Transciliary filtration using the Fugo Blade. *Ann Ophthalmol* 2002; 34(3): 183-7.

POLICY HISTORY:

Adopted for Blue Advantage, October 2005

Available for comment October 29-December 13, 2005

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

Medical Policy Group, October 2007

Medical Policy Group, February 2009

Medical Policy Group, February 2010

Medical Policy Group, RETIRED June 14, 2011

Medical Policy Group, December 2015

Medical Policy Group, November 2019

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 plans contracts.