BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Transciliary Fistulization for the Treatment of Glaucoma

Policy #: 255
Latest Review Date: March 2022
Category: Ophthalmology

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:

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 one of the top causes of blindness in the United States for individuals over age 40. Elevated intraocular pressure is a major contributing factor to developing glaucoma, however, glaucoma might be of multifactorial origin due to a noted relationship between elevated intraocular pressure and optic nerve damage. Glaucoma is characterized by degeneration of the optic disc.

Treatment of glaucoma aims to reduce elevated intraocular pressure, either by administering ocular medications or by using surgical procedures. The goal of ocular medications is to slow aqueous-fluid production. The goal of surgical procedures is to directly drain aqueous humor from the eye or increase the rate of fluid circulation.

Topic medication (eye drops) is usually the first therapeutic option. These medications may aid in increasing the outflow of fluid inside the eye, or help limit aqueous humor production while improving fluid outflow. If 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 (trabeculectomy or drainage implants), and as a last resort, ablation of the ciliary body. Incisional or filtering surgery using transciliary fistualization is discussed in this evidence review.

Transciliary fistulization is a glaucoma filtering procedure in which a specialized thermocauterization device (Fugo Blade) is used to create a filter track from the sclera through the ciliary body to allow aqueous fluid to drain into subconjunctival lymphatics from the eye's posterior chamber (behind the iris), where it is slowly absorbed by the body. The IOP of the eye is decreased as a result. This technique differs from conventional filtering surgeries because plasma ablation with the Fugo Blade allows the highly vascular ciliary body to be penetrated with little or no bleeding. Aqueous fluid is filtered from the posterior chamber of the eye, in contrast to conventional filtering surgeries that filter from the anterior chamber of the eye.

KEY POINTS:

This policy has been regularly updated with literature reviews. The most recent literature update was performed through March 24, 2022.

Summary of Evidence

Little evidence on this procedure has been identified. 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 has been identified. At six months that intraocular pressures were reduced to 21 mm Hg or below without medication in 132 eyes. The decrease in intraocular pressures 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. Another study that was identified is limited by the absence of a concurrent control, lack of detail in the reporting, and the loss to follow-up. Further studies with longer term follow-up are needed.

No Randomized Controlled Trials were identified on transciliary fistulization for the treatment of glaucoma. This technology should be compared to the current standard of care (trabeculectomy) in well-designed clinical trials. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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."

No evidence based guidelines were identified 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

APPROVED BY GOVERNING BODIES:

The Fugo Blade (Medisurg, Ltd) for glaucoma was granted U.S. Food and Drug Administration 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.

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. http://www.aao.org/education/library/ppp/upload/Primary_Open-Angle_Glaucoma.pdf. Accessed March 24, 2022.
2. American Academy of Ophthalmology. Primary Open-Angle Glaucoma Summary Benchmarks for Preferred Practice Guidelines-2021. https://www.aao.org/summary-benchmark-detail/glaucoma-summary-benchmarks-2020. Accessed March 24, 2022.
3. Dow CT and deVenecia G. Transciliary filtration (Singh filtration) with the Fugo plasma blade. Ann Ophthalmol (Skokie), Spring 2008; 40(1): 8-14.
4. Francis BA et al. Novel glaucoma procedures: A report by the American Academy of Ophthalmology. Ophthalmology 2011 July; 118(7):1466-80.
5. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
6. Lavia C, Dallorto L, et al. Minimally-invasive glaucoma surgeries (MIGS) for open angle glaucoma: A systematic review and meta-analysis. PloS one. 2017; 12(8):e0183142.
7. Singh D and Singh K. Transciliary filtration using the Fugo Blade. Ann Ophthalmol 2002; 34(3): 183-7.
8. 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; 20(3):217-20.

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
Medical Policy Group, March 2021: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, March 2022: Reviewed by consensus. References added. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

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.