BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Viscocanalostomy and Canaloplasty

Policy #: 505
Category: Surgery

Latest Review Date: March 2021
Policy Grade: A

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 and after October 4, 2017:

Blue Advantage will treat **canaloplasty as a covered benefit** as a method to reduce intraocular pressure in **patients with chronic primary open-angle glaucoma under the following conditions:**

- **Medical therapy has failed** to adequately control intraocular pressure, AND
- **The patient is not a candidate for any other intraocular pressure lowering procedure** (e.g., trabeculectomy or glaucoma drainage implant) due to a high risk for complications.

Blue Advantage will treat **canaloplasty as a non-covered benefit** and as **investigational** under all other conditions, **including angle-closure glaucoma.**

Blue Advantage will treat **viscocanalostomy as a non-covered benefit and as investigational**.

Blue Advantage will treat **trabeculectomy surgery using ab interno** (i.e. **Trabectome™**) as a **non-covered benefit** and as **investigational**.

Effective for dates of service on and after January 1, 2011 and prior to October 4, 2017:

Blue Advantage will treat **canaloplasty as a covered benefit** as a method to reduce intraocular pressure in **patients with chronic primary open-angle glaucoma under the following conditions:**

- **Medical therapy has failed** to adequately control intraocular pressure, AND
- **The patient is not a candidate for any other intraocular pressure lowering procedure** (e.g., trabeculectomy or glaucoma drainage implant) due to a high risk for complications.

Blue Advantage will treat **canaloplasty as a non-covered benefit** and as **investigational** under all other conditions, **including angle-closure glaucoma.**

Blue Advantage will treat **viscocanalostomy 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 surgery is intended to reduce intraocular pressure when the target intraocular pressure cannot be reached with medications. Due to complications with established surgical approaches (e.g., trabeculectomy), alternative surgical treatments (e.g., transluminal dilation by viscocanalostomy or canaloplasty) are being evaluated for patients with glaucoma.

Impaired Aqueous Humor Drainage

In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork and/or the inner wall of Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in intraocular pressure and glaucoma risk.

Treatment

Surgical intervention may be indicated in patients with glaucoma when the target intraocular pressure cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir with a filtering "bleb" on the eye, which can effectively reduce intraocular pressure, but is associated with numerous and sometimes sight-threatening complications (e.g., leaks, hypotony, choroidal effusions and hemorrhages, hyphemas or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed herein) include trabecular laser ablation and deep sclerectomy, which removes the outer wall of Schlemm canal and excises deep sclera and peripheral cornea.

More recently, the Trabectome™, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm canal without external access or creation of a subconjunctival bleb. Intraocular pressure with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. Aqueous shunts may also be placed to facilitate drainage of aqueous humor (discussed in another policy). Complications from anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva.

Alternative nonpenetrating methods being evaluated to treat glaucoma are viscocanalostomy and canaloplasty. Viscocanalostomy is a variant of deep sclerectomy and unroofs and dilates the Schlemm canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution (e.g., sodium hyaluronate) is used to open the canal and create a passage from the canal to a scleral reservoir. It has been proposed that viscocanalostomy may lower intraocular pressure while avoiding bleb-related complications.

Canaloplasty, which evolved from viscocanalostomy, involves dilation and tension of the Schlemm canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack illuminated microcatheter to access and dilate the length of the Schlemm canal and to pass the suture loop through the canal. An important difference between viscocanalostomy and canaloplasty is that canaloplasty attempts to open the entire length of the Schlemm canal, rather than one section.

Because aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system is critical for reaching the target intraocular pressure. Therefore, some procedures may not reduce intraocular pressure below the pressure of the distal outflow system used (e.g., <15 mm Hg), and are not indicated for patients for whom very low intraocular pressure is desired (e.g., those with advanced glaucoma).

KEY POINTS:

The most recent literature review was updated through December 13, 2020.

Summary of Evidence

For individuals who have open-angle glaucoma who have failed medical therapy who receive viscocanalostomy, the evidence includes small randomized controlled trials (RCTs) comparing viscocanalostomy with trabeculectomy. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. Meta-analysis of these trials has indicated that trabeculectomy has a greater intraocular pressure lowering effect than viscocanalostomy. Reduction in intraocular pressure was greater with canaloplasty than viscocanalostomy in a small within-subject comparison. Viscocanalostomy has not been shown to be as good as or better than established alternatives. The evidence is sufficient to determine that the technology is unlikely to result in an improvement in the net health outcome.

For individuals who have open-angle glaucoma who have failed medical therapy who receive canaloplasty, the evidence includes an RCT, a comparative effectiveness review, and several case series. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. The RCT found not only significantly higher complete success rates with trabeculectomy than with canaloplasty, but also higher complication rates. The qualified success rate (with medication) was similar between groups. A systematic review found that canaloplasty provided modest intraocular pressure reduction (to ~16 mm Hg) with minor intraoperative or postoperative complications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

American Academy of Ophthalmology

A technology assessment from the American Academy of Ophthalmology (2011) included canaloplasty in its review of novel glaucoma procedures. The Academy concluded that all the techniques and devices reviewed were still in the initial stage (≤5 years) of clinical experience and lacked widespread use, with only Level III evidence (cohort studies) supporting the procedures. In addition to describing potential advantages and disadvantages of the procedure, it was noted that the long-term effects of a foreign body in the Schlemm canal are not known.

National Institute for Health and Clinical Excellence

In 2017, the National Institute for Health and Care Excellence (NICE) updated its 2008 guidance on canaloplasty for primary open-angle glaucoma. The current recommendation is that the "evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is inadequate is support the use of this procedure.…"

Similarly, in 2017, NICE updated its 2009 guidance on the diagnosis and management of chronic open-angle glaucoma. When comparing penetrating surgery (trabeculectomy) with nonpenetrating surgery (deep sclerectomy and viscocanalostomy), NICE found moderate-quality evidence that trabeculectomy is more effective than nonpenetrating surgery in reducing the number of eyes with an unacceptable intraocular pressure (IOP), but was more likely to cause cataract formation and persistent hypotony at 12- to 36-month follow-up. There was very low quality evidence that trabeculectomy is more effective than nonpenetrating surgery in reducing IOP from baseline to six- and 12-month follow-up, but the effect size might have been too small to be clinically significant. The guidance recommended offering information on the risks and benefits associated with surgery and offering surgery (type not specified) with pharmacologic augmentation to people with chronic open-angle glaucoma at risk of progressing to sight loss, despite treatment.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
iTrack, Viscocanalostomy, Canaloplasty, surgical ophthalmic microcannula, Trabectome, Trabeculectomy, Viscocanalostomy, ab interno, Trabeculotomy

APPROVED BY GOVERNING BODIES:
In 2004, the iTrack (iScience Interventional) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process as a surgical ophthalmic microcannula that is indicated for the general purpose of "fluid infusion and aspiration, as well as illumination, during surgery." In 2008, the iTrack received FDA clearance for "catheterization and viscodilation of Schlemm canal to reduce intraocular pressure in adult patients with open angle glaucoma." FDA product code: MPA.

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

CURRENT CODING:
CPT Codes:

66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent
66175	; with retention of device or stent

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POLICY HISTORY:

Adopted for Blue Advantage, January 1, 2011
Medical Policy Group, October 2012
Medical Policy Group, September 2013
Medical Policy Group, September 2014
Medical Policy Group, September 2015
Medical Policy Group, March 2016
Medical Policy Group, March 2017
Medical Policy Group, October 2017
Medical Policy Group, March 2018
Medical Policy Group, April 2019
Medical Policy Group, March 2020
Medical Policy Group, March 2021