Corporate Medical Policy

Viscocanalostomy and Canaloplasty

File Name: viscocanalostomy_and_canaloplasty
Origination: 11/2011
Last Review: 6/2023

Description of Procedure or Service

Glaucoma is the leading cause of irreversible blindness worldwide and is characterized by elevated intraocular pressure (IOP). In 2020, glaucoma affected approximately 52.7 million individuals globally, with a projected increase to 79.8 million in 2040. Glaucoma has been reported to be 7 times more likely to cause blindness and 15 times more likely to cause visual impairment in Black individuals as compared to White individuals. In the U.S. in 2010, Black individuals had the highest prevalence rate of primary open angle glaucoma at 3.4% compared to 1.7% among White individuals.

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, alternative surgical treatments such as transluminal dilation by viscocanalostomy and 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 IOP and glaucoma risk.

Treatment

Surgical intervention may be indicated in patients with glaucoma when the target IOP 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 IOP, 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 in this policy) 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’s canal without external access or creation of a subconjunctival bleb. IOP 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. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva.

Alternative nonpenetrating methods that have been used to treat glaucoma are viscocanalostomy and canaloplasty, although neither procedure is performed often. Viscocanalostomy is a variant of deep sclerectomy and unroofs and dilates Schlemm canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution, such as 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 IOP while avoiding bleb-related complications.

Canaloplasty, which evolved from viscocanalostomy, involves dilation and tension of 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 (Ellex) to access and dilate the length of 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 Schlemm canal, rather than one section of it.

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

Regulatory Status

The iTrack (Ellex) received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2004 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 the indication of "catheterization and viscodilation of Schlemm canal to reduce intraocular pressure in adult patients with open angle glaucoma."

In 2017, the OMNI® Surgical System (Sight Sciences, Inc.) was cleared for marketing by the FDA through the 510(k) process as a manually operated device for the delivery of small amounts of viscoelastic fluid during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures (K173332). In 2020, the OMNI® Plus Surgical System was cleared for the same indications for use as the predicate OMNI system (K201953). In 2021, the OMNI® Surgical System was cleared for marketing by the FDA through the 510(k) process for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma (K202678).

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for canaloplasty when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Viscocanalostomy is considered not medically necessary.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Viscocanalostomy and Canaloplasty are covered

Canaloplasty may be considered medically necessary 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.

When Viscocanalostomy and Canaloplasty are not covered

Canaloplasty is considered **investigational** under all other conditions, including angle-closure glaucoma.

Viscocanalostomy is considered **not medically necessary.**

Policy Guidelines

Tensioning devices are only able to reduce intraocular pressure (IOP) to the mid-teens, and may be inadequate when very low IOP is needed to reduce glaucoma damage.

For individuals who have open-angle glaucoma and have failed medical therapy who receive viscocanalostomy, the evidence includes small randomized trials (RCTs) that compare viscocanalostomy with trabeculectomy. Relevant outcomes include symptoms, morbid events, quality of life, and medication use. Meta-analysis of these trials indicates that trabeculectomy has a greater intraocular pressure–lowering effect than viscocanalostomy. Reduction in IOP has also been shown to be greater with canaloplasty than viscocanalostomy in a small within-subject comparison. This evidence is not sufficient to determine whether viscocanalostomy is at least as good as established alternatives.

For individuals who have open-angle glaucoma and 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 a significantly higher complete success rate with trabeculectomy than with canaloplasty, but a higher complication rate as well. The qualified success rate (with medication) was similar between the groups. A systematic review found that canaloplasty provided modest IOP reduction (to ~16 mm Hg) with minor intraoperative or postoperative complications.

Clinical input in 2011 considered canaloplasty to be appropriate for a select group of patients, including patients who are at risk for infection or hypotony, who have surface disease precluding the creation of good trabeculectomy bleb, or who would not be able to cover a glaucoma drainage device implant. In this clinical context, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 66174, 66175

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Medical Director Review 11/2011

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Medical Director review 6/2018

Medical Director review 8/2018

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National Institute for Health and Care Evidence (NICE). Ab externo canaloplasty for primary open-angle glaucoma [IPG591]. 2017; https://www.nice.org.uk/guidance/ipg591. Accessed February 25, 2022.

National Institute for Health and Care Evidence (NICE). Canaloplasty for primary open-angle glaucoma [IPG260]. 2008; https://www.nice.org.uk/guidance/ipg260. Accessed February 23, 2022.

National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management [NG81]. 2017; https://www.nice.org.uk/guidance/NG81. Accessed February 24, 2022.

National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management of chronic open angle glaucoma and ocular hypertension [CG85]. 2009; https://www.nice.org.uk/guidance/cg85. Accessed February 26, 2022.

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National Institute for Health and Care Evidence (NICE). Ab externo canaloplasty for primary open-angle glaucoma [IPG591]. 2017; https://www.nice.org.uk/guidance/ipg591. Accessed January 30, 2023.

National Institute for Health and Care Evidence (NICE). Canaloplasty for primary open-angle glaucoma [IPG260]. 2008; https://www.nice.org.uk/guidance/ipg260. Accessed January 29, 2023.

National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management [NG81]. 2017; https://www.nice.org.uk/guidance/NG81. Accessed January 28, 2023.

National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management of chronic open angle glaucoma and ocular hypertension [CG85]. 2009; https://www.nice.org.uk/guidance/cg85. Accessed January 27, 2023.

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Specialty Matched Consultant Advisory Panel review- 6/2023

Medical Director review 6/2023

Policy Implementation/Update Information

11/22/11 New policy issued. Canaloplasty may be considered medically necessary 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 t**he 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. Canaloplasty is considered **investigational** under all other conditions, including angle-closure glaucoma. Viscocanalostomy is considered **investigational.** Notification given 11/22/11. Effective date 2/21/12. Reviewed with Medical Director. (lpr)

11/13/12 Specialty Matched Consultant Advisory Panel Reviw 10/17/2012. Reference updated. No change to policy statement. (lpr)

7/16/13 Specialty Matched Consultant Advisory panel review 6/19/2013. No change to policy statement. (lpr)

9/10/13 Reference updated. No change to guideline statement. (lpr)

7/15/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. (lpr)

10/28/14 Reference added. (lpr)

7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)

10/30/15 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)

4/29/16 Updated Policy Guidelines. Reference added. No change to policy statement. (lpr)

7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)

4/28/17 Viscocanalostomy changed to not medically necessary from investigational under "When Not Covered" section. Policy statement for Viscocanalostomy changed to not medically necessary. Reference added. Medical Director review 3/2017. (lpr)

7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)

9/28/18 Updated Description and Policy Guidelines sections. Reference added. Specialty Matched Consultant Advisory Panel review 6/2018. No change to policy statement. Medical Director review 8/2018. (lpr)

7/16/19 Specialty Matched Consultant Advisory Panel review 6/19/2019. Reference added. Updated description section. No change to policy statement. Medical Director review 6/2019. (lpr)

6/30/20 Specialty Matched Consultant Advisory Panel review 6/17/2020. Reference added. No change to policy statement. Medical Director review 6/2020.(lpr)

7/13/21 Specialty Matched Consultant Advisory Panel review 6/16/2021. Reference added. Medical Director review 6/2021. No change to policy statement. (lpr)

7/26/22 Specialty Matched Consultant Advisory Panel review 6/2022. Updated description section and added references. Medical Director review 6/2022. (lpr)

7/18/23 Specialty Matched Consultant Advisory Panel review 6/21/2023. Updated description section and regulatory status. References added. Medical Director review 6/2023. No change to policy statement. (lpr)