Medical Coverage Policy | Viscocanalostomy and Canaloplasty

EFFECTIVE DATE: 08|19|2014
POLICY LAST UPDATED: 04|19|2023

OVERVIEW
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 individuals with glaucoma.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans and Commercial Products
Canaloplasty may be considered medically necessary as a method to reduce intraocular pressure in individuals with chronic primary open-angle glaucoma under the following conditions:

- Medical therapy has failed to adequately control intraocular pressure, AND
- The individual 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.

Medicare Advantage Plans
Canaloplasty is not covered under all other conditions, including angle-closure glaucoma, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Viscocanalostomy is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Canaloplasty is considered not medically necessary under all other conditions, including angle-closure glaucoma, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Viscocanalostomy is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery not medically necessary/not covered benefits/coverage.

BACKGROUND
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 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. 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 are being evaluated for glaucoma are viscocanalostomy and canaloplasty. 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 was developed from viscocanalostomy and 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 (iScience Interventional) 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 be able to reduce IOP below the pressure of the distal outflow system used (e.g., below 15 mm Hg), and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma).

Health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy if the procedure is unsuccessful, complications, and durability of the procedure.

In 2004, iTrack™ (iScience Interventional) was cleared for marketing by the U.S. Food and Drug Administration 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, iTrack™ was cleared by the Food and Drug Administration for "catheterization and viscodilation of [the] 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.

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 withcanaloplasty 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 insufficient to determine that the technology results 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 mmHg) with minor intraoperative or postoperative complications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. However, clinical input obtained in 2011 considered canaloplasty to be appropriate for a select group of patients, including those at risk for infection or hypotony, who have surface disease precluding the creation of good trabeculectomy bleb, or for whom a patch would not 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.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) are considered medically necessary:

66174 Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or Stent (Text revised 1/01/2023)

66175 Transluminal dilation of aqueous outflow canal (eg, canaloplasty); with retention of device or stent (Text revised 1/01/2023)

Note: When these codes are used to report Viscocanalostomy, they are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products.

RELATED POLICIES

Aqueous Shunts and Stents for Glaucoma

PUBLISHED

Provider Update, June 2023
Provider Update, July 2022
Provider Update, September 2021
Provider Update, June 2020
Provider Update, September 2019

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