Viscocanalostomy and Canaloplasty

Policy # 00280
Original Effective Date: 11/16/2010
Current Effective Date: 07/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of canaloplasty as a method to reduce intraocular pressure (IOP) in individuals with chronic primary open-angle glaucoma to be **eligible for coverage**** under the following conditions:

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

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers canaloplasty under all other conditions, including angle-closure glaucoma, to be **investigational.***

Based on review of available data, the Company considers viscocanalostomy to be **investigational.***

Policy Guidelines

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

Background/Overview

Glaucoma

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.

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 the Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

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 (eg, 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. 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 (eg, 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 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 (eg, <15 mm Hg), and are not indicated for patients for whom very low intraocular pressure is desired (eg, those with advanced glaucoma).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2004, 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, iTrack™‡ was cleared by the FDA for "catheterization and viscodilation of [the] Schlemm canal to reduce intraocular pressure in adult patients with open angle glaucoma." FDA product code: MPA.

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). FDA product code: MRH.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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Description
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 (eg, trabeculectomy), alternative surgical treatments (eg, transluminal dilation by viscocanalostomy or canaloplasty) are being evaluated for individuals with glaucoma.

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 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 2 RCTs, a comparative effectiveness review, and several case series. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. The RCTs found a significantly higher complete success rate with trabeculectomy than with canaloplasty in one trial and a significantly lower mean intraocular pressure in another trial. However, higher complication rates were also observed with trabeculectomy. A non-randomized study found both canaloplasty and iStent bypass implantation, when combined with phacoemulsion, had similar 1 year post-surgery intraocular pressure and glaucoma medication reductions, but canaloplasty resulted in more early postoperative complications. 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.

Additional Information
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.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers,

input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests on viscocanalostomy, input was received from 1 specialty medical society and 3 academic medical centers while this policy was under review in 2011. Although some considered viscocanalostomy to be medically necessary in a select group of patients who would be at risk for suffering a blinding complication with trabeculectomy, input was mixed. For example, 1 reviewer considered outcomes with viscocanalostomy to be inferior to other currently used nonpenetrating techniques.

In response to requests on canaloplasty, input was received from 1 specialty medical society and 2 academic medical centers while this policy was under review in 2011. One ophthalmology association provided a statement indicating that the case series cited are sufficient to show efficacy of canaloplasty to lower intraocular pressure to treat open-angle glaucoma. Other reviewers considered canaloplasty to be investigational but medically necessary for a select group of patients (eg, patients 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).

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.

Another technology assessment from the AAO (2024) evaluated intraocular pressure reduction with various trabecular procedures combined with cataract surgery vs cataract surgery alone.37, The following results were reported: "Based on studies that performed a medication washout, adding a trabecular procedure to cataract surgery provided an additional 1.6 to 2.3 mmHg of IOP [intraocular pressure] reduction in subjects with hypertensive, mild to moderate open-angle glaucoma (OAG) at 2 years over cataract surgery alone, which itself provided approximately 5.4 to 7.6 mmHg IOP reduction. In other words, adding a trabecular procedure provided an additional 3.8% to 8.9% IOP reduction over cataract surgery alone, which itself provided 21% to 28% IOP reduction. There was

no clear benefit of one trabecular procedure over another. Patient-specific considerations that can guide procedure selection include uveitis predisposition, bleeding risk, metal allergy, and narrowing of Schlemm's canal. There are no level I data on the efficacy of trabecular procedures in subjects with pretreatment IOP of 21 mmHg or less."

National Institute for Health and Care Excellence
In 2017, the National Institute for Health and Care Excellence (NICE) updated its 2008 guidance on ab externo 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 adequate is support the use of this procedure..."

Similarly, in 2017 (amended in 2022), 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, 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 intraocular pressure from baseline to 6- 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 (recommendation 1.4.21).

In 2022, NICE published an interventional procedures guidance on ab interno canaloplasty for open-angle glaucoma. The current recommendation states that "evidence on the safety of ab interno canaloplasty for open-angle glaucoma shows no major safety concerns. Evidence on the efficacy is limited in quality and quantity, particularly in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."

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

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05564091a	Cataract Surgery in Conjunction With Ab-interno Canaloplasty Compared to Cataract Surgery Only in Patients With Mild to Moderate Primary Open-Angle Glaucoma (CATALYST)	78	Oct 2025
NCT05786196a	Multicenter Glaucoma Study Investigating Standalone Canaloplasty, Randomized Controlled Trial: iTrack Advance (Nova Eye, Inc.) Compared to OMNI (Sight Sciences)	140	Dec 2025
NCT05696561a	Clinical Trial to Evaluate the Safety and Effectiveness of a Canaloplasty Device in Subjects With Open-Angle Glaucoma	40	Dec 2025

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

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11/04/2010	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. New policy.
12/31/2010	Coding Updated
09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee approval. Title changed from "Canaloplasty for Primary Open Angel Glaucoma" to "Viscocanalostomy and Canaloplasty". Coverage for canaloplasty revised to be eligible under specified conditions. Viscocanalostomy added as investigational.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. No change to coverage.
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review

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06/21/2017	Medical Policy Implementation Committee approval. No change to coverage.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. No change to coverage.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. No change to coverage.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2026

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	66174, 66175, 66999
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a individual for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the individual's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the individual, physician or other health care provider, and not more costly than an alternative service or sequence of services

at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that individual's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Individual's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.