LOUISIANA BLUE

Aqueous Shunts and Stents for Glaucoma

Policy # 00421
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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.

Note: Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma is addressed separately in medical policy 00089.

Note: Viscocanalostomy and Canaloplasty is addressed separately in medical policy 00280.

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 insertion of ab externo aqueous shunts approved by the U.S. Food and Drug Administration (FDA) as a method to reduce intraocular pressure (IOP) in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure (IOP) to be **eligible for coverage.****

Based on review of available data, the Company may consider insertion of ab interno aqueous stents approved by the U.S. Food and Drug Administration (FDA) as a method to reduce intraocular pressure (IOP) in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure (IOP), is considered to be **eligible for coverage.****

Based on review of available data, the Company may consider implantation of 1 or 2 U.S. Food and Drug Administration (FDA)-approved ab interno stents in conjunction with cataract surgery in individuals with mild-to-moderate open-angle glaucoma treated with ocular hypotensive medication to be **eligible for coverage.****

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 the use of an ab externo aqueous shunt for all other conditions, including in individuals with glaucoma when intraocular pressure (IOP) is adequately controlled by medications, to be **investigational.***

Based on review of available data, the Company considers the use of ab interno stents for all other conditions, to be **investigational.***

Policy Guidelines

Shunts and stents 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.

Examples of FDA-approved traditional aqueous humor shunting devices with extraocular reservoir (66179, 66180) include:

- Baerveldt Glaucoma Shunt (Advanced Medical Optics, Inc., Santa Ana, CA);
- Ahmed™‡ Glaucoma Valve AGV™‡ (New World Medical, Inc., Rancho Cucamonga, CA);
- Krupin (Eagle Vision, Inc, Memphis, TN);
- Molteno Implant (Molteno Ophthalmic Ltd., Dunedin, New Zealand).

According to 2018 CPT Assistant article, codes 66179 and 66180 (with extraocular reservoir) require more extensive extraocular and intraocular tissue dissection and are performed when a substantial reduction in intraocular pressure is needed. There are often periods of very low pressure that require more intensive postoperative monitoring.

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.

Treatment

Ocular Medication

First-line treatment typically involves pharmacologic therapy. Topical medications either increase the aqueous outflow (prostaglandins, alpha-adrenergic agonists, cholinergic agonists, Rho-kinase

inhibitors) or decrease aqueous production (alpha-adrenergic agonists, beta-blockers, carbonic anhydrase inhibitors). Pharmacologic therapy may involve multiple medications, have potential side effects, and may be inconvenient for older adults or incapacitated patients.

Surgery
Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Surgical procedures for glaucoma aim to reduce IOP from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm canal. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, which involves dissecting the conjunctiva, creating a scleral flap and scleral ostomy, then suturing down the flap and closing the conjunctiva, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir, which can effectively reduce IOP, but commonly results in filtering "blebs" on the eye, and is associated with numerous complications (eg, hemorrhage, scarring, hypotony, infection, leaks, bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed herein) include trabecular laser ablation, deep sclerectomy (which removes the outer wall of the Schlemm canal and excises deep sclera and peripheral cornea), and viscocanalostomy (which unroofs and dilates the Schlemm canal without penetrating the trabecular meshwork or anterior chamber) (see medical policy 000280). Canaloplasty 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 (iScience Interventional) to access and dilate the entire length of the Schlemm canal and to pass the suture loop through the canal (see medical policy 00280).

Insertion of shunts from outside the eye (ab externo) is another surgical option to lower IOP. Examples of ab externo devices cleared by the U.S. Food and Drug Administration (FDA) include the Ahmed, Baerveldt, Molteno, and EX-PRESS mini-shunt, which shunt aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ by explant surface areas, shape, plate thickness, presence or absence of a valve, and details of surgical installation. Generally, the risk of hypotony (low pressure) is reduced with aqueous shunts compared with trabeculectomy, but IOP outcomes are worse than after standard guarded filtration surgery. The risk of postoperative infection is lower with shunts than with trabeculectomy, and failure rates are similar (»10% of devices fail annually). The primary indication for aqueous shunts is for failed medical or surgical therapy, although some ophthalmologists have advocated their use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

Minimally Invasive Glaucoma Surgeries
Minimally invasive glaucoma surgeries (MIGS) are alternative, less invasive techniques that are being developed and evaluated. MIGS, which use microscopic-sized equipment and smaller incisions, involve less surgical manipulation of the sclera and the conjunctiva compared with other surgical techniques. There are several categories of MIGS: miniaturized trabeculectomy, trabecular

bypass, milder laser photocoagulation, and totally internal or suprachoroidal stents. Shunts and stents can be administered through an external flap of the conjunctiva and sclera (ab externo) or in a small incision in the cornea with the devices inserted through the anterior chamber of the eye (ab interno). Some ab interno microstents may be inserted with injectors.

Examples of ab interno devices either approved or given marketing clearance by the FDA include the iStent, which is a 1-mm long stent inserted into the end of the Schlemm canal through the cornea and anterior chamber, iStent inject, iStent infinite, and XEN gelatin stent.

Because aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system is critical for reaching the target IOP. Therefore, some devices may be unable to 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 (eg, those with advanced glaucoma). It has been proposed that stents such as the iStent, iStent inject, and Hydrus Microstent may be useful in patients with early-stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is patients with glaucoma who require cataract surgery. An advantage of ab interno stents is that they may be inserted into the same incision and at the same time as cataract surgery. Also, most devices do not preclude subsequent trabeculectomy if needed. It is possible to insert more than 1 stent to achieve desired IOP.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The regulatory status of the various ab externo and ab interno aqueous shunts and microstents are summarized in Table 1.

The first-generation Ahmed™‡ (New World Medical), Baerveldt®‡ (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno®‡ (Molteno Ophthalmic) ab externo aqueous shunts were cleared for marketing by the FDA through the 510(k) process between 1989 and 1993; modified Ahmed and Molteno devices were cleared in 2006. They are indicated for use "in patients with intractable glaucoma to reduce IOP where medical and conventional surgical treatments have failed." The AquaFlow™‡ Collagen Glaucoma Drainage Device (STAAR Surgical) was approved by the FDA through the premarket approval process for the maintenance of the subscleral space following nonpenetrating deep sclerectomy. In 2003, the ab externo EX-PRESS®‡ Mini Glaucoma Shunt was cleared for marketing by the FDA through the 510(k) process.

In 2016, the XEN®‡ Glaucoma Treatment System (Allergan), which consists of the XEN45 Gel Stent preloaded into the XEN Injector, was cleared for marketing by the FDA through the 510(k) process as an ab interno aqueous stent for management of refractory glaucoma. The approval was for patients with refractory glaucoma who failed previous surgical treatment or for patients with primary open-angle glaucoma unresponsive to maximum tolerated medical therapy. The FDA determined that this

device was substantially equivalent to existing devices, specifically the Ahmed™‡ Glaucoma Valve and the EX-PRESS®‡ Glaucoma Filtration Device.

In 2018, the first microstent, the iStent®‡ Trabecular Micro-Bypass Stent preloaded into the iStent *inject* device (Glaukos), was approved by the FDA through the 515(d) process for use in conjunction with cataract surgery for the reduction of IOP in adults with mild-to-moderate OAG currently treated with ocular hypotensive medication. In 2022, iStent infinite®‡ was FDA-approved for primary OAG when medical and surgical treatment have failed. Notably, this device is not required to be performed in conjunction with cataract surgery and contains 3 stents preloaded into an injector system.

In August 2018, Alcon announced an immediate voluntary recall of the CyPass microstent, which had been approved by the FDA in 2016 for use in conjunction with cataract surgery in adults with mild-to-moderate OAG. The recall was based on 5 year postsurgery data from the COMPASS-XT long-term safety study. Results showed a statistically significant increase in endothelial cell loss among patients receiving the CyPass microstent compared with patients receiving cataract surgery alone.

In September 2023, a randomized controlled trial (NCT01881425) reported two-year follow-up outcomes comparing the PRESERFLO MicroShunt (Santen) to trabeculectomy in patients with mild to severe primary OAG inadequately controlled by maximum tolerated medical therapy. As of October 2024, FDA approval of the device is still pending.

Table 1. Regulatory Status of Aqueous Shunts and Stents

Device	Manufacturer	Type	FDA Status	Date
AquaFlow™‡	STAAR Surgical	Drainage device	PMA	2001
Ahmed™‡	New World Medical	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Baerveldt®‡	Advanced Medical Optics	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Krupin	Eagle Vision	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Molteno®‡	Molteno Ophthalmic	Aqueous glaucoma shunt, ab externo	510(k)	<1993
EX-PRESS®‡	Alcon	Mini-glaucoma shunt, ab externo	510(k)	2003
XEN®‡ Gel Stent; XEN injector	AqueSys/Allergan	Aqueous glaucoma stent, ab interno	510(k)	2016

Device	Manufacturer	Type	FDA Status	Date
iStent®‡; iStent inject®‡	Glaukos	Microstent, ab interno	515(d) in conjunction with cataract surgery	2018
iStent *supra*®‡	Glaukos	Suprachoroidal stent	Not approved; in clinical trial	
CyPass®‡	Alcon	Suprachoroidal stent, ab interno	Company voluntarily recalled	2018
Hydrus™‡	Ivantis	Microstent, ab interno	PMA approval	2018
Beacon Aqueous Microshunt	MicroOptx	Micro-Shunt, ab externo	Not approved; in clinical trial	
PRESERFLO™‡ MicroShunt (previously InFocus)	Santen	Micro-Shunt, ab externo	Not approved; in clinical trial	
iStent infinite®‡	Glaukos	Microstent, ab interno	510(k)	2022

FDA: U.S. Food and Drug Administration; PMA: premarket approval.
FDA product codes: OGO, KYF.

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.

Description

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached using medications. Due to complications with established surgical approaches (eg, trabeculectomy), a variety of shunts and stents are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma. Microstents are also being evaluated in patients with mild-to-moderate open-angle glaucoma (OAG) currently treated with ocular hypotensive medication.

Summary of Evidence

For individuals who have refractory OAG who receive ab externo aqueous shunts, the evidence includes RCTs, retrospective studies, and systematic reviews. Relevant outcomes are a change in

disease status, functional outcomes, medication use, and treatment-related morbidity. Randomized controlled trials assessing FDA-approved shunts have shown that the use of large externally placed shunts reduces IOP to slightly less than standard filtering surgery (trabeculectomy). Reported shunt success rates show that these devices are noninferior to trabeculectomy in the long term. The FDA-approved shunts have different adverse event profiles and avoid some of the most problematic complications of trabeculectomy. Two trials have compared the Ahmed and Baerveldt shunts. Both found that eyes treated with the Baerveldt shunt had slightly lower average IOP at 5 years than eyes treated with the Ahmed but the Baerveldt also had a higher rate of serious hypotony-related complications. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have refractory OAG who receive ab interno aqueous stents, the evidence includes systematic reviews, an RCT, nonrandomized comparative studies, and a single-arm study. Relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. The RCT found XEN45 to be noninferior to trabeculectomy. The nonrandomized comparative studies reported that patients receiving the stent experienced similar, reductions in IOP and medication use as patients undergoing trabeculectomy. The single-arm study with 12-month follow-up results, consistently showed that patients receiving the stents experienced reductions in IOP and medication use. In addition, the FDA has given clearance to a gel stent based on equivalent IOP and medication use reductions as seen with ab externo shunts. Clearance for the stent was based on a review in which the FDA concluded that while there were technical differences between the stent and predicate devices (shunts), the differences did not affect safety and effectiveness in lowering IOP and medication use. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have mild-to-moderate OAG who are undergoing cataract surgery who receive aqueous microstents, the evidence includes RCTs and meta-analyses of RCTs. Relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. Implantation of 1 or 2 microstents has received FDA approval for use in conjunction with cataract surgery for reduction of IOP in adults with mild-to-moderate OAG currently treated with ocular hypotensive medication. When compared to cataract surgery alone, the studies showed modest but statistically significant decreases in IOP and medication use through the first 2 years when stents were implanted in conjunction with cataract surgery. A decrease in topical medication application is considered to be an important outcome for patients and reduces the problem of non-compliance that can affect visual outcomes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with mild-to-moderate OAG who are not undergoing cataract surgery who receive aqueous microstents as a stand-alone procedure, the evidence includes a nonrandomized trial, RCTs and a systematic review of 3 heterogeneous RCTs. Relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. Several RCTs have evaluated

the use of multiple microstents but comparators differed. Two RCTs indicate that implantation of a microstent can reduce IOP at a level similar to ocular medications at 12-month follow-up. Reduction in medications is an important outcome for patients with glaucoma. Whether microstents remain patent after 12 months is uncertain, and whether additional stents can subsequently be safely implanted is unknown. Some evidence on longer-term outcomes is provided by an RCT that compared implantation of a single iStent to implantation of multiple iStents. At longer-term (42-month) follow-up, the need for additional medication increased in eyes implanted with a single microstent but not with multiple microstents. The durability of multiple iStents is unknown. A fourth RCT compared implantation of the Hydrus microstent to 2 iStents. Outcomes from the Hydrus microstent were significantly better than 2 iStents, both statistically and clinically, for all outcome measures. The primary limitation of this study is that the duration of follow-up in the publication is limited to 12 months. Longer-term follow-up from this study is continuing and will answer important questions on the durability of the procedure. Corroboration in an independent study and comparison with a medical therapy control group would also increase confidence in the results. The evidence is insufficient 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, input was received from 1 physician specialty society and 2 academic medical centers while this policy was under review in 2013. Input supported the use of aqueous shunts in patients with glaucoma uncontrolled by medication. Input supported the use of a single microstent in patients with mild-to-moderate glaucoma undergoing cataract surgery to reduce the adverse events of medications and to avoid noncompliance.

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

The American Academy of Ophthalmology (AAO; 2008) published a technology assessment on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices, which was last reviewed for currency in 2014. The assessment indicated that, in general,

intraocular pressure (IOP) would settle at higher levels (≥18 mm Hg) with shunts than after standard trabeculectomy (14 to 16 mm Hg). Five-year success rates of 50% were found for the 2 procedures, indicating that aqueous shunts are comparable with trabeculectomy for IOP control and duration of benefit (based on level I evidence; well-designed randomized controlled trials). The assessment also indicated that although aqueous shunts have generally been reserved for intractable glaucoma when prior medical or surgical therapy has failed, indications for shunts have broadened (based on level III evidence; case series, case reports, and poor-quality case-control or cohort studies). The AAO concluded that, based on level I evidence, aqueous shunts offer a valuable alternative to standard filtering surgery and cyclodestructive therapy for many patients with refractory glaucoma.

In 2020, the AAO updated its preferred practice pattern on primary open-angle glaucoma (POAG). The document notes that aqueous shunts have traditionally been used to manage medically uncontrolled glaucoma when trabeculectomy has failed to control IOP or is deemed unlikely to succeed; however, the indications for using aqueous shunts have been broadening, and these devices are being increasingly used in the surgical management of glaucoma. The preferred practice pattern notes that "several studies have compared aqueous shunts with trabeculectomy" and that the "selection of aqueous shunts or trabeculectomy should be left to the discretion of the treating ophthalmologist, in consultation with the individual patient."

American Glaucoma Society
In 2020, the American Glaucoma Society published a position paper on microinvasive glaucoma surgery. The Society supports efforts that facilitate patient access to these procedures, including more flexible regulatory pathways for new devices, expansion of the indications for already approved devices, and greater availability of information obtained by regulatory authorities.

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (2017) updated guidance on trabecular stent bypass microsurgery for open-angle glaucoma (OAG). The guidance stated that “Current evidence on trabecular stent bypass microsurgery for OAG raises no major safety concerns. Evidence of efficacy is adequate in quality and quantity."

The National Institute for Health and Care Excellence (2018) published guidance entitled "Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for POAG". The guidance states that evidence is limited in quantity and quality and therefore, the procedure should only be used with special arrangements and that patients should be informed of the uncertainty of the procedure.

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 ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05439161	Multicentric Evaluation of Best Corrected Visual Acuity of the XEN Implant Versus Classic Trabeculectomy in Open Angle Glaucoma Subjects	196	Apr 2025
NCT05411198[a]	A Prospective, Multicenter Clinical Study to Evaluate the Safety and Effectiveness of Ab Externo Implantation of Glaucoma Gel Stent	65	Aug 2025
NCT04440527	Intraocular Pressure After Preserflo/Innfocus Microshunt vs Trabeculectomy: a Prospective, Randomised Control-trial (PAINT-Study)	70	Jul 2024
NCT04624698[a]	iStent Inject Trabecular Micro-Bypass System New Enrollment Post-Approval Study	358	Jun 2026
NCT06066645[a]	Multicenter, Randomized, Double-masked Trial to Evaluate the Safety and Efficacy of iDose®‡ TR (Travoprost Intraocular Implant) in Conjunction With the Placement of iStent Infinite vs. iStent Infinite Alone in Subjects With Open-angle Glaucoma or Ocular Hypertension	150	Nov 2025
NCT06057051[a]	A Prospective, Multicenter Study of the Glaukos®‡ iStent Infinite Trabecular Micro-Bypass System Model iS3 in Subjects With Mild to Moderate Primary Open-angle Glaucoma	245	Aug 2027
NCT04635020[a]	A Prospective Randomised Trial Comparing Selective Laser Trabeculoplasty (SLT) and iStent Trabecular Micro-bypass Stent Implantation	285	Sep 2033

	Combined With Cataract Surgery in Exfoliation Glaucoma		
NCT05583591[a]	Prospective, Randomized Controlled Study Comparing Combined Phacoemulsification With iStent Inject W Versus Hydrus for Mild to Moderate Open Angle Glaucoma (COMPETE)	390	Oct 2025
NCT05280366[a]	A Prospective, Randomized, Multi-center Evaluation of the Safety and Effectiveness of the STREAMLINE®‡SURGICAL SYSTEM Compared to iStent Inject W®‡ in Patients With Open-Angle Glaucoma	150	Jun 2026
NCT06289491[a]	Randomized Trial of Hydrus Microstent Versus Goniotomy	243	Apr 2029
NCT04553523[a]	The Hydrus®‡ Microstent New Enrollment Post-Approval Study: A Prospective, Non-Randomized, Multicenter, Single Arm, Clinical Trial	545	Jun 2028
NCT05949242[a]	Comparison of Clinical Outcomes in Patients Undergoing Cataract Surgery With OMNI Canaloplasty vs Cataract Surgery With OMNI Canaloplasty and Hydrus Stent	80	Oct 2024
NCT03904381[a]	Efficacy and Safety of XEN®‡ Gel Stent and Post-operative Management in Patients With Open Angle Glaucoma Compared to Classic Glaucoma Surgeries (Trabeculectomy and Sclerectomy) as Well as Other Minilally Invasive Glaucoma Surgery (MIGS)	100	Jan 2025
NCT05340647[a]	NorMIGS - a Prospective Study of Micro-invasive Glaucoma Surgery	100	Jun 2028
Unpublished			
NCT02327312[a]	Multicenter Investigation of Trabecular Micro-Bypass Stents vs. Laser Trabeculoplasty	91	Aug 2020
NCT04629521[a]	An Observational Multicenter Clinical Study to Provide Additional Long-Term Follow-up Beyond 60 Months for Subjects Implanted With a CyPass Micro-Stent in the COMPASS Trial	54	Apr 2023

NCT04658095[a]	A Prospective, Randomized, Multicenter Study To Compare The Safety And Effectiveness Of The OMNI®‡ Surgical System And The iStent Inject In Pseudophakic Eyes With Open Angle Glaucoma. The TRIDENT European Trial	20	Aug 2022
NCT01841450[a]	A Prospective, Controlled, Multicenter Post-Approval Study of the Glaukos®‡ iStent®‡ Trabecular Micro-Bypass Stent System in Conjunction with Cataract Surgery	360	Nov 2021
NCT01444040[a]	A Prospective, Randomized Evaluation of Subjects With Open-angle Glaucoma, Pseudoexfoliative Glaucoma, or Ocular Hypertension Naïve to Medical and Surgical Therapy, Treated With Two Trabecular Micro-bypass Stents (iStent Inject) or Travoprost Ophthalmic Solution 0.004%	196	Mar 2019
NCT01461278[a]	A Prospective, Randomized, Single-Masked, Controlled, Parallel Groups, Multicenter Clinical Investigation of the Glaukos®‡ Suprachoroidal Stent Model G3 In Conjunction With Cataract Surgery	505	Mar 2020

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

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Policy History

Original Effective Date: 05/21/2014
Current Effective Date: 03/01/2025
05/01/2014 Medical Policy Committee review
05/21/2014 Medical Policy Implementation Committee approval. New policy.

09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2015	Coding Update
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2016	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2016	Coding update
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Replaced the insertion of "aqueous shunts" with "ab externo shunts" as a method to reduce intraocular pressure (IOP) in patients with glaucoma where medical therapy has failed to adequately control IOP to be eligible for coverage. Added "the insertion of ab interno aqueous stents approved by the U.S. FDA as a method to reduce IOP in patients with glaucoma where medical therapy has failed to adequately control IOP, to be investigational.*" Replaced the use of an "aqueous shunt" with "ab externo aqueous shunt or ab interno aqueous stent" for all other conditions, including in patients with glaucoma when IOP is adequately controlled by medications, to be investigational.*
02/07/2019	Medical Policy Committee review
02/20/2019	Medical Policy Implementation Committee approval. Insertion of ab interno aqueous stents approved by the Food and Drug Administration as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure, was changed from investigational to eligible for coverage. Changed the eligible for coverage statement for implantation of "a single U.S. FDA approved microstent" to "1 or 2 U.S. FDA-approved ab interno stents" in conjunction with cataract surgery in patients with mild-to-moderate open-angle glaucoma treated with ocular hypotensive medication. Investigational statements for ab externo shunt and ab interno aqueous stent separated into two statements for clarity. Removed the investigational statement for the use of a microstent for all other indications.
02/06/2020	Medical Policy Committee review

02/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/04/2021	Medical Policy Committee review
02/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/17/2021	Coding Update
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Replaced "patients" with "individuals" in the policy statements. Coverage eligibility unchanged.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Added information and examples of FDA-approved traditional aqueous humor shunting devices with extraocular reservoir (66179, 66180) to the Policy Guidelines. Coverage eligibility unchanged.

Coding

The five character codes included in the Louisiana Blue 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.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

Aqueous Shunts and Stents for Glaucoma

Policy # 00421
Original Effective Date: 05/21/2014
Current Effective Date: 03/01/2025

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

Code Type	Code
CPT	0253T, 0449T, 0450T, 0474T, 0671T, 66183, 66989, 66991 Add codes effective 03/01/2025: 66179, 66180
HCPCS	C1783, L8612
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 patient 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 patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, 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 patient'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 Patient'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.