



Louisiana

Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 03/08/2021

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: Visco canalostomy 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 an externo aqueous shunt approved by the U.S. Food and Drug Administration (FDA) as a method to reduce intraocular pressure (IOP) in patients 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 an interno aqueous stent approved by the U.S. Food and Drug Administration (FDA) as a method to reduce intraocular pressure (IOP) in patients 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 patients with mild-to-moderate open-angle glaucoma treated with ocular hypotensive medication to be **eligible for coverage.****

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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 patients 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.

Background/Overview

Glaucoma

Glaucoma is characterized by elevated intraocular pressure (IOP), which results in visual field loss and irreversible blindness if left untreated. 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.

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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 00280 Viscocanalostomy and Canaloplasty). 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 Viscocanalostomy and Canaloplasty).

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. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of postoperative infection is lower with shunts than with trabeculectomy, and failure rates are similar ($\approx 10\%$ 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.

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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, involves 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 (ab interno). This policy evaluates the placement of ab interno stents.

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; the CyPass suprachoroidal stent; 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, CyPass, 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 are 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 may also be possible to insert more than 1 stent to achieve desired IOP. Therefore, health outcomes of interest are the IOP achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

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 is summarized in Table 1. The first-generation Ahmed^{TM†} (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

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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 subcleral 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 open-angle glaucoma currently treated with ocular hypotensive medication. The regulatory status of additional glaucoma devices is shown in Table 1.

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 open-angle glaucoma. 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.

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

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Device	Manufacturer	Type	FDA Status	Date
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
iStent ^{®‡} ; iStent inject ^{®‡}	Glaukos	Microstent, ab interno	515(d) in conjunction with cataract surgery	2018
iStent <i>supra</i> ^{®‡}	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
SOLX ^{®‡} Gold	SOLX	Micro-Shunt, ab externo	Not approved; in clinical trial	
Beacon Aqueous Microshunt	MicroOptx	Micro-Shunt, ab externo	Not approved; in clinical trial	
PRESERFLO ^{®‡} MicroShunt	Santan	Micro-Shunt, ab externo	Not approved; in clinical trial	

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

FDA product codes: OGO, KYF.

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Rationale/Source

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 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.

For individuals who have refractory OAG who receive ab externo aqueous shunts, the evidence includes randomized controlled trials (RCTs), retrospective studies, and systematic reviews. Relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. RCTs assessing U.S. Food and Drug Administration (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 a meaningful improvement in the net health outcome.

For individuals who have refractory OAG who receive ab interno aqueous stents, the evidence includes a nonrandomized retrospective comparative study and several single-arm studies. Relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. The comparative study reported that patients receiving the stent experienced similar reductions in IOP and medication use as patients undergoing trabeculectomy. The single-arm studies, with 12-month follow-up results, consistently showed that patients receiving the stents experienced reductions in IOP and medication use. Reductions in IOP ranged from 4 mm Hg to over 15 mm Hg. 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 a meaningful improvement in the net health outcome.

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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 the 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 a meaningful 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 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 present 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 the effects of the technology on health outcomes.

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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

American Academy of Ophthalmology

The AAO (2008) published a technology assessment on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices. The assessment indicated that, in general, IOP would settle at higher levels (≈ 18 mm Hg) with shunts than after standard trabeculectomy (14-16 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.

The AAO's (2015) preferred practice patterns on primary open-angle glaucoma indicated that the Academy considered laser trabeculoplasty as initial therapy in select patients or an alternative for patients who cannot or will not use medications reliably due to cost, memory problems, difficulty with installation, or intolerance to the medication. The AAO stated that aqueous shunts have traditionally been used to manage refractory glaucoma when trabeculectomy has failed to control

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IOP or is unlikely to succeed, but these devices are being increasingly used in other indications for the surgical management of glaucoma. The AAO also stated that micro-invasive glaucoma surgeries that are frequently combined with phacoemulsification have limited long-term data but seem to result in modest IOP reduction with postoperative pressures in the mid to upper teens. Although they are less effective in lowering IOP than trabeculectomy and aqueous shunt surgery, micro-invasive glaucoma surgeries may have a more favorable safety profile in the short term.

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. The guidance stated that “Current evidence on trabecular stent bypass microsurgery for open-angle glaucoma 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 primary open-angle glaucoma". 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.

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Louisiana

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Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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	1200	Dec 2020
NCT01841450 ^a	A Prospective, Randomized, Controlled, Parallel Groups, Multicenter Post-Approval Study Of The Glaukos ^{®‡} iStent ^{®‡} Trabecular Micro-Bypass Stent System In Conjunction With Cataract Surgery	360	Jul 2021
NCT04440527	Intraocular Pressure After Preserflo/Innofocus Microshunt vs Trabeculectomy: a Prospective, Randomised Control-trial (PAINT-Study)	70	Jul 2024
<i>Unpublished</i>			
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%	200	Jun 2018(unknown)
NCT01461291 ^a	A Prospective, Randomized, Single-Masked, Controlled, Parallel Groups, Multicenter Clinical Investigation of the Glaukos ^{®‡} Trabecular Micro-Bypass Stent Model GTS400	1200	Dec 2019

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Louisiana

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	Using the G2-M-IS Injector System in Conjunction With Cataract Surgery		
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NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Louisiana

Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 03/08/2021

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Louisiana

Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 03/08/2021

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Policy History

Original Effective Date: 05/21/2014

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- 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

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Louisiana

Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 03/08/2021

- 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.
- Next Scheduled Review Date: 02/2022

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Louisiana

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Policy # 00421

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Current Effective Date: 03/08/2021

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 2020 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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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0191T, 0253T, 0376T, 0449T, 0450T, 0474T, 66183
HCPCS	C1783, L8612
ICD-10 Diagnosis	H40.001-H40.069, H40.10X0-H40.1214, H40.111, H40.1110-H40.1114, H40.1120-H40.1124, H40.1130-H40.1134, H40.1190-H40.1194, H40.1220-H40.1224, H40.1230-H40.1234, H40.1290-H40.1294, H40.1310-H40.1314, H40.1320-H40.1324, H40.1330-H40.1334, H40.1390-H40.1394, H40.1410-H40.1414, H40.1420-H40.1424,

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Louisiana

Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 03/08/2021

	<p>H40.1430-H40.1434, H40.1490-H40.1494, H40.151-H40.159, H40.20X0-H40.20X4, H40.211-H40.219, H40.2210-H40.2214, H40.2220-H40.2224, H40.2230-H40.2234, H40.2290-H40.2294, H40.231-H40.239, H40.241-H40.249, H40.30X0-H40.30X4, H40.31X0-H40.31X4, H40.32X0-H40.32X4, H40.33X0-H40.33X4, H40.40X0-H40.40X4, H40.41X0-H40.41X4, H40.42X0-H40.42X4, H40.43X0-H40.43X4, H40.50X0-H40.50X4, H40.51X0-H40.51X4, H40.52X0-H40.52X4, H40.53X0-H40.53X4, H40.60X0-H40.60X4, H40.61X0-H40.61X4, H40.62X0-H40.62X4, H40.63X0-H40.63X4, H40.811-H40.819, H40.821-H40.829, H40.831-H40.839, H40.89, H40.9, H42, Q15.0</p>
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***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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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,

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Louisiana

Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 03/08/2021

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.

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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.

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