Capital BLUE

MEDICAL POLICY

POLICY TITLE	AQUEOUS SHUNTS AND STENTS FOR GLAUCOMA
POLICY NUMBER	MP-2.149

Original Issue Date (Created):	**10/1/2010**
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I. POLICY

Insertion of ab externo aqueous shunts approved by the U.S. Food and Drug Administration (FDA)* may be considered **medically necessary** as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure.

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, is considered **investigational.**

*For a list of FDA-approved shunts refer to Table 1 on page 4. For a list of aqueous shunts and stents not approved by the FDA, refer to the Appendix at the end of this policy.
Use of an ab externo aqueous shunt or ab interno aqueous stent for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered **investigational.** There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Implantation of a single FDA-approved microstent in conjunction with cataract surgery may be considered **medically necessary** in patients with mild-to-moderate open-angle glaucoma treated with ocular hypotensive medication.

Use of a microstent for all other conditions is considered **investigational.** There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines
Shunts and stents are only able to reduce intraocular pressure (IOP) to the mid-teens and may be inadequate when very low IOP is needed to reduce glaucoma damage.

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Cross-reference:

MP-2.056 Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: Refer to FEP Medical Policy Manual MP-9.03.21, Aqueous Shunts and Devices for Glaucoma. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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GLAUCOMA

Surgical procedures for glaucoma aim to reduce intraocular pressure (IOP) resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm canal. 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

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, 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 (e.g., 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 evidence review 9.03.26). 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.

Currently, minimally invasive glaucoma surgeries (MIGS) are alternative, less invasive techniques that are being developed and evaluated. Similar to trabeculectomy, the objective of MIGS is to lower IOP by improving outflow of eye fluid; however, MIGS involves less surgical manipulation of the sclera and the conjunctiva compared than a trabeculectomy. MIGS can either be performed outside the eye (ab externo) or inside the eye (ab interno).

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 (≈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.

Examples of ab interno devices either approved or given marketing clearance by 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 (e.g., <15 mm Hg) and are not indicated for patients for whom very low IOP is desired (e.g., 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 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 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.

REGULATORY STATUS

The regulatory status of the various ab externo and ab interno aqueous shunts and microstents is 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 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 intraocular pressure where medical and conventional surgical treatments have failed." The AquaFlow™ Collagen Glaucoma Drainage Device (STAAR Surgical) was approved by FDA through the premarket approval (PMA) 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 FDA through the 510(k) process. The EX-PRESS® shunt is placed under a partial thickness scleral flap and transports aqueous fluid from the anterior chamber of the eye into a conjunctival filtering bleb. 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 FDA through the 510(k) process as an ab interno aqueous shunt 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. FDA determined that this device was substantially equivalent to existing devices, specifically the Ahmed™ Glaucoma Valve and the EX-PRESS® Glaucoma Filtration Device.

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	AqueSys/Allergan	Aqueous glaucoma shunt, ab interno	510(k)	2016
iStent®	Glaukos	Microstent, ab interno	PMA	2012
CyPass®	Transcend Medical	Suprachoroidal stent, ab interno	PMA	2016
Hydrus™	Ivantis	Microstent, ab interno	Not approved; PMA submission	2017
SOLX® Gold	SOLX	Micro-Shunt, ab externo	Not approved; in clinical trial	
iStent *inject*®	Glaukos	Suprachoroidal stent	Not approved; PMA submission	2017
iStent *supra*®	Glaukos	Suprachoroidal stent	Not approved; in clinical trial	

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

In 2012, the iStent® Trabecular Micro-Bypass Stent (Glaukos) was approved by FDA through the PMA 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 labeling describes the following precautions[1]:

1. "The safety and effectiveness of the iStent® Trabecular Micro-Bypass Stent has not been established as an alternative to the primary treatment of glaucoma with medications. The effectiveness of this device has been demonstrated only in patients with mild-to-moderate open-angle glaucoma who are currently treated with ocular hypotensive medication and who are undergoing concurrent cataract surgery for visually significant cataract.

2. The safety and effectiveness of the iStent® Trabecular Micro-Bypass Stent has not been established in patients with the following circumstances or conditions, which were not studied in the pivotal trial:
    - In children
    - In eyes with significant prior trauma
    - In eyes with abnormal anterior segment
    - In eyes with chronic inflammation
    - In glaucoma associated with vascular disorders
    - In pseudophakic patients with glaucoma
    - In uveitic glaucoma
    - In patients with prior glaucoma surgery of any type, including argon laser trabeculoplasty
    - In patients with medicated IOP greater than 24 mmHg
    - In patients with unmedicated IOP less than 22 mmHg nor greater than 36 mmHg after 'washout' of medications
    - For implantation of more than a single stent
    - After complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitrectomy required, corneal injuries, or complications requiring the placement of an anterior chamber IOL [intraocular lens]
    - When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract"

FDA product codes: OGO, KYF.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have refractory open-angle glaucoma who receive ab externo aqueous shunts, the evidence includes RCTs, retrospective studies, and systematic reviews. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. RCTs assessing U.S. Food and Drug Administration–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. Food and Drug Administration–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 open-angle glaucoma who receive ab interno aqueous stents, the evidence includes a nonrandomized comparative study and several single-arm studies. Relevant outcomes are 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. However, there was no discussion on how the patients were chosen to receive the different treatments. The single-arm studies have reported 12-month follow-up results and found that patients receiving the stents experienced reductions in IOP and medication use. Comparative studies with longer follow-up periods are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have mild-to-moderate open-angle glaucoma who are undergoing cataract surgery who receive aqueous microstents, the evidence includes RCTs. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. Two microstents have received the Food and Drug Administration approval for use in conjunction with cataract surgery for reduction of IOP in adults with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication. RCTs have been conducted in patients with cataracts and less advanced glaucoma, where IOP is at least partially controlled with medication. Trial results have shown that IOP may be lowered below baseline with a decreased need for medication through the first 2 years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with indications for glaucoma treatment other than cataract surgery or refractory open-angle glaucoma who receive aqueous shunts or microstents, the evidence includes RCTs. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. Several RCTs have evaluated the use of multiple microstents, but comparators differed. One RCT compared a single microstent with multiple microstents. This trial reported no difference in the primary outcome (percentage of patients with ≥20% reduction in IOP); secondary outcomes favored the multiple microstent groups. One RCT compared 2 iStents with travoprost. This trial did not report statistical comparisons. The evidence is insufficient to determine the effects of the technology on health outcomes.

Evidence on nonapproved devices is discussed in the Appendix.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's

individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: *This list of codes may not be all-inclusive and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.*

Investigational; therefore, not covered:

CPT Codes®								
0376T	0449T	0450T						

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Covered when medically necessary:

CPT Codes®								
66179	66180	66183	66184	66185	0191T	0253T	0474T	

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HCPCS Codes	Description
C1783	Ocular implant, aqueous drainage assist device
L8612	Aqueous shunt

ICD-10-CM Diagnosis Codes	Description
H40.1111	Primary open-angle glaucoma, right eye, mild stage

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ICD-10-CM Diagnosis Codes	Description
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1113	Primary open-angle glaucoma, right eye, severe stage
H40.1114	Primary open-angle glaucoma, right eye, indeterminate stage
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1124	Primary open-angle glaucoma, left eye, indeterminate stage
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1133	Primary open-angle glaucoma, bilateral, severe stage
H40.1134	Primary open-angle glaucoma, bilateral, indeterminate stage
H40.1211	Low-tension glaucoma, right eye, mild stage
H40.1212	Low-tension glaucoma, right eye, moderate stage
H40.1213	Low-tension glaucoma, right eye, severe stage
H40.1214	Low-tension glaucoma, right eye, indeterminate stage
H40.1221	Low-tension glaucoma, left eye, mild stage
H40.1222	Low-tension glaucoma, left eye, moderate stage
H40.1223	Low-tension glaucoma, left eye, severe stage
H40.1224	Low-tension glaucoma, left eye, indeterminate stage
H40.1231	Low-tension glaucoma, bilateral, mild stage
H40.1232	Low-tension glaucoma, bilateral, moderate stage
H40.1233	Low-tension glaucoma, bilateral, severe stage
H40.1234	Low-tension glaucoma, bilateral, indeterminate stage
H40.1311	Pigmentary glaucoma, right eye, mild stage
H40.1312	Pigmentary glaucoma, right eye, moderate stage
H40.1313	Pigmentary glaucoma, right eye, severe stage
H40.1314	Pigmentary glaucoma, right eye, indeterminate stage
H40.1321	Pigmentary glaucoma, left eye, mild stage
H40.1322	Pigmentary glaucoma, left eye, moderate stage
H40.1323	Pigmentary glaucoma, left eye, severe stage
H40.1324	Pigmentary glaucoma, left eye, indeterminate stage
H40.1331	Pigmentary glaucoma, bilateral, mild stage
H40.1332	Pigmentary glaucoma, bilateral, moderate stage
H40.1333	Pigmentary glaucoma, bilateral, severe stage

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ICD-10-CM Diagnosis Codes	Description
H40.1334	Pigmentary glaucoma, bilateral, indeterminate stage
H40.1411	Capsular glaucoma with pseudoexfoliation of lens, right eye, mild stage
H40.1412	Capsular glaucoma with pseudoexfoliation of lens, right eye, moderate stage
H40.1413	Capsular glaucoma with pseudoexfoliation of lens, right eye, severe stage
H40.1414	Capsular glaucoma with pseudoexfoliation of lens, right eye, indeterminate stage
H40.1421	Capsular glaucoma with pseudoexfoliation of lens, left eye, mild stage
H40.1422	Capsular glaucoma with pseudoexfoliation of lens, left eye, moderate stage
H40.1423	Capsular glaucoma with pseudoexfoliation of lens, left eye, severe stage
H40.1424	Capsular glaucoma with pseudoexfoliation of lens, left eye, indeterminate stage
H40.1431	Capsular glaucoma with pseudoexfoliation of lens, bilateral, mild stage
H40.1432	Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage
H40.1433	Capsular glaucoma with pseudoexfoliation of lens, bilateral, severe stage
H40.1434	Capsular glaucoma with pseudoexfoliation of lens, bilateral, indeterminate stage
H40.151	Residual stage of open-angle glaucoma, right eye
H40.152	Residual stage of open-angle glaucoma, left eye
H40.153	Residual stage of open-angle glaucoma, bilateral
H40.211	Acute angle-closure glaucoma, right eye
H40.212	Acute angle-closure glaucoma, left eye
H40.213	Acute angle-closure glaucoma, bilateral
H40.2211	Chronic angle-closure glaucoma, right eye, mild stage
H40.2212	Chronic angle-closure glaucoma, right eye, moderate stage
H40.2213	Chronic angle-closure glaucoma, right eye, severe stage
H40.2214	Chronic angle-closure glaucoma, right eye, indeterminate stage
H40.2221	Chronic angle-closure glaucoma, left eye, mild stage
H40.2222	Chronic angle-closure glaucoma, left eye, moderate stage
H40.2223	Chronic angle-closure glaucoma, left eye, severe stage
H40.2224	Chronic angle-closure glaucoma, left eye, indeterminate stage
H40.2231	Chronic angle-closure glaucoma, bilateral, mild stage
H40.2232	Chronic angle-closure glaucoma, bilateral, moderate stage
H40.2233	Chronic angle-closure glaucoma, bilateral, severe stage
H40.2234	Chronic angle-closure glaucoma, bilateral, indeterminate stage
H40.231	Intermittent angle-closure glaucoma, right eye
H40.232	Intermittent angle-closure glaucoma, left eye
H40.233	Intermittent angle-closure glaucoma, bilateral

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ICD-10-CM Diagnosis Codes	Description
H40.241	Residual stage of angle-closure glaucoma, right eye
H40.242	Residual stage of angle-closure glaucoma, left eye
H40.243	Residual stage of angle-closure glaucoma, bilateral
H40.31X1	Glaucoma secondary to eye trauma, right eye, mild stage
H40.31X2	Glaucoma secondary to eye trauma, right eye, moderate stage
H40.31X3	Glaucoma secondary to eye trauma, right eye, severe stage
H40.31X4	Glaucoma secondary to eye trauma, right eye, indeterminate stage
H40.32X1	Glaucoma secondary to eye trauma, left eye, mild stage
H40.32X2	Glaucoma secondary to eye trauma, left eye, moderate stage
H40.32X3	Glaucoma secondary to eye trauma, left eye, severe stage
H40.32X4	Glaucoma secondary to eye trauma, left eye, indeterminate stage
H40.33X1	Glaucoma secondary to eye trauma, bilateral, mild stage
H40.33X2	Glaucoma secondary to eye trauma, bilateral, moderate stage
H40.33X3	Glaucoma secondary to eye trauma, bilateral, severe stage
H40.33X4	Glaucoma secondary to eye trauma, bilateral, indeterminate stage
H40.41X1	Glaucoma secondary to eye inflammation, right eye, mild stage
H40.41X2	Glaucoma secondary to eye inflammation, right eye, moderate stage
H40.41X3	Glaucoma secondary to eye inflammation, right eye, severe stage
H40.41X4	Glaucoma secondary to eye inflammation, right eye, indeterminate stage
H40.42X1	Glaucoma secondary to eye inflammation, left eye, mild stage
H40.42X2	Glaucoma secondary to eye inflammation, left eye, moderate stage
H40.42X3	Glaucoma secondary to eye inflammation, left eye, severe stage
H40.42X4	Glaucoma secondary to eye inflammation, left eye, indeterminate stage
H40.43X1	Glaucoma secondary to eye inflammation, bilateral, mild stage
H40.43X2	Glaucoma secondary to eye inflammation, bilateral, moderate stage
H40.43X3	Glaucoma secondary to eye inflammation, bilateral, severe stage
H40.43X4	Glaucoma secondary to eye inflammation, bilateral, indeterminate stage
H40.51X1	Glaucoma secondary to other eye disorders, right eye, mild stage
H40.51X2	Glaucoma secondary to other eye disorders, right eye, moderate stage
H40.51X3	Glaucoma secondary to other eye disorders, right eye, severe stage
H40.51X4	Glaucoma secondary to other eye disorders, right eye, indeterminate stage
H40.52X1	Glaucoma secondary to other eye disorders, left eye, mild stage
H40.52X2	Glaucoma secondary to other eye disorders, left eye, moderate stage
H40.52X3	Glaucoma secondary to other eye disorders, left eye, severe stage

POLICY TITLE	AQUEOUS SHUNTS AND STENTS FOR GLAUCOMA
POLICY NUMBER	MP-2.149

ICD-10-CM Diagnosis Codes	Description
H40.52X4	Glaucoma secondary to other eye disorders, left eye, indeterminate stage
H40.53X1	Glaucoma secondary to other eye disorders, bilateral, mild stage
H40.53X2	Glaucoma secondary to other eye disorders, bilateral, moderate stage
H40.53X3	Glaucoma secondary to other eye disorders, bilateral, severe stage
H40.53X4	Glaucoma secondary to other eye disorders, bilateral, indeterminate stage
H40.61X1	Glaucoma secondary to drugs, right eye, mild stage
H40.61X2	Glaucoma secondary to drugs, right eye, moderate stage
H40.61X3	Glaucoma secondary to drugs, right eye, severe stage
H40.61X4	Glaucoma secondary to drugs, right eye, indeterminate stage
H40.62X1	Glaucoma secondary to drugs, left eye, mild stage
H40.62X2	Glaucoma secondary to drugs, left eye, moderate stage
H40.62X3	Glaucoma secondary to drugs, left eye, severe stage
H40.62X4	Glaucoma secondary to drugs, left eye, indeterminate stage
H40.63X1	Glaucoma secondary to drugs, bilateral, mild stage
H40.63X2	Glaucoma secondary to drugs, bilateral, moderate stage
H40.63X3	Glaucoma secondary to drugs, bilateral, severe stage
H40.63X4	Glaucoma secondary to drugs, bilateral, indeterminate stage
H40.811	Glaucoma with increased episcleral venous pressure, right eye
H40.812	Glaucoma with increased episcleral venous pressure, left eye
H40.813	Glaucoma with increased episcleral venous pressure, bilateral
H40.821	Hypersecretion glaucoma, right eye
H40.822	Hypersecretion glaucoma, left eye
H40.831	Aqueous misdirection, right eye
H40.832	Aqueous misdirection, left eye
H40.833	Aqueous misdirection, bilateral
H40.89	Other specified glaucoma

IX. REFERENCES

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X. POLICY HISTORY

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MP-2.149	**CAC 5/25/10** New policy. BCBSA was adopted.
	CAC 4/26/11 Consensus
	CAC 11/22/11 Minor revision. Added a statement that canaloplasty may be considered medically necessary to reduce intraocular pressure in patient with glaucoma for specific indications. Previously, canaloplasty was investigational for all indications. Viscocanaloplasty was added as investigational.
	02/25/13 Unspecified codes removed from policy, codes reviewed
	05/13/13 Administrative code review complete.
	CAC 6/4/13 Minor revision. Title changed: Aqueous Shunts and Stents for Glaucoma (formerly Aqueous Shunts and Devices for Glaucoma) A statement was added that use of a micro-stent is considered investigational. Extracted information regarding Viscocanalostomy and Canaloplasty and a separate policy created. See MP 2.117. Added Medicare variation to reference LCD L31686.
	CAC 1/28/14 Minor revision. A policy statement was added that **i**mplantation of a single FDA-approved micro-stent in conjunction with cataract surgery may be considered medically necessary in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. Use of a micro-stent for all other conditions is considered investigational. References and rationale updated. New 2014 codes added to policy, removed 0192T as deleted.
	CAC 1/27/15 Consensus review. No changes to the policy statements. References and rationale updated.

	CAC 12/31/14 Coding updated/reviewed but no changes.
	01/2015- New 2015 CPT code added to policy.
	11/2/15 Administrative change. LCD number changed from L34355 to L35087 due to Novitas update to ICD-10.
	CAC 1/26/16 Consensus review. No changes to the policy statements. Background, rationale, and reference update. Coding reviewed.
	9/23/16 Administrative change. Removed Medicare variation to L35087 Glaucoma Treatment with Aqueous Drainage Device – LCD was retired effective 8/11/16.
	Administrative Update 1/1/17: Added new codes 0449T-0450T, effective 1/1/17. New diagnosis codes added effective 10/1/2016. Variations reformatted.
	CAC 3/28/17 Consensus review. Information about the FDA approval of CyPass added. Summary statements revised to change "quantitatively" to "qualitatively". No changes to the policy statements. Background, references and rationale updated. Coding reviewed.
	Administrative Update 6/7/17 – Table 1 Regulatory Status of Aqueous Shunts and Stents revised to include most currently approved devices to include CyPass and XEN Gel Stent as having FDA-approval 2016**.** The regulatory status section was also updated.
	Administrative Update 7/3/17 – Added new code (0474T), effective 7/1/17.
	12/19/17 Consensus review. No change to the policy statements. Background, rationale and references updated.
	Admin posting 2/12/18. Policy statement revised. Added not to refer to the table on page 4 for a list of FDA-approved shunts**.**
	8/29/18 Consensus review. Previously, ab externo and ab interno devices were combined in one policy statement. Now there are 2 separate policy statements, one for ab externo devices and one for ab interno devices. Background and rationale revised. References updated. Appendix added which includes non-FDA approved devices.

Top

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APPENDIX

AQUEOUS SHUNTS AND STENTS NOT APPROVED BY FDA

iStent *inject*

A 2014 industry-sponsored, multicenter, unblinded, randomized trial compared implantation of 2 iStent *inject* devices with 2 ocular hypotensive agents.[47] The 192 patients enrolled in this

unmasked trial had an IOP not controlled by 1 hypotensive medication. At 12-month follow-up, the 2 groups were comparable for IOP reduction of at least 20%, IOP of 18 mm Hg or less, and mean decrease in IOP. A greater proportion of patients in the iStent *inject* group achieved an IOP reduction of at least 50% (53.2% vs 35.7%, respectively). One patient in the iStent *inject* group experienced elevated IOP (48 mm Hg) and 4 required ocular hypotensive medication. Longer term studies are in progress.

Gonnermann et al (2017) conducted a study on 27 patients with moderate open-angle glaucoma and cataracts who underwent trabeculectomy in 1 eye and implantation of 2 iStent inject devices in the other eye.[48] Outcomes of interest were IOP and glaucoma medication use through 12 months of follow-up. Mean IOP and number of antiglaucoma medications decreased significantly with both treatments. There was no statistically significant difference in outcomes between groups, supporting the noninferiority of the iStent *inject* to trabeculectomy.

Two case series evaluating the use of 2 iStent *inject* devices for treatment of patients with uncontrolled open-angle glaucoma in stand-alone procedures were published in 2017.[49,50] Berdahl et al (2017) treated 53 patients and reported that 91% of patients achieved an IOP reduction of at least 20% at the 12-month follow-up.[49] Chang et al (2017) treated 39 patients and reported that 97% of patients achieved an IOP reduction of at least 20% after 3 years of follow-up. No device-related adverse events were reported in either study.

iStent *supra*

Myers et al (2018) presented 4-year outcomes of a single-arm study implanting 2 iStent trabecular micro-bypass stents and 1 iStent *supra* suprachoroidal stent in 80 patients with refractory glaucoma.[51] At 4-years follow-up, patients experienced a 37% or more mean reduction in IOP. All patients received travoprost following the procedure, with 6 patients requiring additional medication when IOP exceeded 21 mm Hg. No intraoperative adverse events were reported.

Hydrus Microstent

Pfeiffer et al (2015) reported on a single-masked, randomized trial with 100 patients (100 eyes) that compared the effectiveness of the Hydrus Microstent plus cataract surgery with cataract surgery alone.[52] At the 24-month follow-up, the proportion of patients with a 20% reduction in IOP was significantly higher with the Hydrus Microstent (80% vs 46%, $p<0.001$) and the mean IOP after medication washout was lower (16.9 mm Hg vs 19.2 mm Hg, $p=0.009$) compared with cataract surgery alone, respectively. The microstent group used significantly fewer medications (0.5 vs 1.0, $p=0.019$) and had a higher proportion of patients taking no hypotensive medications at the time of cataract surgery (73% vs 38%, $p=0.001$).

Fea et al (2017) conducted a 2-center study in which 56 patients with uncontrolled primary open-angle glaucoma received either laser trabeculoplasty or a Hydrus Microstent, depending on the center at which the patient was seen.[53] Patients were followed for 12 months postsurgery and evaluated for IOP and glaucoma medication use. Both treatments resulted in significant reductions in IOP; however, only patients receiving the microstent experienced significant

reductions in medication use. No complications were reported in the trabeculoplasty group. In the microstent group, temporary reductions in visual acuity and IOP spikes occurred.

SOLX Gold Shunt

Tanito et al (2017) published results from a 2-center single-arm study in which 24 patients with refractory open-angle glaucoma received the SOLX Gold Shunt.[54] Outcomes evaluated at baseline through 1 year of follow-up included medication use, IOP, and surgical complications. IOP was significantly reduced at every follow-up visit, with an average 23% reduction from baseline at 1-year follow-up ($p<0.001$). Patients also experienced a 40% reduction in medication use at 1-year follow-up from baseline ($p<0.001$). Inflammation-related complications were reported.