



MASSACHUSETTS

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## Medical Policy

### Aqueous Shunts and Stents for Glaucoma

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#### Policy Number: 223

BCBSA Reference Number: 9.03.21 (For Plan internal use only)

#### Related Policies

- Ophthalmologic Techniques that Evaluate the Posterior Segment for Glaucoma, #[053](#)
- Visco canalostomy and Canaloplasty, #[372](#)

#### Policy

##### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Insertion of ab externo aqueous stents approved by the U.S. Food and Drug Administration may be considered **MEDICALLY NECESSARY** as a method to reduce intraocular pressure in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure.

Use of an ab externo aqueous shunt for all other conditions, including in individuals with glaucoma when intraocular pressure is adequately controlled by medications, is considered **INVESTIGATIONAL**.

Insertion of ab interno aqueous stents approved by the Food and Drug Administration as a method to reduce intraocular pressure in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure, is considered **MEDICALLY NECESSARY**.

Implantation of 1 or 2 Food and Drug Administration-approved interno stents in conjunction with cataract surgery may be considered **MEDICALLY NECESSARY** in individuals with mild- to-moderate open-angle glaucoma treated with ocular hypotensive medication.

Use of ab interno stents for all other conditions is considered **INVESTIGATIONAL**.

#### Prior Authorization Information

##### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

##### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	<b>Outpatient</b>
<b>Commercial Managed Care (HMO and POS)</b>	Prior authorization is <b>not required</b> .
<b>Commercial PPO and Indemnity</b>	Prior authorization is <b>not required</b> .

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

#### CPT Codes

<b>CPT codes:</b>	<b>Code Description</b>
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; into the subarachnoid space
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft
66180	Aqueous shunt to extraocular reservoir (eg, Molteno, Schocket, Denver-Krupin) with graft
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

#### HCPCS Codes

<b>HCPCS codes:</b>	<b>Code Description</b>
C1783	Ocular implant, aqueous drainage assist device

L8612	Aqueous shunt
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The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and/or HCPCS codes above if medical necessity criteria are met:

### ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
H40.001	Preglaucoma, unspecified, right eye
H40.002	Preglaucoma, unspecified, left eye
H40.003	Preglaucoma, unspecified, bilateral
H40.009	Preglaucoma, unspecified, unspecified eye
H40.011	Open angle with borderline findings, low risk, right eye
H40.012	Open angle with borderline findings, low risk, left eye
H40.013	Open angle with borderline findings, low risk, bilateral
H40.019	Open angle with borderline findings, low risk, unspecified eye
H40.021	Open angle with borderline findings, high risk, right eye
H40.022	Open angle with borderline findings, high risk, left eye
H40.023	Open angle with borderline findings, high risk, bilateral
H40.029	Open angle with borderline findings, high risk, unspecified eye
H40.031	Anatomical narrow angle, right eye
H40.032	Anatomical narrow angle, left eye
H40.033	Anatomical narrow angle, bilateral
H40.039	Anatomical narrow angle, unspecified eye
H40.041	Steroid responder, right eye
H40.042	Steroid responder, left eye
H40.043	Steroid responder, bilateral
H40.049	Steroid responder, unspecified eye
H40.051	Ocular hypertension, right eye
H40.052	Ocular hypertension, left eye
H40.053	Ocular hypertension, bilateral
H40.059	Ocular hypertension, unspecified eye
H40.061	Primary angle closure without glaucoma damage, right eye
H40.062	Primary angle closure without glaucoma damage, left eye
H40.063	Primary angle closure without glaucoma damage, bilateral
H40.069	Primary angle closure without glaucoma damage, unspecified eye
H40.10x0	Unspecified open-angle glaucoma, stage unspecified
H40.10x1	Unspecified open-angle glaucoma, mild stage
H40.10x2	Unspecified open-angle glaucoma, moderate stage
H40.10x3	Unspecified open-angle glaucoma, severe stage
H40.10x4	Unspecified open-angle glaucoma, indeterminate stage
H40.1110	Primary open-angle glaucoma, right eye, stage unspecified
H40.1111	Primary open-angle glaucoma, right eye, mild stage
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
H40.1120	Primary open-angle glaucoma, left eye, stage unspecified
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
H40.1130	Primary open-angle glaucoma, bilateral, stage unspecified
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
H40.1190	Primary open-angle glaucoma, unspecified eye, stage unspecified
H40.1191	Primary open-angle glaucoma, unspecified eye, mild stage
H40.1192	Primary open-angle glaucoma, unspecified eye, moderate stage
H40.1193	Primary open-angle glaucoma, unspecified eye, severe stage
H40.1194	Primary open-angle glaucoma, unspecified eye, indeterminate stage
H40.1210	Low-tension glaucoma, right eye, stage unspecified
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
H40.1220	Low-tension glaucoma, left eye, stage unspecified
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
H40.1230	Low-tension glaucoma, bilateral, stage unspecified
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
H40.1290	Low-tension glaucoma, unspecified eye, stage unspecified
H40.1291	Low-tension glaucoma, unspecified eye, mild stage
H40.1292	Low-tension glaucoma, unspecified eye, moderate stage
H40.1293	Low-tension glaucoma, unspecified eye, severe stage
H40.1294	Low-tension glaucoma, unspecified eye, indeterminate stage
H40.1310	Pigmentary glaucoma, right eye, stage unspecified
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
H40.1320	Pigmentary glaucoma, left eye, stage unspecified
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
H40.1330	Pigmentary glaucoma, bilateral, stage unspecified
H40.1331	Pigmentary glaucoma, bilateral, mild stage
H40.1332	Pigmentary glaucoma, bilateral, moderate stage
H40.1333	Pigmentary glaucoma, bilateral, severe stage
H40.1334	Pigmentary glaucoma, bilateral, indeterminate stage
H40.1390	Pigmentary glaucoma, unspecified eye, stage unspecified
H40.1391	Pigmentary glaucoma, unspecified eye, mild stage
H40.1392	Pigmentary glaucoma, unspecified eye, moderate stage
H40.1393	Pigmentary glaucoma, unspecified eye, severe stage
H40.1394	Pigmentary glaucoma, unspecified eye, indeterminate stage

H40.1410	Capsular glaucoma with pseudoexfoliation of lens, right eye, stage unspecified
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
H40.1420	Capsular glaucoma with pseudoexfoliation of lens, left eye, stage unspecified
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
H40.1430	Capsular glaucoma with pseudoexfoliation of lens, bilateral, stage unspecified
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
H40.1490	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, stage unspecified
H40.1491	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, mild stage
H40.1492	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, moderate stage
H40.1493	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, severe stage
H40.1494	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, 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
H40.159	Residual stage of open-angle glaucoma, unspecified eye
H40.20x0	Unspecified primary angle-closure glaucoma, stage unspecified
H40.20x1	Unspecified primary angle-closure glaucoma, mild stage
H40.20x2	Unspecified primary angle-closure glaucoma, moderate stage
H40.20x3	Unspecified primary angle-closure glaucoma, severe stage
H40.20x4	Unspecified primary angle-closure glaucoma, indeterminate stage
H40.211	Acute angle-closure glaucoma, right eye
H40.212	Acute angle-closure glaucoma, left eye
H40.213	Acute angle-closure glaucoma, bilateral
H40.219	Acute angle-closure glaucoma, unspecified eye
H40.2210	Chronic angle-closure glaucoma, right eye, stage unspecified
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
H40.2220	Chronic angle-closure glaucoma, left eye, stage unspecified
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
H40.2230	Chronic angle-closure glaucoma, bilateral, stage unspecified
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
H40.2290	Chronic angle-closure glaucoma, unspecified eye, stage unspecified
H40.2291	Chronic angle-closure glaucoma, unspecified eye, mild stage
H40.2292	Chronic angle-closure glaucoma, unspecified eye, moderate stage

H40.2293	Chronic angle-closure glaucoma, unspecified eye, severe stage
H40.2294	Chronic angle-closure glaucoma, unspecified eye, 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
H40.239	Intermittent angle-closure glaucoma, unspecified eye
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
H40.249	Residual stage of angle-closure glaucoma, unspecified eye
H40.30x0	Glaucoma secondary to eye trauma, unspecified eye, stage unspecified
H40.30x1	Glaucoma secondary to eye trauma, unspecified eye, mild stage
H40.30x2	Glaucoma secondary to eye trauma, unspecified eye, moderate stage
H40.30x3	Glaucoma secondary to eye trauma, unspecified eye, severe stage
H40.30x4	Glaucoma secondary to eye trauma, unspecified eye, indeterminate stage
H40.31x0	Glaucoma secondary to eye trauma, right eye, stage unspecified
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
H40.32x0	Glaucoma secondary to eye trauma, left eye, stage unspecified
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
H40.33x0	Glaucoma secondary to eye trauma, bilateral, stage unspecified
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
H40.40x0	Glaucoma secondary to eye inflammation, unspecified eye, stage unspecified
H40.40x1	Glaucoma secondary to eye inflammation, unspecified eye, mild stage
H40.40x2	Glaucoma secondary to eye inflammation, unspecified eye, moderate stage
H40.40x3	Glaucoma secondary to eye inflammation, unspecified eye, severe stage
H40.40x4	Glaucoma secondary to eye inflammation, unspecified eye, indeterminate stage
H40.41x0	Glaucoma secondary to eye inflammation, right eye, stage unspecified
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
H40.42x0	Glaucoma secondary to eye inflammation, left eye, stage unspecified
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
H40.43x0	Glaucoma secondary to eye inflammation, bilateral, stage unspecified
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
H40.50x0	Glaucoma secondary to other eye disorders, unspecified eye, stage unspecified

H40.50x1	Glaucoma secondary to other eye disorders, unspecified eye, mild stage
H40.50x2	Glaucoma secondary to other eye disorders, unspecified eye, moderate stage
H40.50x3	Glaucoma secondary to other eye disorders, unspecified eye, severe stage
H40.50x4	Glaucoma secondary to other eye disorders, unspecified eye, indeterminate stage
H40.51x0	Glaucoma secondary to other eye disorders, right eye, stage unspecified
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
H40.52x0	Glaucoma secondary to other eye disorders, left eye, stage unspecified
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
H40.52x4	Glaucoma secondary to other eye disorders, left eye, indeterminate stage
H40.53x0	Glaucoma secondary to other eye disorders, bilateral, stage unspecified
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
H40.60x0	Glaucoma secondary to drugs, unspecified eye, stage unspecified
H40.60x1	Glaucoma secondary to drugs, unspecified eye, mild stage
H40.60x2	Glaucoma secondary to drugs, unspecified eye, moderate stage
H40.60x3	Glaucoma secondary to drugs, unspecified eye, severe stage
H40.60x4	Glaucoma secondary to drugs, unspecified eye, indeterminate stage
H40.61x0	Glaucoma secondary to drugs, right eye, stage unspecified
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
H40.62x0	Glaucoma secondary to drugs, left eye, stage unspecified
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
H40.63x0	Glaucoma secondary to drugs, bilateral, stage unspecified
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
H40.819	Glaucoma with increased episcleral venous pressure, unspecified eye
H40.821	Hypersecretion glaucoma, right eye
H40.822	Hypersecretion glaucoma, left eye
H40.823	Hypersecretion glaucoma, bilateral
H40.829	Hypersecretion glaucoma, unspecified eye
H40.831	Aqueous misdirection, right eye
H40.832	Aqueous misdirection, left eye
H40.833	Aqueous misdirection, bilateral
H40.839	Aqueous misdirection, unspecified eye

H40.89	Other specified glaucoma
H40.9	Unspecified glaucoma
H42	Glaucoma in diseases classified elsewhere
Q15.0	Congenital glaucoma

The following CPT code is considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

### CPT Codes

CPT codes:	Code Description
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space

The following CPT codes are considered investigational for **Medicare HMO Blue and Medicare PPO Blue:**

### CPT Codes

CPT codes:	Code Description
0376T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion (List separately in addition to code for primary procedure)
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)

## Description

### 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.<sup>1</sup> 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 ~~evidence review 9.03.26~~ policy #372). 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 policy #372).

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 externo devices are the Ahmed, Baerveldt, and EX-PRESS shunts. 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, 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 may also be possible to insert more than 1 stent to achieve desired IOP.

## Summary

### 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 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. Randomized controlled trials assessing 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 an improvement in the net health outcome.

For individuals who have refractory OAG who receive ab interno aqueous stents, the evidence includes systematic reviews, 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 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 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.

## Policy History

Date	Action
11/2022	Annual policy review. Description, summary, and references updated. Minor editorial refinements to policy statements; intent unchanged.
1/2022	Clarified coding information.
10/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
11/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2019	Annual policy review. New medically necessary indications described. The use of FDA-approved stent in a stand-alone procedure to reduce IOP pressure is medically necessary. Policy edited to clarify the differences between ab externo shunts and ab interno stents. Clarified coding information. References updated. Effective 5/1/2019.
7/2018	Annual policy review. Policy statements clarified, 2 separate policy statements, one for ab externo devices and one for ab interno devices.
1/2018	Annual policy review. The term “aqueous shunts” modified with “ab externo” and “ab interno” in the Background section.
7/2017	Clarified coding information.
5/2017	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2016	Annual policy review. Summary statements revised to change “quantitatively” to “qualitatively.” Coding information clarified.
4/2016	Annual policy review. New references added.
11/2015	Annual policy review. New references added.
1/2015	Clarified coding information.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
3/2014	Annual policy review. New medically necessary indications described. Effective 3/1/2014.
1/2014	Updated to add new CPT code 66183 and remove deleted code 0192T.
11/2013	Added CPT code 66180 as it meets the intent of the policy.
6/2013	Annual policy review. New investigational indications described. Effective 6/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
3/2011	Updated to add new CPT Code 66175.
2/2011	Reviewed - Medical Policy Group – Psychiatry and Ophthalmology. No changes to policy statements.
8/1/2010	Medical Policy #223 effective 8/1/2010 created.

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