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Subject: Aqueous Shunts and Stents for Glaucoma

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DESCRIPTION:

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.

First-line treatment typically involves pharmacologic therapy. Topical medications either increase 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 adults.

Surgical intervention may be indicated in individuals 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 (eg, hemorrhage, scarring, hypotony, infection, leaks, bleb-related endophthalmitis) and long-term failure. Other surgical procedures include trabecular laser ablation, and deep sclerectomy (which removes the outer wall of the Schlemm canal and excises deep sclera and peripheral cornea).

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 to a trabeculectomy. MIGS can either be performed outside the eye (ab externo) or inside the eye (ab interno).

POSITION STATEMENT:

Insertion of the AquaFlow™ Collagen Glaucoma Drainage Device **meets the definition of medical necessity** when used for the maintenance of the subscleral space following non-penetrating deep sclerectomy.

Insertion of **ab externo** aqueous shunts approved by the U.S. Food and Drug Administration (FDA) (Ahmed™, Baerveldt®, Krupin, Molteno®, Ex-PRESS™) **meets the definition of medical necessity** as a method to reduce intraocular pressure in individuals with glaucoma where medications have 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 **experimental or investigational**.

Insertion of **ab interno** aqueous stents approved by the U.S. Food and Drug Administration (FDA) (iStent®, iStent inject®, XEN® Gel, XEN® injector, Hydrus™) as a method to reduce intraocular pressure in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure, **meets the definition of medical necessity**.

Implantation of 1 or 2 ab interno aqueous stents approved by the U.S. Food and Drug Administration (FDA) (iStent®, iStent inject®, XEN® Gel, XEN® injector, Hydrus™), in conjunction with cataract surgery also **meets the definition of medical necessity** 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 **experimental or investigational**.

Use of an ab interno suprachoroidal shunt or stent (iStent supra®, CyPass®) is considered **experimental or investigational**.

BILLING/CODING INFORMATION:

CPT Coding:

66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach, with graft
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir, with graft
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; initial insertion
0253T	Insertion of anterior segment aqueous drainage device, without extraocular

	reservoir; internal approach, into the suprachoroidal space (investigational)
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)
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)
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space (investigational)

ICD-10 Diagnosis Codes That Support Medical Necessity:

H40.10X0 – H40.10X4	Unspecified open-angle glaucoma
H40.1110 – H40.1194	Primary open-angle glaucoma, staged
H40.1210 – H40.1294	Low-tension glaucoma
H40.1310 – H40.1394	Pigmentary glaucoma
H40.1410 – H40.1494	Capsular glaucoma with pseudoexfoliation of lens
H40.151 – H40.159	Residual stage of open-angle glaucoma
H40.20X0 – H40.20X4	Unspecified primary angle-closure glaucoma
H40.211 – H40.219	Acute angle-closure glaucoma
H40.2210 – H40.2294	Chronic angle-closure glaucoma
H40.231 – H40.239	Intermittent angle-closure glaucoma
H40.241 – H40.249	Residual stage of angle-closure glaucoma
H40.30X0 – H40.33X4	Glaucoma secondary to eye trauma
H40.40X0 – H40.43X4	Glaucoma secondary to eye inflammation
H40.50X0 – H40.53X4	Glaucoma secondary to other eye disorders
H40.60X0 – H40.63X4	Glaucoma secondary to drugs
H40.811 – H40.819	Glaucoma with increased episcleral venous pressure
H40.821 – H40.829	Hypersecretion glaucoma
H40.831 – H40.839	Aqueous misdirection
H40.89	Other specified glaucoma
H40.9	Unspecified glaucoma
H42	Glaucoma in diseases classified elsewhere
Q15.0	Congenital glaucoma

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT.**

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Non-covered Services (L33777) located at fcso.com.

DEFINITIONS:

Ab externo: outside the eye (non-penetrating).

Ab interno: inside the eye (penetrating).

RELATED GUIDELINES:

[01-92000-17, Scanning Computerized Ophthalmic Diagnostic Imaging](#)

OTHER:

Index terms:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

AquaFlow™ collagen drainage device (FDA-approved for maintenance of the subscleral space following non-penetrating deep sclerectomy)

Ahmed™ aqueous shunt (ab externo)

Baerveldt® aqueous shunt (ab externo)

Krupin aqueous shunt (ab externo)

Molteno® aqueous shunt (ab externo)

Ex-PRESS™ mini-shunt (ab externo)

iStent® microstent (ab interno)

iStent inject® microstent (ab interno)

iStent supra® (suprachoroidal stent) (not FDA approved as of last guideline review date)

CyPass® micro-stent (suprachoroidal, ab interno) (voluntarily recalled by manufacturer as of last guideline review date)

XEN® Gel aqueous stent (ab interno)

XEN® injector aqueous stent (ab interno)

Hydrus™ microstent (ab interno)

SOLX® Gold microshunt (ab externo) (not FDA approved as of last guideline review date)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 03/28/19.

GUIDELINE UPDATE INFORMATION:

01/15/13	New Medical Coverage Guideline.
11/15/13	Scheduled review. Revised description section, position statement, program exceptions section and index terms. Updated references and reformatted guideline.
01/01/14	Annual CPT update. Added 66183; deleted 0192T.
05/15/14	Revision; updated position statement. Revised CPT coding and index terms. Updated references and reformatted guideline.
09/15/14	Scheduled review. Position statement maintained. Revised CPT, ICD9 and ICD10 coding. Updated references. Reformatted guideline.
01/01/15	Annual CPT/HCPCS update. Added 66179, 66184, 0376T. Revised 66180, 66185, 0191T descriptors.
09/15/15	Scheduled review. Position statement maintained. Updated references.
11/01/15	Revision: ICD-9 Codes deleted.
08/15/16	Scheduled review. Maintained position statement. Revised description section and index terms. Updated references.
10/01/16	ICD-10 coding update: deleted codes H40.11X0 – H40.11X4; added codes H40.1110 – H40.1194 and H40.40X0 – H40.43X4.
01/01/17	Annual CPT/HCPCS update. Added 0449T, 0450T.
07/01/17	Quarterly CPT/HCPCS update. Added code 0474T. Reformatted guideline.
08/15/17	Scheduled review. Revised description. Added clarification regarding micro-stent coverage. Revised index terms. Updated references.
12/15/17	Unscheduled review. Maintained position statement and updated references.
08/15/18	Scheduled review. Revised description, definitions, and index terms. Maintained position statement and updated references.
04/15/19	Scheduled review. Revised description, position statement and index terms. Updated references.