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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).

Summary and Analysis of Evidence: Evidence for the use of ab externo aqueous shunts for the treatment of OAG uncontrolled by medications includes RCTs comparing shunts with trabeculectomy [Wagschal et al (2015); Gonzalez-Rodriguez et al (2016); Konopinska et al (2021)]. Outcomes of interest are IOP and anti-glaucoma medication use. Follow-up among the trials ranged from 1 to 5 years. Results from ab externo aqueous shunts are similar to trabeculectomy, while adverse event rates were higher among patients undergoing trabeculectomy. The comparative effectiveness of 2 ab externo devices (the Ahmed and Baerveldt shunts) has been evaluated in 2 trials, the AVB trial [Christakis et al (2016)] and the ABC trial [Budenz, Barton et al (2015); Budenz, Feuer et al (2016)]. These trials reported similar results, with both devices lowering IOP significantly. Compared with patients receiving the Ahmed shunt, patients receiving the Baerveldt shunt experienced lower IOP and needed fewer medications. However, patients receiving the Baerveldt shunt experienced higher rates of hypotony-related complications.

Clearance for the XEN gel stent as a stand-alone procedure 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. Evidence for the use of the XEN implant includes systematic reviews [Lim et al (2022); Yang et al (2022)], an RCT [Sheybani et al (2023)], and non-randomized comparative studies [Wagner et al, (2020); Schlenker et al (2017)], which retrospectively reviewed charts of patients either receiving the XEN implant or undergoing a trabeculectomy or implantation of an EX-PRESS shunt. The RCT found XEN45 to be noninferior to trabeculectomy. The nonrandomized comparative studies included patients with different types of glaucoma and found that patients receiving the XEN implant experienced reductions in IOP and medication use similar to patients undergoing trabeculectomy. A retrospective study compared the XEN implant with the EX-PRESS implant and found fewer adverse events in the first 3 months, but lower efficacy and higher failure rates at 1 year [Stoner et al, 2021). Although there was little information on how patients were chosen to receive the different treatments in these comparative trials, statistical methods were used to address baseline differences between the groups. The single-arm studies, with up to 3 years of follow-up, consistently show that patients receiving the XEN implant experience reductions in IOP and medication use. Randomized controlled trials with larger sample sizes and longer follow-up are needed to compare the outcomes of the different surgical treatments.

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. Randomized controlled trials [Pfeiffer et al (2015); Samuelson et al (2019)]and meta-analyses of RCTs have compared cataract surgery alone to microstent implantation in conjunction with cataract surgery when IOP is at least partially controlled with medication [Le et al (2019)]. 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

on microstents as a stand-alone procedure in patients with mild-to-moderate glaucoma that is controlled on medical therapy includes a nonrandomized study [Sarkisian et al (2023)] and RCTs [Ahmed et al (2019); Vold et al (2016)]. Two RCTs indicate that implantation of a microstent can reduce IOP at a level similar to ocular medications at 12-month follow-up.

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**. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

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**. There is insufficient published clinical evidence to support safety and effectiveness for all other conditions.

Use of an ab interno suprachoroidal shunt or stent (iStent supra®, CyPass®) is considered **experimental or investigational**, as there is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

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
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the suprachoroidal space **(investigational)**
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)**
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more

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 Determinations (LCDs) were reviewed on the last guideline reviewed date: Micro-Invasive Glaucoma Surgery (MIGS) (L38233), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

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)

XEN® Gel aqueous stent (ab interno)

XEN® injector aqueous stent (ab interno)

Hydrus™ microstent (ab interno)

SOLX® Gold microshunt (ab externo)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/27/24.

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.
04/15/20	Scheduled review. Maintained position statement and updated references.
06/15/21	Scheduled review. Maintained position statement and updated references.
01/01/22	Annual CPT/HCPCS coding update. Added 0671T. Deleted 0191T, 0376T.
05/22/23	Update to Program Exceptions section.
08/15/23	Scheduled review. Maintained position statement and updated references.
07/15/24	Scheduled review. Revised description. Maintained position statement and updated references.