Oscar Clinical Guideline: Glaucoma Surgery (CG034, Ver. 9)

Glaucoma Surgery

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Glaucoma is a medical condition where increased eye pressure on the optic nerve responsible for vision leads to peripheral vision loss and can ultimately lead to blindness. It is the leading cause of blindness in people over the age of 60. The most common subtype is called open-angle glaucoma, where the optic nerve is gradually damaged. This was historically thought to be a result of the gradual buildup of intraocular pressure due to problems with the drainage system of the eye. More recently, it has been better defined as progressive atrophy of the optic nerve head with or without elevated intraocular pressure. The second subtype is angle-closure glaucoma, where the drainage system is completely and often acutely blocked, resulting in a more rapid increase in pressure and sudden-onset symptoms. Most people with glaucoma are not aware of the symptoms until the disease has progressed significantly. Diagnosis is usually performed by an ophthalmologist and at-risk patients may require regular screening exams. For most patients, treatment with oral and/or topical medications is adequate to control the intraocular pressure, however some patients may require more aggressive primary therapies. For patients who continued to have elevated pressure despite appropriate medical therapy, a number of surgical or minimally invasive options are available for treatment. This guideline provides clinical criteria, exclusions, and details for the surgical and minimally invasive treatment of glaucoma. These procedures should be performed by a licensed ophthalmologist with expertise in the selected procedure.

Definitions

"Intraocular Pressure" (i.e., IOP) is the pressure that is generated by the fluid inside of the eye known as "Aqueous Humor."

"Trabecular Meshwork" is a structure in the anterior portion of the eye that drains the aqueous humor via a structure called Schlemm's canal and into the general blood circulation.

"Optic Nerve" is the nerve responsible for vision. When compressed or damaged, visual loss may occur.

"Glaucoma" is an irreversible condition where damage occurs to the optic nerve resulting in visual impairment. Risk factors include increased intraocular pressure, obesity, high blood pressure, and family history. There are different types of glaucoma (e.g., open-angle, closed-angle, secondary glaucoma). Open-angle glaucoma (most common) is thought to occur when the fluid in the eye drains through the trabecular network too slowly, resulting in slow increase in pressure, although it can be associated with normal intraocular pressures as well. Acute-angle glaucoma occurs when the iris blocks the trabecular meshwork, resulting in rapid increase in pressure and more sudden and severe symptoms. The specific treatments for each type of glaucoma differ, however, the goal is to reduce intraocular pressure in both and treat any other underlying conditions.

"American Academy of Ophthalmology Glaucoma Severity Scale", which provides guidance in determining the appropriate treatment interventions (medical vs. surgical) to control intraocular pressure:

- Mild: Optic nerve abnormalities consistent with glaucoma and a normal visual field as tested with standard automated perimetry
- Moderate: Optic nerve abnormalities consistent with glaucoma and visual field abnormalities in one hemifield that are not within 5 degrees of fixation as tested with standard automated perimetry
- Severe: Optic nerve abnormalities consistent with glaucoma and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with standard automated perimetry

"Trabeculoplasty" is a laser treatment for open-angle glaucoma where the structure of the trabecular meshwork is disrupted to improve drainage of aqueous humor, most often using an argon laser ("Argon Laser Trabeculoplasty" or "ALT"). It can also be performed as "selective laser trabeculoplasty" or "SLT", where a different type of laser is used that is considered to cause less scarring inside the eyeball.

"Trabeculectomy" is a surgical procedure similar to trabeculoplasty, except that instead of laser treatment, a small part of the trabecular meshwork is surgically opened so that the fluid can exit the intraocular system and drain into a subconjunctival bleb.

"Ab interno trabeculotomy" is a surgical procedure where a small portion of the trabecular meshwork is surgically ablated to improve the outflow of intraocular fluid.

"Laser Iridotomy" is a laser treatment for closed or narrow acute-angle glaucoma to create a small opening in the iris to reduce the intraocular pressure.

"Laser Iridoplasty" is a procedure using laser energy to shrink the peripheral iris; also called gonioplasty.

"Iridectomy" is the surgical removal of part of the iris.

"Glaucoma Drainage Implants or Aqueous Shunts" are small implants or gel-like substances used to relieve pressure inside anterior chamber by shunting the aqueous humor elsewhere in an effort to reduce intraocular pressure.

"Canaloplasty" is considered one of the non-penetrating procedures for glaucoma, where a small incision is made and a microcatheter is inserted to open up the canal of Schlemm in order to reduce intraocular pressure.

"Viscocanalostomy" is similar to canaloplasty except that instead of a microcatheter, a viscous gel-like substance is injected to open the canal. It also differs in that the canal is only partially opened, where it is fully expanded in canaloplasty.

"Ocular Drug-Eluting Stents or Implants" include an array of procedures and devices that are implanted into or onto structures of the eye to automatically release ocular medications directly.

"Cyclodestruction" or "Cyclophotocoagulation" refers to the use of laser or endoscopic intervention to decrease the rate of aqueous fluid production through destruction of ciliary body function.

"Minimally invasive glaucoma surgery" (MIGS) refers to several newer types of glaucoma surgery that aim to be safer than traditional incisional glaucoma surgery by avoiding conjunctival dissection. Current approaches to MIGS include: increasing trabecular outflow (Trabectome, iStent, Hydrus stent, gonioscopy-assisted transluminal trabeculotomy, excimer laser trabeculotomy); reducing aqueous production (endocyclophotocoagulation); and subconjunctival filtration (XEN gel stent). Most MIGS procedures are combined with cataract surgery.

Clinical Indications

General Criteria

The Plan considers surgery or procedures medically necessary for glaucoma when ALL of the following are met:

1. The procedure or surgery is ONE of the following:
    a. Selective or argon laser trabeculoplasty; *or*
    b. Surgical trabeculoplasty; *or*
    c. Surgical trabeculectomy; *or*

d. Trabeculectomy and associated fistulization procedures, with or without stents or drainage device such as:
    i. Ahmed glaucoma valve implant; *or*
    ii. Baerveldt tube shunt; *or*
    iii. Molteno implant; *or*
    iv. XEN 45 Gel Stent / XEN Glaucoma Treatment System; *or*
e. ExPRESS mini glaucoma shunt; *or*
    i. Note: Adjunctive use of antifibrotic agents with ExPRESS mini shunt are considered medically necessary
f. Krupin-Denver eye valve; *and*

2. The member has a documented diagnosis of primary open-angle glaucoma; *and*
3. An adequate trial of first-line (e.g., latanoprost or timolol) AND second-line (e.g., brimonidine or dorzolamide) medications have failed to control intraocular pressure.
    a. Note: Members who are unlikely to be compliant with topical therapy, those with severe visual deficits at baseline, or those with specific contraindications to appropriate medication classes listed above, may qualify for laser trabeculoplasty as a first-line treatment when documented by the treating physician.

Hydrus Microstent

The Plan considers the FDA-approved Hydrus microstent with one stent per eye medically necessary when ALL of the following are met:

1. General Criteria for glaucoma (above) are met OR MCG criteria (A-0190) for cataract removal are met; *and*
2. The member has mild to moderate primary open angle glaucoma; *and*
3. Cataract in the same eye as the glaucoma; *and*
4. Current treatment with at least one ocular hypotensive medication(s); *and*
5. The Hydrus Microstent is performed simultaneous to the cataract surgery; *and*
6. None of the following contraindications have been identified:
    a. Primary or secondary angle-closure glaucoma; *or*
    b. Noticeable birth irregularities on the front of the eye; or
    c. Malignant glaucoma; *or*
    d. Neovascular glaucoma; *or*
    e. Traumatic glaucoma; *or*
    f. Uveitic glaucoma or inflammation of eye tissue (uvea).

iStent Procedure

The Plan considers the FDA-approved original iStent Trabecular Micro-Bypass model (Models GTS100R and GTS100L) with one stent per eye medically necessary when ALL of the following are met:

1. General Criteria for glaucoma (above) are met OR MCG criteria (A-0190) for cataract removal are met; *and*
2. The member has mild to moderate primary open angle glaucoma; *and*

3. Cataract in the same eye as the glaucoma; *and*
4. Current treatment with at least one ocular hypotensive medication(s); *and*
5. The iStent Procedure is performed simultaneous to the cataract surgery; *and*
6. None of the following contraindications have been identified:
    a. Primary or secondary angle-closure glaucoma; *or*
    b. Neovascular glaucoma; *or*
    c. Retrobulbar tumor; *or*
    d. Thyroid eye disease; *or*
    e. Sturge-Weber syndrome or port-wine stain involving the eye.

The Plan considers the FDA-approved second generation model iStent Inject Trabecular Micro-Bypass G2 (Model G2-M-IS) for two stents per eye medically necessary when ALL of the following are met:

1. General Criteria for glaucoma (above) are met OR MCG criteria (A-0190) for cataract removal are met; *and*
2. The member has mild to moderate primary open angle glaucoma; *and*
3. Cataract in the same eye as the glaucoma; *and*
4. Current treatment with at least one ocular hypotensive medication(s); *and*
5. The iStent Procedure is performed simultaneous to the cataract surgery; *and*
6. None of the following contraindications have been identified:
    a. Primary or secondary angle-closure glaucoma; *or*
    b. Quick or sudden increase in eye pressure; *or*
    c. Inflammation of the eye tissue (uvea); *or*
    d. Malignant or neovascular glaucoma (a severe form of glaucoma that is characterized by an abnormal growth of new blood vessels in the eye); *or*
    e. Noticeable birth irregularities on the front of the eye; *or*
    f. Orbital tumor (tumor in the eye socket); *or*
    g. Thyroid eye disease; *or*
    h. Sturge-Weber Syndrome (neurological/nerve disorder marked by a distinctive port-wine stain on the forehead, scalp or around the eye); *or*
    i. Any other type of condition that may cause elevated pressure in the veins of the eye (episcleral venous pressure)

XEN 45 Gel Stent / XEN Glaucoma Treatment System

The member has refractory primary open-angle glaucoma, pseudoexfoliative or pigmentary glaucoma (PEX) with open angles that are unresponsive to alternative treatment as defined by:

1. The failure, intolerance or contraindication to conventional medical (maximum tolerated medical therapy of ocular hypotensive medications) and surgical treatment for reduction of intraocular pressure; *and*
2. No more than one XEN 45 Gel Stent per eye.

For the following procedures, the member meets medical necessity when the member meets the criteria below (General Criteria not required):

Canaloplasty

The Plan considers canaloplasty (ab externo) medically necessary when ALL of the following are met:

1. An adequate trial of first-line (e.g. latanoprost or timolol) AND second-line (e.g. brimonidine or dorzolamide) medications have failed to control intraocular pressure; *and*
2. The member is not a candidate for the above medically necessary procedures (a-h) due to specific contraindications, is high-risk due to other comorbidities, or has an anatomical abnormality; *and*
3. The procedure is performed by a physician with expertise in the procedure and the appropriate instrumentation.
4. None of the following contraindications have been identified:
    a. Chronic angle closure; *or*
    b. Narrow angles; *or*
    c. Angle recession; *or*
    d. Neovascular glaucoma; *or*
    e. Ocular hypertension due to increased episcleral venous pressure; *or*
    f. Previous surgery that precludes Schlemm's canal cannulation such as trabeculectomy, trabeculotomy, goniotomy, and argon laser trabeculoplasty.

Cyclophotocoagulation

The Plan considers cyclophotocoagulation (either transscleral CPC or endoscopic) medically necessary when at least ONE of the following criteria are met:

1. Member is a poor candidate for glaucoma filtration surgery or drainage implant due to comorbidities or contraindications; *or*
2. Pain relief is desired due to elevated IOP in a blind, painful eye; *or*
3. Elevated IOP in an eye with poor vision or poor visual potential; *or*
4. Glaucoma refractory to first and second line treatment as defined in General Criteria above.

Laser (nd:YAG) Iridotomy

The Plan considers thermal or laser (nd:YAG) iridotomy medically necessary when at least ONE of the following criteria is met:

1. Treatment of an eye with acute angle closure glaucoma, acute angle closure crisis, or primary chronic angle closure; *or*
2. Treatment of the contralateral eye when the other eye has had an episode of angle closure AND the chamber angle is anatomically narrow in the contralateral eye; *or*
3. Treatment of an eye with symptoms of intermittent angle closure AND gonioscopy demonstrates an anatomically narrow chamber angle.

Laser Iridoplasty and Surgical Iridectomy

The Plan considers laser iridoplasty or surgical iridectomy medically necessary when at least ONE of the following criteria is met:

1. Treatment of an eye with acute angle closure crisis (AACC) when laser iridotomy is not possible; *or*
2. Treatment of an eye with AACC that cannot be medically broken.

Experimental or Investigational / Not Medically Necessary

The Plan does NOT consider medically necessary procedures or surgeries which are experimental, unproven, or investigational, including, but not limited to, the following:

1. Transciliary filtration (e.g. Fugo Blade, Singh Filtration)
    a. *Rationale:* The evidence for the Singh Filtration procedure and the updated version (Fugo Blade) are limited to case series and reports on feasibility by the primary author. Further large-scale, randomized trials with long-term outcomes and comparison to validated techniques are required to guide clinical implementation.
2. Glaucoma drainage devices or stents that are not FDA approved, including, but not limited to, the following:
    a. EyePass Glaucoma Implant
    b. DeepLight SOLX Gold Shunt
    c. iStent G3 Supra
    d. STARflo
    e. Aquashunt
3. Any drug-eluting implant or stent, including but not limited to the following, as they lack FDA-approval and there is insufficient peer-reviewed evidence for use in glaucoma:
    a. OTX-DP
    b. Bimatoprost SR
    c. Travoprost XR
    d. MicroPump
4. Durysta (Allergan) Implant for Treatment of Glaucoma
    a. As per Hayes, there is a lack of clinical studies, systematic reviews, or practice guidelines to support Durysta (Allergan) Implant for reducing intraocular pressure (IOP) in glaucoma patients. Allergan has received FDA approval in 2020.
5. Beta radiation
    a. *Rationale:* Kirwan et al (2009) performed a Cochrane review on beta radiation during trabeculectomy and found 4 trials randomizing 551 total patients. They concluded that there was a lower risk of failure but higher rates of cataract formation, and that direct comparisons to antimetabolite treatment were needed. Dhalia et al (2016) performed this direct comparison of beta radiation vs. 5-FU in 301 randomized patients in an African population and found "no evidence of an important difference between the use

of 5FU and beta radiation…". Further, large-scale, randomized trials are needed to confirm any potential benefit with beta radiation in this setting.

6. Ab interno trabeculectomy (e.g., Trabectome)
    a. *Rationale:* The literature on the efficacy, safety, and long-term outcomes of trabectome is insufficient and limited to case reports and small retrospective reviews. Kaplowitz et al (2016) performed a systematic review of 17 studies (12 case series, 5 retrospective) looking at ab interno trabeculectomy. 14 of the studies met the inclusion criteria. Average success rates ranged from 12-80%. At the present time, further evidence with prospective, large, randomized trials is required to determine the clinical application of this technique. Furthermore, the FDA has not approved the Trabectome for use in glaucoma and issued a warning letter to the company in 2014 regarding this application.[73-78]
7. Subconjunctival antivascular endothelial growth factor injections to control wound healing
    a. *Rationale:* The clinical efficacy of these injections has not yet been established, limiting clinical use to the experimental and investigational setting.
8. Viscocanalostomy
    a. *Rationale:* There is a general lack of long-term randomized data on this procedure, and many of the existing studies demonstrate inferior efficacy in lowering IOP. Kobayashi et al (2003) compared viscocanalostomy and trabeculectomy on lowering intraocular pressure in 25 patients with primary open-angle glaucoma, and found that viscocanalostomy had fewer complications but was inferior at lowering IOP. They concluded that the role of this procedure needed further data to guide widespread clinical implementation. Studies by several other groups have found similar findings to the Kobayashi study. A meta-analysis by Chai et al (2010) looked at 10 randomized controlled trials comparing viscocanalostomy with trabeculectomy and found the latter was superior in lowering IOP, reducing post-operative medication needs, and had a lower relative risk of perforation of Descemet membrane. Further long-term, randomized evidence is needed to define the clinical role of viscocanalostomy.
9. iStent Procedure in the following circumstances, as it is considered experimental or investigational:
    i. iStent Infinite- There are no published trials, pending results from https://clinicaltrials.gov/ct2/show/study/NCT03639870. There are no recommendations or guidelines from national society or international society guidelines specific to iStent and furthermore, as a standalone procedure. FDA approved in 2022.
    ii. Children
    iii. Prior significant eye trauma
    iv. Abnormal anterior segment
    v. Eyes with chronic inflammation
    vi. Glaucoma associated with vascular disorders, uveitic glaucoma, pseudophakic glaucoma

vii. Prior glaucoma surgery, including any type of trabeculoplasty
viii. Medicated intraocular pressure >24 mmHg
ix. Unmedicated intraocular pressure <22 or >36
x. For implantation of more than one stent
xi. After complications of cataract surgery

10. Cypass Micro-Stent
    a. *Rationale:* The Cypass Micro-Stent is considered experimental or investigational, as its safety and efficacy has not been established. The Cypass Micro-Stent was recalled by the FDA in 2018 due to concerns regarding significant endothelial cell loss and reductions in endothelial cell density (ECD).

Applicable Billing Codes (CPT/HCPCS/ICD-10 Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device [XEN45 Gel Stent]
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) [XEN45 Gel stent]
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more [when billed for medically necessary procedures as indicated in this guideline]
65850	Trabeculotomy ab externo
65855	Trabeculoplasty by laser surgery
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery [Trabeculectomy]
66172	Fistulization of sclera for glaucoma; trabeculectomy ab externo in presence of previous surgery [Trabeculectomy]
66174	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent

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 [ExPress Mini Shunt]
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft
66710	Ciliary body destruction; cyclophotocoagulation, transscleral
66711	Ciliary body destruction; cyclophotocoagulation, endoscopic, without concomitant removal of crystalline lens
66720	Ciliary body destruction; cryotherapy
66761	Iridotomy/iridectomy by laser surgery (eg, for glaucoma) (per session)
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 [Hydrus, iStent]
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 [Hydrus, iStent]
C1783	Ocular implant, aqueous drainage assist device [iStent or Hydrus, XEN 45 Gel Stent]
L8612	Aqueous shunt
ICD-10 codes considered medically necessary if criteria are met:	
H40.1110-H40.1194	Primary open-angle glaucoma
Additional ICD-10 codes *required* for iStent 66989, 66991, C1783 :	
H25.011 - H26.9	Cataract [must be billed with H40.1110 - H40.1194]

ICD-10 codes considered medically necessary for thermal or laser iridotomy (66761) if criteria are met:	
H40.211 – H40.219	Acute angle-closure glaucoma

ICD-10 codes considered experimental, investigational, or *not* medically necessary for canaloplasty (66174, 66175):	
H21.551 - H21.559	Recession of chamber angle
H40.031 - H40.039	Anatomical narrow angle
H40.051 - H40.059	Ocular hypertension
H40.221 - H40.229	Chronic angle-closure glaucoma
H40.50x0 - H40.53x4	Glaucoma secondary to other eye disorders
H40.89	Other specified glaucoma
ICD-10 codes considered experimental, investigational, or *not* medically necessary for the iStent or Hydrus Procedures (66989, 66991, C1783)	
C69.60 - C69.62	Malignant neoplasm of orbit
E05.00 - E05.01	Thyrotoxicosis with diffuse goiter
H04.021 - H04.029	Chronic dacryoadenitis
H04.031 - H04.039	Chronic enlargement of lacrimal gland
H04.411 - H04.419	Chronic dacryocystitis
H04.421 - H04.429	Chronic lacrimal canaliculitis
H05.10	Unspecified chronic inflammatory disorders of orbit

H20.10 - H20.13	Chronic iridocyclitis
H40.051 - H40.059	Ocular hypertension
H40.20x0 - H40.20x4	Primary angle-closure glaucoma
H40.31x1 - H40.33x4	Glaucoma secondary to eye trauma
H40.41x1 - H40.43x4	Glaucoma secondary to eye inflammation
H40.50x0 - H40.53x4	Glaucoma secondary to other eye disorders
H40.89	Other specified glaucoma
H59.011 - H59.099	Disorders of the eye following cataract surgery
Q85.8	Other phakomatoses, not elsewhere classified [Sturge-Weber Syndrome]

CPT/HCPCS codes considered experimental, investigational, or *not* medically necessary:	
Code	*Description*
65820	Goniotomy [when used for Ab interno trabeculectomy]
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery [Viscocanalostomy]
66999	Unlisted procedure, anterior segment of eye [not covered for Trabectome, Viscocanalostomy, Transciliary fistulization/filtration]
77401 - 77412	Radiation treatment delivery
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space [Cypass Micro-Stent]
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral
0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral

0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more [when billed for iStent Infinite]
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each
G6001 - G6014	Radiation treatment delivery

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