Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

Clinical guidelines are applicable to certain plans. Clinical guidelines are applicable to members enrolled in Medicare Advantage plans only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of a prior authorization request. Services are subject to the terms, conditions, limitations of a member’s policy and applicable state and federal law. Please reference the member’s policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

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 coverage criteria, exclusions, and benefit 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 as 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 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.

“Glaucma 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 and Coverage

General Coverage Criteria

Oscar covers surgery or procedures 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. Ahmed glaucoma valve implant; or
   e. Baerveldt tube shunt; or
   f. ExPRESS mini glaucoma shunt; or
      i. Note: Adjunctive use of antifibrotic agents with ExPRESS mini shunt are considered medically necessary and covered
   g. Krupin-Denver eye valve; or
   h. Molteno implant.

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.

Canaloplasty

Oscar covers canaloplasty 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 covered 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.

**iStent Procedure**
Oscar covers the FDA-approved iStent Procedure when ALL of the following are met:
1. The member has mild to moderate primary open angle glaucoma; and
2. Cataract in the same eye as the glaucoma; and
3. Current treatment with at least two ocular hypotensive medication(s); and
4. The iStent Procedure is performed simultaneous to the cataract surgery; and
5. 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.

**Cyclophotocoagulation**
Oscar covers cyclophotocoagulation (either transscleral CPC or endoscopic) when any 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 above.

**Laser (nd:YAG) Iridotomy**
Oscar covers thermal or laser (nd:YAG) iridotomy 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**

Oscar covers laser iridoplasty or surgical iridectomy 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**

Oscar does **NOT** cover 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 for non-coverage:** 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. 64-66
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. iStent Inject
   e. STARflo
   f. Aquashunt
   g. Hydrus MicroStent
3. Xen Gel stent
   a. **Rationale for non-coverage:** The existing peer-reviewed literature on the Xen Gel Stent is limited to case reports, animal studies, retrospective reviews, and small prospective studies. While initial results may be promising, there is inadequate randomized, large-scale, long-term data to guide clinical implementation. 67-70
4. 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
5. Beta radiation
   a. Rationale for non-coverage: 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.71-72
6. Ab interno trabeculectomy (e.g., Trabectome)
   a. Rationale for non-coverage: 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 for non-coverage: The clinical efficacy of these injections has not yet been established, limiting clinical use to the experimental and investigational setting.
8. Viscocanalostomy
   a. Rationale for non-coverage: 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.79-84

9. iStent Procedure in the following circumstances, as it is considered experimental or investigational:
   i. Children
   ii. Prior significant eye trauma
   iii. Abnormal anterior segment
   iv. Eyes with chronic inflammation
   v. Glaucoma associated with vascular disorders, uveitic glaucoma, pseudophakic glaucoma
   vi. Prior glaucoma surgery, including any type of trabeculoplasty
   vii. Medicated intraocular pressure >24 mmHg
   viii. Unmedicated intraocular pressure <22 or >36
   ix. For implantation of more than one stent
   x. After complications of cataract surgery

10. Cypass Micro-Stent
    a. Rationale for non-coverage: 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)

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<thead>
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<td><strong>Code</strong></td>
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**ICD-10 codes covered if criteria are met:**

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<th>Code</th>
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<td>H40.110-</td>
<td>Primary open-angle glaucoma</td>
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<td>H40.1194</td>
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**Additional ICD-10 codes required for iStent 0191T:**
Cataract [must be billed with H40.1110 - H40.1194]

**ICD-10 codes covered for thermal or laser iridotomy (66761) if criteria are met:**

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<td>H40.211 – H40.219</td>
<td>Acute angle-closure glaucoma</td>
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**ICD-10 codes not covered for canaloplasty (66174, 66175):**

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<tr>
<td>H21.551 - H21.559</td>
<td>Recession of chamber angle</td>
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<td>H40.031 - H40.039</td>
<td>Anatomical narrow angle</td>
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<td>H40.051 - H40.059</td>
<td>Ocular hypertension</td>
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<td>H40.221 - H40.229</td>
<td>Chronic angle-closure glaucoma</td>
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<td>H40.50x0 - H40.53x4</td>
<td>Glaucoma secondary to other eye disorders</td>
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<td>H40.89</td>
<td>Other specified glaucoma</td>
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**ICD-10 codes not covered for the iStent Procedure (0191T, C1783):**

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<td>C69.60 - C69.62</td>
<td>Malignant neoplasm of orbit</td>
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<td>E05.00 - E05.01</td>
<td>Thyrotoxicosis with diffuse goiter</td>
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<td>H04.021 - H04.029</td>
<td>Chronic dacryoadenitis</td>
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<td>Chronic enlargement of lacrimal gland</td>
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<td>H04.411 - H04.419</td>
<td>Chronic dacryocystitis</td>
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<tr>
<td>65820</td>
<td>Goniotomy [when used for Ab interno trabeculectomy]</td>
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<td>66170</td>
<td>Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery [Viscocanalostomy]</td>
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<td>66999</td>
<td>Unlisted procedure, anterior segment of eye [not covered for Trabectome, Viscocanalostomy, Transciliary fistulization/filtration]</td>
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<td>77401 - 77412</td>
<td>Radiation treatment delivery</td>
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<td>Code</td>
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<td>0123T</td>
<td>Fistulization of sclera for glaucoma, through ciliary body [Singh filtration]</td>
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<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion</td>
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<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space [Cypass Micro-Stent]</td>
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<td>0356T</td>
<td>Insertion of drug-eluting implant (including punctual dilation and implant removal when performed) into lacrimal canalicus, each</td>
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<td>0444T</td>
<td>Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral</td>
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<td>0445T</td>
<td>Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral</td>
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<td>0449T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device [Xen Gel stent]</td>
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<td>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) [Xen Gel stent]</td>
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<tr>
<td>G6001-G6014</td>
<td>Radiation treatment delivery</td>
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References


   https://eyewiki.aao.org/Suprachoroidal_Devices#iStent_Suprachoroidal_Bypass_System...28Stent_Supra.29 Updated April 2020.


Clinical Guideline Revision / History Information

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