Aqueous Shunts and Stents Treatment For Glaucoma

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
**POLICY DESCRIPTION:**

This policy describes the use of a variety of devices, including micro-stents and shunts, as alternatives to surgical treatment for patients with inadequately controlled glaucoma.

Glaucoma refers to a group of eye diseases where vision is lost due to damage of the optic nerve, which carries visual information from the eye to the brain. Though it is not preventable, available treatments may slow the progression of glaucoma; therefore early detection is important. Treatments for glaucoma may include eye drops, laser surgery, or incisional surgery. The aim of treatment is to reduce the pressure of the fluid in the eye, known as intraocular pressure (IOP), in an attempt to prevent further damage to the optic nerve.

**COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:**

A. Insertion of aqueous shunts (glaucoma drainage devices), such as the ExPRESS™ Mini Glaucoma Shunt, may be considered **MEDICALLY NECESSARY** as a method to reduce intra-ocular pressure (IOP) in patients with refractory primary open-angle glaucoma, when the following criteria are met
   - The aqueous shunt is used according to U.S. Food and Drug Administration (FDA) labeled indications, AND
   - Medical therapy has failed to adequately control IOP.

Use of an aqueous shunt for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered **EXPERIMENTAL AND/OR INVESTIGATIONAL**.

B. Implantation of a micro-stent, such as the iStent Trabecular Micro-Bypass Stent System, may be considered **MEDICALLY NECESSARY** as a method to reduce IOP in adult patients with mild to moderate open-angle glaucoma, in conjunction with cataract surgery, when the following criteria are met:
   - The micro-stent is used according to FDA labeled indications, AND
   - Medical therapy has failed to adequately control IOP.

Use of a micro-stent for all other conditions is considered **EXPERIMENTAL AND/OR INVESTIGATIONAL**, including:
   - Patients with glaucoma when intraocular pressure is adequately controlled by medications
   - Pseudoexfoliative glaucoma
   - Pigmentary glaucoma
   - Other secondary open-angle glaucomas

C. Glaucoma drainage devices, such as Eyepass, DeepLight SOLX® Gold Shunt and other shunts that do not have FDA approval are **INVESTIGATIONAL AND UNPROVEN** for the treatment of glaucoma. Clinical evidence is limited to small studies; therefore, additional studies are needed to establish the safety and efficacy of these devices.
Clinical Considerations:
The iStent is indicated for use in conjunction with cataract surgery for IOP reduction in adult patients with mild to moderate open-angle glaucoma who are currently being treated with ocular hypotensive medication. Treatment with the iStent is performed by an ophthalmologic surgeon.

Precautions: According to the FDA approved product labeling, the safety and effectiveness of the iStent has not been established in patients with the following circumstances or conditions which were not studied in the pivotal trial:

- Children
- Eyes with significant prior trauma
- Eyes with abnormal anterior segment
- Eyes with chronic inflammation
- Glaucoma associated with vascular disorders
- Pseudophakic patients with glaucoma
- Uveitic glaucoma
- Prior glaucoma surgery of any type including argon laser trabeculoplasty
- Medicated intraocular pressure > 24 mm Hg
- Unmedicated IOP < 22 mm Hg or > 36 mm Hg after washout of medications
- Implantation of more than a single stent
- Complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitrectomy required, corneal injuries, or complications requiring the placement of an anterior chamber IOL
- Implantation without concomitant cataract surgery with IOL implantation for visually significant cataract

Contraindications: According to the FDA-approved product labeling, the iStent is contraindicated:

- In eyes with primary angle-closure glaucoma, or secondary angle-closure glaucoma, including neovascular glaucoma, because the angle of the eye prevents drainage of fluid and the iStent will not work.
- In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber syndrome, port-wine stain involving the upper eye, or any other type of condition that may cause elevated episcleral venous pressure.

BACKGROUND:

Glaucoma describes a complex group of eye diseases characterized by damage to the optic nerve, leading to irreversible vision loss and blindness. Glaucoma affects more than 60 million people worldwide, and approximately 4 million people in the United States. Glaucoma usually begins with a subtle loss of peripheral vision and, if left undiagnosed and untreated, will eventually progress to complete blindness. It is estimated that 12.3% of all cases of blindness globally are due to glaucoma, making it the second leading cause of blindness after cataracts. Because glaucoma is treatable, and because the visual impairment from glaucoma is irreversible, early detection of the disease is critical.
There are several types of glaucoma, all associated with optic nerve damage, leading to visual impairment. The most common type is primary open-angle glaucoma (POAG), also known as chronic open-angle glaucoma, thought to account for up to 75% of all cases of glaucoma worldwide, and up to 90% of glaucoma cases in the United States. The prevalence of POAG in adults more than 40 years of age in the United States is estimated to be approximately 2%. POAG is usually, though not always, associated with increased intraocular pressure (IOP), which can potentially damage the delicate fibers of the optic nerve head, located at the back of the eye. A fluid, known as aqueous humor, is produced in the eye by the ciliary body, located behind the iris. Most of this fluid flows through the pupil and drains away at the open angle between the cornea and the iris. The aqueous humor then passes through a porous tissue, known as the trabecular meshwork, and into a collector channel known as Schlemm’s canal.

The 2010 American Academy of Ophthalmology (AAO) Preferred Practice Patterns Guidelines report on primary open-angle glaucoma, states that the severity of glaucoma damage can be estimated using the following classification:

- **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

Increased IOP is one of the main risk factors for POAG, although it is not a requirement for diagnosis, and often occurs in patients with IOPs within the normal range. Other risk factors for POAG include: older age, family history, African or Latino ancestry, and type 2 diabetes. Despite the fact that not all patients diagnosed with POAG have elevated IOP, current evidence suggests that reducing IOP has a significant preventive effect on the progression of glaucoma, regardless of whether IOP is abnormal at diagnosis.

**TREATMENTS**

Medications (e.g., eye drops), laser treatments, and surgery can all be used to lower IOP, which is currently the only known modifiable risk factor for POAG. The goal of treatment for POAG is to maintain IOP in a range at which further optic nerve damage is unlikely to occur, while minimizing side effects. In general, the initial target is to lower IOP by 20% to 50% of the original pressure at which damage occurred. The most common incisional surgical treatment for POAG is a type of filtration surgery known as trabeculectomy. In this technique, a small portion of the trabecular meshwork, or surrounding tissue, is removed, creating an alternative path for the release of aqueous humor into an outer cyst (or bleb). Antifibrotic agents, such as mitomycin-C and 5-fluorouracil, may be used intraoperatively and postoperatively to reduce scarring and prevent closure of the new channel. Trabeculectomy is often effective in lowering IOP, but complications may include infection, bleb leakage, and progressive worsening of cataracts. Despite potential complications, trabeculectomy remains the current standard against which newer surgical techniques are measured.

Glaucoma drainage devices, such as iStent, Eyepass, or DeepLight SOLX® Gold Shunt (suprachoroidal shunt) divert aqueous fluid from the anterior chamber directly into Schlemm's canal (Samuelson, 2008). These stenting/shunting procedures are similar to viscocanalostomy in that they lower IOP without the formation of a filtering bleb.
**Aqueous Shunt:** Another alternative for patients with glaucoma is an aqueous shunt, a drainage device that assists in filtration by physically shunting aqueous humor to the subtenons or to the supraciliary space. These devices provide an artificial pathway for drainage of the aqueous humor and aid in lowering IOP. Several types of shunts are available, and their intended goal is to lower IOP with fewer complications than trabeculectomy. Aqueous shunt drainage devices include the ExPRESS Mini Glaucoma Shunt, the Molteno implant, the Baerveldt tube shunt, or the Ahmed glaucoma valve implant. The ExPRESS Mini Glaucoma Shunt is a small stainless steel device that is placed beneath the scleral flap into the anterior chamber instead of creating a punch or excisional sclerostomy, thereby bypassing the trabecular meshwork and directing aqueous fluid to form a perilimbal conjunctiva-covered bleb. The Molteno, Baerveldt and Ahmed glaucoma implants consist of a length of flexible plastic tubing that is inserted into anterior or posterior chamber and connect to a plastic or silicone plate with a large surface area that is secured to the posterior sclera between two of the extraocular muscles, and covered by conjunctiva. The plate acts as a physical barrier to scarring of the conjunctiva to the sclera providing a large surface area bleb posterior to the limbus.

**iStent® Trabecular Micro-Bypass Stent** (Models GTS100R and GTS100L): This device is intended to create a permanent opening from the anterior chamber into Schlemm's canal to improve aqueous humor outflow past the trabecular meshwork, thereby reducing IOP. The iStent consists of a heparin-coated surgical-grade nonferromagnetic titanium implant and a single-use sterile insertion device. Measuring 1 millimeter (mm) in length and 0.33 mm in height, and weighing 60 nanograms (µg), the iStent is the smallest medical implant for commercial use. The iStent is implanted by an ophthalmologic surgeon using an ab interno approach via the clear corneal incision made during phacoemulsification surgery with or without intraocular lens (IOL) implantation for cataract. In the United States, iStent implantation is approved only in conjunction with cataract surgery. Outside the United States, the iStent is being implanted as a stand-alone procedure via a 1.5-mm incision. The procedure is performed on an outpatient basis using topical anesthesia. Implantation of an iStent adds approximately 15 minutes to the cataract surgery procedure. The iStent is indicated for use in conjunction with cataract surgery for IOP reduction in adult patients with mild to moderate open-angle glaucoma who are currently being treated with ocular hypotensive medication.

**Viscocanalostomy:** Procedure used to treat glaucoma that involves surgical incisions and injection of a viscous, elastic material into the eye. The goal of this procedure is to reduce intraocular pressure by creating a channel that allows excess fluid to drain from the eye.

**Canaloplasty:** Surgical technique for glaucoma which aims to restore the natural drainage of fluid from the eye (NICE, 2008). Canaloplasty involves viscodilation of the Schlemm's canal with an illuminated tipped microcatheter. The microcatheter is used to place an intracanalicular suture that cinches and stretches the trabecular meshwork inwards while permanently opening the Schlemm's canal.

**Transciliary Fistulization:** This procedure is also known as transciliary filtration or Singh filtration. It uses a thermocauterization device called the Fugo Blade to create a plasma-ablated pore or filter track from the sclera through the ciliary body to allow aqueous fluid to ooze into the subconjunctival lymphatics from the posterior chamber (behind the iris) of the eye.
### REGULATORY STATUS:

**1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

The following received U.S. Food and Drug Administration (FDA) clearance for marketing:

- Trabectome (NeoMedix Corp.)
- Aqueous Shunts
  - Ahmed™ (New World Medical)
  - Baerveldt (Advanced Medical Optics)
  - Krupin (Eagle Vision)
  - Molteno® (Molteno Ophthalmic)
- Micro-Stents
  - Ex-PRESS™ Micro Shunt (Alco)
  - iStent Micro-Bypass® (Glaukos® Corporation; the stent was approved for use in combination with cataract surgery in adult patients with mild or moderate open-angle glaucoma and cataract who are currently being treated with medication to reduce IOP)

The following have not yet received FDA approval:

- iStent supra® and inject® (Glaukos Corporation) Suprachoroidal stent
- SOLX® gold (SOLX) which shunts aqueous humor between the anterior chamber and the suprachoroidal space
- CyPass® Micro-Stent (Transcend Medical, Inc.) suprachoroidal stent
- The EyePass Bi-Directional Glaucoma Implant (GMP Companies)

Additional information is available at:

- [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm309667.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm309667.htm)
- [http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080030b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080030b.pdf)
- [http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080030c.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080030c.pdf)
- [http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm312053.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm312053.htm)

**2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

**National Coverage Determination (NCD)**

Medicare does not have a NCD for use of iStent shunt for treatment of glaucoma.

Medicare does not have a NCD for glaucoma drainage devices.

**Local Coverage Determinations (LCDs)**

Insertion of Anterior Segment Aqueous Drainage Device, Without Extraocular Reservoir, External
Approach (0192T) – Related to LCD L25275 (A48259)

An anterior segment aqueous drainage device, without extraocular reservoir, implanted under a partial thickness scleral flap may be a safe alternative or adjunct to standard guarded trabeculectomy, especially for patients with advanced glaucoma in need of low intraocular pressures with a high risk for hypotonous complication.

Limitations: Other indications for 0192T remain investigational or not medically necessary.

Note: Only CPT code 0192T should be reported for insertion of the anterior segment aqueous drainage device. Do not report CPT codes 66170, 66172, 66180 or other procedure codes formerly used for the insertion of this device.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Minnesota DHS does not have a policy statement regarding Aqueous Drainage Devices or Stent Shunts for treatment of glaucoma in its Provider Manual or other specific provider references.

CLINICAL EVIDENCE:

SUMMARY:

Aqueous Shunts With an Extraocular Reservoir (e.g., Ahmed, Baerveldt, Krupin, Molteno).
Standard aqueous shunts that drain to an extraocular reservoir have been available for many years and have evolved into a standard of care as a method to reduce intraocular pressure in patients with glaucoma when medical therapy has failed to adequately control intraocular pressure. The standard shunts have been studied in a few randomized trials that compared them to the current standard of care, trabeculectomy. Therefore, standard aqueous shunts with an extraocular reservoir may be considered medically necessary as a method to reduce intraocular pressure in patients with glaucoma when medical therapy has failed to adequately control intraocular pressure.

Aqueous Shunts Without an Extraocular Reservoir (e.g., Ex-PRESS Micro Shunt, iStent Micro-Bypass).
Use of micro-stents has been studied in patients with both cataracts and less advanced glaucoma, where the intraocular pressure (IOP) is at least partially controlled with medication. Results from these studies indicate that IOP may be lowered below baseline with decreased need for medication, although the benefit appears to diminish after the first year.

Ex-PRESS™ Micro Shunt: Scientific evidence on the Ex-PRESS Micro Shunt for the treatment of glaucoma is very limited. The shunt has been evaluated in only a few unreliable randomized trials. Consequently, it is not possible to reach reliable conclusions concerning the safety and efficacy of the Ex-PRESS micro shunt compared with the current surgical standard of care, trabeculectomy. In addition, this micro-shunt has not received clearance from the Federal Drug Administration (FDA) for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP). Therefore, the Ex-PRESS micro shunt is considered investigational.

iStent Micro-Bypass®: The iStent Micro-Bypass has received approval from the Federal Drug Administration (FDA) for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. Recent evidence has demonstrated a considerable reduction in the need for medications
after implantation of the iStent Micro-Bypass at the one year follow-up. In addition, the America Glaucoma Society (AGS) position statement support the use of technologies which reduce the need for pressure medication and complications related to more invasive procedures. Therefore, use of the iStent Micro-Bypass may be considered medically necessary when implanted concurrently with cataract surgery, in patients whose intraocular pressure is not well-controlled with medication.

No studies have directly compared the iStent with other glaucoma treatments, such as shunt or trabeculectomy. Existing evidence suggests that iStent implantation is associated with a lower rate of complications than these other procedures due to the ab interno approach via a cataract incision. Direct comparative studies of competing glaucoma treatments are necessary to provide more definitive conclusions regarding clinical outcomes and complications, and to define patient selection criteria.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>Open-angle glaucoma unspecified</td>
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<td>Residual stage of open angle glaucoma</td>
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<td>Open-angle glaucoma</td>
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<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork</td>
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<td>0192T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach</td>
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<tr>
<td>0253T</td>
<td>Internal approach, into the suprachoroidal space</td>
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<td>66172</td>
<td>Fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma [includes injection of antifibrotic agents</td>
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CPT® is a registered trademark of the American Medical Association.
REFERENCES:


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<td>• Added applicable ICD-10 codes to the Coding Section. The list of codes may not be all-inclusive and does not denote coverage.</td>
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