Glaucoma Surgical Treatments

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Policy Number: WI.PA-1119-000
Line of Business: Medicare

Medical Coverage Policy

Table of Contents

Related Medical/Pharmacy Coverage Policies
Related Documents
Description
Coverage Determination
Coverage Limitations
Coding Information
References
Appendix
Change Summary

Disclaimer
The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member’s coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medical/Pharmacy Coverage Policies

For information regarding Durysta, please refer to Durysta (bimatoprost implant) Pharmacy Coverage Policy.

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

<table>
<thead>
<tr>
<th>Type</th>
<th>Title</th>
<th>ID Number</th>
<th>Jurisdiction Medicare</th>
<th>Applicable States/Territories</th>
</tr>
</thead>
<tbody>
<tr>
<td>LCD (and pertinent LCA)</td>
<td>Category III Codes</td>
<td>Administrator Contractors (MACs)</td>
<td>State(s)</td>
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Description

Glaucoma is an irreversible group of conditions/diseases involving damage to the optic nerve and loss of peripheral vision. It was once thought that glaucoma was generally due to increased intraocular pressure (IOP); however, the condition is also found in individuals with normal or low eye pressure. In open-angle glaucoma, the angle between the iris and the cornea is wide and open, as it should be. Symptoms develop gradually and may go unnoticed until damage has occurred. Angle-closure glaucoma (also referred to as narrow-angle), is caused by blocked drainage canals and characterized by a closed or narrowed angle between the iris and cornea. Noticeable symptoms develop quickly and require immediate medical attention. Glaucomas are further subdivided into primary (cause of outflow resistance or angle closure is unknown) and secondary (outflow resistance results from a known disorder). Glaucomas are classified by stages, ranging from mild to severe. Although primary open-angle glaucoma (POAG) is the most common form, all types of glaucoma will result in blindness if left untreated.

Prescription medication, in the form of eye drops, pills or both, is the most common early treatment for glaucoma. The medication helps to lower IOP by improving aqueous humor (fluid) drainage from the eye or by decreasing the amount of fluid produced by the eye and must be taken regularly. If medication fails, other interventions may be suggested.

Current standard surgical treatments for open-angle glaucoma include trabeculectomy or trabeculoplasty (incisional or laser). Iridotomy, iridectomy or iridoplasty may be necessary for angle-closure glaucoma.

The term aqueous drainage device refers to a broad class of tools used to facilitate aqueous flow out of the anterior chamber to control IOP. They may also be referred to as glaucoma drainage devices, tubes or shunts, and may be valved or nonvalved. Such drainage devices may be placed in individuals with advanced disease in whom medical and laser therapies are inadequate and who have an underlying diagnosis that increases the risk of failure of conventional surgery. Examples of these standard devices that received US Food & Drug Administration (FDA) approval decades ago, include Ahmed glaucoma valve, Baerveldt glaucoma implant, Krupin eye valve and Molteno implant.

Other established and proposed treatments for glaucoma include, but may not be limited to:

**Canaloplasty** began as a modification of viscocanalostomy, a surgical procedure in which tissue flaps are cut in the conjunctiva and the sclera (ab externo) to expose Schlemm’s canal (the drainage area). Canaloplasty attempts to open the entire drainage area surrounding the anterior chamber (360°) instead of just a portion of it, as in viscocanalostomy below. A very small catheter is placed in the opening and used to inject the high-viscosity elastic gel into the entire drainage area forming a ring around the anterior chamber. A suture loop is left in the canal to help maintain tension and keep the canal open. The canal is expanded by the injection to promote better fluid drainage. A newer, purportedly less invasive approach (ab interno) accesses Schlemm’s canal via a small corneal incision rather than conjunctival dissection. The iTrack Microcatheter is an FDA-approved noncutting device for the delivery of viscoelastic in 360° procedures. The Omni Surgical System is an FDA-approved device that combines the functions of cutting the trabecular meshwork and delivering viscoelastic. Both devices may be used for either ab interno or ab externo approaches.
Drug-eluting devices are in development to combat low patient adherence with medications since many eye drops require multiple doses daily. These types of devices are implanted or inserted into the eye temporarily and purportedly release a steady dose of medication until they are removed, dissolve or are washed out via the tear duct. Methods of delivery include, but may not be limited to:

- Anterior segment intraocular nonbiodegradable drug-eluting system
- Biodegradable collagen matrix scaffold impregnated with medication, formed into a wafer, and implanted in the sclera
- Contact lens-like clear plastic flexible polymer infused with medication that rests on the sclera and may be worn for up to 120 days
- Injections into the anterior chamber or subconjunctival space that deliver a medication-laden dissolvable medium. For information regarding Durysta, please refer to Durysta (bimatoprost implant) Pharmacy Coverage Policy.
- Ophthalmic micropump implanted in the sclera and programmed to dispense medication at certain times for up to 12 months; refillable and requires removal
- Punctal plugs made of resorbable material inserted into the lacrimal punctum (tear duct) to emit sustained-release medication for 30 - 60 days until degrading and exiting via the nasolacrimal system

Excimer laser trabeculostomy (ExTrA ELT) is an evolving procedure that uses a nonthermal excimer laser to create multiple microscopic openings in Schlemm’s canal. The use of the nonthermal laser purportedly prevents scarring, so the channels remain open, allowing fluid to flow through the trabecular meshwork, thereby lowering intraocular pressure. According to the manufacturer, this is not yet FDA approved.

Ex-Press glaucoma filtration device, a stainless steel nonvalved shunt, is inserted through a conjunctival flap to drain aqueous fluid from the anterior chamber without removal of any scleral or iris tissue.

Gonioscopy-assisted transluminal trabeculotomy (GATT) combines ab interno canaloplasty with trabeculotomy (surgical opening of trabecular meshwork). A catheter is advanced into Schlemm’s canal, where viscoelastic is inserted to dilate it. The iTrack Microcatheter is an FDA-approved noncutting device for the delivery of viscoelastic in 360° procedures. The Omni Surgical System is an FDA-approved device that combines the functions of cutting the trabecular meshwork and delivering viscoelastic.

Hydrus microstent, a flexible, crescent-shaped scaffold is implanted permanently into Schlemm’s canal, to open the trabecular meshwork and dilate the canal, thus reducing IOP. It is approved for use in individuals with mild-to-moderate POAG undergoing cataract surgery.

iStent family of microbypass glaucoma stents include:
• **iStent (trabecular bypass device or microbypass implant)** is the original first-generation device approved for use in individuals also undergoing cataract surgery. It consists of a preloaded applicator containing a single small heparin-coated, titanium implant, placed into Schlemm’s canal, intended to restore more normal fluid drainage and reduce IOP in individuals who are also undergoing cataract surgery.

• **iStent inject W** is a second-generation device which includes two multidirectional titanium stents that are preloaded in a single use injector system. The stent is designed for placement in either eye, with the head positioned in the anterior chamber and the rear extending into Schlemm’s canal, creating a bypass for the outflow of aqueous humor. It is indicated for use in conjunction with cataract surgery.

• **iStent infinite** is a third-generation device which includes three heparin-coated titanium stents preloaded into an auto-injection system. It is the first of the iStent devices designed for use alone or at the time of cataract surgery to reduce IOP.

• **iStent Supra (suprachoroidal bypass system)** is a third generation iStent device under development. It is inserted under gonioscopic view through a clear corneal incision into the suprachoroidal space and is proposed for use alone or at the time of cataract surgery.

**Optical coherence tomography (OCT)-guided laser trabeculotomy** creates a new pathway for fluid inside the eye to be drained through a flap in the sclera, which is then covered by the conjunctiva. Trabeculotomy using an operating microscope and trabeculotome (specialized surgical instrument) is a standard procedure for treating certain types of pediatric glaucoma, while the use of laser has been proposed more recently for individuals of varying ages. Intraoperative high-resolution OCT imaging is being explored as an enhancement to the procedure.

**Transciliary fistulization (transciliary filtration, Singh filtration)** uses a thermo-cauterization device called the Fugo Blade to create a filter track from the sclera through the ciliary body to allow aqueous fluid to drain from the posterior chamber of the eye. This differs from conventional filtering surgeries in which aqueous fluid is filtered from the anterior chamber.

**Viscocanalostomy**, the precursor to canalostomy, involves cutting tissue flaps in the conjunctiva and the sclera. The creation of these flaps exposes a portion of Schlemm’s canal into which viscoelastic (a high-viscosity elastic gel) is injected. The viscoelastic opens and enlarges the canal purportedly enhancing fluid flow out of the anterior chamber. The tissue flaps are then closed. The amount of angle treated in this procedure is minor in comparison to a canaloplasty (generally less than 90 degrees). The Omni Surgical System is an FDA-approved device that combines the functions of cutting the trabecular meshwork and delivering viscoelastic.

The **XEN glaucoma treatment system (XEN45 gel stent)** is an aqueous drainage stent made of porcine gel that is placed via a preloaded injector, to create an outflow pathway from the anterior chamber to the subconjunctival space through which aqueous humor can flow. It is indicated for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of POAG, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.
Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Please refer to the member’s applicable pharmacy benefit to determine benefit availability and the terms and conditions of coverage for medication for the treatment of glaucoma.

Trabeculectomy, trabeculoplasty, iridotomy, iridectomy and/or iridoplasty are generally considered medically necessary and are not subject to the criteria within this medical coverage policy.

The initial placement or revision of the Ahmed glaucoma valve, Baerveldt glaucoma implant, Krupin eye valve and Moltene implant is generally considered medically necessary and is not subject to the criteria within this medical coverage policy.

Canaloplasty

Canaloplasty will be considered medically reasonable and necessary when the following requirements are met:

- Absence of contraindications; AND
- Individual diagnosed with open-angle glaucoma (eg, juvenile-onset, pigmentary dispersion, POAG, pseudoexfoliation, steroid-induced);

AND EITHER of the following:

- Conventional medical therapy (topical and/or oral) has failed; OR
- Inability to administer medical therapy or adhere to the schedule required due to cognitive or physical impairment

Ex-Press glaucoma filtration device

The Ex-Press glaucoma filtration device will be considered medically reasonable and necessary when the following requirements are met:

- The device is used according to FDA-approved indications; AND
- Individual diagnosed with glaucoma; AND
- Conventional medical therapy (topical and/or oral) has failed; AND
• At least one of the following conventional surgical techniques has failed:
  
  o Laser trabeculoplasty; OR
  o Trabeculectomy

**Hydrus microstent**

The **Hydrus microstent** will be considered medically reasonable and necessary when all of the following requirements are met:

• Absence of contraindications; AND
• Individual currently treated with ocular hypotensive medication; AND
• The device is used according to the following FDA-approved indications:
  
  o Individual diagnosed with mild to moderate open-angle glaucoma; AND
  o The procedure is being performed in conjunction with cataract surgery; AND

• One device (Hydrus microstent) per eye is allowed

**iStent (trabecular bypass device or microbypass implant)**

The *trabecular bypass (microbypass implant)* (eg, *iStent*) will be considered medically reasonable and necessary when the following requirements are met:

• Absence of contraindications; AND
• The device is used according to the following FDA-approved indications:
  
  o Individual diagnosed with mild to moderate open-angle glaucoma; AND
  o Individual currently treated with ocular hypotensive medication; AND
  o The procedure is being performed in conjunction with cataract surgery

**iStent infinite**

The *iStent infinite* will be considered medically reasonable and necessary when the following requirements are met:

• Absence of contraindications; AND
• One injector, containing up to 3 devices (stents) per eye is allowed; AND
• The device is used according to the following FDA-approved indications:
  
  o Individual is diagnosed with refractory open-angle glaucoma; AND
  o Maximum tolerated conventional medical therapy (topical and/or oral) has failed; AND/OR
  o At least one filtering or cilioablative procedure has failed

**iStent inject W**
The iStent inject W will be considered medically reasonable and necessary when the following requirements are met:

- Absence of contraindications; AND
- Exactly two stents per affected eye are inserted; AND
- Individual currently treated with ocular hypotensive medication; AND
- The device is used according to the following FDA-approved indications:
  - Individual diagnosed with mild to moderate open-angle glaucoma; AND
  - The procedure is being performed in conjunction with cataract surgery

(Please refer to Coverage Limitations Section for additional information regarding iStent, iStent infinite, iStent inject W and iStent Supra)

**XEN glaucoma treatment system (XEN45 gel stent)**

The XEN glaucoma treatment system (XEN45 gel stent) will be considered medically reasonable and necessary when the following requirements are met:

- Absence of contraindications; AND
- One device (XEN) per eye is allowed; AND
- The device is used according to the following FDA-approved indications:
  - Individual diagnosed with refractory glaucoma (eg, open-angle, pseudoexfoliative, pigmentary); AND
  - Maximum tolerated conventional medical therapy (topical and/or oral) has failed; AND/OR
  - At least one filtering or cilioablative procedure has failed

**Revision**

Surgical revision (with or without a graft) of the following devices will be considered medically reasonable and necessary: Ex-Press glaucoma filtration device, Hydrus microstent, trabecular bypass (microbypass implant) (eg, iStent, iStent infinite, iStent inject W) or XEN glaucoma treatment system.

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

**Coverage Limitations**

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

**Canaloplasty**
Canaloplasty will not be considered medically reasonable and necessary if either of the following contraindications are present:

- Any diagnosis other than open-angle glaucoma (e.g., angle-closure, congenital, neovascular); OR
- History of blunt ocular trauma or prior surgery resulting in scarring which limits the canal space

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Ex-Press glaucoma filtration device
The Ex-Press glaucoma filtration device will not be considered medically reasonable and necessary for any indications other than those listed above.

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Hydrus microstent
Hydrus microstent will not be considered medically reasonable and necessary for any indications other than those listed above including, but may not be limited to:

- Device placement without concomitant cataract surgery; OR
- More than one device (Hydrus microstent) per eye; OR

- If any of the following contraindications are present:
  
  - Angle closure glaucoma; OR
  - Discernible congenital anomalies of the anterior chamber angle; OR
  - Malignant glaucoma; OR
  - Neovascular glaucoma; OR
  - Traumatic glaucoma; OR
  - Uveitic glaucoma

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.
iStent (trabecular bypass device or microbypass implant)
The trabecular bypass (microbypass implant) (eg, iStent) will not be considered medically reasonable and necessary for any indications other than those listed above including, but may not be limited to:

- Device placement without concomitant cataract surgery; OR

- If any of the following contraindications are present:
  - Primary angle-closure glaucoma or secondary angle-closure glaucoma including neovascular glaucoma; OR
  - Retrobulbar tumor, thyroid eye disease, Sturge-Weber syndrome or any other type of condition that may cause elevated episcleral venous pressure

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

iStent infinite
The iStent infinite will not be considered medically reasonable and necessary for any indications other than those listed above including, but may not be limited to:

- Any more than three devices (stents) per eye; OR

- If any of the following contraindications are present:
  - Angle-closure glaucoma; OR
  - Acute traumatic, malignant, active uveitic or active neovascular glaucoma; OR
  - Discernible congenital anomalies of the anterior chamber angle; OR
  - Retrobulbar tumor, thyroid eye disease, Sturge-Weber syndrome or any other type of condition that may cause elevated episcleral venous pressure

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

iStent inject W
The **iStent inject W** will not be considered medically reasonable and necessary for any indications other than those listed above including, but may not be limited to:

- Any more than or less than **two** devices per eye; **OR**
- Device placement without concomitant cataract surgery; **OR**
- If any of the following contraindications are present:
  - Angle-closure glaucoma; **OR**
  - Discernible congenital anomalies of the anterior chamber angle; **OR**
  - Retrobulbar tumor, thyroid eye disease, Sturge-Weber syndrome or any other type of condition that may cause elevated episcleral venous pressure; **OR**
  - Malignant glaucoma; **OR**
  - Neovascular glaucoma; **OR**
  - Traumatic glaucoma; **OR**
  - Uveitic glaucoma

*A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.*

**XEN glaucoma treatment system (XEN45 gel stent)**

The **XEN glaucoma treatment system (XEN45 gel stent)** will not be considered medically reasonable and necessary for any indications other than those listed above including, but may not be limited to:

- More than one device per eye; **OR**
- If any of the following contraindications are present:
  - Active inflammation; **OR**
  - Angle-closure glaucoma where angle has not been surgically opened; **OR**
  - Anterior chamber intraocular lens; **OR**
  - Intraocular silicone oil; **OR**
o Iris neovascularization (active or within six months of surgical date); OR

o Previous glaucoma shunt/valve in the target quadrant (where device will be placed); OR

o Presence of conjunctival scarring, prior surgery, or other conjunctival pathology (eg, pterygium) in the target quadrant; OR

o Presence of vitreous in the anterior chamber

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

The following emerging methods of glaucoma treatment will not be considered medically reasonable and necessary:

- Any device that has not received FDA approval (eg, Aquashunt, Gold Microshunt, Starflo)
- Any device that has been recalled (eg, Cypass Micro-Stent, MINIject Drainage System);
- Drug-eluting devices;
- Excimer laser trabeculostomy (ExTraELT);
- Gonioscopy-assisted transluminal trabeculotomy (GATT);
- iStent Supra;
- OCT-guided laser trabeculotomy;
- Transciliary fistulization (transciliary filtration, Singh filtration);
- Viscocanalostomy

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

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<td>66174</td>
<td>Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent</td>
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<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach</td>
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<td>66184</td>
<td>Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft</td>
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<td>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</td>
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<td>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</td>
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<td>68841</td>
<td>Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each</td>
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CPT® Category III Code(s)
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<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>Trabeculostomy ab interno by laser; with use of ophthalmic endoscope</td>
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<tr>
<td>0660T</td>
<td>Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach</td>
<td></td>
</tr>
<tr>
<td>0661T</td>
<td>Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant</td>
<td></td>
</tr>
<tr>
<td>0671T</td>
<td>Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more</td>
<td></td>
</tr>
<tr>
<td>0730T</td>
<td>Trabeculotomy by laser, including optical coherence tomography (OCT) guidance</td>
<td></td>
</tr>
</tbody>
</table>

**HCPCS Code(s)**

<table>
<thead>
<tr>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1783</td>
<td>Ocular implant, aqueous drainage assist device</td>
</tr>
<tr>
<td>L8612</td>
<td>Aqueous shunt</td>
</tr>
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</table>


### Appendix

**Appendix A**

**Glaucoma Stage Classification**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Findings</th>
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</thead>
<tbody>
<tr>
<td>Mild/Early</td>
<td>Optic nerve abnormalities consistent with glaucoma but no visual field abnormalities on any visual field test or abnormalities present only on short-wavelength automated perimetry or frequency doubling perimetry</td>
</tr>
<tr>
<td>Moderate</td>
<td>Optic nerve abnormalities consistent with glaucoma and glaucomatous visual field abnormalities in one hemifield and not within 5 degrees of fixation (note: 5 degrees = involvement of spots nearest fixation)</td>
</tr>
<tr>
<td>Advanced/Late/Severe</td>
<td>Optic nerve abnormalities consistent with glaucoma and glaucomatous visual field abnormalities in both hemisfields and/or loss within 5 degrees of fixation in at least one hemifield</td>
</tr>
</tbody>
</table>

### Change Summary

- 01/01/2024 New Policy.