


MEDICAL POLICY – 9.03.510

Glaucoma, Invasive Procedures

Ref. Policy: MP-124	
Effective Date: July 1, 2024	RELATED MEDICAL POLICIES:
Last Revised: June 24, 2024	None
Replaces: N/A	

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Introduction

Glaucoma is a group of diseases that damage the optic nerve when the pressure in the eye is too high. Glaucoma can cause vision loss and blindness. Certain surgeries and devices can be used to treat glaucoma by improving the eye’s drainage system and reducing eye pressure to normal levels. This policy describes when invasive procedures for glaucoma may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Invasive procedures for glaucoma	Use of invasive procedures to treat glaucoma may be considered medically necessary for the following indications:

Service	Medical Necessity
	<ul style="list-style-type: none"> • Ex-PRESS Mini Glaucoma Shunt and US Food and Drug Administration (FDA)-approved aqueous drainage devices: <ul style="list-style-type: none"> ○ Indicated for refractory open-angle glaucoma to reduce intraocular pressure (IOP) in individuals where documented medical and conventional surgical treatments have failed. The specific model of the implanted device must be FDA-approved and be used according to FDA-approved indications. • iSTENT Trabecular Micro-Bypass Stent: <ul style="list-style-type: none"> ○ Indicated for use in conjunction with cataract surgery for the reduction of IOP in adult individuals with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. • Canaloplasty is considered medically necessary for an IOP of 21 mm Hg or higher and a diagnosis of primary open-angle glaucoma (POAG), pigmentary glaucoma, exfoliation glaucoma, or POAG mixed with another mechanism under any of the following circumstances: <ul style="list-style-type: none"> ○ Failed trabeculectomy in opposite eye ○ Failed laser trabeculoplasty without scarring ○ Documented case with medical reason why target IOP is unlikely to be achieved on maximum doses of ophthalmic medications ○ IOP has not been achieved over 6 months on maximum dose of ophthalmic medications alone ○ Keloid formers ○ Individuals with significant ocular surface disease ○ Individuals with ocular pemphigoid ○ Concern about further loss of vision in individuals with any of the following: <ul style="list-style-type: none"> ▪ High myopia (-6 diopters or higher) ▪ Advanced previous glaucoma damage, ie, visual field lost and visual fixation is split ▪ Ocular hypotony in opposite eye 2° to trabeculectomy ▪ Immuno-suppressed ▪ Anti-coagulation



Service	Medical Necessity
	<ul style="list-style-type: none"> ▪ Diabetes mellitus with documented early retinopathy or diabetic macular edema ○ Requirements for canaloplasty: <ul style="list-style-type: none"> ▪ Procedure must be completed with an FDA-approved device or system ▪ Providers must have evidence of credentialing and privileges for performing canaloplasty at the surgical facility/center where the procedure is performed ▪ Ophthalmic surgeon must be formally trained with documentation of training to perform the canaloplasty procedure

Coding

Code	Description
CPT	
Ex-PRESS Mini Glaucoma Shunt, FDA-Approved Aqueous Drainage Devices, and iSTENT Trabecular Micro-Bypass Stent:	
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
Canaloplasty	
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal; with retention device or stent
ICD-10 Codes Covered if Selection Criteria are Met	
H40.10X0-H40.10X4	Open angle glaucoma, unspecified
H40.1110	Primary open-angle glaucoma, right eye, stage unspecified
H40.1111	Primary open-angle glaucoma, right eye, mild stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1113	Primary open-angle glaucoma, right eye, severe stage
H40.1114	Primary open angle glaucoma, right eye, undetermina



Code	Description
H40.1120	Primary open-angle glaucoma, left eye, stage unspecified
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1124	Primary open-angle glaucoma, left eye, indeterminate stage
H40.1130	Primary open-angle glaucoma, bilateral, stage unspecified
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1133	Primary open-angle glaucoma, bilateral, severe stage
H40.1134	Primary open-angle glaucoma, bilateral, indeterminate stage
H40.1190	Primary open-angle glaucoma, unspecified eye, stage unspecified
H40.1191	Primary open-angle glaucoma, unspecified eye, mild stage
H40.1192	Primary open-angle glaucoma, unspecified eye, moderate stage
H40.1193	Primary open-angle glaucoma, unspecified eye, severe stage
H40.1194	Primary open-angle glaucoma, unspecified eye, indetermi
H40.11X0-H40.11X4	Primary open angle glaucoma
H40.1290	Low-tension glaucoma, unspecified eye, stage unspecified
H40.1310-H40.1394	Pigmentary glaucoma
H40.1410-H40.1494	Pseudoexfoliation glaucoma
H40.151-H40.159	Residual state of open angle glaucoma
H40.50X0-H40.63X4	Glaucoma secondary to other eye disorders/drugs
H40.89-H40.9	Other specified glaucoma
Q15.0	Congenital glaucoma

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Related Information

N/A

Evidence Review

Background

The Centers of Medicare and Medicaid Services (CMS) categorize glaucoma as a group of diseases, frequently characterized by raised intraocular pressure (IOP) which affects the optic nerve. Glaucoma is the second leading cause of blindness in the world (approximately 8.4 million people blind from glaucoma), but with early detection and treatment, serious vision loss can be prevented. Risk factors for glaucoma include: African Americans over age 40, everyone over age 60 (especially Mexican Americans), and people with a family history of glaucoma.

The American Academy of Ophthalmology defines primary open-angle glaucoma (POAG) as a progressive, chronic, optic neuropathy in adults in which IOP and other currently unknown factors contribute to damage and in which, in the absence of other identifiable causes, there is a characteristic acquired atrophy of the optic nerve and loss of retinal ganglion cells and their axons. This condition is associated with an anterior chamber angle that is open by gonioscopic appearance.

The EX-PRESS is a glaucoma filtration device designed to regulate intraocular pressure in eyes suffering from glaucoma. The device works by diverting aqueous humor through the implant from the anterior chamber to the intrascleral space, the bleb.

The iStent trabecular micro-bypass stent creates a permanent opening from the anterior chamber into Schlemm's canal, thus improving aqueous humor outflow and ultimately reducing IOP.

The iTrack 250A canaloplasty procedure attempts to widen the eye's natural drainage canal and therefore re-establish normal eye pressure.



References

1. Alcon, Inc., The Ex-PRESS Glaucoma Filtration Device Preloaded on EDS. ©2010, Alcon., http://bmctoday.net/glaucomatoday/express-shunt/images/EX-PRESS_DFU.pdf. Link archived..
2. American Academy of Ophthalmology. Primary Open-Angle Glaucoma Suspect Benchmarks for Preferred Practice Pattern Guidelines. November 2020. <https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-suspect-ppp>. Last accessed May 22, 2024.
3. Centers for Medicare and Medicaid Services (CMS). Medicare Learning Network: MLN Matters No. MM6087- Revised. July Update to the 2008 Medicare Physician Fee Schedule Database (MPFSDB). Revision Date: June 9, 2008. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1528CP.pdf>. Last accessed May 22, 2024.
4. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) L37244: Micro-Invasive Glaucoma Surgery (MIGS). Revision Effective Date: 12/01/2019. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=37244&ContrId=275>. Last accessed May 22, 2024.
5. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article (LCA) A55707: Response to Comments: Micro-Invasive Glaucoma Surgery (MIGS). Revision Effective Date: 12/01/2017. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55707&ver=9&bc=0>. Last accessed May 22, 2024.
6. Dahan E, Ben Simon GJ, Lafuma A. Comparison of trabeculectomy and Ex-PRESS implantation in fellow eyes of the same patient: a prospective, randomized study. *Eye*. 2012 May;26(5):703-710. doi: 10.1038/eye.2012.13. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351049/pdf/eye201213a.pdf>. Last accessed May 22, 2024.
7. Le K, Saheb H. iStent trabecular micro-bypass stent for open-angle glaucoma. *Clin Ophthalmol*. 2014 Sep 23;8:1937-1945. doi: 10.2147/OPTH.S45920. eCollection 2014. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4181749/>. Last accessed May 22, 2024.
8. Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: Three-year results of circumferential viscodilation and tensioning of Schlemm canal using a microcatheter to treat open angle glaucoma. *J Cataract Refract Surg*. 2011 April; 37:682-690. doi:10.1016/j.jcrs.2010.10.055. <http://www.ncbi.nlm.nih.gov/pubmed/21420593>. Last accessed May 22, 2024.
9. Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: circumferential viscodilation and tensioning of Schlemm canal using a flexible microcatheter for the treatment of open angle glaucoma. Two-year interim clinical study results. *J Cataract Refract Surg*. 2009 May; 35(5):814-824. doi: 10.1016/j.jcrs.2009.01.010. <http://www.ncbi.nlm.nih.gov/pubmed/19393879>. Last accessed May 22, 2024.
10. Minckler DS, Francis BA, Hodapp EA, et al. Ophthalmic Technology Assessment. Aqueous shunts in glaucoma. A report by the American Academy of Ophthalmology Ophthalmology. 2008 Jun;115(6):1089-1098. doi: 10.1016/j.ophtha.2008.03.031. <http://www.aao.org/ophthalmic-technology-assessment/aqueous-shunts-in-glaucoma-ota>. Last accessed May 22, 2024.
11. National Eye Institute (NEI). At a Glance: Glaucoma. <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/glaucoma#:~:text=Glaucoma%20is%20a%20group%20of,a%20comprehensive%20dilated%20eye%20exam>. Last accessed May 22, 2024.
12. National Institute for Health and Clinical Excellence (NICE), Interventional Procedure Guidance (IPG): Canaloplasty for Primary Open Angle Glaucoma. IPG 591. Published Date: September 2017. <https://www.nice.org.uk/guidance/ipg591>. Last accessed May 22, 2024
13. Royal National Institute of Blind People: Myopia and High Degree Myopia. © 2014, Royal National Institute of Blind People, London. Accessed: 07/30/2019. <https://www.rnib.org.uk/your-eyes/eye-conditions-az/myopia-and-pathological-myopia/#how-is-myopia-graded>. Last accessed May 22, 2024.



14. Salim S. Current variations of glaucoma filtration surgery. *Curr Opin Ophthalmol*. 2012 Mar;23(2):89-95. doi: 10.1097/ICU.0b013e32834ff401. <http://www.ncbi.nlm.nih.gov/pubmed/22249236>. Last accessed May 22, 2024.
15. Shingleton B, Tetz M, Korber N. Circumferential viscodilation and tensioning of Schlemm canal (canaloplasty) with temporal clear corneal phacoemulsification cataract surgery for open-angle glaucoma and visually significant cataract: one-year results. *2008 Mar;34(3):433-440*. doi: 10.1016/j.jcrs.2007.11.029 <http://www.ncbi.nlm.nih.gov/pubmed/18299068>. Last accessed May 22, 2024.
16. US Food and Drug Administration (FDA). 510 (K) Summary, Blunt Tip Ex-PRESS Mini Glaucoma Shunt. K030350. (Submitter: OPTONOL, Ltd.). March 13, 2003. http://www.accessdata.fda.gov/cdrh_docs/pdf3/k030350.pdf. Last accessed May 22, 2024.
17. US Food and Drug Administration (FDA). 510 (k) Summary, Ex-PRESS Miniature Glaucoma Implant. K012852. (Submitter: OPTONOL, Ltd.). March 26, 2002. http://www.accessdata.fda.gov/cdrh_docs/pdf/k012852.pdf. Last accessed May 22, 2024.
18. US Food and Drug Administration (FDA). Glaukos iStent Trabecular Micro-Bypass Stent (Models: GTS-100R, GTS-100L) and Inserter (GTS-100i)- P080030. July 16, 2012. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P080030>. Last accessed May 22, 2024.

History

Date	Comments
09/16/19	New policy, approved August 13, 2019, effective January 1, 2020. Invasive procedures (stents and canaloplasty) for use in the treatment of glaucoma may be considered medically necessary when criteria are met.
10/01/20	Annual Review, approved September 17, 2020. No changes to policy statement, references updated.
05/01/21	Annual Review, approved April 1, 2021. No changes to policy statement, references updated.
07/01/22	Annual Review, approved June 27, 2022. No changes to policy statement, references updated. Removed CPT codes 0191T and 0253T.
10/01/22	Interim Review, approved September 12, 2022. References updated, no other changes to the policy.
03/01/23	Annual Review, approved February 6, 2023. References updated, no other changes to the policy. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 24, 2024. No changes to policy statement, references updated.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and



local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy only applies to Individual Plans.

