

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: MP.124.MH
Last Review Date: 02/25/2021
Effective Date: 05/01/2021

MP.124.MH – Glaucoma, Invasive Procedures

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers Invasive Procedures for Glaucoma medically necessary for the following indications:

- 1. Ex-PRESS™ Mini Glaucoma Shunt and FDA-Approved Aqueous Drainage Devices:** Refractory open-angle glaucoma to reduce intraocular pressure (IOP) in patients 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.
- 2. iSTENT® Trabecular Micro-Bypass Stent:** Indicated 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.
- 3. 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:
 - A. Failed trabeculectomy in opposite eye
 - B. Failed laser trabeculoplasty without scarring
 - C. Documented case with medical reason why target IOP is unlikely to be achieved on maximum doses of ophthalmic medications
 - D. IOP has not been achieved over 6 months on maximum dose of ophthalmic medications alone
 - E. Keloid formers
 - F. Patients with significant ocular surface disease
 - G. Patients with ocular pemphigoid
 - H. Concern about further loss of vision in patients with any of the following:
 - High myopia (-6 diopters or higher)
 - Advanced previous glaucoma damage = visual field lost & visual fixation is split
 - Ocular hypotony in opposite eye 2° to trabeculectomy
 - Immuno-suppressed

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- Anti-coagulation
- Diabetes mellitus with documented early retinopathy or diabetic macular edema

Requirements for Canaloplasty:

1. Procedure must be completed with an FDA-approved device or system
2. Providers must have evidence of credentialing and privileges for performing canaloplasty at the surgical facility/center where the procedure is performed
3. Ophthalmic surgeon must be formally trained with documentation of training to perform the canaloplasty procedure

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 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 the 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-establishing normal eye pressure.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes

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Code	Description
Ex-PRESS™ Mini Glaucoma Shunt, FDA-Approved Aqueous Drainage Devices, and iSTENT® Trabecular Micro-Bypass Stent:	
CPT codes	
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
ICD-10 codes covered if selection criteria are met:	
H40.10X0- H40.10X4	Open angle glaucoma, unspecified
H40.11X0- H40.11X4	Primary open angle glaucoma
H40.1290	Low-tension glaucoma, unspecified eye, stage unspecified
H40.1310- H40.1394	Pigmentary open angle glaucoma
H40.151- H40.159	Residual state of open angle glaucoma
H40.50X0- H40.63X4	Glaucoma secondary to other eye disorders/drugs
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
H40.1133	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

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H40.1194	Primary open-angle glaucoma, unspecified eye, indetermi
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
Q15.0	Congenital glaucoma
Canaloplasty	
CPT codes	
66174	Transluminal dilation of aqueous outflow canal; without retention of device of 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	Unspecified open angle glaucoma
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
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

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H40.1131	Primary open-angle glaucoma, bilateral, mild 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
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H40.1114	Primary open angle glaucoma, right eye, undetermina

References

1. Alcon, Inc., The Ex-PRESS® Glaucoma Filtration Device Preloaded on EDS. Accessed: 07/30/2019. ©2010, Alcon., http://bmctoday.net/glaucomatoday/express-shunt/images/EX-PRESS_DFU.pdf
2. American Academy of Ophthalmology. Primary Open-Angle Glaucoma Suspect Benchmarks for Preferred Practice Pattern® Guidelines. October 2015. <https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp-2015>
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. <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6087.pdf>
4. 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>

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5. Hayes Health Technology Brief. EX-PRESS Glaucoma Filtration Device (Alcon Inc.) for Treatment of Primary Open-Angle Glaucoma. Publication Date February 26, 2015. Archived July 16, 2019.
6. Hayes Health Technology Brief. iStent inject Trabecular Micro-Bypass Stent (Glaukos Corp.) in Combination with Cataract Surgery for Management of Open-Angle Glaucoma. Annual Review October 27, 2020.
7. Hayes Health Technology Brief. Canaloplasty (iTrack 250A Canaloplasty Microcatheter; iScience Interventional Inc.) for Primary Open-Angle Glaucoma. Annual Review September 27, 2013. Archived Oct 16, 2014.
8. Hayden FA: An Update on Canaloplasty, American Society of Cataract & Refractive Surgery, Issued September 2011.
<http://www.eyeworld.org/printarticle.php?id=6032>
9. 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/>
10. 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>
11. 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>
12. 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.opthta.2008.03.031, <http://www.aao.org/ophthalmic-technology-assessment/aqueous-shunts-in-glaucoma-ota>
13. National Eye Institute (NEI). Facts about Glaucoma
https://nei.nih.gov/health/glaucoma/glaucoma_facts
14. 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>
15. Royal National Institute of Blind People: Myopia and High Degree Myopia. © 2014, Royal National Institute of Blind People, London. Accessed: 07/30/2019.
http://www.rnib.org.uk/eyehealth/eyeconditions/eyeconditionsdn/Pages/high_deg_ree_myopia.aspx

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16. 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>
17. 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>
18. U.S. 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
19. U.S. 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
20. U.S. 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.glaukos.com/wp-content/uploads/2017/01/45-0177-Rev-1-28FINAL29-IFU2C-GTS1002C-Australia-Commerical-9.11.17.pdf>

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