

Aqueous Shunts and Stents for Glaucoma

Policy ID:	HHO-DE-MP-1024
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	
Original Effective Date:	N/A
Annual Approval Date:	09/2022
Last Revision Date:	09/20/2021
Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary aqueous shunts and stents for glaucoma.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Glaucoma – When fluid builds up in the front part of the eye, increasing pressure, resulting in damage of the eyes optic nerve.

Aqueous shunts – Artificial filtering devices which lower the intraocular pressure (IOP) by draining aqueous humor to the external subconjunctival space.

Ab externo aqueous shunts – The insertion of shunts from outside of the eye. Insertion of ab externo aqueous shunts approved by the U.S. Food and Drug Administration (FDA) may be considered medically necessary as a method to reduce IOP in individuals with glaucoma where medical therapy has failed to adequately control IOP.

Ab interno aqueous shunts – An incisional approach where the device may be inserted into the eye. Insertion of ab interno aqueous shunts approved by the FDA may be considered medically necessary as a method to reduce IOP in individuals with glaucoma where medical therapy has failed to adequately control intraocular pressure.

PROCEDURES

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, a variety of devices, including aqueous shunts, are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma. Microstents are also being evaluated in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

1. Members diagnosed with open-angle glaucoma who meet both criteria (American Academy of Ophthalmology, 2018; American Optometric Association, 2010; Tseng, 2017):
 - Progressive visual field loss on maximal medical therapy, intolerance to glaucoma medications,
 - or poor adherence to current treatment plan.
 - Failure or likely failure of angle surgery (e.g., laser trabeculoplasty or trabeculectomy) to
 - adequately control intraocular pressure (e.g., neovascular glaucoma, uveitic glaucoma,
 - conjunctival scarring from previous ocular surgery, or cicatrizing diseases of the conjunctiva).
2. Members with congenital or pediatric glaucoma who meet either criterion (American Academy of Ophthalmology, 2018; American Association for Pediatric Ophthalmology and Strabismus, 2018; Chen, 2014):
 - Failure or likely failure of primary goniotomy or trabeculotomy to adequately reduce intraocular
 - pressure to an acceptable level (e.g., less than 21 mmHg).
 - Presence of aphakia that may require contact lens wear for visual rehabilitation.
3. Use of ab externo or ab interno aqueous shunt(s) for all other conditions when IOP is adequately controlled by medications is considered experimental/investigational and therefore non-covered, because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service

Experimental/investigational (E/I) services are not covered regardless of place of service.

The use of aqueous shunts and stents for glaucoma is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent.
66183	Insertion of anterior segment aqueous drainage device. Without extraocular reservoir, external approach.
66175	Transluminal dilation of aqueous outflow canal; with retention of device or stent.

Covered Diagnosis Codes for procedure codes 66174 and 66183

H40.001	H40.002	H40.003	H40.011	H40.012	H40.013	H40.021
H40.022	H40.023	H40.041	H40.042	H40.043	H40.051	H40.052
H40.053	H40.061	H40.062	H40.063	H40.10X0	H40.10X1	H40.10X2
H40.10X3	H40.10X4	H40.1110	H40.1111	H40.1112	H40.1113	H40.1114
H40.1120	H40.1121	H40.1122	H40.1123	H40.1124	H40.1130	H40.1131
H40.1132	H40.1133	H40.1134	H40.1210	H40.1211	H40.1212	H40.1213
H40.1214	H40.1220	H40.1221	H40.1222	H40.1223	H40.1224	H40.1230
H40.1231	H40.1232	H40.1233	H40.1234	H40.1310	H40.1311	H40.1312
H40.1313	H40.1314	H40.1320	H40.1321	H40.1322	H40.1323	H40.1324
H40.1330	H40.1331	H40.1332	H40.1333	H40.1334	H40.1410	H40.1411
H40.1412	H40.1413	H40.1414	H40.1420	H40.1421	H40.1422	H40.1423
H40.1424	H40.1430	H40.1431	H40.1432	H40.1433	H40.1434	H40.151
H40.152	H40.153	H40.20X0	H40.20X1	H40.20X2	H40.20X3	H40.20X4
H40.211	H40.212	H40.213	H40.2210	H40.2211	H40.2212	H40.2213
H40.2214	H40.2220	H40.2221	H40.2222	H40.2223	H40.2224	H40.2230
H40.2232	H40.2233	H40.2234	H40.231	H40.232	H40.233	H40.241
H40.242	H40.243	H40.31X0	H40.31X1	H40.31X2	H40.31X3	H40.31X4
H40.32X0	H40.32X1	H40.32X2	H40.32X3	H40.32X4	H40.33X0	H40.33X1
H40.33X2	H40.33X3	H40.33X4	H40.41X0	H40.41X1	H40.41X2	H40.41X3
H40.41X4	H40.42X0	H40.42X1	H40.42X2	H40.42X3	H40.42X4	H40.43X0
H40.43X1	H40.43X2	H40.43X3	H40.43X4	H40.51X0	H40.51X1	H40.51X2
H40.51X3	H40.51X4	H40.52X0	H40.52X1	H40.52X2	H40.52X3	H40.52X4
H40.53X0	H40.53X1	H40.53X2	H40.53X3	H40.53X4	H40.61X0	H40.61X1
H40.61X2	H40.61X3	H40.61X4	H40.62X0	H40.62X1	H40.62X2	H40.62X3
H40.62X4	H40.63X0	H40.63X1	H40.63X2	H40.63X3	H40.63X4	H40.811
H40.812	H40.813	H40.821	H40.822	H40.823	H40.831	H40.832
H40.833	H40.89	H42	Q15.0			

Covered Diagnosis Codes for procedure code 66175

H25.011	H25.012	H25.013	H25.019	H25.031	H25.032	H25.033
H25.039	H25.041	H25.042	H25.043	H25.049	H25.091	H25.092
H25.093	H25.099	H25.10	H25.11	H25.13	H25.811	H25.812
H25.813	H25.89	H25.9	H26.001	H26.002	H26.003	H26.009
H26.011	H26.012	H26.013	H26.019	H26.031	H26.032	H26.033
H26.039	H26.041	H26.042	H26.043	H26.049	H26.051	H26.052
H26.053	H26.059	H26.061	H26.062	H26.063	H26.069	H26.09

H26.101	H26.102	H26.103	H26.109	H26.111	H26.112	H26.113
H26.119	H26.121	H26.122	H26.123	H26.129	H26.131	H26.132
H26.133	H26.139	H26.20	H26.211	H26.212	H26.213	H26.219
H26.221	H26.222	H26.223	H26.229	H26.231	H26.232	H26.233
H26.239	H26.30	H26.31	H26.32	H26.33	H26.40	H26.411
H26.412	H26.413	H26.419	H26.491	H26.492	H26.493	H26.499
H26.8	H26.9	H40.10X0	H40.10X1	H40.10X2	H40.10X3	H40.10X4
H40.1110	H40.1111	H40.1112	H40.1113	H40.1114	H40.1120	H40.1121
H40.1122	H40.1123	H40.1124	H40.1130	H40.1131	H40.1132	H40.1133
H40.1134	H40.1210	H40.1211	H40.1212	H40.1213	H40.1214	H40.1220
H40.1221	H40.1222	H40.1223	H40.1224	H40.1230	H40.1231	H40.1232
H40.1233	H40.1234	H40.1310	H40.1311	H40.1312	H40.1313	H40.1314
H40.1320	H40.1321	H40.1322	H40.1323	H40.1324	H40.1330	H40.1331
H40.1332	H40.1333	H40.1334	H40.1410	H40.1411	H40.1412	H40.1413
H40.1414	H40.1420	H40.1421	H40.1422	H40.1423	H40.1424	H40.1430
H40.1431	H40.1432	H40.1434	H40.151	H40.152	H40.153	H40.61X0
H40.61X1	H40.61X2	H40.61X3	H40.61X4	H40.62X0	H40.62X1	H40.62X2
H40.62X3	H40.62X4	H40.63X0	H40.63X1	H40.63X2	H40.63X3	H40.63X4
H42	Q15.0					

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

American Glaucoma Society (AGS) – 2012

A position statement by the AGS indicated that new technology whose intraocular pressure (IOP)-lowering effect allows for a reduction in medications, or a reduction in the need for more advanced surgical care, or improves patient adherence to care, would provide benefits to glaucoma patients. If effective and safe, AGS suggested these benefits and the fact that these technologies would not have bleb-related complications would represent an “improvement in net health outcomes.” Also, AGS stated that some categories of new surgical devices and techniques are used at the time of concomitant cataract surgery. Because cataract surgery alone has been shown to lower IOP, a control group of patients with similar entry criteria undergoing cataract surgery alone may be appropriate for these technologies.

References

American Academy of Ophthalmology. (2021). Glaucoma. Retrieved from https://www.aaopt.org/eye-health/diseases/what-is-glaucoma?gclid=CjwKCAjwmK6lBhBqEiwAocMc8s2JO0pArP87J83Be809sExyWvUoZJGy6KU3hP5yh9EtXSe56dhmYxoCv1kQAvD_BwE

American Academy of Ophthalmology. Primary open-angle glaucoma preferred practice pattern guideline. <https://www.aaopt.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp-2015>. Published November 2015. Updated 2018. Accessed March 13, 2020.

American Optometric Association. Optometric clinical practice guideline. Care of the patient with open angle glaucoma. <https://www.aaopt.org/documents/optometrists/CPG-9.pdf>. Published 1995. Revised 2010 [update in progress]. Accessed March 13, 2020.

- American Association for Pediatric Ophthalmology and Strabismus. Glaucoma for children. <https://aapos.org/glossary/glaucoma-for-children>. Updated September 2018. Accessed March 13, 2020.
- Chen TC, Chen PP, Francis BA, et al. Pediatric glaucoma surgery: A report by the American Academy of Ophthalmology. *Ophthalmology*. 2014;121(11):2107-2115. Doi: 10.1016/j.ophtha.2014.05.010.
- Tseng VL, Coleman AL, Chang MY, Caprioli J. Aqueous shunts for glaucoma. *Cochrane Database Syst Rev*. 2017;7:CD004918. Doi: 10.1002/14651858.CD004918.pub3.
- Wang, J., & Barton, K. (2017). Aqueous shunt implantation in glaucoma. *Taiwan journal of ophthalmology*, 7(3), 130–137. https://doi.org/10.4103/tjo.tjo_35_17
- Netland PA, Sarkisian SR, Jr., Moster MR, et al. Randomized, prospective, comparative trial of EX-PRESS glaucoma filtration device versus trabeculectomy (XVT study). *Am J Ophthalmol*. 2014;157(2):433-440.
- Pfeiffer N, Garcia-Feijoo J, Martinez-de-la-Casa JM, et al. A Randomized Trial of a Schlemm's Canal Microstent with Phacoemulsification for Reducing Intraocular Pressure in Open-Angle Glaucoma. *Ophthalmology*. 2015;122(7):1283-1293.
- American Glaucoma Society. Position statement on new glaucoma surgical procedures. 2012; http://www.americanglaucomasociety.net/professionals/policy_statements/new_glaucoma_surgical_procedures. Accessed February 6, 2018.
- Prum BE, Jr., Rosenberg LF, Gedde SJ, et al. Primary open-angle glaucoma Preferred Practice Pattern((R))guidelines. *Ophthalmology*. Jan 2016;123(1):P41-p111. PMID 26581556. Accessed February 6, 2018.
- National Institute for Health and Care Evidence (NICE). Trabecular stent bypass microsurgery for open-angle glaucoma [IPG575]. 2017; <https://www.nice.org.uk/guidance/ipg575>. Accessed February 6, 2018.
- Kotecha A, Feuer WJ, Barton K, et al. Quality of life in the tube versus trabeculectomy study. *Am J Ophthalmol*. 2017; 176:228-235.
- Wang X, Khan R, Coleman A. Device-modified trabeculectomy for glaucoma. *Cochrane Database Syst Rev*. 2015;12(12):CD010472.
- Wagschal LD, Trope GE, Jinapriya D, et al. Prospective randomized study comparing ExPRESS to trabeculectomy: 1-Year results. *J Glaucoma*. 2015; 27(8):625-9.
- Gonzalez-Rodriguez JM, Trope GE, Drori-Wagschal L, et al. Comparison of trabeculectomy versus Ex-PRESS: 3-year follow-up. *Br J Ophthalmol*. 2016; 100(9):1269-73.
- Dib Bustros Y, Fechtner R, S Khouri A. Outcomes of Ex-PRESS and trabeculectomy in a glaucoma population of African origin: One year results. *J Curr Glaucoma Pract*. 2017;11(2):42–47.
- Omatsu S, Hirooka K, Nitta E, Ukegawa K. Changes in corneal endothelial cells after trabeculectomy and EX-PRESS shunt: 2-year follow-up. *BMC Ophthalmol*. 2018;18(1):243.
- Budenz DL, Barton K, Gedde SJ, et al. Five-year treatment outcomes in the Ahmed Baerveldt comparison study. *Ophthalmology*. 2015;122(2):308–316.

European Glaucoma Society Terminology and Guidelines for Glaucoma, 4th Edition – Chapter 3: Treatment principles and options Supported by the EGS Foundation: Part 1: Foreword; Introduction; Glossary; Chapter 3 Treatment principles and options. *Br J Ophthalmol.* 2017;101(6):130–195.

Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma. [IPG612]. 2018; <https://www.nice.org.uk/guidance/ipg612/chapter/1-Recommendations>. Accessed October 3, 2019.

Trabecular stent bypass microsurgery for open-angle glaucoma [IPG575]. 2017; <https://www.nice.org.uk/guidance/ipg575>. Accessed October 3, 2019.

Prum BE Jr, Rosenberg LF, Gedde SJ, et al. Primary open-angle glaucoma preferred practice pattern® guidelines. *Ophthalmol.* 2016; 123(1):41-111.

Katz LJ, Erb C, Carceller Guillamet A, et al. Long-term titrated IOP control with one, two, or three trabecular micro-bypass stents in open-angle glaucoma subjects on topical hypotensive medication: 42-month outcomes. *Clin Ophthalmol.* 2018;12:255–262.

Katz LJ, Erb C, Carceller GA, et al. Prospective, randomized study of one, two, or three trabecular bypass stents in open-angle glaucoma subjects on topical hypotensive medication. *Clin Ophthalmol.* 2015;9:2313–2320.

Vold SD, Voskanyan L, Tetz M, et al. Newly Diagnosed Primary Open-Angle Glaucoma Randomized to 2 Trabecular Bypass Stents or Prostaglandin: Outcomes Through 36 Months [published correction appears in *Ophthalmol Ther.* 2016 Dec;5(2):173]. *Ophthalmol Ther.* 2016;5(2):161–172.

De Gregorio A, Pedrotti E, Russo L, Morseli S. Minimally invasive combined glaucoma and cataract surgery: Clinical results of the smallest ab interno gel stent. *Int Ophthalmol.* 2018; 38(3):1129-1134.

Fea AM, Ahmed II, Lavis C, et al. Hydrus microstent compared to selective laser trabeculoplasty in primary open angle glaucoma: One year results. *Clin Exp ophthalmol.* 2017; 45(2):120-127.

Samuelson TW, Chang DF, Marquis R, et al. A schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract. *Ophthalmol.* 2019; 126(1):29-37.

Vlasov A, Kim WI. The Efficacy of Two Trabecular Bypass Stents Compared to One in the Management of Open-Angle Glaucoma. *Military Medicine.* 2017; 182(1):222–225.

Donnenfeld ED, Solomon KD, Voskanyan L, et al. A prospective 3-year follow-up trial of implantation of two trabecular microbypass stents in open-angle glaucoma. *Clin Ophthalmol.* 2015;9:2057–2065.

Ferguson T, Swan R, Ibach M, et al. Evaluation of a trabecular microbypass stent with cataract extraction in severe primary open-angle glaucoma. *J Glaucoma.* 2018; 27(1):71-76.

Kurji K, Rudinsky CJ, Rayat JS, et al. Phaco-trabectome verses phaco-iStent in patients with open-angle glaucoma. *Can J Ophthalmol.* 2017; 52(1):99-106.

Fea AM, Consolandi G, Zola M, et al. Micro-Bypass Implantation for Primary Open-Angle Glaucoma Combined with Phacoemulsification: 4-Year Follow-Up. *J Ophthalmol.* 2015;2015:795357.

Agrawal P, Bradshaw SE. Systematic Literature Review of Clinical and Economic Outcomes of Micro-Invasive Glaucoma Surgery (MIGS) in Primary Open-Angle Glaucoma. *Ophthalmol Ther.* 2018;7(1):49–73.

Mansouri K, Guidotti J, Rao HL, et al. Propective evaluation of standalone XEN gel implant and combined phacoemulsification-XEN gel implant surgery: 1-Year result. *J Glaucoma*. 2018;27(2):140-147.

Tan SZ, Walkden A, Au L. One-year result of XEN45 implant for glaucoma: efficacy, safety, and postoperative management. *Eye (Lond)*. 2018;32(2):324–332.

Ozal Sa, Kaplaner O, Basar BB, et al. An innovation in glaucoma surgery: XEN45 gel stent implantation. *Arq Bras Offamol*. 2017; 80(6): 382-385.

Galal A, Bilgic A, Eltanamly R, Osman A. XEN Glaucoma Implant with Mitomycin C 1-Year Follow-Up: Result and Complications. *J Ophthalmol*. 2017;2017:5457246.

Hengerer FH, Kohnen T, Mueller M, et al. Ab interno gel implant for the treatment of glaucoma patients with or without prior glaucoma surgery: 1-year results. *J Glaucoma*. 2017; 26(12):1130-1136.

Grovers DS, Flynn WJ, Bashford KP, et al. Performance and safety of a new ab interno gelatin stent in refractory glaucoma at 12 months. *Am J Ophthamol*. 2017; 183:25-36.

Schlenker MB, Gulamhusein H, Conrad-Hengerer I, et al. efficacy, safety and risk factors for failure of standalone ab interno gelatin microstent implantation verses standalone trabeculectomy. *Ophthalmol*. 2017; 124(11):1579-1588.

Budenz DL, Feuer WJ, Barton K, et al. Postoperative Complications in the Ahmed Baerveldt Comparison Study During Five Years of Follow-up. *Am J Ophthalmol*. 2016;163:75–82.

Christakis PG, Kalenak JW, Tsai JC, et al. The Ahmed verses Baerveldt study: Five-year outcomes. *Ophthalmol*. 2016; 123(10): 2093-102.

Christakis PG, Zhang D, Budenz DL, et al. Five-year pooled data analysis of the Ahmed Baerveldt comparison study and the Ahmed verses Baerveldt study. 2017; 176:118-126.

Bo W, Dai D, Sun F. Observation of curative effects of Ex-PRESS and AGV implantation in the treatment of refractory glaucoma. *Exp Ther Med*. 2018;15(5):4419–4425.

POLICY UPDATE HISTORY

<Date>	<Event>
--------	---------