



## Medical Policy Manual

**Approved Revised Policy: Do Not Implement Until 4/30/19**

### Aqueous Shunts and Stents for Glaucoma

#### DESCRIPTION

Aqueous shunts and stents for the treatment of glaucoma create an alternative path for aqueous humor to leave the anterior chamber of the eye and thus lower the intraocular pressure (IOP). They are intended for use in individuals with inadequately controlled glaucoma.

Glaucoma is the second most common cause of blindness worldwide. It is a progressive optic neuropathy characterized by nerve atrophy and loss of vision. Signs of disease include an elevated intraocular pressure (IOP) and loss of peripheral vision. Damage caused by IOP is permanent and not reversed even when the IOP is reduced. Pharmacological treatment in the form of eye drops is first-line therapy followed by laser therapy (trabeculoplasty) when drugs fail.

Surgery is considered for individuals who are inadequately controlled or intolerant of medical and laser therapy. The traditional surgical procedure is called a trabeculectomy, in which part of the sclera is removed to allow aqueous humor to drain in a controlled manner from the anterior chamber into the sub-conjunctival space. The surgery may fail over time due to scar formation at the drainage site. Due to the potential complications and a relatively high failure rate (approximately 20%) a variety of alternative devices are being developed.

Aqueous shunts (e.g., Ahmed®, Baerveldt® Krupin, EXPRESS®) drain aqueous humor away from the anterior chamber by a variety of surgical installation details (e.g., canals, filters, valves). The incisional approach cuts through the conjunctiva and sclera (ab externo) and complications include corneal endothelial failure, infection and erosion of the overlying conjunctiva.

Emerging minimally invasive glaucoma surgery (MIGS) devices, also known as micro-stents (e.g., iStent®, iStent® inject, Hydrus™) have been used in individuals with mild to moderate open-angle glaucoma where optimal IOP has not been achieved with medication. The incisional approach is similar to cataract surgery (ab interno) and the initial devices approved by the FDA were inserted at the same time as cataract surgery. Later devices (Xen® Glaucoma Treatment System or Gel Stent) can be inserted either with cataract surgery or as stand-alone procedures. Studies indicate that IOP may be lowered below baseline with very few untoward effects. While the need for ocular hypotensive medication may not be eliminated entirely with micro-stent insertion it will likely be decreased.

**Examples of FDA approved aqueous shunts and stents currently available**

Name	Type of Device	Procedural Approach
Ahmed®	glaucoma valve implant (shunt)	Ab externo
AquaFlow™	collagen shunt	Ab externo
Baerveldt®	glaucoma shunt	Ab externo
Krupin	glaucoma valve implant (shunt)	Ab externo
Molteno®	glaucoma valve implant (shunt)	Ab externo
Ex-PRESS®	glaucoma mini-shunt	Ab externo
iStent®	micro-stent (titanium)	Ab interno; for use with cataract surgery
iStent® inject	Injector pre-loaded with 2 micro-stents	Ab interno; for use with cataract surgery
Hydrus™	Micro-stent	Ab interno; for use with cataract surgery
XEN®	micro-stent (gel)	Ab interno; for use with or without cataract surgery

#### POLICY

- **Insertion** of an **ab externo** aqueous shunt as a method to reduce intraocular pressure is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**



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- Insertion of an **ab externo** aqueous shunt for all other **diseases/conditions** is considered **investigational**.
- Insertion of a **ab interno aqueous** micro-stent as a method to reduce intraocular pressure is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Insertion of an **ab interno aqueous** micro-stent for all other **diseases/conditions** is considered **investigational**.
- Any aqueous shunt or **micro-stent** device utilized must have FDA approval specific to the indication, otherwise it will be considered **investigational**.

### MEDICAL APPROPRIATENESS

- Insertion of an **aqueous shunts or micro-stents** to control and/or treat increased intraocular pressure are considered **medically appropriate** if **ANY ONE** of the following are met:
  - An **ab externo** aqueous shunt (e.g., Ahmed™, Baerveldt®, Krupin, EXPRESS®) if **ALL** of the following criteria are met:
    - A diagnosis of glaucoma
    - **Ocular hypotensive medications have** failed to adequately control intraocular pressure
  - Insertion of **ab interno aqueous micro-stents** (e.g., XEN® Gel Stent) if **ALL** of the following are met:
    - A diagnosis of glaucoma
    - **Ocular hypotensive medication(s) has not** adequately controlled intraocular pressure
  - One or two implanted **ab interno aqueous micro-stents** (e.g. iStent®, iStent® inject, Hydrus™) if **ALL** of the following are met:
    - A diagnosis of glaucoma
    - Currently being treated with **ocular hypotensive** medication(s)
    - Performed in conjunction with cataract surgery

### IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

### ADDITIONAL INFORMATION

Well-designed studies with long-term outcomes are not available that address the use of aqueous shunts and stents for indications other than those listed above.

### SOURCES

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American Academy of Ophthalmology. (2015). *Primary open-angle glaucoma*. Retrieved March 27, 2017 from <https://www.aaopt.org/about-preferred-practice-patterns>

Ansari, E. (2017, July) An update on implants for minimally invasive glaucoma surgery (MIGS). *Ophthalmology Therapy*, (6), 233-241. (Level 2 evidence)

Arriola-Villalobos, P., Martinez-de-la-Casa, J. M., Diaz-Valle, D., Fernández-Pérez, C., García-Sánchez, J., & García-Feijó, J. (2012). Combined iStent trabecular micro-bypass stent implantation and phacoemulsification for coexistent open-angle glaucoma and cataract: A long-term study. *British Journal Ophthalmology*, 96 (5); 645-649. (Level 3 evidence)

Belovay, G., Naqi, A., Chan, B., Rateb, M., and Ahmed, I. (2012, November) Using multiple trabecular micro-bypass stents in cataract patients to treat open-angle glaucoma. *Journal of Cataract & Refractive Surgery*, 38(11), 1911-7. Abstract retrieved May 2018 from PubMed database.

BlueCross BlueShield Association. Evidence Positioning System (12:2018). *Aqueous shunts and stents for glaucoma* (9.03.21). Retrieved December 20, 2018 from <http://www.evidencepositioningsystem.com> . (56 articles and/or guideline reviewed)

BlueCross BlueShield of Tennessee network physicians. 2018.

California Technology Assessment Forum. (2011, June). *Aqueous shunts for the treatment of glaucoma*. Retrieved July 15, 2015 from <http://ctaf.org/reports/aqueous-shunts-treatment-glaucoma> (100 articles and /or guidelines reviewed)

Chen, G., Li, W., Jiang, F., May, S., & Tong, Y. (2014). Ex-PRESS implantation versus trabeculectomy in open-angle glaucoma: a meta-analysis of randomized controlled clinical trials. *PLoS One*, 9 (1). Abstract retrieved July 15, 2015 from PubMed database.

Christakis, P. G., Kalenak, J. W., Tsai, J. C., Zurakowski, D., Kammer, J. A., Harasymowycz, P. J., et al. (2016). The Ahmed versus Baerveldt study: Five-year treatment outcomes. *Ophthalmology*, 123 (10), 2093-2102. Abstract retrieved March 27, 2017 from PubMed database.

Craven, E. R., Katz, L. J., Wells, J. M., & Giamporcaro, J. E. (2012). Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: Two-year follow-up. *Journal of Cataract & Refractive Surgery*, 38 (8), 1339-1345. (Level 2 evidence - Industry sponsored)

DeGregorio, A., Pedrotti, E., Stevan, G., Bertocello, A., and Morselli, S. (2018) XEN gel stent in the management of glaucoma. *Clinical Ophthalmology*, (12), 773-782. (Level 4 evidence)

de Jong, L. A. (2009). The Ex-PRESS glaucoma shunt versus trabeculectomy in open-angle glaucoma: A prospective randomized study. *Advances in Therapy*, 26 (3), 336-345. Abstract retrieved July 9, 2012 from PubMed database.

ECRI Institute. Emerging Technology Evidence Report. (2013, March). *Trabecular micro-bypass stent (iStent) for treating open-angle glaucoma*. Retrieved July 15, 2015 from ECRI Institute. (50 articles and/or guideline reviewed)

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ECRI Institute. Clinical Comparison. (2017, June). *Overview of three eye stents for treating glaucoma*. Retrieved December 20, 2018 from ECRI Institute. (21 articles and/or guideline reviewed)

Fea, A. M. (2010). Phacoemulsification versus phacoemulsification with micro-bypass stent implantation in primary open-angle glaucoma: Randomized double-masked clinical trial. *Journal of Cataract & Refractive Surgery*, 36 (3), 407-412. (Level 2 evidence)

Fox, A., Risma, T., and Bettis, D. (2017, September) *MIGS: minimally invasive glaucoma surgery*. Retrieved May 17, 2018 from <https://webeye.ophth.uiowa.edu/eyeforum/tutorials/migs>

Gedde, S. J., Singh, K., Schiffman, J. C., & Feuer, W. J. (2012). The tube versus trabeculectomy study: interpretation of results and application to clinical practice. *Current Opinion in Ophthalmology*, 23 (2), 118-126. Abstract retrieved March 27, 2017 from PubMed database.

Grover, D., Flynn, W., Bashford, K., Lewis, R., Duh, Y., Nangia, R., et al. (2017, November) Performance and safety of a new ab interno gelatin stent in refractory glaucoma at 12 Months. *American Journal of Ophthalmology*, 2017 (183), 25-36. (Level 3 evidence)

Katz, L., Erb, C., Guillaumet, A., Fea, A., Voskanyan, L., Giamporcaro, J., et al. (2018, January) 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. *Clinical Ophthalmology*, 2018 (12), 255-262. (Level 2 evidence)

Lee, J., Amoozgar, B. and Han, Y. (2017, July) Minimally invasive modalities for treatment of glaucoma: an update. *Journal of Clinical & Experimental Ophthalmology*, 8 (4). (Level 2 evidence)

Macher, T., Häberle, H., Wächter, J., Thannhäuser, C., Aurich, H., and Pham, D. (2018, January) Trabecular microbypass stents as minimally invasive approach after conventional glaucoma filtration surgery. *Journal of Cataract & Refractive Surgery*, 44(1), 50-55. Abstract retrieved May 17, 2018 from PubMed database.

National Institute for Health and Clinical Evidence (NICE). (2017, February). *Interventional procedural guidance: Trabecular stent bypass microsurgery for open-angle glaucoma*. Retrieved March 27, 2017 from <http://www.nice.org.uk>

Samuelson, T. W., Katz, L. J., Wells, J. M., Duh, Y., & Giamporcaro, J. E. (2011). Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. *Ophthalmology*, 118 (3), 459-467. (Level 2 evidence - Industry sponsored)

Schlenker, M., Gulamhusein, H., Conrad-Hengerer, I., Somers, A., Lenzhofer, M., Stalmans, I, et al. (2017, November) Efficacy, safety, and risk factors for failure of standalone ab interno gelatin microstent implantation versus standalone trabeculectomy. *Ophthalmology*, 124(11),1579-1588. Abstract retrieved May 17, 2018 from PubMed database.

U. S. Food and Drug Administration. (2016, October). *Center for Devices and Radiological Health. 510K Notification Database. K161457. (Xen Glaucoma Treatment System)*. Retrieved May 21, 2018 from <http://www.accessdata.fda.gov>

U. S. Food and Drug Administration. (1993, November). Center for Devices and Radiological Health. *510K Notification Database. K925636 (Ahmed®)*. Retrieved June 10, 2016 from <http://www.accessdata.fda.gov>



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U. S. Food and Drug Administration. (2012, June). *Center for Devices and Radiological Health. Premarket Approval Database. P080030 (iStent®)*. Retrieved December 4, 2012 from <http://www.accessdata.fda.gov> .

U. S. Food and Drug Administration. (2018, August). *Center for Devices and Radiological Health. Premarket Approval Database. P170034 (Hydras®)*. Retrieved December 14, 2018 from <https://www.accessdata.fda.gov>

Vold, S., Ahmed, I., Craven, E., Mattox, C., Stamper, R., Packer, M. et al. (2016, October). Two-year COMPASS trial results: supraciliary microstenting with phacoemulsification in patients with open-angle glaucoma and cataracts. *Ophthalmology*, 123(10), 2103-12. Abstract retrieved May 17, 2018 from PubMed database.

Wang, S., Gao, X., & Qian, N. (2016). The Ahmed shunt versus the Baerveldt shunt for refractory glaucoma: a meta-analysis. *BMC Ophthalmology*, 16 (83). Abstract retrieved March 27, 2017 from PubMed database.

Winifred S. Hayes, Inc. Health Technology Brief. (2016, March; last update search February 2017) iStent trabecular micro-bypass (Glaukos Corp.) in combination with cataract surgery for treatment of open-angle glaucoma. Retrieved April 2, 2018 from [www.hayesinc.com](http://www.hayesinc.com) (38 guidelines and/or articles reviewed)

**EFFECTIVE DATE**                      4/30/2019

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