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Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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WellCare Health Insurance of Arizona, Inc.*

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Viscocalostomy and Canaloplasty

Policy Number: HS-126

Original Effective Date: 8/20/2009

Revised Date(s): 8/20/2010; 8/2/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND*Viscocanalostomy*

Viscocanalostomy is a procedure used to treat glaucoma that involves surgical incisions and injection of a viscous, elastic material into the eye. The goal of this procedure is to reduce intraocular pressure by creating a channel that allows excess fluid to drain from the eye.

Viscocanalostomy can be performed under peribulbar or retrobulbar anesthesia and should be performed by an ocular surgeon who has been specifically trained in this technique. During this procedure, a limbal-based, half-thickness scleral flap is dissected deeply into clear cornea and a second flap is dissected near the ciliary body. Schlemm's canal is unroofed by gentle pulling on the scleral flap and by simultaneously peeling the fibrotic lining from the bottom of the canal and the juxtacanalicular trabecular meshwork. After the membrane is cleaved from the cornea to create a corneal "window," the inner scleral flap is excised. A cannula is then inserted in Schlemm's canal, the canal is filled with sodium hyaluronate, the cannula is removed, and the flaps are sutured closed (Hayes, 2003).

Hayes Statement on Viscocanalostomy

"Additional randomized controlled trials of viscocanalostomy are required to determine if the lower frequency of complications associated with viscocanalostomy outweighs its lower efficacy relative to trabeculectomy with regard to control of IOP. Based on the available evidence, a HAYES Rating™ of D has been assigned to viscocanalostomy. This Rating reflects the available evidence, which suggests that viscocanalostomy is less effective than trabeculectomy. "

Canaloplasty

Transluminal dilation of aqueous outflow canal also known as canaloplasty is a new non-penetrating surgical procedure to treat glaucoma. It has some similarities to viscocanalostomy. A canaloplasty is a 360 degree viscodilation of the Schlemm's canal with an illuminated beacon-tipped microcatheter. The microcatheter is used to place an intracanalicular suture that cinches and stretches the trabecular meshwork inwards while permanently opening Schlemm's canal. The difference between a viscocanalostomy and a canaloplasty is that the canaloplasty aims at opening the entire length of the canal, not just one section of it.

American Academy of Ophthalmology (AAO) Statement

In their Preferred Practice Pattern for primary open-angle glaucoma, the American Academy of Ophthalmology (AAO) (2005) cites limited studies of nonpenetrating glaucoma surgery but does not specifically address canaloplasty. The AAO concludes: "The precise role of nonpenetrating surgery in the surgical management of glaucoma remains to be determined."

National Institute for Health and Clinical Excellence (NICE) Statement

The National Institute for Health and Clinical Excellence (NICE) (2008) issued guidance on canaloplasty and stated: "Current evidence on the safety and efficacy of canaloplasty for primary open-angle glaucoma is inadequate in both quality and quantity. Therefore, this procedure should only be used in the context of research or formal prospective data collection."

POSITION STATEMENT

Viscocanalostomy and Canaloplasty **are considered experimental and investigational** for the treatment of all conditions, including primary open-angle glaucoma.

CODING**Non-covered CPT®* Level III Codes**

- 0176T** Transluminal dilation of aqueous outflow canal; without retention of device or stent
0177T Transluminal dilation of aqueous outflow canal; with retention of device or stent

ICD-9-CM Procedure Codes - No applicable codes

HCPCS Codes - No applicable codes

ICD-9-CM Diagnosis Codes

- 360.42** Blind hypertensive eye [absolute glaucoma]
365.00 - 365.9 Glaucoma
743.20 - 743.22 Buphthalmos [congenital or newborn glaucoma]

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

REFERENCES**Peer Reviewed**

1. Carassa RG, Bettin P, Fiori M, Brancato R. Viscocanalostomy versus trabeculectomy in white adults affected by open-angle glaucoma: a 2-year randomized, controlled trial. *Ophthalmology*. 2003;110(5):882-887.
2. Hayes, Inc Directory. Visvocanalostomy for Treatment of Glaucoma. October 30, 2003.
3. Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults: interim clinical study analysis. *J Cataract Refract Surg*. 2007; 33(7):1217-1226.
4. 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. *J Cataract Refract Surg*. 2008; 34(3):433-440.

Government Agencies, Professional and Medical Organizations

1. American Academy of Ophthalmology (AAO). Primary Open angle glaucoma. Preferred Practice Pattern. Revised September 2005.
2. National Institute for Health and Clinical Excellence (NICE). Canaloplasty for open-angle glaucoma. Interventional Procedure Guidance 260. London, UK: NICE; May 2008.

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
8/2/2011	<ul style="list-style-type: none">• Approved by MPC.