Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
XEN® Glaucoma Treatment System (Allergan, Inc., Irvine, CA) is investigative and unproven and therefore NOT COVERED for the treatment of glaucoma (open-angle glaucoma; refractory, primary and secondary) to reduce intraocular pressure (IOP). There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description
Glaucoma is a chronic disorder involving increased pressure in the eye due to fluid buildup. There are several forms of glaucoma with open angle glaucoma (OAG) being the most common. The increased pressure associated with OAG can lead to optic neuropathies characterized by visual field loss and structural damage to the optic nerve. If left untreated, glaucoma can result in partial or complete visual impairment. Currently, IOP is the only treatable risk factor for glaucoma, and lowering IOP has proven beneficial in reducing the progression of loss of vision.

Surgical intervention is indicated in the management of glaucoma when medication therapies have failed to adequately reduce IOP. The current standard surgical procedures for reduction of IOP, for which alternatives modalities have been compared, include trabeculectomy and cataract surgery. For the majority of individuals, trabeculectomy is the most common surgery that allows drainage of aqueous humor from within the eye to underneath the conjunctiva where it is absorbed.

Minimally invasive or microincisional glaucoma surgery (MIGS) has been proposed to provide a medication-sparing, conjunctival-sparing approach to lower IOP for patients with mild-to-moderate glaucoma. MIGS is proposed to be safer than traditional incisional glaucoma surgery. One current approach is subconjunctival filtration (e.g., XEN gel stent).

The XEN Glaucoma Treatment System (Allergan, Inc. Aliso Viejo, CA) consists of the crosslinked XEN Gel Stent preloaded into the XEN Injector. The Stent is composed of a gelatin derived from porcine dermis, formed into a tube, and then cross-linked with glutaraldehyde. The stent is proposed to create a permanent channel through the sclera allowing an outflow of aqueous humor from the anterior chamber to the subconjunctival space resulting in a conjunctival bleb. The goal of the XEN is to lower IOP without relying on physiologic outflow pathways.
FDA Approval
On November 21, 2016 the XEN Glaucoma Treatment System (consisting of the XEN45 Gel Stent and the XEN Injector) was granted FDA clearance for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open-angle glaucoma (POAG), and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
- 0499T - Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
- 0450T - Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)

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