Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

Definition: Glaucoma refers to a disease of the optic nerve characterized by elevated intraocular pressure (IOP), changes in the nerve structure, and progressive, irreversible loss of vision. There are several types of glaucoma; the two main types are open-angle glaucoma (OAG) and angle-closure glaucoma. Primary OAG is the most common type of glaucoma.

Initial treatment of OAG includes medications (and/or laser treatments) that lower IOP, while surgical approaches may be indicated if treatment does not lower IOP adequately or if disease progression is observed. Available surgical treatments aim to either facilitate the exit of aqueous humor from the eye or decrease its production. The most common incisional surgical treatment for primary OAG is a type of filtration surgery known as trabeculectomy. Another alternative for patients with OAG is an aqueous shunt, which assists in filtration by physically shunting aqueous humor to the supraciliary or sub-Tenons space.

Medical Necessity:

I. The Company considers glaucoma drainage devices (i.e., Ahmed™ glaucoma valve implant, Baerveldt® glaucoma implant, ExPRESS™ mini glaucoma shunt, Krupin Eye Valve, or the Molteno® implant) (CPT Codes 66179, 66180, 66183, and HCPCS Codes C1783, L8612) medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

   ▪ Refractory OAG; and
   ▪ Conventional treatments have failed or are contraindicated.

II. The Company considers the iStent® Trabecular Micro-Bypass Stent (CPT Code 0191T), the iStent inject® (CPT Code 0191T billed with 0376T), or the Hydrus® Microstent (CPT Code 0191T) medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

   ▪ Patient has definitive diagnoses of cataract and mild to moderate open angle glaucoma; and
   ▪ Implant used to relieve IOP; and
   ▪ Implantation is in conjunction with cataract surgery; and
   ▪ Single insertion of a device per medically necessary eye; and
   ▪ One of the following medical criteria are met:
     - Patient is currently being treated with ocular hypotensive medication; or
III. The Company considers the XEN® Glaucoma Treatment System (CPT Codes 0449T, 0450T) medically necessary and eligible for reimbursement for management of refractory OAG when both maximum tolerated medical therapy and previous surgical treatments have failed.

IV. Based upon our findings, the Company has determined the following devices have not demonstrated equivalence or superiority to currently accepted standard means of treatment. The Company considers the following devices investigational and not eligible for reimbursement (this list is not all-inclusive):

- CyPass Micro-Stent (CPT Codes 0253T, 0474T)
- iStent G3 Supra (CPT Code 0253T)
- Trabectome (ab interno trabeculectomy) (CPT Code 65820†)

V. The Company considers traditional (ab externo) canaloplasty (CPT Codes 66174, 66175) medically necessary and eligible for reimbursement for treatment of primary OAG when conventional medical management has failed or is contraindicated.

VI. Based upon our findings, the Company has determined the following interventions have not demonstrated equivalence or superiority to currently accepted standard means of treatment. The Company considers the following interventions investigational and not eligible for reimbursement (this list is not all-inclusive):

- Transciliary fistulization (transciliary filtration, Singh filtration, Fugo Blade transciliary filtration) (CPT Code 66999††)
- Viscocanalostomy (including phacoviscocanalostomy) (CPT Code 66999††)

The Company considers glaucoma drainage devices for all other clinical conditions, including for indications outside of the FDA approval/clearance, not medically necessary and not eligible for reimbursement.

The Company considers glaucoma drainage devices that do not have FDA approval/clearance, as well as devices that have been recalled, not medically necessary and not eligible for reimbursement.

The Company considers iStent Trabecular Micro-Bypass Stent, the iStent Inject, the Hydrus Microstent, and the XEN Glaucoma Treatment System for all other clinical conditions not medically necessary and not eligible for reimbursement.

†When goniotomy (CPT Code 65820) is determined to be trabectome (ab interno trabeculectomy).

††When unlisted procedure, anterior segment of eye (CPT Code 66999) is determined to be transciliary fistulization or viscocanalostomy.
Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

NOTE: After reviewing the relevant documentation, the Company reserves the right to apply this policy to the service, or procedure, supply, product, or accommodation performed or furnished regardless of how the service, or procedure, supply, product, or accommodation was coded by the Provider.

Approval or clearance by the U.S. Food and Drug Administration alone is not a basis for coverage.

Coverage may differ for Medicare Advantage plan members; please see any applicable national and/or local coverage determinations for details. This information may be available at the Centers for Medicare & Medicaid Services (CMS) website.
Sources of Information:

- Hayes, Inc., Landsale, PA: Author
Medical Policy