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 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) 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 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
   - Implantation is of one device per medically necessary eye; and
   - One of the following medical criteria are met:
     - Patient is currently being treated with ocular hypotensive medication; or
     - Ocular hypotensive medications have failed to adequately control IOP.
III. 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 investigative and not eligible for reimbursement (this list is not all-inclusive):

- CyPass Micro-Stent
- Hydrus
- XEN System

IV. 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 investigative and not eligible for reimbursement (this list is not all-inclusive):

- Canaloplasty
- Viscocanalostomy

The Company considers glaucoma drainage devices for all other clinical conditions not medically necessary and not eligible for reimbursement.

The Company considers iStent Trabecular Micro-Bypass Stent for all other clinical conditions not medically necessary and not eligible for reimbursement.

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.
Sources of Information:

- Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. Several devices (listed below). Food and Drug Administration [website]. Available at:
  - iStent Trabecular Micro-Bypass Stent (GTS-100R, GTS-100L); inserter (GTS-100i): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmm/pmn.cfm?ID=P080030
• Optimed Glaucoma Pressure Regulator: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K903462
• Modified Molteno(Tm) Implants: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K902489
• Molteno Implant: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K890598
• Molteno Valve Seton: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K875099


• Hayes, Inc., Landsale, PA: Author


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