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Clinical Review Criteria
MicroInvasive Glaucoma Surgery (MIGS)

- Cypass

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Criteria

For Medicare & Non-Medicare Members
iStent device – CPT 0191T
All requests must go for Medical Director review

Cypass device – CPT 0474T
The Cypass device was taken off the market 8/29/2018 by the manufacturer due to safety concerns. This device will no longer be covered KPWA members.

Background

The term micro-invasive or minimally invasive glaucoma surgery (MIGS) refers to a group of newer surgical procedures that are performed by using an ab interno (from inside the eye) approach via gonioscopic guidance and involve minimal trauma to ocular tissues. In contrast to external filtration surgeries such as trabeculectomy and aqueous tube shunt, these procedures are categorized as internal filtration surgeries. Compared with traditional filtration surgery, MIGS holds the promise of faster recovery time and less severe complications.

It is this potentially improved safety profile that opened up the indications for MIGS to include patients with early-stage glaucoma to reduce the burden of medications and problems with compliance (due to eye drop application difficulty, cost, cosmetic effects, and frequency). Another area of investigation is patients with glaucoma who require cataract surgery. An advantage of ab interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. Therefore, health outcomes of interest are the IOP achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

There are three FDA approved/cleared micro-invasive surgical stents, the iStent Trabecular Micro-Bypass Stent (2011), the CyPass Micro-Stent System (July, 2016), and the XEN Glaucoma Treatment System (Nov, 2016). The iStent is a small (1 mm x 0.5 mm) L-shaped titanium device that is inserted into Schlemm's canal to augment the natural outflow system. CyPass is a 6.35 mm long fenestrated microstent made of biocompatible polyimide inserted into the supraciliary space, thus using an alternative outflow system. The XEN45 is a 6 mm long porcine-derived gelatin stent inserted into the subconjunctival space, bypassing the natural outflow system.

Both iStent and CyPass were FDA approved for use in combination with cataract surgery to reduce IOP in adults with mild or moderate OAG and a cataract that are currently being treated with medication to reduce IOP. XEN45 was granted FDA clearance for the management of refractory glaucoma, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy

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02/06/2018	02/06/2018[MPC],	10/08/2018

[MPC] Medical Policy Committee

Revision History	Description
06/05/2018	MPC approved criteria for commercial members
10/08/2018	Non-coverage language for the CyPass device
11/14/2018	Language regarding iStent added

Codes

CPT: 0474T, 0191T, 0376T, 0253T

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