Micro-Invasive Glaucoma Surgery (Aqueous Stents)

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<th>Policy Number:</th>
<th>Original Effective Date:</th>
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<td>MM.06.029</td>
<td>02/01/2019</td>
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<th>Line(s) of Business:</th>
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<td>HMO; PPO; QUEST Integration</td>
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<td>Surgery</td>
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I. Description

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached using medications. Due to complications with established surgical approaches (e.g., trabeculectomy), a variety of shunts are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma. Microstents are also being evaluated in patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication. This policy focuses exclusively on aqueous microstent.

For individuals who have mild-to-moderate open-angle glaucoma who are undergoing cataract surgery who receive aqueous microstents, the evidence includes RCTs. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. Two microstents have received the Food and Drug Administration approval for use in conjunction with cataract surgery for reduction of IOP in adults with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication. The FDA approved microstents include iStent and Cypass. Cypass was taken off the market in December 2018. RCTs have been conducted in patients with cataracts and less advanced glaucoma, where IOP is at least partially controlled with medication. Trial results have shown that IOP may be lowered below baseline with decreased need for medication through the first two years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with indications for glaucoma treatment other than cataract surgery or refractory open-angle glaucoma who receive aqueous shunts or microstents, the evidence includes RCTs. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. Several RCTs have evaluated the use of multiple microstents, but comparators differed. One RCT compared a single microstent with multiple microstents. This trial reported no difference in the primary outcome (percentage of patients with 20% reduction in IOP); secondary outcomes favored the multiple microstent groups. One RCT compared two iStents with travoprost. This trial did not report statistical comparisons. The evidence is insufficient to determine the effects of multiple stents on health outcomes.
Clinical input was obtained in 2013 to evaluate the medical necessity of microstents in patients undergoing cataract surgery for whom IOP is not adequately controlled with hypotensive medication and for patients with mild-to-moderate glaucoma undergoing cataract surgery for whom IOP is adequately controlled with hypotensive medications. Input was also sought on the off-label use of more than 1 microstent. Input supported the use of a single microstent in patients with mild-to-moderate glaucoma undergoing cataract surgery to reduce the adverse events of medications and to avoid noncompliance.

II. Criteria/Guidelines
The implantation of a single FDA-approved micro-stent package (e.g., iStent, iStent inject, Hydrus) is covered (subject to Limitations and Administrative Guidelines) when all of the following criteria are met:

A. The stent placement is in conjunction with cataract surgery;
B. The patient has mild or moderate open-angle glaucoma (see section II. C.1 and II.C.2);
   1. Mild Glaucoma is defined as:
      a. Definite optic disc or retinal nerve fiber layer (RNFL) abnormalities consistent with glaucoma
         i. Optic disc findings consistent with glaucoma include at least one of the following:
            a. Cup to disc ratio > 0.5 (e.g. 0.55, 0.6, 0.7)
            b. Focal thinning of the optic nerve rim
            c. Small hemorrhages at the disk edge
            d. Optic nerve excavation
         ii. RNFL abnormalities defined as: RNFL thinning demonstrated on optical coherence tomography (OCT)
      b. Normal visual field as tested with standard automated perimetry (SAP)
   2. Moderate Glaucoma defined as:
      a. Definite optic disc or RNFL abnormalities consistent with glaucoma as detailed above
      b. Glaucomatous visual field abnormalities in one hemifield not within 5 degrees of fixation as tested with SAP
C. The patient is currently being treated with ocular hypotensive medication (e.g. beta blockers, prostaglandins)

III. Limitations
A. Stents are only able to reduce intraocular pressure to the mid-teens and may be inadequate when very low intraocular pressure is needed to reduce glaucoma damage.
B. Use/insertion of multiple micro-stents, not concurrently with cataract surgery, or for all other diseases/conditions is not FDA approved
C. Severe glaucoma is not covered because it is not known to be effective in improving long-term health outcomes. Indeterminate glaucoma is reviewed on a case by case basis.
   1. Severe glaucoma defined as: definite optic disc or RNFL abnormalities consistent with glaucoma as detailed above, and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with SAP.
2. Indeterminate glaucoma defined as: definite optic disc or RNFL abnormalities consistent with glaucoma as detailed above, inability of patient to perform visual field testing, unreliable/uninterpretable visual field test results, or visual fields not performed yet.

IV. Administrative Guidelines
Precertification is required. To precertify, please complete HMSA’s Precertification Request and mail or fax the form, or use iExchange as indicated. Precertification requests must include all of the following documentation from the medical record:
A. Results of visual field tests
   a. Glaucomatous Field Defects Y/N
   b. One hemifield or two hemifield
   c. Within 5 degrees fixation
B. Results of optic nerve OCT or other optic nerve imaging modality indicating glaucoma
C. Description of glaucomatous optic nerve findings that must include cup to disc ratio
D. Currently prescribed glaucoma drops
E. Patient’s Current average IOP

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<thead>
<tr>
<th>CPT Codes</th>
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<tr>
<td>0191T (single iStent)</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion</td>
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<tr>
<td>0376T (iStent inject)</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion (List separately in addition to code for primary procedure) (No additional reimbursement for this code)</td>
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The following ICD-10-CM diagnosis codes describe conditions that are consistent with the FDA labeled indication for iStent, and iStent inject.

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<th>ICD-10 CM Diagnosis Codes</th>
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<tr>
<td>H40.1111</td>
<td>Primary open angle glaucoma, right eye, mild stage</td>
</tr>
<tr>
<td>H40.1112</td>
<td>Primary open angle glaucoma, right eye, moderate stage</td>
</tr>
<tr>
<td>H40.1121</td>
<td>Primary open angle glaucoma, left eye, mild stage</td>
</tr>
<tr>
<td>H40.1122</td>
<td>Primary open angle glaucoma, left eye, moderate stage</td>
</tr>
<tr>
<td>H40.1131</td>
<td>Primary open angle glaucoma, bilateral, mild stage</td>
</tr>
<tr>
<td>H40.1132</td>
<td>Primary open angle glaucoma, bilateral, moderate stage</td>
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V. Scientific Background

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached using medications. Due to complications with established surgical approaches (e.g., trabeculectomy), a variety of shunts are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma.

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.

iStent was approved for use in combination with cataract surgery to reduce IOP in adults with mild or moderate OAG and cataract(s) currently being treated with medication to reduce IOP.

Micro-stents may be useful to lower IOP in patients with early stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is for patients with glaucoma who require cataract surgery. An advantage of ab interno stents 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. It may also be possible to insert more than 1 stent to achieve desired IOP. Therefore, health outcomes of interest are the IOP achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

Summary of Evidence:
Clinical input was obtained in 2013 to evaluate the medical necessity of microstents in patients undergoing cataract surgery for whom IOP is not adequately controlled with hypotensive medication and for patients with mild-to-moderate glaucoma undergoing cataract surgery for whom IOP is adequately controlled with hypotensive medications. Input was also sought on the off-label use of more than 1 microstent. Input supported use of a single microstent in patients with mild-to-moderate glaucoma undergoing cataract surgery to reduce the adverse events of medications and to avoid noncompliance.
Medical Necessity/Cost Effectiveness:

iStent:

Fea et al (2010) reported on a randomized, double-blind, trial of 36 cataract surgery patients who did or did not receive an iStent implantation (2:1 ratio). Inclusion criteria were a previous diagnosis of primary open-angle glaucoma with an IOP above 18 mm Hg at 3 separate visits and taking 1 or more hypotensive medications. Investigators were masked to the treatment condition and conducted follow-up at 24 hours, 1 week, and 1, 2, 3, 6, 9, 12, and 15 months. Prescription of hypotensive medications was performed according to preset guidelines. Primary outcomes were IOP and reduction in medication use over 15 months and IOP after a 1-month washout of ocular hypotensive agents (16 months postoperatively). Eight (67%) of 12 patients in the stent group and 5 (24%) of 21 in the control group did not require ocular hypotensive medication. Because treatment compliance is an ongoing concern for most ophthalmologists, trials sought to keep patients as medication-free as possible postoperatively. Patients in the stent group had significantly lower medication use than patients in the cataract-alone group. After washout of medications, mean IOP was 16.6 mm Hg in the stent group and 19.2 mm Hg in the control group.

Lordanous et al (2014), a Canadian study, found that at 6-years MIGS only cost an additional CAD$21 when compared to one medication, and generated cost savings of CAD $1273 versus two medications and CAD $2,125 versus three medications. Berdahl et al (2017) implemented a population-based, annual state-transition probabilistic, cost-of-care model to compare costs of MIGS, selective laser trabeculoplasty (SLT) and medications. Results claimed a cost savings of $309 and $1,797 over 5 years for MIGS compared to SLT and medications respectively.

Glaukos prepared and submitted Application No. 1483 - Micro-bypass stenting for open-angle glaucoma (in trabecular meshwork) to Australia’s Medical Services Advisory Committee (MSAC).

The economic model measured the incremental cost per QALY gained of adding MIGS to the treatment algorithm. Over the model duration of 15 years, TB MIGS therapy is associated with increased healthcare costs of $562 per patient. In decreasing order of magnitude, the cost of MIGS is offset by lower surgery (~$619 per patient), medication (~$406 per patient) and laser therapy costs (~$359 per patient). For MIGS+SOC versus SOC the incremental cost is calculated to be $562 with an incremental effectiveness of 0.071, resulting in an incremental cost-effectiveness ratio of $7,879.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-
1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References