Local Coverage Article:
Response to Comments: Micro-Invasive Glaucoma Surgery (MIGS) (A57907)

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As an important part of Medicare Local Coverage Determination (LCD) development, Noridian solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the Micro-Invasive Glaucoma Surgery (MIGS) LCD. The official notice period for the final LCD begins on February 6, 2020, and the final determination will become effective on March 23, 2020.

Response to Comments

Response to Comments

NUMBER	COMMENT	RESPONSE
1	There should not be a requirement for intraocular pressure to be above 20 for XEN device placement. Many patients have glaucoma with normal pressures. ICD 10 codes should include mild glaucoma.	Peer-reviewed, published literature was not submitted to support a change in required pressures or in ICD coding for the associated LCD article. At the time of the review, the published literature was lacking in quality (no RCT), size and length of follow-up (longer-term follow-up is especially relevant when a device is permanently implanted.) Below is a summary of the published studies of XEN45 that Noridian has been made aware of to date. There are two case reports, three small, uncontrolled, prospective case series with one-year follow-up and one retrospective case study comparing XEN and trabeculectomy at least one month after surgery, the only study to have a control group. While the results are uniformly promising, the authors also generally call for longer follow-up and randomized study. In a retrospective study of 354 eyes (185 microstent and 169 trabeculectomy) in patients with uncontrolled glaucoma but no prior incisional surgery (1), there was no statistical difference in either risk of failure or safety profiles, at least 1 month after surgery, between the two treatments. The authors conclude that "Further research is warranted to investigate these 2 interventions. A randomized controlled trial (unlikely able to mask) would be welcomed to eliminate confounding." A prospective case series of 13 eyes treated with XEN for open-angle glaucoma (OAG), 10 with simultaneous phacoemulsification (2) showed that at one year, 42% achieved complete success (>=20% IOP drop without medications) and

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		66%qualified success (>=20% IOP drop with medications). Complications included choroidal detachment in 2 eyes and implant extrusion in 1 eye. Two eyes underwent trabeculectomy. The authors conclude: "This new technique needs further assessment for longer follow-up survival." A prospective case series of 41 eyes treated with combined XEN and cataract surgery for OAG (3) at one year showed 80.4% achieved complete success (IOP>=6 and <=17mmHg without medications) and 97.5% qualified success (IOP>=6 and <=17 mmHg with medications). A prospective case series of 30 eyes treated with combined XEN and cataract surgery for OAG (4) showed at one year the preoperative IOP had decreased by approximately 29%. The mean medications required went from 3.07 preoperatively to 0.17 (p,0.001). Complications occurred in 3 eyes, 2 eyes had XEN implantation aborted due to surgical difficulties (subconjunctival hemorrhage and XEN extrusion during preparations) while one eye had filtration bleb failure due to encapsulation 5 months after surgery. The authors conclude: "Randomized and controlled studies with higher numbers of patients and longer terms are necessary to confirm the promising results described above." A case report of a XEN complication and how it was treated (5). A case report of successful XEN implant after descement membrane endothelial keratoplasty (DMEK) (6).
2	Noridian received a presentation from Allergen, the manufacturer of XEN45, primarily based on describing the results of the US Pivotal study (7).	The US Pivotal study does not address the evidentiary deficiencies cited in response #1. It is a relatively small (N=65), non-randomized, non-controlled study with a follow-up of only 12 months.
3	The American Glaucoma Society (AGS) also recommended select off-label coverage of both multiple microstents ("stent dosing") and as a	Noridian disagrees. Below is a summary of the published studies provided (all but one involving iStent) in support of either multiple stenting, use

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	standalone procedure (i.e., without simultaneous cataract surgery). Members argue the concept of "dosing" has an anatomic basis in that "most physiologists believe that canalicular outflow is segmental and while a single stent improves outflow in that portion of the canal and distal outflow system, placing more than one stent provides access to additional collector channels."	as a standalone or both. There is a case report, three small, uncontrolled, prospective case series with only one-year follow-up and one small, retrospective case series in pseudophakic subjects. The most important study, an RCT, failed to show a statistical difference in either primary or secondary outcome measures between one, two or three standalone iStents. As noted by AGS, there is now more than 5 years of experience with iStent since it was FDA approved in 2012. If the evidence accumulated supports dosing and use as a standalone, Noridian would encourage application by the manufacturer for expanded labelling. On a related note, there has been more than enough time to petition for a Category 1 CPT code, a move that would also address complaints about variable pricing by Medicare Contractors. A prospective, randomized, controlled evaluation of OAG uncontrolled uncontrolled on two topical hypotensive medications, treated with one [38], two [41] or three [40] iStents [9] showed there was no significant difference among the three groups on either the primary or secondary outcome measures. Both month 12 IOP reductions>=20% without ocular hypotensive medication vs baseline unmedicated IOP and month 12 unmedicated IOP, 18 mmHg were achieved by 89.2%, 90.2% and 92.1% of one-, two-, and three-stent eyes, respectively. While the authors report other measures (e.g., IOP) which were statistically different between groups, these were not defined in the protocol prior to the study according to clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT01517477). A pilot prospective, non-controlled study of 39 subjects with OAG treated as a standalone procedure [10] showed the primary efficacy end point (IOP reduction >=20% from baseline to 12 months without medication) and the secondary end point (IOP <=18 mmHg at 12 months without medication) were each achieved by 92.3% of subjects. Three-year follow-up in 30 subjects demonstrated persistent IOP reduction in >=20% in 86.2% and IOP <=18 mmHg in 89.7%. The author's note: "We also welcome

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		larger, multicenter controlled studies to further corroborate our findings." A prospective study of 53 eyes with OAG not controlled on two medications, treated with two iStents as a standalone procedure and postoperative topical prostaglandin[11] showed the main outcome measure (the proportion of eyes with intraocular pressure reduction >=20% versus medicated baseline intraocular pressure with reduction of one medication at 12 months), was achieved in 91% of the 53 eyes. A retrospective, consecutive case series of 42 pseudophakic eyes with mild to moderate glaucoma implanted with a single iStent [12] showed IOP was significantly reduced at one and two years but medication use was not. A multi-center, prospective study of 65 subjects with OAG refractory to medical therapy and treated with a single CyPass device [13] showed that among the 55 subjects available for follow-up at one year, IOP was reduced by 34.7% ($p<0.0001$) and medications decreased from 1.4 to 1.3 ($p=0.002$). A case report of 2 iStents implanted into a patient with recurrent OAG 5 years after Ahmed valve implantation [14] reports a decrease in the IOP from a pre-operative baseline of 28 mm Hg to 17 mm Hg at two-year follow-up
4	The manufacturer of iStent inject and some practicing ophthalmologists submitted comments endorsing the proposed coverage criteria of iStent inject. However, their main focus was directed at presenting data intended to support extra payment for multiple stents, specifically the second stent intrinsic to the iStent inject device. They requested that iStent inject be billed with "CPT codes 0191T and 0376T," and that "code 0376T be moved from Group 2 to Group 1 in the related Coding Article A57863, Billing and Coding for Micro-Invasive Glaucoma Surgery."	Noridian disagrees. First, due to changes related to the 21st Century Cures Act, billing and coding information is no longer part of the LCD, and therefore no longer subject to official comment on the LCD. Second, the proposed draft considers coverage of "one device per eye medically reasonable and necessary for the treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication and the procedure is being performed in conjunction with cataract surgery." No change was made to non-coverage of more than one device; therefore, that

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		component of the LCD is not open to comment. A request to expand coverage to include multiple devices can be made via a reconsideration request. However, it is doubtful that such expansion would apply to iStent inject, as the device is a 2-stent system, and therefore, is adequately described by 0191T alone (insertion initial device). The 2-stent device was studied, FDA approved, and now covered by this LCD; there is no coverage for placement of part of the device (i.e., only one of the two stents). If the company feels iStent inject deserves distinct coding from the original iStent device, they can request a unique code, preferably a Category I code, rather than permanently rely on T (temporary) codes
5	**References** 1. Schlenker MB, Gulamhusein H, Conrad-Hengerer I, et al. Efficacy, safety, and risk factors for failure of standalone ab interno gelatin microstent implantation versus standalone trabeculectomy. *Ophthalmology*. 2017:1-10. http://dx.doi.org/10.1016/j.ophtha.2017.05.004 . 2. Galal A, Bilgic A, Eltanamly R, Osman A. Xen Glaucoma implant with mitomycin c 1-year follow-up: result and complications. *Journal of Ophthalmology*. 2017:1-5. https://doi.org/10.1155/2017/5457246. 3. De Gregorio A, Pedrotti E, Russo L, Morselli S. Minimally invasive combined glaucoma and cataract surgery: clinical results of the smallest ab interno gel stent. *Int Ophthalmol*. 2017:1-6. doi: 10.1007/s10792-017-0571. 4. Pérez-Torregrosa VT, Olate-Pérez Á, Cerdà-Ibáñez M. et al. Combined phacoemulsification and Xen 45 surgery from a temporal approach and 2 incisions. *Arch Soc Esp Oftalmol*. 2016;91(9):415-421. 5. Pinto Ferreira N, Abegã Pinto L, Marques-Neves	N/A

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Associated Documents

Related Local Coverage Document(s)

N/A

Related National Coverage Document(s)

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Public Version(s)

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