

Article - Response to Comments: Micro-Invasive Glaucoma Surgery (MIGS) (A57908)

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Article Information

General Information

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Article Title

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Article Type

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Article Guidance

Article Text

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

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

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		<p>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.</p> <p>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."</p> <p>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 ($\geq 20\%$ IOP drop without medications) and 66% qualified success ($\geq 20\%$ 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."</p> <p>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 ≤ 17 mmHg without medications) and 97.5% qualified success (IOP ≥ 6 and ≤ 17 mmHg with medications).</p> <p>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</p>

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		<p>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."</p> <p>A case report of a XEN complication and how it was treated (5).</p> <p>A case report of successful XEN implant after descemet membrane endothelial keratoplasty (DMEK) (6).</p>
2	<p>Noridian received a presentation from Allergan, the manufacturer of XEN45, primarily based on describing the results of the US Pivotal study (7).</p>	<p>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.</p>
3	<p>The American Glaucoma Society (AGS) also recommended select off-label coverage of both multiple microstents ("stent dosing") and as a 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."</p>	<p>Noridian disagrees. Below is a summary of the published studies provided (all but one involving iStent) in support of either multiple stenting, use 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.</p> <p>A prospective, randomized, controlled evaluation</p>

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		<p>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 $\geq 20\%$ 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).</p> <p>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 $\geq 20\%$ 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 $\geq 20\%$ in 86.2% and IOP ≤ 18 mmHg in 89.7%. The author's note: "We also welcome larger, multicenter controlled studies to further corroborate our findings."</p> <p>A prospective study of 53 eyes with OAG not controlled on two medications, treated with two iStents as a standalone procedure and postoperative topical prostaglandin¹¹ showed the main outcome measure (the proportion of eyes with intraocular pressure reduction $\geq 20\%$ versus medicated baseline intraocular pressure with reduction of one medication at 12 months), was achieved in 91% of the 53 eyes.</p> <p>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.</p>

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		<p>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).</p> <p>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</p>
4	<p>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 <u>and</u> 0376T," and that "code 0376T be moved from Group 2 to Group 1 in the related Coding Article <u>A57864</u>, Billing and Coding for Micro-Invasive Glaucoma Surgery."</p>	<p>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 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</p>
5	<p>References</p>	<p>N/A</p>

NUMBER	COMMENT	RESPONSE
	<ol style="list-style-type: none"> <li data-bbox="228 153 899 422">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. <i>Ophthalmology</i>. 2017:1-10. http://dx.doi.org/10.1016/j.ophtha.2017.05.004 <li data-bbox="228 485 870 709">2. Galal A, Bilgic A, Eltanamly R, Osman A. Xen Glaucoma implant with mitomycin c 1-year follow-up: result and complications. <i>Journal of Ophthalmology</i>. 2017:1-5. https://doi.org/10.1155/2017/5457246. <li data-bbox="228 726 883 951">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. <i>Int Ophthalmol</i>. 2017:1-6. doi: 10.1007/s10792-017-0571. <li data-bbox="228 968 870 1192">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. <i>Arch Soc Esp Oftalmol</i>. 2016;91(9):415-421. <li data-bbox="228 1209 883 1381">5. Pinto Ferreira N, Abegã Pinto L, Marques-Neves C. Xen gel stent internal ostium occlusion: ab-interno revision. <i>J Glaucoma</i>. 2017;26(4):e150–e152. <li data-bbox="228 1398 889 1570">6. Hohberger B, Welge-LüBen UC, Lämmer R. ICE-Syndrome: A case report of implantation of a microbypass Xen gel stent after DMEK transplantation. <i>J</i> 2017;26(2):e103–e104. <li data-bbox="228 1587 886 1856">7. Grover DS, Flynn WJ, Bashford KP, Lewis RA, Duh Y-J, Nangia RS, Niksch B, Performance and safety of a new ab interno gelatin stent in refractory glaucoma at 12 months, <i>American Journal of Ophthalmology</i> (2017), doi: 10.1016/j.ajo.2017.07.023. <li data-bbox="228 1873 899 2003">8. Stalmans I, Vera, V. Evaluation of the XEN implant in patients with moderate primary open-angle glaucoma: 1-year results. Abstract 	

NUMBER	COMMENT	RESPONSE
	<p>presented at the European Glaucoma Society 2016 Congress (EGS), June 19-22, 2016, Prague, Czech Republic.</p> <p>9. Katz, LJ, Erb C, Carceller GA, et al. Prospective, randomized study of one, two, or three trabecular bypass stents in open-angle glaucoma subjects on topical hypotensive medication. <i>Clinical Ophthalmology</i> (Auckland, NZ) 9 (2015): 2313.</p> <p>10. Donnenfeld ED, Solomon KD, Voskanyan L, et al. A prospective 3-year follow-up trial of implantation of two trabecular microbypass stents in open-angle glaucoma. <i>Clinical Ophthalmology</i> (Auckland, NZ) 9 (2015): 2057.</p> <p>11. Berdahl J, Voskanyan L, Myers JS, et al. Implantation of two second-generation trabecular micro-bypass stents and topical travoprost in open-angle glaucoma not controlled on two preoperative medications: 18-month follow-up. <i>Clinical & Experimental Ophthalmology</i> (2017).</p> <p>12. Ferguson, Tanner J, Berdahl JP, Schweitzer JA et al. Evaluation of a trabecular micro-bypass stent in pseudophakic patients with open-angle glaucoma. <i>Journal of glaucoma</i>11 (2016): 896-900.</p> <p>13. Garcia-Feijoo J, Rau M, Grisanti S, et al. Supraciliary micro-stent implantation for open-angle glaucoma failing topical therapy: 1-year results of a multicenter study. <i>Am J Ophthalmol</i> 2015;159(6):1075–1081.</p> <p>14. Roelofs K, Arora S, Dorey MW. Implantation of 2 trabecular microbypass stents in a patient with primary open-angle glaucoma refractory to previous glaucoma-filtering surgeries. <i>Journal of Cataract & Refractive Surgery</i>8 (2014): 1322-1324.</p>	

Associated Documents

Related Local Coverage Documents

Articles

[A57864 - Billing and Coding: Micro-Invasive Glaucoma Surgery \(MIGS\)](#)

LCDs

[L38301 - Micro-Invasive Glaucoma Surgery \(MIGS\)](#)

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