GLAUKOS®
Transforming Glaucoma Therapy

January 4, 2023

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Re:LCD Reconsideration Request to Cover CPT 0671T in Local Coverage Determination (LCD) Micro-Invasive Glaucoma Surgery (MIGS) (L37578) and Revise Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS) (A56491) for J-15.

Dear Dr. Loveless,

Following up on the informal meeting held with Glaukos® Corporation (Glaukos®) on September 16, 2022, we are writing to request a reconsideration to Local Coverage Determination (LCD) L37578, Micro-Invasive Glaucoma Surgery (MIGS), for CGS Administrators, LLC(CGS) to provide coverage for the procedure described by ***Current Procedural Terminology (CPT)[1] code 0671T, Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more.*** We believe that beneficiaries in your jurisdiction should have access to this procedure, which uses Glaukos' third-generation product, iStent infinite® Trabecular Micro-Bypass System Model iS3 (herein after referred to as iStent infinite®) as this meets Medicare's definition of "reasonable and necessary". In addition, we ask that coverage be extended to an additional device in the iStent family (iStent inject® W) that was cleared by the Food and Drug Administration (FDA) in July 2020, which was after the last substantive revision of this LCD. Consistent with guidance from the Centers for Medicare & Medicaid Services (CMS) and CGS[2] below we detail the specific language changes we seek for the MIGS LCD L37578 and A56491 and provide the justification for such changes based on new evidence in the medical literature.

I. Background

Glaukos® is an ophthalmic medical technology and pharmaceutical company focused on the development and commercialization of micro-scale devices and sustained pharmaceutical therapies designed to transform the treatment of glaucoma, one of the world's leading causes of blindness. The company pioneered Micro-Invasive Glaucoma Surgery (MIGS) to revolutionize the traditional glaucoma treatment and management paradigm.

Since LCD L37578 was last revised substantively in 2019, another product in the Glaukos iStent family (in addition to iStent and iStent inject, which are mentioned in the current LCD) iStent inject W was cleared by the FDA in July 2020, as a PMA-supplement which included a slight design modification with a 360-micron base (opposed to the 230 micron base with iStent inject). This modification was designed to optimize stent visualization and is the same stent used in the iStent Infinite (iStent inject W PMA number: P170043/S005, FDA letter attached as ***Exhibit A***).

Subsequently, another addition to the Glaukos® trabecular micro-bypass family of products - the iStent infinite® MIGS device. Glaukos® received 510(k) clearance from the FDA for iStent infinite® on August 2, 2022 (510(k) number: K220032, FDA letter attached as ***Exhibit B***).

Use of the iStent infinite® reduces the intraocular pressure (IOP) of the eye designed to minimize or prevent future disease progression while maintaining a high safety profile. It is indicated for use in adult patients with primary open-

[1] CPT copyright 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
[2] *See* Medicare Program Integrity Manual, Chapter 13, Section 13.3;
https://www.cgsmedicare.com/jb/coverage/reconsideration.html

angle glaucoma (POAG) in whom previous medical and surgical treatment has failed. It provides an important option to prevent the progression of glaucoma, an incurable chronic disease leading to permanent blindness, for indicated patients.

The iStent infinite® is implanted ab interno into the trabecular meshwork by an ophthalmologist, creating bypass channels into the Schlemm's canal. This mechanism aims to lower IOP by increasing aqueous outflow through the conventional pathway of the trabecular meshwork and is based on the same mechanism of action as iStent technologies, which have been implanted in over one million eyes, globally. However, unlike the iStent and iStent inject, the iStent infinite® is not labeled solely for use with concomitant cataract removal. This provides an important opportunity for equal access to a trabecular micro-bypass procedure for glaucoma patients who do not have a co-morbid cataract.

The iStent infinite® is a sterile, single-use injector system preloaded with three micro-scale wide-flange stents manufactured from implant grade titanium (Ti6Al4V ELI) and coated with stearalkonium heparin (i.e., identical stents that are used in the iStent *inject* W trabecular micro-bypass system). The stents have a symmetrical single piece design and can be implanted in either eye. Each stent has the dimensions of 360 µm in diameter, 360 µm in height, and the central inlet and outlet lumen has a diameter of 80 µm. The head of the stent has four side outlets that each have a diameter of 50 µm. Full details of the design of iStent infinite® are provided in section 1 of the Instructions for Use attached to this request as ***Exhibit C***.

The procedure for the insertion of iStent infinite® without a concurrent cataract procedure is described by CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more), which became effective on January 1, 2022.

A summary comparing the differences of Glaukos' iStent Trabecular Micro-Bypass technologies is attached to this request as ***Exhibit D***.

II. Recommended Language Changes to LCD L37578

In light of the FDA clearances of products in the iStent family (iStent *inject*® W and iStent infinite®) and new peer-reviewed published evidence (discussed below), we respectfully request that LCD L37578 is reconsidered to address the following:

Coverage Indications, Limitations, and/or Medical Necessity section of **Coverage Guidance** is updated to identify iStent *inject*® W and iStent infinite®. We recommend the following revisions, with proposed new language in red:

This LCD addresses use of a group of new surgical procedures for glaucoma referred to as micro-invasive glaucoma surgery (MIGS). CGS considers one iStent, iStent inject, iStent inject W, or Hydrus 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. One XEN45 device per eye is covered for the management of refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP ≥20 mm Hg) on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues). XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management. iStent Infinite® medically reasonable and necessary to reduce intraocular pressure of the eye for patients in whom previous medical therapy and surgical treatment has failed.

The **Summary of Evidence** section of **Coverage Guidance.** We recommend the following revisions to the last two paragraphs, with proposed new language in red:

There are 6 Food and Drug Administration (FDA) approved/cleared micro-invasive surgical stents, the iStent Trabecular Micro-Bypass Stent (2011), the CyPass Micro-Stent System (July, 2016), the XEN® Glaucoma Treatment

System (Nov., 2016), the Hydrus Microstent System (Aug., 2018) the iStent inject® (Jun, 2018), iStent *inject* W (July, 2020) and the iStent infinite (Aug., 2022). 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. The iStent inject system comprises 2 heparin-coated titanium stents (each having 0.23 mm diameter x 0.36 mm height, 0.08 mm central lumen diameter, and 4 0.05 mm side outlets to allow for multidirectional outflow), both inserted into Schlemm's canal using a pre-loaded auto-injection trocar. The iStent inject W Trabecular Micro-Bypass System Model G2-W contains two preloaded intraocular stents that are manufactured from titanium (Ti6Al4V ELI) and are coated with stearalkonium heparin. The stent has a single piece design, is 360 µm in diameter, 360 µm in height, and the central inlet and outlet lumen has a diameter of 80 µm data from the clinical study of the Model G2-M-IS system, a prior iteration of the iStent inject W Model G2-W System, was used to support the safety and effectiveness of the G2-W system. The G2-W stents include a wider proximal end in the anterior chamber of 360 µm, rather than 230 µm for Model G2-M-IS. The iStent infinite is a sterile, single-use injector system preloaded with three micro-scale wide-flange stents (each having 0.36 mm diameter x 0.36 mm height, 0.08 mm central inlet and outlet lumen diameter, and 4 0.05mm side outlets to allow for multidirectional outflow), inserted into Schlemm's canal. Hydrus is a 8 mm nitinol, crescent-shaped microstent with alternating spines for support and windows to provide outflow, also placed into Schlemm's canal. 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.

iStent, iStent *inject*, iStent *inject* W, Hydrus, and Cypass are FDA approved (Cypass recalled by FDA for safety concerns Sept., 2018) 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. The iStent inject® and iStent inject W® Trabecular Micro-Bypass System Model G2-W is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma. The iStent infinite® is indicated for use in adult patients with primary open-angle glaucoma (POAG) in whom previous medical and surgical treatment has failed. The published pivotal trial data for each, constituting the main evidentiary support, is summarized in the attached table. MIGS Pivotal Trials

The table attached to the LCD titled "Pivotal Trials for FDA Approved Micro-Invasive Glaucoma Surgery" should be updated with iStent infinite information, which is in the following:

Study	**Year**	**Journal**	**FDA**	**Study Design**	**No. of Eyes**	**Follow-up (yrs)**	**IOP ≤ 21mm Hg ~~no Meds~~**	**↓ IOP ≥ 20% on same # or fewer meds**	**Mean # meds at 12 months**	**Mean IOP reduction (mm Hg)**	**Conclusions**
iStent infinite	2022	Journal of Glaucoma	510(k)	prospective, open-label, multicenter, single-arm pivotal clinical	72	1 year	90.9%	76.1%*	2.7 ± 1.3	5.9 mmHg	iStent infinite standalone surgery achieved clinically significant IOP reduction and favorable safety in patients with OAG uncontrolled by prior therapy.

* >50% of patients achieved a 30% or greater reduction in MDIOP from baseline

In the **Analysis of Evidence (Rationale for Determination)** section we recommend the following revisions to paragraphs after the first paragraph, with proposed new language in red:

In summary, CGS considers one iStent, iStent inject, iStent inject W, or Hydrus 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. In that setting these procedures offer a reduction in IOP, decreased dependence on glaucoma medications, and an excellent safety profile. However, their role within the glaucoma treatment algorithm continues to be clarified and differs from the role of more invasive, external filtration glaucoma surgeries such as trabeculectomy or external aqueous drainage implants. Therefore, all other indications are considered not reasonable and necessary at this time. There is no additional payment for multiple stents (so-called "dosing"), regardless of method, since a statistical benefit has not been demonstrated (27), especially in conjunction with cataract surgery.

The XEN45 device received 510K clearance based on having a similar mechanism (subconjunctival pathway) as "gold standard" filtration procedures (trabeculectomy and tube shunts), demonstrating "substantial equivalence" in the pivotal prospective study of patients with refractory glaucoma (17). Equivalency was further established by a relatively large retrospective cohort study comparing XEN45 with trabeculectomy, finding "no detectable difference in risk of failure and safety profiles" (11). In addition, the American Glaucoma Society (AGS), the New York State Ophthalmological Society (NYSOS), and numerous glaucoma experts wrote CGS to support XEN45 as a minimally invasive method that, "would improve the access of older patients with refractory glaucoma to surgical care with reduction in post-operative discomfort, shorter post-operative disability, equivalent efficacy and safety."

CGS considers one XEN45® device per eye medically reasonable and necessary for the management of refractory glaucoma, defined (based on the pivotal trial criteria) as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP ≥20 mm Hg) on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues). XEN45® insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

The iStent Infinite® device received 510(k) clearance with an indication for use to reduce the intraocular pressure of the eye for adult patients with primary open-angle glaucoma in whom previous medical and surgical treatment has failed.

CGS considers iStent Infinite® medically reasonable and necessary to reduce intraocular pressure of the eye for patients in whom previous medical therapy and surgical treatment has failed.

In **Associated Information, Documentation Requirements**, of the **General Information** section, recommend the following revision, with proposed new language in red:

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. The medical record and/or test results documenting medical necessity should be maintained and made available on request.

iStent®, iStent inject®, iStent *inject*® W and Hydrus® must be performed in conjunction with cataract surgery on the same date of service and documented in the medical record.

III. Recommended Language Changes to LCA A56491

With respect to the article Billing and Coding: Micro-Invasive Glaucoma Surgery A56491, we respectfully recommend the following changes (highlighted in red):

In the **Frequency Limitations** section, update as follows, with proposed new language in red and suggested deletions in ~~red strikethrough~~:

Medicare may cover only 1 unit per eye, per date of service of CPT code 66991 and 66989 for insertion of glaucoma drainage device(s) into the trabecular meshwork (e.g., iStent®, iStent inject® iStent inject W®, or Hydrus), when performed in conjunction with cataract surgery and when the medically reasonable and necessary criteria as stated in the LCD are met. ~~Although more than one drainage device into the trabecular meshwork of a single eye on a single day of service, using an insertion tool loaded with more than one device, (e.g., iStent inject®), may be performed, once the insertion tool is deployed within the eye, there is negligible increase in work or expense.~~ Therefore only one unit of 66991 and 66989 per eye, per day may be billed, regardless of the number of devices inserted into a single eye on the date of service.

Medicare may cover only **1 unit per eye, per date of service of CPT code 0449T** for insertion of glaucoma drainage device(s) into the subconjunctival space (e.g., XEN45®), when the medically reasonable and necessary criteria as stated in the LCD are met.

In the **Coding Information** section, revise Groups 2 and 3 by moving CPT code 0671T from Group 3 to Group 2 as follows, with proposed new language in red and proposed deletions in ~~strike through~~:

Group 2 (2 Codes)
Group 2 Paragraph The CPT codes in Group 2 are considered medically necessary when the Indications of Coverage are met. The 90-day global periods applies.
Do not report 0671T in conjunction with 66989 or 66991
Group 2 Codes

Code	Description
0449T	INSERTION OF AQUEOUS DRAINAGE DEVICE, WITHOUT EXTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE SUBCONJUNCTIVAL SPACE; INITIAL DEVICE
0671T	INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE INTO THE TRABECULAR MESHWORK, WITHOUT EXTERNAL RESERVOIR, AND WITHOUT CONCOMITANT CATARACT REMOVAL, ONE OR MORE

Group 3 (3 Codes)
Group 3 Paragraph
The following CPT codes are considered not medically reasonable and necessary (non-covered).
~~Do not report 0671T in conjunction with 66989 or 66991~~

Code	Description
0253T	INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE, WITHOUT EXTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE SUPRACHOROIDAL SPACE
0450T	INSERTION OF AQUEOUS DRAINAGE DEVICE, WITHOUT EXTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE SUBCONJUNCTIVAL SPACE; EACH ADDITIONAL DEVICE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
0474T	INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE, WITH CREATION OF INTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE SUPRACILIARY SPACE
~~0671T~~	~~INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE INTO THE TRABECULAR MESHWORK, WITHOUT EXTERNAL RESERVOIR, AND WITHOUT CONCOMITANT CATARACT REMOVAL, ONE OR MORE~~

IV. Justification for Proposed Changes to MIGS LCD and Coverage Article

CGS already has recognized the clinical value of MIGS procedures performed with the iStent® and iStent inject® devices as evidenced by coverage for procedures performed with these devices consistent with their FDA labels in the

MIGS LCD for use in conjunction with a cataract procedure. However, an iStent® device can also be furnished without the patient also undergoing a cataract procedure. Specifically, the iStent infinite® combines the existing advantages possessed by the Glaukos® trabecular micro-bypass family of products (iStent® and iStent inject®), with a broader span of aqueous humor outflow enhancement, due to an additional stent being implanted, correlating directly to incremental efficacy while maintaining similar safety, and facilitating the use of an iStent® for patients not also undergoing a cataract procedure concurrently. In addition, it builds on the clinical foundational research of more than 197 peer-reviewed articles in use of iStent technologies in cataract combination and 54 with stand-alone utilization with a safety profile similar to that of cataract surgery alone.

In summarizing the evidence, a previous peer-reviewed and published manuscript utilizing the first-generation iStent® demonstrated that placement of two stents resulted in better IOP outcomes compared to one and placing a third stent further improved those outcomes (Katz LJ *et al*., 2018).[3] In these patients, the placement of three iStents® reduced pre-operative unmedicated IOP by 43% (25.1±1.9 to 14.2±1.5 mmHg) at 36-37 months post-op (n=38). Comparatively, patients with one- (n = 38) or two- (n = 41) successfully placed iStents® demonstrated IOP reductions of 30% or 37% from baseline, respectively. Similarly, the medication burden in these patients was reduced from 1-3 medications pre-op to zero in all groups immediately post-op. Consequently, by 42 months post-op, 18 eyes in the single-stent group required supplemental medication to reduce IOP below 18 mmHg, compared to 4 eyes in the 2-stent group and 3 eyes in the 3-stent group. These data make a compelling case that placement of three stents lowers IOP to a greater extent and with fewer medications compared to one or two. These data are further corroborated by more recent data demonstrating markedly improved aqueous humor drainage through the Schlemm's canal and downstream collector channels with three iStent infinite® compared to two iStent inject devices (Sarkisian Jr SR *et al*., 2022).[4] The injector system of the iStent infinite® holds three preloaded stents allowing for precise ab interno implantation into the trabecular meshwork. This is important for the indicated patient population (adult patients with POAG in whom previous medical and surgical treatment has failed), because they have fewer treatment options than newly diagnosed patients.

The pivotal study results reported by Sarkisian Jr SR *et al*. (2022) in the *Journal of Glaucoma*, demonstrate clinically meaningful benefits after iStent infinite® implantation in terms of both safety and effectiveness.[4]

The investigators conducted a 12-month, multicenter, prospective, open-label, single-arm pivotal clinical trial to demonstrate the safety and efficacy of iStent infinite® inserted as a stand-alone procedure in 72 eyes of 72 patients (mean age 71.9 years) from 15 clinical study sites in the United States.

In the iStent infinite pivotal single-arm study of 72 patients (72 eyes) who continue to have elevated IOP despite prior treatment with glaucoma medications (MTMT subgroup) and/or conventional glaucoma surgery (Failed-Surgery subgroup), the majority of eyes in the overall trial population (76.1%) achieved ≥20% reduction in mean diurnal IOP (MDIOP) at 12 months, while remaining on the same or fewer medication classes and without safety events (responder effectiveness endpoint). Among the MTMT and Failed-Surgery subgroup, the proportion of eyes which achieved responder effectiveness was 90.9% and 73.4%, respectively. Additionally:

- The mean reduction in MDIOP from baseline to 12 months in all patients was 5.9 mmHg (23.4 vs. 17.5 mmHg, respectively; 95% confidence interval 4.8, 7.1). Subgroup analysis revealed a mean IOP reduction of 8.1 mmHg in the MTMT subgroup and 5.5 mmHg in the Failed-Surgery subgroup.

  In terms of safety results:

- All 72 eyes were successfully implanted with 3 iStent infinite stents with no failed implantation attempts.
- 93% of patients maintained their preoperative best spectacle-corrected visual acuity or had a decrease of <2 lines after 12 months. There were no serious postoperative ocular AEs such as corneal decompensation,

[3] Katz, L.J. *et al*. (2018) Long-term titrated IOP control with one, two, or three trabecular micro-bypass stents in open-angle glaucoma subjects on topical hypotensive medication: 42-month outcomes. *Clinical Ophthalmology (Auckland, N.Z.)* 12,255-262. https://doi.org/10.2147/OPTH.S152268. **(*Exhibit E*)**

[4] Sarkisian Jr, S. R., *et al*. (2022) Effectiveness and Safety of iStent infinite Trabecular Micro-Bypass For Uncontrolled Glaucoma. *Journal of Glaucoma*, 10-1097 (***Exhibit F***)

choroidal hemorrhage, hypotony maculopathy or stent explantation, and the incidence of all AEs were generally low (<10%).

- There were no serious device-related AEs. Non-serious device-related AEs (n=13) were largely transient, mild to moderate in severity, and without long-term clinical sequelae. Secondary surgical interventions were performed for 3 eyes with non-device-related AEs.

In terms of peer reviewed published evidence that was not referenced in LCD (L37531), a summary of the studies are provided as follows:

Guedes RAP *et al*., *Ophthalmology and Therapy* 2022; *11*(1), 271-292.[5]

This real-world study compared the effectiveness of implanting 2–3 iStent and/or iStent *inject* stents (multi-stent arm) vs. trabeculectomy in patients with inadequate prior response to MTMT and/or laser procedures up to 24 months. In addition:

- The study compared patients with moderate to severe glaucoma on medications at risk for filtration surgery who received either 2 or 3 stents (multiple stents group) or trabeculectomy with mitomycin C.
- The safety-adjusted treatment success (defined as ≥ 20% intraocular pressure (IOP) reduction on the same or fewer medications without clinically significant safety events) was 62.9% for the multiple stents group compared to 30.0% for the trabeculectomy group.
- The multiple stents group had fewer postoperative visits and reinterventions within 3 months, longer time to first reintervention, fewer total reinterventions, and earlier lifting of postoperative restrictions vs. the trabeculectomy group.
- Exploratory subgroup analyses observed that the use of 3 stents has a greater potential for IOP reduction than 2 stents, with higher proportions of eyes in the 3-stent subgroup achieving target IOPs compared with the 2-stent subgroup (≤15 mmHg [medicated]: 86.1% vs. 61.8%, p=0.0198; ≤12 mmHg [medication-free]: 22.2% vs. 2.9%, p=0.028).

Healey PR, *et al. Journal of Glaucoma.* 2021; 30:606-620.[6]

This systematic literature review and meta-analysis analyzed IOP, the number of medications, and the safety of 788 open angle-glaucoma eyes implanted with one or two stents from 13 studies with up to 60 months of postoperative follow-up.

- The pooled weighted mean IOP showed sustained reductions for up to 60 months (60 months: 32.9% reduction, -7.6 mm Hg) and a weighted mean medication reduction of 1.2 after 36 to 60 months.

Only 2.6% of 788 eyes required additional glaucoma surgery.

In summary, results from both the pivotal trial and real-world studies consistently demonstrate the value of the placement of an iStent device without a concurrent cataract procedure in achieving greater safety-adjusted treatment success than trabeculectomy.

- This standalone procedure is therefore a safe trabecular micro-bypass MIGS procedure that can lower mean IOP in patients who continue to have elevated IOP despite prior medical and/or surgical treatment, by restoring and rejuvenating the aqueous outflow system.
- It also has the potential to reduce postoperative management and the risk of AEs compared with traditional bleb-forming incisional surgeries.

As detailed above, the standalone anterior segment aqueous drainage device insertion procedure offers patients a beneficial reduction in IOP and decreased dependence on medications, while also having an excellent safety protocol.

[5] Guedes R. A. P., *et. al*. (2022). Standalone Implantation of 2–3 Trabecular Micro-Bypass Stents (iStent inject±iStent) as an Alternative to Trabeculectomy for Moderate-to-Severe Glaucoma. *Ophthalmology and Therapy*, 11(1), 271-292. (***Exhibit G)***

[6] Healey P. R., *et al*. (2021). Standalone iStent trabecular micro-bypass glaucoma surgery: A systematic review and meta-analysis. *Journal of Glaucoma*, *30*(7), 606-620. ***(Exhibit H)***

To summarize, the pivotal trial patients were a tougher to treat patient population as compared to other MIGS pivotal trials, and despite this, the results were clearly beneficial to these patients who would have otherwise lost more vision or had another invasive procedure.

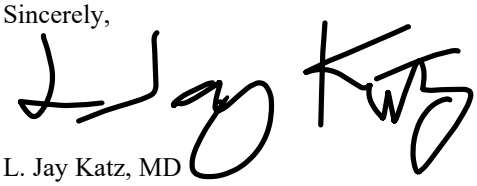
The clinical evidence, therefore, supports the requested changes to the MIGS LCD to authorize coverage for the procedure reported with CPT code 0671T.

V. CONCLUSION

Based upon the information we have provided, Glaukos believes that the procedure described by CPT code 0671T is reasonable and necessary as demonstrated by peer reviewed, published literature demonstrating the efficacy of this standalone procedure for the treatment of patients with POAG in whom previous medical and surgical treatment has failed. Thus, the procedure should no longer be treated as a non-covered service, which can be effectuated by making the suggested changes to the MIGS LCD L37578 and associated Billing and Coding Article A56491 to ensure beneficiary access for this difficult to treat patient population. In addition, for reasons discussed above (and in places in the LCD noted above), both iStent *inject*® W and iStent infinite should be added as named devices in the LCD.

Thank you for the opportunity to submit this policy reconsideration. If there is additional information required to assist with your policy decision making, please do not hesitate to contact me or Paul Harris, Payer Relations Director at pharris@glaukos.com.

Sincerely,



L. Jay Katz, MD
Chief Medical Officer

Attachments

Exhibit A – FDA clearance letter for iStent *inject*® W
Exhibit B - FDA clearance letter for iStent infinite®
Exhibit C - Instructions for Use of iStent infinite® Trabecular Micro-Bypass System
Exhibit D – Summary of Glaukos Trabecular Micro-Bypass Technologies
Exhibit E – The full copy of the peer-reviewed publication by Katz *et. al*.
Exhibit F - The full copy of the peer-reviewed publication by Sarkisian *et al*.
Exhibit G - The full copy of the peer-reviewed publication by Guedes *et. al*.
Exhibit H - The full copy of the meta-analysis publication by Healey *et. al*.