SIGHT SCIENCES

June 21, 2022

VIA EMAIL TO CMD.INQUIRY@cgsadmin.com

CGS Administrators
Attn: Chief Medical Director
J15 A/B MAC LCD Reconsideration
26 Century Blvd Ste ST610
Nashville, TN 37214-3685

Re: **LCD Reconsideration Request L37578 - Micro-Invasive Glaucoma Surgery (MIGS)**

Dear CGS Medical Directors:

Sight Sciences, Inc. submits the enclosed reconsideration of the local coverage determination (LCD) for micro-invasive glaucoma surgery (MIGS) (LCD L37578) to clarify the coverage and coding criteria applicable to two procedure combinations: **(1)** goniotomy (CPT 65820) in conjunction with aqueous drainage device insertion (CPT 66989, 66991, 0671T); and (2) unlisted viscoinjection procedure (CPT 66999) in conjunction with aqueous drainage device insertion. This letter requests that CGS establish new medical policy criteria, consistent with the current state of clinical evidence, with respect to the aforementioned procedure combinations.

We have enclosed the following materials in support of this request:

- Proposed LCD and Local Coverage Article (LCA) Language (Appendix A); and
- Full-Text Copies of Sources Cited (Appendix B).

We appreciate your consideration of this important matter. Please do not hesitate to contact John Liu at JLiu@sightsciences.com with any questions.

Sincerely,

Reay Brown, M.D.
Chief Medical Officer

John C. Liu
SVP Global Market Access

INTRODUCTION

Sight Sciences submits this reconsideration request in response to recent developments relating to the commercial launch of several new devices that are being promoted for use in performing several emerging and clinically unproven glaucoma surgeries. These activities have focused heavily on use of these devices in combination with the insertion of anterior segment aqueous drainage devices ("stents"), for reasons that appear to be driven by the prospect of additional Medicare reimbursement rather than the reasonable and necessary use of these devices. This circumstance, and the lack of any clinical support in peer-reviewed literature for these procedure combinations, has created significant concern and provider confusion about the appropriate use of these devices.

Sight Sciences manufacturers the OMNI device, which is a MIGS device used to treat glaucoma. Sight Sciences markets its products to facilities and suppliers nationwide and does business in CGS's jurisdiction. As the manufacturer of a MIGS device and developer of additional glaucoma treatment devices used in the procedures addressed here, and an organization whose mission is to improve care for glaucoma patients, Sight Sciences has an important interest in ensuring that Medicare coverage of MIGS procedures is consistent with the current state of clinical evidence, and we are aligned with CGS in its goal of ensuring appropriate use of Medicare funds to facilitate access to clinically validated glaucoma treatments.

The procedure combinations of concern combine: (1) either goniotomy (CPT 65820) or viscoinjection procedures (CPT 66999 or CPT 66174), with (2) the insertion of an anterior segment aqueous drainage device (reported with CPT 66989 or 66991 when combined with cataract surgery; reported with CPT 0671T when performed in a standalone procedure):

Table 1: Coding Combinations of Concern

	Combination	Combination	Combination
Cate2on: 1 **Goniotomy + Stent Combinations**	CPT **65820** *(goniotomy)* + CPT **66989** *(stent insertion combined with complex cataract surgery)*	CPT **65820** *(goniotomy)* + CPT **66991** *(stent insertion combined with routine cataract surgery)*	CPT **65820** *(goniotomy)* + CPT **0671T** *(standalone stent insertion, with no cataract procedure)*
Categon: 2 **Viscoinjection Procedure+ Stent Combination**	CPT **66999** or CPT **66174** + CPT **66989** *(stent insertion combined with complex cataract surgery)*	CPT **66999** or CPT **66174** + CPT **66991** *(stent insertion combined with routine cataract surgery)*	CPT **66999** or CPT **66174** + CPT **0671T** *(standalone stent insertion, with no cataract procedure)*

As outlined below, there is **no** evidence in the peer-reviewed medical literature evaluating the safety and effectiveness of these combination stent procedures, yet we continue to see devices being marketed to physicians primarily as a means to perform and bill Medicare and other third-party payors for multiple costly procedures. Due to the lack of published evidence supporting the medical necessity of combination stent procedures and the significant patient safety concerns raised by these opportunistic marketing efforts, we urge CGS to amend its LCD L37578 to include the limitations discussed below and presented in Appendix A.

I. GONIOTOMY IN COMBINATION WITH STENT INSERTION - NOT MEDICALLY NECESSARY

These combination stent procedures are untested and therefore not reasonable and necessary under Medicare's criteria. Based on our review, there is no published peer-reviewed clinical evidence regarding the safety and effectiveness of goniotomy performed in conjunction with aqueous drainage device insertion. For example, a recent PubMed search[1] identified no published clinical studies of stent insertion in combination with goniotomy, and no such use is described or referenced in the AAO's Preferred Practice Pattern guidelines (AAO PPP).[2] Two MACs, Novitas Solutions, Inc. and First Coast Service Options, Inc, already include coverage limitations in their MIGS LCDs, denying coverage of goniotomy procedures performed in combination with the insertion of an aqueous drainage device by concluding that the combination of these two procedures is not medically reasonable and necessary.[3] The coverage limitation requested here would align CGS's policy with those two existing MIGS LCDs.

The new devices that prompted this request are the Streamline Viscoelastic Injector and the iAccess Trabecular Trephine. These devices are described by the manufacturers and their physician consultants as being "designed to create precise goniotomies in the trabecular meshwork" (Streamline),[4] or as being used to create multiple "small goniotomies" (iAccess).[5-6] In

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[1] Based on PubMed searches conducted April 25, 2022: (1) Search Terms: viscocanalostomy & (stent OR iStent OR hydros OR microstent); and (2) Search Terms: goniotomy & (stent OR iStent OR hydrus OR microstent)

[2] American Academy of Ophthalmology, "Primary Open-Angle Glaucoma Preferred Practice Pattern®" (Nov. 2020) available at htt.ps://www.aao.org/preferred-practice-pattem/primary-open-angle-glaucoma-ppp

[3] *See* First Coast Service Options, Inc. Local Coverage Determination (LCD) [L38233 - Micro-Invasive Glaucoma Surgery (MIGS)] and Novitas Solutions, Inc. Local Coverage Determination (LCD) [L38223 - Micro-Invasive Glaucoma Surgery (MIGS)], both MACs which have adopted the following language: "The following are considered not medically reasonable and necessary: ... Goniotomy procedure performed in conjunction with the insertion of a glaucoma drainage device."

[4] *See* New World Medical press release dated March I, 2022, describing the design of its Streamline surgical system product (available at htt.ps://www.newworldmedical.com/new-world-medical-announces-launch-details-for-the-streamline-surgical-systemD. *See* also a video by Malik Y. Kahook, MD entitled "The streamline surgical system and top tips for pseudoexfoliation glaucoma" available at htt.ps://www.youtube.com/watch?v=DbSr6LgHYM4, stating that Streamline creates "precision goniotomies and catheterization."

[5] *See* Corcoran Consulting Group "iAccess™ Trabecular Trephine - How to Code" (April 19, 2022) available at htt.ps://www.corcoranccg.com/news/iaccess-trabecular-trephine-how-to-code/ (Enclosed in Appendix 8) (quoting htt.ps://www.youtube.com/watch?v=JB_4knSf_FE).

[6] *See* FDA Registration for iAccess Trabecular Trephine at htt_ps://www.accessdata.fda.gov/scrlpts/cdrh/cfdocs/cfRL/rl.cfm?lid=343596&lpcd=HRH showing that the

the case of iAccess, the manufacturer has promoted the device to be used in combination with stent insertion. For instance, in a YouTube demonstration video, J.T. Kavanagh, MD, states that by using the new iAccess trabecular trephine, a surgeon can make "small goniotomies in between the istent injects." Dr. Kavanagh further describes the procedure as a "combination goniotomy and stenting of the trabecular meshwork."[7] In a 2020 Glaukos Corporation Earnings Call, Chris M. Calcaterra, COO of Glaukos Corporation, described use of the iAccess device as a means for obtaining additional reimbursement: "the concept there is that you expand the canal, and then you place a trabecular bypass device in as well. So 2 separate codes. They're able to be used in harmony with each other."[8]

In the case of Streamline, the manufacturer has issued a reimbursement guide in which it encourages providers to "get reimbursed by using this established CPT code [CPT 65820] for goniotomy with ... the Streamline Surgical System."[9] In a demonstration video Malik Y. Kahook, MD, states that the Streamline Surgical System can be used to perform a goniotomy and states on the caption of the video that the appropriate CPT code is CPT 65820.[10] In another demonstration, the viewer is told that Streamline can "also" perform a "microgoniotomy", in addition to releasing viscoelastic in either direction of the "microgoniotomy."[11] Notably, the American Medical Association (AMA) does not recognize new terminology being promoted (e.g. "precision goniotomy or microgoniotomy"), with no CPT code assigned for either phrase.

A. Small Punctures Are Ineffective for Lowering IOP, With No Evidence Supporting Effectiveness If Combined With Stent Insertion Procedures.

Clinically, microgoniotomies lack the necessary safety and efficacy data in peer reviewed publications to demonstrate their ability to lower intraocular pressure in glaucoma patients. To the contrary, as reported in the medical literature, small punctures have been proven ineffective for lowering IOP. Groundbreaking work published by Grant (1963)[12] and Rosenquist et al. (1989)[13] in human anterior segment models, showed that the aqueous outflow system is segmented, and therefore, a small trabeculotomy, defined as an incision less than one clock hour, does not work for lowering IOP. Similarly, Epstein (2013) pointed out the false promise of

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Regulation Number (886.4350) describes the category for iAccess (a Class I device) as follows: "A manual ophthalmic surgical instrument is a nonpowered, handheld device intended to aid or perform ophthalmic surgical procedures."

[7] *See* "Glaukos !Access Trabecular Trephine J.T. Kavanagh MD Ophthalmologist/Glaucoma Specialist San Antonio," available at https://www.youtube.com/watch?v=tB_4knSf_FE

[8] Glaukos Corp Earnings Call, Q4 2020 (Feb. 25, 2021, 9:30pm GMT) (Enclosed in Appendix B)

[9] New World Medical, 2022 CPT Code at Your Fingertips (January 2022) (Enclosed in Appendix B)

[10] *See* "The Streamline Surgical System and Top Tips for Pseudoexfoliation Glaucoma" available at https://www.youtube.com/watch?v=DbSr6LqHYM4. Based on most recently available CMS Open Payments data, Dr. Kahook has a financial stake in this device.

[11] *See* "Streamline Surgical System With iStent" (March 10, 2022) available at https://eyetube.net/videos/streamline-surgical-system-with-istent

[12] Grant WM. Experimental aqueous perfusion in enucleated human eyes. Arch Ophthalmol. 1963;69:783-801.

[13] Rosenquist RC, Epstein DL, Melamed S, et al. Outflow resistance of enucleated human eyes with two different perfusion pressures and different extents of trabeculotomy. Curr Eye Res. 1989;8:1233-1240.

"trabeculopuncture" or "goniopuncture" surgery .[14] Epstein and others further studied the efficacy of such procedures in monkey subjects and in live patients, and all attempts failed to lower IOP.[15] These studies confirmed Grant's and Rosenquist' s prior findings that such small punctures were ineffective for lowering IOP.

Only one study that we identified has assessed the clinical use of the Streamline device; this study was a single-arm, non-randomized study of 20 test subjects in Mexico.[16] Importantly, the study did not assess the efficacy of Streamline when used in combination with anterior segment aqueous drainage devices. No published peer-reviewed studies exist with respect to the iAccess Trabecular Trephine.

B. Clarification of Goniotomy Procedure Coding

In addition to not being reasonable and necessary, these procedures (stent insertion and "microgoniotomy") should not be separately reported under coding instructions published by the AAO. AAO coding guidance dating from 2018 states that "goniotomy should not be coded in addition to any other angle procedure ***or canal implant."***[17] AAO recently reconfirmed this coding instruction in a Goniotomy Fact Sheet published on June 7, 2022, which states CPT 65820 (goniotomy) "should not be coded in addition to other angle surgeries, stent insertion or Schlemm canal implants, or if the incision into the trabecular meshwork is minimal or incidental to another procedure."[18] Devices like the iStent and iStent inject already include their own disposable injector that is used to access Schlemm's canal and place the stent. We are concerned that using a second device in combination with these stent insertions, and reporting two separate codes for the procedure, conflicts with this coding instruction from the AAO and may introduce additional safety concerns without providing any demonstrated benefit to the glaucoma patient.[19]

The combination billing for glaucoma procedures is especially concerning with these new devices because neither one is capable of performing a goniotomy procedure. Goniotomy (CPT 65820) is described by the AMA as a procedure whereby a "gonioknife is used to enter the cornea, pass across the iris, and slit Barkan's membrane for the desired area, usually 180 degrees."[20] The AMA guidance further states that a "goniotomy includes extensive incision of the trabecular

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[14] Epstein, DL. Schlemm Canal Surgery. Glaucoma Today. September 2013.

[15] *See* Melamed S, Pei J, Puliafito CA, Epstein DL. Q-Switched neodymium-YAG laser trabeculopuncture in monkeys. Arch Ophthalmol. 1985;103(1):129-133; Epstein DL, Melamed S, Puliafito CA, Steinert RF. Neodymium: YAG laser trabeculopuncture in open-angle glaucoma. Ophthalmology. 1985;92(7):931-937; and Melamed S. Latina MA, Epstein DL. Neodymium:YAG laser trabeculopuncture in juvenile open-angle glaucoma. Ophthalmology. 1987;94(2):163-170.

[16] Lazcano-Gomez G, Garg SJ, Yeu E, Kahook MY. Interim Analysis of STREAMLINE®Surgical System Clinical Outcomes in Eyes with Glaucoma. *Clin Ophthalmol.* 2022;16:1313-1320. Published 2022 Apr 27. doi:10.2147/OPTH.S358871

[17] *See American Academy of Ophthalmology,* "How to Code for Glaucoma Procedures in the Anterior Chamber Angle" by Cynthia Mattox, MD and Sue Vicchrilli, COT, OCS, OCSR (2018) (Enclosed in Appendix B)

[18] *See American Academy of Ophthalmology,* Fact Sheet: Goniotomy (June 7, 2022)

[19] *Id.*

[20] CPT Assistant, Vol. 28, Iss. 7, at 5 (July 2018). (Enclosed in Appendix B)

meshwork around the eye, rather than just the small portion penetrated by a stent in MIGS."[21] In June 2022, the AAO issued more specific guidance regarding the requirements of a goniotomy procedure reported with CPT 65820, noting the following:

- Goniotomy may only be reported when excision or incisions are performed to "open the trabecular meshwork over an area of at least 90 degrees" or "for at least several clock hours"; and

- If a procedure "consists of several punctures, injection of a small amount of viscoelastic, or other limited interventions" it should be reported using unlisted CPT code 66999.[22]

Consistent with AAO's recent Fact Sheet, experienced ophthalmic coding consultants concluded that procedures performed with these devices should be reported with CPT 66999, not CPT 65820. The Corcoran Consulting Group (CCG) published an article in April 2022, stating that "there is a substantial difference between an injection and a lengthy incision in [the trabecular meshwork], and that goniotomy (CPT 65820) is not accurate to describe the use of the Streamline® Viscoelastic Injector.'m CCG made similar findings with respect to the iAccess device, concluding that "goniotomy (CPT 65820) is not accurate to describe the use of the Glaukos !ACCESS™ trabecular trephine."[24] In contrast to the "extensive incision" required for goniotomy under AMA guidance, the iAccess Trephine has been described as creating a puncture only 220 microns in diameter.[25] Under the recent AAO clarification, the punctures or minimal incisions created by devices like the Streamline and iAccess should not be reported with CPT 65820.

For these reasons, we urge CGS to update its LCD to state that Goniotomy is not medically reasonable or necessary when performed in conjunction with the insertion of an anterior segment aqueous drainage device (with or without cataract surgery), consistent with the restrictions already in place in other Medicare jurisdictions. Moreover, consistent with the AAO's recent guidance, we request that CGS issue a coding instruction that procedures utilizing Streamline or iAccess devices should be reported with CPT 66999, not CPT 65820.

II. VISCOELASTIC DELIVERY PROCEDURES IN COMBINATION WITH STENT INSERTION - NOT MEDICALLY NECESSARY

New devices are also being marketed to perform viscoelastic delivery procedures in combination with the insertion of an anterior segment aqueous drainage device. These devices

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[21] *Id.* at 4 (emphasis added)

[22] *See American Academy of Ophthalmology,* Fact Sheet: Goniotomy (June 7, 2022)

[23] *See* Corcoran Consulting Group "Streamline® Viscoelastic Injector - How to Code?" (April 19, 2022) available at https://www.corcoranccg.com/news/streamline-viscoelastic-injector-how-to-code/ (Enclosed in Appendix B)

[24] *See* Corcoran Consulting Group "iAccess™ Trabecular Trephine - How to Code" (April 19, 2022) available at https://www.corcoranccg.com/news/iaccess-trabecular-trephine-how-to-code/ (Enclosed in Appendix B)

[25] *See* Eye Associates, "Glaucoma Specialist San Antonio" available at https://www.eyeassociatesofsouthtexas.com/glaucoma-specialist-san-antonio/

include both the Streamline Viscoelastic Injector noted above,[26] as well as iPrime Viscodelivery System.[27] The viscoelastic delivery procedures in question are described in FDA labeling as procedures that use "a manually operated device for the delivery of small amounts of viscoelastic fluid" during ophthalmic surgery (iPrime),[28] or that use "a single-use disposable cannula for use during ophthalmic surgical procedures to deliver small amounts of viscoelastic fluid" (Streamline).[29]

Similar to the concerning trends described above with respect to goniotomy-stent combinations, we are concerned that these new device entrants will result in unnecessary viscoinjection-stent combination procedures as well.[30] This combination is suspect under AMA and AAO coding guidance.[31] Viscoinjection-stent combination procedures are also not supported by the state of clinical evidence. A recent PubMed search[32] identified no published clinical studies of stent insertion performed in combination with viscocanalostomy or other viscoinjection procedures, and no such use is described in the AAO PPP. As noted above, only one small, single-arm study has been published with respect to the Streamline Viscoelastic Injector - and this study did not assess the use of Streamline in combination with anterior segment aqueous drainage devices; no published peer-reviewed studies exist concerning the iPrime Viscodelivery System.

To address the concerns highlighted above and lack of clinical evidence with respect to these procedure combinations, **we request CGS update its policy to state that injection of viscoelastic fluid (e.g., Streamline, iPrime) is not medically reasonable or necessary when performed in conjunction with the insertion of an anterior segment aqueous drainage device (with or without cataract surgery). Moreover, we request that CGS issue coding guidance to confirm that procedures involving devices indicated for the injection of a small amount of viscoelastic should be reported with CPT 66999, not CPT 65820 or CPT 66174.**

III. CONCLUSION

Given the significant costs associated with these combination stent procedures and the lack of published evidence, coupled with industry statements suggesting an effort to encourage utilization of these untested procedure combinations, we believe greater clarity in CGS's LCD would prevent these untested combination stent procedures from being performed on patients and would provide necessary guidance to providers about the appropriate utilization of these

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[26] FDA 510(k) Clearance of Streamline Surgical System, available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211680.pdf

[27] FDA 510(k) Clearance ofiPrime Viscodelivery System, available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K212797.pdf(Enclosed in Appendix B)

[28] *Id.*

[29] *See supra* note 23.

[30] Procedure combinations of concern: (I) 66999 + 66989; (2) 66999 + 66991; (3) 66999 + 0671T.

[31] *See supra* note 18; *see also* AMA CPT Assistant, Vol. 29 Iss. 9, at 11 (Sept. 2019); CPT Assistant, Vol. 28, Iss. 12 (Dec. 2018) (indicating that separate coding is not permitted when the incision inherent in one procedure is incidental to the second procedure).

[32] Based on PubMed searches conducted April 25, 2022 Search Terms: viscocanalostomy & (stent OR iStent OR hydrus OR microstent)

procedures. This policy update would also promote consistency between CGS's policy and those of other Medicare Administrative Contracts that have addressed the same or similar issues.[33]

Therefore, we request that CGS amend the "Indications and Limitations of Coverage" Section of LCD L37578 by adopting the language outlined in Appendix A and excerpted below:

> **Proposed LCD Amendment #1:** "Goniotomy is not medically reasonable or necessary when performed in conjunction with the insertion of an anterior segment aqueous drainage device (with or without cataract surgery)."
>
> **Proposed LCD Amendment #2:** "Injection of viscoelastic fluid (e.g., Streamline, iPrime) is not medically reasonable or necessary when performed in conjunction with the insertion of an anterior segment aqueous drainage device (with or without cataract surgery)."

We also request that CGS adopt a corresponding amendment to LCA A56491 outlined in Appendix A to: **(1)** define goniotomy as requiring extensive incision of the trabecular meshwork (usually 180 degrees); and (2) instruct that devices used to create only a small incision in the trabecular meshwork or to deliver small amounts of viscoelastic must be coded using CPT 66999, as excerpted below:

> **Proposed LCA Amendment:** "Goniotomy is a procedure in which trabecular meshwork is incised and/or excised with a blade or other surgical instrument for at least several clock hours to create an opening into Schlemm canal from the anterior chamber, via an internal approach through the anterior chamber. If the procedure performed consists of several punctures, injection of a small amount of viscoelastic fluid, or other limited interventions, report using unlisted CPT code 66999.
>
> Procedures involving devices cleared or approved by the FDA for the delivery of small amounts of viscoelastic fluid (e.g., Streamline, iPrime) should be reported using CPT code 66999."

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[33] *See* First Coast Service Options, Inc. Local Coverage Detennination (LCD) [L38233 - Micro-Invasive Glaucoma Surgery (MIGS)] and Novitas Solutions, Inc. Local Coverage Detennination (LCD) [L38223 - Micro-Invasive Glaucoma Surgery (MIGS)], both MACs which have adopted the following language: "The following are considered not medically reasonable and necessary: ... Goniotomy procedure performed in conjunction with the insertion of a glaucoma drainage device."