

August 6, 2021

Elise Barringer, Designated Federal Official
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mailstop C5-08-27
Baltimore, MD 21244–1850

Submitted via email to: APCPanel@cms.hhs.gov

Re: Submission for Presentation at the August 23, 2021 Meeting of the Advisory Panel on Hospital Outpatient Payment

Dear Ms. Barringer:

On behalf of Glaukos Corporation, I am pleased to submit this information pertinent to our request to present at the upcoming meeting of the Advisory Panel on Hospital Outpatient Payment (Panel) on the Ambulatory Payment Classification (APC) assignment of three new Current Procedural Terminology (CPT®) codes and to identify a speaker to present to the Panel in support of our requested recommendations for the Panel to make to the Centers for Medicare & Medicaid Services (CMS). Specifically, we ask the Panel to make the following recommendations to CMS:

1. Assign new Category I CPT codes 669X1 and 669X2¹ to APC 5493 (Level 3 Intraocular Procedures);
2. Assign new Category III CPT code 0X12T² to APC 5492 (Level 2 Intraocular Procedures); and
3. Utilize the claims data for CPT code 0191T to determine the device offset percentage for CPT codes 669X1, 669X2, and 0X12T.

Separately, we will submit a registration email for the speakers that we would like to have on this topic. Here is the needed information for those speakers:

- Name – John Berdahl, MD
- Organization or company name – Vance Thompson Vision
- Company or organization speaker is representing – Glaukos Corporation
- Email address – john.berdahl@vancethompsonvision.com
- Name – Stuart Langbein
- Organization or company name – Hogan Lovells

¹ The descriptors for these new Category I codes are: **669X1** “Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more” and **669X2** “Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more”.

² The descriptor for new CPT code 0X12T is “Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more”.

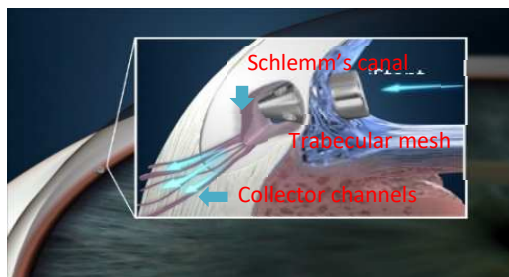
- Company or organization speaker is representing – Glaukos Corporation
- Email address – stuart.langbein@hoganlovells.com

In addition, we attach a completed form CMS-20017 that contains the pertinent information for both speakers.

BACKGROUND

Glaucoma is a chronic progressive disease of the eye that, if left untreated, can lead to permanent visual impairment and blindness. Approximately 2 percent of the population over 40 years of age have glaucoma, which increases to 12 percent in patients over 75 years of age. Thus, the vast majority of glaucoma patients are Medicare beneficiaries. Glaucoma is commonly associated with increased pressure in the eye due to an imbalance in production and outflow of ocular fluid. The most common treatment for high eye pressure and glaucoma is prescription eye drops, with regimens that must be strictly adhered to and often require placement of the drops multiple times per day. Non-adherence rates for eye drop regimens are significant and are associated with disease progression and blindness.³ Micro-invasive glaucoma surgery (MIGS) procedures involve inserting devices like the Glaukos iStent *inject* and the Ivantis Hydrus, which increases the outflow of ocular fluid and lower intraocular pressure by creating a bypass through the trabecular meshwork, providing a direct channel between the anterior chamber and Schlemm's canal as depicted in Image 1.

Image 1



Both the iStent and the Hydrus devices are indicated for use in conjunction with cataract surgery. Thus, nearly all MIGS procedures involving the iStent and Hydrus devices are reported using CPT code 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion), along with a CPT code for a cataract procedure (CPT codes 66982 or 66984). Effective January 1, 2022, CPT code 0191T will be deleted and replaced with two new Category I CPT codes for the combination of the MIGS procedure and a cataract procedure (CPT code 669X1 for complex cataract procedures and CPT code 669X2 for noncomplex cataract procedures), and a new stand-alone (i.e., independent of a cataract procedure) Category III code, 0X12T.

The current calendar year (CY) 2021 hospital outpatient department (HOPD) and ambulatory surgical center (ASC) rates for the existing codes are as follows:

CPT Code	APC Assignment	Hospital Outpatient Rate	ASC Rate
0191T	5492 (Level 2 Intraocular Procedures)	\$3,917.74	\$2,825.97
66982	5491 (Level 1 Intraocular Procedures)	\$2,079.16	\$1,039.30
66984	5491 (Level 1 Intraocular Procedures)	\$2,079.16	\$1,039.30

³ Paula Newman-Casey, et. al, *Most Common Barriers to Glaucoma Medication Adherence: A Cross-Sectional Survey*, Ophthalmology, 2015 Jul; 122(7): 1308-1316.

Thus, in CY 2021, when CPT code 0191T and a cataract procedure are performed during the same outpatient encounter, the HOPD receives \$3,917.74 (since CPT code 0191T has a J1 status indicator), and the ASC is paid \$3,345.62 (payment for CPT code 0191T plus 50 percent of the payment for CPT code 66982 or 66984). CPT code 0191T is a device intensive procedure (device offset percentage in excess of 50 percent for 2021).

Under the CY 2022 OPSS proposed rule, CMS would assign the new combined codes for MIGS procedure and cataract procedure, CPT code 669X1 and 669X2, to the same APC that it currently assigns the MIGS procedures reported separately from a cataract procedure, APC 5492. With regard to the new stand-alone CPT code 0X12T, instead of including the procedure in APC 5492 where the MIGS procedure code reported separately from the cataract procedure is currently assigned, CMS proposes, in OPSS Addendum B, to assign the procedure to APC 5491, although the proposed ASC rate in ASC Addendum AA seems suggestive of an assignment to APC 5492. The proposed device offset percentage for all three codes is 31%. These payment rate proposals are captured in the table below:

CPT Code	APC Assignment	Hospital Outpatient Rate	ASC Rate
669X1	5492 (Level 2 Intraocular Procedures)	\$4,018.82	\$2,515.86
669X2	5492 (Level 2 Intraocular Procedures)	\$4,018.82	\$2,515.86
0X12T	5491 (Level 1 Intraocular Procedures)	\$2,131.25	\$2,515.86

As noted above, when the MIGS procedure and cataract procedure are performed together in CY 2021, the ASC is paid \$3,345.62. However, when the MIGS procedure and cataract procedure are performed together in CY 2022, under the CMS proposal, the total payment would decrease by \$829.76 solely because of the code change. Similarly, for a stand-alone MIGS procedure, the change from current CPT code 0191T to CPT code 0X12T would lead to a \$1,786.49 reduction in payment to hospital outpatient departments for no apparent reason.

DISCUSSION

The proposals by CMS to implement the three new MIGS procedure codes are flawed for varying reasons. For the new Category I combination codes, the proposed APC assignment fails to reflect the fact that the new codes represent the combination of two procedures currently in different APCs. The proposal for the new stand-alone MIGS procedure code, inexplicably, is to place the code in a lower level APC than where the current MIGS procedure code, addressed separately from the cataract procedure, is assigned. Finally, CMS uses a default device offset threshold in violation of its own stated policy applicable to a situation like this. Collectively, these improper proposals impact very significantly the payment levels to ASCs, where 85 percent of these procedures are furnished. Accordingly, the Panel should make the three recommendations detailed below to address these mistaken proposals.

I. The Panel Should Recommend that CMS Assign CPT Codes 669X1 and 669X2 to APC 5493

CPT codes 669X1 and 669X2 represent the combination of two distinct procedures (cataract procedure and MIGS procedure). Currently, the cataract procedure is assigned to the Level 1 Intraocular Procedures APC (5491) and the MIGS procedure is assigned to the Level 2 Intraocular Procedures APC (5492). CMS's proposal is to assign the combination codes to the same APC as the MIGS procedure (5492), which functionally disregards the resources and costs associated with the cataract procedure, particularly in the ASC setting.

Instead, CMS should take the approach that it did in the CY 2020 final rule for a different combination cataract procedure code - the combined cataract removal with endoscopic cyclophotocoagulation (ECP) procedure.⁴ Similar to the situation here, effective January 1, 2020, the CPT Editorial Panel established two new codes to describe cataract removal with ECP (66987 and 66988) to be used instead of continuing to report separate codes for both the ECP procedure and the cataract procedure since the ECP procedure was almost always being performed with a cataract procedure.

CMS proposed to assign the new CPT codes to a Level 1 APC, but commenters raised concerns that the lower payment rate would not adequately capture the resources expended for the combined procedures. Guided by the public comments, its medical advisors and its review of the components of the procedures, CMS determined “that the resources associated with the new codes are higher than the routine cataract and ECP procedures when performed by themselves” and assigned the new CPT codes to the next level APC in the family.⁵ To illustrate this point, we have provided crosswalk tables below:

Crosswalk of Finalized APCs for ECP and Cataract/Complex-Cataract to ECP with Combined Cataract/Complex-Cataract

Procedure(s)	CPT Code	APC Assignment
ECP	66711	5491 (Level 1 Intraocular Procedures)
Cataract	66984	5491 (Level 1 Intraocular Procedures)
ECP + Cataract	66988	<u>5492 (Level 2 Intraocular Procedures)</u>

Procedure(s)	CPT Code	APC Assignment
ECP	66711	5491 (Level 1 Intraocular Procedures)
Cataract	66982	5491 (Level 1 Intraocular Procedures)
ECP + Complex Cataract	66987	<u>5492 (Level 2 Intraocular Procedures)</u>

Crosswalk of Proposed APCs for MIGS and Cataract/Complex-Cataract to ECP with Combined Cataract/Complex-Cataract

Procedure(s)	CPT Code	APC Assignment
MIGS	0191T	5492 (Level 2 Intraocular Procedures)
Cataract	66984	5491 (Level 1 Intraocular Procedures)
MIGS + Cataract	669X2	<u>5492 (Level 2 Intraocular Procedures)</u>

Procedure(s)	CPT Code	APC Assignment
MIGS	0191T	5492 (Level 1 Intraocular Procedures)
Cataract	66982	5491 (Level 1 Intraocular Procedures)
MIGS + Complex Cataract	669X2	<u>5492 (Level 2 Intraocular Procedures)</u>

Here too, rather than the proposed APC 5492, the resources associated with the insertion of the MIGS procedure and the cataract procedure justify the new CPT codes being assigned to the next level APC in the

⁴ 84 Fed. Reg. 61,142, 61,229 (Nov. 12, 2019).

⁵ *Id.* at 61,229-61,230.

family – APC 5493 – particularly when consideration is given to the resulting ASC payment rate compared to the current payments to an ASC performing both a cataract removal and a MIGS procedure. For these reasons, we ask the Panel to recommend that CMS assign CPT codes 669X1 and 669X2 to APC 5493.

II. The Panel Should Recommend that CMS Assign CPT Code 0X12T to APC 5492

New CPT code 0X12T functionally replaces CPT code 0191T, which can be observed in the code descriptors:

- CPT code 0191T - Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion
- CPT code 0X12T - Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more

The language is virtually identical, with some variation in the ordering of the code descriptor and with 0X12T stating that the code is without cataract removal. The variation in the ordering of the code descriptor does not connote a difference in the procedures as, both codes are for the insertion of an anterior segment aqueous drainage device without a reservoir. The mention of without cataract removal likewise does not reflect a difference between CPT codes 0191T and 0X12T.

Given CPT codes 0191T and 0X12T are for the same procedure, there is no reason for CMS to depart from its longstanding treatment of CPT code 0191T – assignment to APC 5492, where the code has been assigned since the Intraocular Procedures APC family was created effective January 1, 2016. Further, the 2019 claims data for CPT code 0191T, which supported its assignment to APC 5492 (the geometric mean of \$4,621.94 was the 4th highest of the 35 procedures assigned to APC 5492), certainly supports assignment of CPT code 0X12T into APC 5492 and does not support assignment to APC 5491, the geometric mean for which is \$2,023.18.

Perhaps the assignment of CPT code 0X12T to APC 5491 in Addendum B released with the proposed rule is an error by CMS because the proposed ASC payment of \$2,515.86 is more than the hospital outpatient rate for the code and is consistent with the ASC rate for other procedures assigned to APC 5492 (see second table in the Background section above).

Regardless, it is clear that CPT code 0X12T should be assigned to APC 5492 and we thus ask the Panel to recommend that CMS assign CPT code 0X12T to APC 5492.

III. The Panel Should Recommend that CMS use the Data Associated with CPT Code 0191T to Determine the Device Offset Percentage for CPT Codes 669X1, 669X2, and 0X12T

As noted earlier, CMS is proposing to utilize the default 31% device offset threshold to determine the ASC payment rate for all three new MIGS procedure codes. This is contrary to CMS's own stated policy. Specifically, in the CY 2021 OPPS/ASC final rule CMS stated:

In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply

the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage.⁶

Under this policy, the device offset percentage for CPT code 0191T (in excess of 50%) should be utilized for CPT codes 669X1, 669X2, and 0X12T since CPT code 0191T is clinically related and similar to these new CPT codes. The Panel thus should recommend that CMS follow its own stated policy and use the device offset percentage for CPT code 0191T when determining the ASC payment rate for these new codes.

CONCLUSION

The proposed incorporation of the new MIGS procedure codes would create significant reductions in payment from CY 2021 to CY 2022, which can adversely impact access to these procedures. To prevent reductions that are driven solely by the change in codes, and which are in part contrary to the available claims data, we ask that the Panel make the following recommendations to CMS:

1. Assign new Category I CPT codes 669X1 and 669X2 to APC 5493 (Level 3 Intraocular Procedures);
2. Assign new Category III CPT code 0X12T to APC 5492 (Level 2 Intraocular Procedures); and
3. Utilize the claims data for the predecessor codes for CPT codes 669X1 669X2, and 0X12T to determine the device offset percentage for CPT code 669X1, 669X2, and 0X12T.

Thank you for your consideration. Please let me know if you need anything further.

Sincerely,



Matt Bauer
Senior Director, Market Access Strategy and Reimbursement

Attachment: Glaukos CMS Form 20017

⁶ 85 Fed. Reg. 85866, 86015 (Dec. 29, 2020) (emphasis added).