

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

VIA ELECTRONIC SUBMISSION – APCPanel@cms.hhs.gov

Re: Speaker for August 23, 2021 Advisory Panel on Hospital Outpatient Payment Meeting

Dear Ms. Barringer:

Through this letter, Ocular Therapeutix, Inc. (Ocular) wishes to offer comments to the Advisory Panel on Hospital Outpatient Payment (Panel) on the Ambulatory Payment Classification (APC) assignment of a new Category I Current Procedural Terminology (CPT®) code and to identify a speaker to present to the Panel in support of our request that the Panel recommend that CPT code 68XXX be assigned to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) for the reasons detailed below.

Consistent with the July 23, 2021 Federal Register notice announcing this meeting, we are separately submitting a registration email for the speakers that we would like to have on this topic. Here is the needed information for that speaker:

- Name – Michael Goldstein, MD
- Organization or company name – Ocular Therapeutix, Inc.
- Company or organization speaker is representing – Ocular Therapeutix, Inc.
- Email address – MGoldstein@ocutx.com

- Name – Stuart Langbein
- Organization or company name – Hogan Lovells US LLP
- Company or organization speaker is representing – Ocular Therapeutix, Inc.
- Email address – Stuart.Langbein@hoganlovells.com

In addition, we attach a completed form CMS-20017.

BACKGROUND

Ocular is a biopharmaceutical platform company leveraging its formulation expertise to develop transformational drug treatments that enhance people's lives. Our lead product, DEXTENZA® (Dextenza) is approved for the treatment of ocular inflammation and pain following ophthalmic surgery. Dextenza, reported using J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), is a physician-administered corticosteroid intracanalicular insert. Following insertion, Dextenza resorbs slowly through the course of treatment and exits the nasolacrimal system without the need for removal. In contrast to some topical drops, Dextenza does not contain preservatives (e.g., benzalkonium chloride), which may be toxic to the ocular surface and may lead to inflammation and damage to the cornea. Survey results based on the responses from 201 Dextenza patients who participated in the most recent Phase 3 study reported highly favorable outcomes in



comfort, convenience, and satisfaction, and 93 percent were likely to request the insert for future treatment.

The procedure to deliver Dextenza is currently reported using CPT code 0356T (*Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each*). In this procedure the product is inserted through the punctum, a natural opening in the eye lid, and into the canaliculus. For the insertion procedure, anesthetic is applied to the punctal area. The punctum and lacrimal system are dilated to determine the anatomical angle of the lacrimal system and to stretch the punctal opening and lacrimal system for insertion, being careful not to perforate the tissue. The surrounding tissue is dried, and the lid is stabilized for insertion; this may require a technician to assist. An applicator or forceps is used to insert the drug-eluting insert through the punctum into the canaliculus. The insert is positioned to sit 1-2 mm below the punctal opening and is repositioned following initial insertion. This procedure is typically performed after the completion of an ophthalmic procedure (e.g., cataract, glaucoma, or retina procedure), about 20% of the time in the hospital outpatient department and about 80% of the time in an ambulatory surgical center (ASC). CPT code 0356T will be replaced with a Category I CPT code effective January 1, 2022, and in the calendar year (CY) 2022 hospital outpatient prospective payment system (OPPS)/ASC proposed rule (Proposed Rule), this code is referred to as 68XXX (Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each).

In the Proposed Rule, the Centers for Medicare & Medicaid Services (CMS) proposes to assign 68XXX to APC 5692 (Level 2 Drug Administration) with a proposed payment rate of \$63.62, based on having no data on the code or its predecessor code, CPT 0356T, as there are no single procedure claims for the service. Significantly, this APC assignment for the insertion procedure would mean no payment to an ASC for the service because services with an OPPS status indicator of Q1, which the code would have by virtue of this APC assignment, are not separately payable in the ASC.

THE PANEL SHOULD RECOMMEND THAT CPT CODE 68XXX BE ASSIGNED TO A DIFFERENT CLINICAL APC THAT PROVIDES MORE CLINICAL AND RESOURCE COHERENCE – APC 5503

The proposed APC assignment of CPT code 68XXX to APC 5692 is improper because it fails to treat similar ocular medication insertion procedures the same on a number of levels. The proposed payment rate for CPT code 68XXX is far less than the payment for other similar ocular medication delivery procedures. Further, those other similar ocular medication delivery procedures are not assigned to a drug administration procedure (as 68XXX is proposed to be), but an ocular procedure APC – APC 5491 (Level 1 Intraocular Procedures). To bring CPT code 68XXX in line with the treatment of these other similar procedures, CMS should assign CPT code 68XXX to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures). Thus, we request that the Panel recommend that CMS assign CPT code 68XXX to APC 5503.

CPT code 68XXX, the description of which is provided earlier, is very similar to CPT code 66030 (Injection, anterior chamber of eye (separate procedure); medication) and CPT code 0X78T (Injection, posterior chamber of eye; medication), with regard to function, the time involved, and the needed equipment and supplies. For all three procedures, the surgeon delivers medication to the eye. The overall procedure time, including the prep time, is similar for all three procedures – approximately 10 minutes. They all involve similar levels of equipment and supplies (e.g., anesthetic, antiseptic, microscope, sponges), though, unlike the other two procedures, CPT code 68XXX requires additional instrumentation for the dilation of, and insertion into, the punctum and may require an additional staff member to assist. CMS proposes to assign CPT codes 66030 and 0X78T to APC 5491, with a proposed payment rate of \$2,131.25, while proposing to pay \$63.62 for CPT code 68XXX. Given the similarity in these procedures, that differential is unjustifiable.

Neither CPT code 0X78T or 68XXX have claims data for CMS to use to determine payment. Given that the claims data available for CPT code 66030 show a geometric mean cost of \$1,742.68 (2019 claims data) and are used by CMS to assign CPT code 0X78T to APC 5491, CMS should similarly use claims data for CPT code 0356T for the APC assignment for



CPT code 68XXX. While clinically, assignment of 68XXX to APC 5491 would not seem appropriate because the procedure is not an intraocular procedure but an extraocular procedure, the similar use of the geometric mean data for CPT code 66030 supports the assignment of CPT code 68XXX to APC 5503, which actually has a slightly lower payment rate than APC 5491 (to which CPT code 0X78T is proposed to be assigned). Further, the geometric mean cost for APC 5503 is \$1,949.14, which is in line with the geometric mean cost for CPT code 66030. As such, the available claims data, by reference to the similar ocular medication insertion procedure, warrants the assignment of CPT code 68XXX to APC 5503.

Notably, what we ask the Panel to recommend for CPT code 68XXX has great significance for payment for the service in the ASC setting, where it is performed about 80% of the time. As noted, the proposed treatment of 68XXX would mean no payment to ASCs for the procedure (even though the proposed APC assignment for 0X78T would result in separate ASC payment), which creates a significant disincentive for ASCs to perform the procedure. As noted earlier, this insertion procedure is a distinctly separate procedure that requires additional time following the completion of the primary ophthalmic surgery. Without payment for the additional time and resources, ASCs are disincentivized to perform the procedure, with the incentive instead being to furnish a different procedure that does in fact reimburse them for facility costs and/or requires patients to receive treatment in a hospital in order to access the service. Ironically, this untoward incentive comes at a time when CMS should be facilitating treatment of beneficiaries in the ASC setting, keeping patients out of hospitals when feasible. Further, ASCs are a more cost-effective site of service for the Medicare program and for Medicare beneficiaries due to the lower ASC payment rate and thus lower beneficiary cost sharing.

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For the reasons detailed above, Ocular urges the Panel to recommend that CMS assign CPT code 68XXX to APC 5503 for CY 2022. If you have any questions about our comment letter or would like to discuss our comment in further detail, please contact me at 469-207-0877 or at obishop@ocutx.com.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Owen Bishop".

Owen Bishop
Executive Director, Market Access

Attachment: Ocular Therapeutix Form 20017

