December 21, 2023

PRMR Clinical Committee
Partnership for Quality Management

VIA ELECTRONIC SUBMISSION

Re: Comments on the 2023 Pre-Rulemaking Measure Review (PRMR) Measure Under Consideration Regarding Cataract Removal with Intraocular Lens (IOL) Implantation (MUC2023-201)

Dear Members of the PRMR Clinical Committee -

On behalf of Ocular Therapeutix, Inc. (Ocular), thank you for the opportunity to comment on the 2023 Pre-Rulemaking Measure Review (PRMR) Measures Under Consideration List, and specifically to address the Cataract Removal with IOL Implantation Measure (Cataract Removal Measure).[1] Ocular is a biopharmaceutical 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, and for the treatment of ocular itching associated with allergic conjunctivitis, and is reported using J1096 (Dexamethasone, lacrimal ophthalmic insert, 0.1 mg). Dextenza is a physician-administered corticosteroid intracanalicular insert that is inserted following an ocular procedure, or as a standalone procedure.

As discussed in more detail below, our comments focus on the following recommendations for the Cataract Removal Measure:

1. The Centers for Medicare & Medicaid Services (CMS) should not include Part B drugs in the Cataract Removal Measure; and
2. Alternatively, if Part B drugs are included in the Cataract Removal Measure, CMS should:
    a. Provide for exclusions for use in patients lacking the ability to use alternative treatments due to various movement disorders and/or cognitive impairment; and
    b. Include Medicare Part D drugs in the Cataract Removal Measure to avoid an unlevel playing field.

I. BACKGROUND

A. Dextenza

Dextenza is the only FDA approved ophthalmic intracanalicular insert, a novel dexamethasone drug delivery system designed to deliver dexamethasone to the ocular surface for up to 30 days. It is approved for the treatment of ocular inflammation and pain following ophthalmic surgery and for the treatment of ocular itching associated with allergic conjunctivitis.[2] Historically, there were limited

[1] Centers for Medicare & Medicaid Services, 2023 Measures Under Consideration (MUC) List (December 1, 2023), https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.
[2] Dextenza Prescribing Information (Revised Oct. 2021), *available at* https://www.dextenza.com/wp-content/uploads/DEXTENZA-Full-Prescribing-Information.pdf.

options to treat ocular inflammation and pain following ophthalmic surgery, such as cataract, glaucoma, and retinal surgeries. Treatment options consisted primarily of patient-administered eye drops that were inundated by patient adherence issues, improper instillation (including missing the eye), instilling an incorrect number of drops, bottle tip contamination with ocular surface contact, and failure to wash hands prior to patient-administered topical therapy.[3] Additionally, topical steroid drops contain preservatives, like benzalkonium chloride, which is toxic to the ocular surface and may lead to inflammation and damage to the tear film.[4]

Dextenza, a corticosteroid intracanalicular insert, offers Medicare beneficiaries an important alternative to eye drops for the treatment of post-surgical ocular inflammation and pain, or for the treatment of ocular itching associated with allergic conjunctivitis. Dextenza is a physician-administered drug that may be inserted as part of a separate procedure that occurs after ocular surgery, thereby eliminating the burden of topical eye drop application, or it may be inserted as part of a procedure that is the only one furnished that day.

Dextenza does not contain anti-microbial preservatives and does not contain benzalkonium chloride. Benzalkonium chloride (BAK) is the most common anti-microbial preservative in topical medications (eye drops). This preservative also causes toxic effects to the eye itself by unleashing free radicals, inducing cell death, and promoting inflammatory cytokines.[5] Side effects attributed to BAK include tear film disruption, ocular surface disease, changes in conjunctival cell differentiation, and corneal toxicity.[6] All these side effects would affect a patient's quality of life and add to the overall ophthalmic treatment costs during the patient's lifetime. Preservative-free Dextenza circumvents these problems and addresses compliance issues for patients that would otherwise use eye drops, if not for Dextenza.

B. Potential Revisions to the Cataract Removal Measure

According to the 2023 Measures Under Consideration (MUC) list, the Cataract Removal Measure (MUC2023-201) is a measure that is in use, but is undergoing substantial changes.[7] The 2023 PRMR Clinician Committee PA Report discusses the potential changes to this measure as including "expanding the measure scope to no longer exclude patients with certain ocular conditions—such as macular degeneration, glaucoma, and diabetic eye disease—and to include the costs of additional clinically related services, such as pre-operative testing, additional telehealth services, durable medical equipment (DME), emergency department (ED) visits for ocular complaints, and durable medical equipment to ensure a more comprehensive evaluation."[8] Based on a listening session that was recently conducted, one of the expected changes is for the broader inclusion of Medicare Part B drugs in the measure, including Dextenza. During the December 14, PRMR 2023 MUC List Clinician Measures Listening Session (Listening Session), in the discussion of the Cataract Removal Measure, a question was posed about why Part D drugs (which represent a significant majority of the

[3] An JA, Kasner O, Samek DA, Lévesque V. Evaluation of eyedrop administration by inexperienced patients after cataract surgery. *J Cataract Refract Surg.* 2014;40(11):1857-1861.
[4] Walsh K, Jones L. The use of preservatives in dry eye drops. *Clin Ophthalmol.* 2019;13:1409-1425. Gomes JAP, Azar DT, Baudouin C, et al. TFOS DEWS II iatrogenic report. *Ocul Surf.* 2017;15(3):511-538.
[5] Pauly A, Brasnu E, Riancho L, Brignole-Baudouin F, Baudouin C. Multiple endpoint analysis of BAC-preserved and unpreserved antiallergic eye drops on a 3D-reconstituted corneal epithelial model. *Mol Vis.* 2011;17:745-755.
[6] Uusitalo H, Egorov E, Kaarniranta K, Astakhov Y, Ropo A. Benefits of switching from latanoprost to preservative-free tafluprost eye drops: a meta-analysis of two Phase IIIb clinical trials. *Clin Ophthalmol.* 2016;10:445-454.
[7] *See* https://www.cms.gov/files/zip/2023-cost-measure-codes-lists.zip (includes Cataract Removal Measure code list).
[8] *See* https://p4qm.org/sites/default/files/2023-12/PRMR-Clinician-Committee-PA-Report.pdf (at page 13).

medications and costs associated with their use post cataract surgery) are excluded from the cost measure while Part B drugs like Dextenza would be included.

A CMS contractor responded by saying that there are concerns that clinicians would not have the information available to make choices about the Part D medications based on the cost of the medication, and that Part D medications are generally low cost so it would be reasonable to only include Part B medications in the cost measure.

II. Discussion

A. Part B Drugs, Like Dextenza, Should not be Included in the Cataract Removal Measure

According to the 2023 PRMR Clinician Committee PA Report, CMS is considering changes to the Cataract Removal Measure "because there are opportunities to improve patient care and reduce the cost to Medicare for cataract removal procedures."[9] If that is the underlying reason for revising the measure, among the changes to the Cataract Removal Measure should not be the inclusion of Medicare Part B drugs. Inclusion of such drugs are likely to have the opposite effect – lessen patient care, patient outcomes and potentially increase Medicare costs.

We explain why inclusion of Part B drugs would run counter to CMS's stated intent by reference to Dextenza, which is not to say that the same would not be true of other Part B drugs that could be pulled into the measure by what is under consideration. Not only would inclusion of Dextenza do nothing to reduce the cost to Medicare for cataract procedures, it would likely negatively impact patient outcomes. If ophthalmologists choose to forgo the use of Dextenza due to inclusion of the product in the Cataract Removal Measure, which is the underlying intent of such a change to the measure, patient care will be harmed, not improved, either because patients will not be able to access the alternative (i.e., topical eye drops) or because they cannot use topical eye drops. Due to pharmacy access issues, many patients rely on Dextenza because it is inserted in the physician administered and outpatient surgery centers setting and does not implicate patient adherence or pharmacy access concerns.

Proper administration of eye drops is a challenge for healthy persons, and those with cognitive or physical limitations. Appropriate eyedrop instillation requires users to 1) fill the prescription; 2) instill the correct number of drops, usually a single drop; 3) instill the drop(s) at the correct time(s) during the day; (4) shake the bottle if instructed to do so; and (5) repeat the dosing each day. Appropriate technique requires manual dexterity, hand-eye coordination, strong memory, and good vision. A prospective study evaluating the eyedrop instillation technique one day after cataract surgery revealed that (n=50) 93 percent of patients either missed their eye, instilled an incorrect number of drops, contaminated the bottle tip, or failed to wash their hands before instillation.[10]

Even for those patients that are able to get topical eye drops, there are many patients, particularly in an elderly population, who cannot successfully utilize topical eye drops due to sight-threatening ocular comorbidities and cognitive or physical limitations. For example, sight-threatening

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[9] Id.

[10] Cynthia Matossian, *Noncompliance with Prescribed Eyedrop Regimens Among Patients Undergoing Cataract Surgery—Prevalence, Consequences, and Solutions*, US Ophthalmic Review 13(1) 18-22 (2020), https://www.touchophthalmology.com/wp-content/uploads/sites/16/2020/04/US-OPHTH_13.1_p18-22-1.pdf.

glaucoma or age-related macular degeneration may impair a patient's ability to successfully instill eye-drops.[11] In addition, there are a number of movement disorders that would prevent individuals from being able to successfully implement a post-surgical drops regimen. The most common such disorders are Parkinson's disease, atypical Parkinsonian disorders, ataxia, tic disorders, functional movement disorders, Huntington's Disease, Essential Tremor, dystonia, Rheumatoid Arthritis, Osteoarthritis, carpal tunnel syndrome, and spasticity due to stroke. Furthermore, there are clinical conditions that cause cognitive decline that also would mean that the use of traditional eye drops is not feasible, such as Alzheimer's disease, Lewy-Body disease, Multiple Sclerosis, Head Injury, Down Syndrome, Huntington's Disease, Ankylosing Spondylitis, and frontotemporal degeneration.[12]

For some patients, other factors make it very unlikely that they will be able to undertake a successful course of topical drops, such that access to an alternative that serves that function is important. Social Determinants Of Health can impact compliance with medication regimens, including eye drop regimens. Adverse social and living circumstances can impact an individual's ability to manage their health problems and adhere to medication regimens. For those with housing instability or food insecurity, for example, they may not be able to devote the time and attention needed for a regimen, particularly one as extensive as a topical drop regimen.

Dextenza offers a necessary alternative to topical eye drops such that regardless of whether patients are unable to get or unable to use prescribed eye drops, the cost to Medicare may actually increase if the product is not available. That may be tied to the added cost of a caregiver or health care practitioner to administer the drops and ensure adherence. Alternatively, for those patients who end up not getting topical eye drops, there is a significant potential for increased Medicare costs stemming from the failure to address post-surgical pain and inflammation. Dextenza is essential for many cataract patients, and any effort by CMS to disincentivize physicians to use it may hurt the most vulnerable patients.

For these reasons, we recommend that Part B drugs not be included in a revised Cataract Removal Measure.

B. Should Part B Drugs be Included in the Cataract Removal Measure, CMS Should Exclude Certain Patients from the Measure and Should Include Medicare Part D Drugs in the Measure

1. Excluding Patients Unable to Administer Topical Eye Drops Due to Clinical Conditions from the Cataract Removal Measure

In the 2023 Cost Measures Codes List for the Cataract Removal Measure, CMS states the exclusions from the cost measure "remove unique groups of patients from the measure in cases where it may be impractical or unfair to compare the costs of caring for these patients to the costs of caring for the measure cohort as a whole."[13] As explained above, there are many patients afflicted with

[11] Daniel Terveen, John Berdahl, et al., *Real-World Cataract Surgery Complications and Secondary Interventions Incidence Rates: An Analysis of US Medicare Claims Database*, Journal of Ophthalmology (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9007656/#:~:text=Common%20comorbidities%20among%20patients%20were,less%20than%2010%25%20of%20patients.

[12] Aayush Dhakal & Bradford Bobrin, Cognitive Defects, StatPeaarls (2023), https://www.ncbi.nlm.nih.gov/books/NBK559052/#:~:text=Differential%20Diagnosis,Wernicke%20Korsakoff%20syndrome.

[13] This file is available at https://www.cms.gov/files/zip/2023-cost-measure-codes-lists.zip.

conditions that prevent them from being able to administer topical eye drops compliantly. For such patients, the typical alternative to address pain and inflammation post-cataract surgery is the provision of a Medicare Part B drug. For patients who cannot administer drops, it would be impractical or unfair to compare the costs of caring for these patients to the cost of caring for patients who can administer topical eye drops. Accordingly, consistent with the policy for exclusions from the Cataract Removal Measure, if CMS decides to include Part B drugs in the Cataract Removal Measure, it should exclude from the measure patients with the following conditions:

- Parkinson's disease
- Atypical Parkinsonian disorders
- Ataxia
- Tic disorders
- Functional movement disorders
- Huntington's Disease
- Essential Tremor
- Dystonia
- Spasticity due to stroke
- Dementia, including Alzheimer's disease and vascular dementia
- Lewy-Body disease
- Rheumatoid Arthritis
- Osteoarthritis
- Carpal tunnel syndrome
- Multiple Sclerosis
- Head Injury
- Down Syndrome
- Huntington's Disease

2. Including Part D Drugs in the Cataract Removal Measure

In a similar vein, should CMS decide to include Part B drugs in the revised Cataract Removal Measure, Medicare Part D drugs should be included in the cost measure as well to ensure a level playing field. As stated by Dr. Green in the Listening Session, the current cost measure under consideration would exempt Medicare Part D drugs (e.g., eye drops) from the revised cost measure. This result would represent CMS putting its thumb on the scale in favor of drops over Part B drugs.

If the revised cost measure moves forward, ophthalmologists will be financially disincentivized to utilize Part B drugs. This would create a competitive imbalance that could result in the use of products other than Dextenza (e.g., drops) purely for MIPS score reasons. Physicians would be incentivized to use other products for intraocular inflammation and pain, notwithstanding the provider's choice of medication and what may be safest or most effective for the patient.

During the Listening Session, when asked to articulate the differential treatment between Medicare Part B and Part D drugs under the revised cost measure, the reasoning provided for the Part D exemption was: (1) that clinicians would not have the information available to make choices about the Part D medications based on the cost of the medication and (2) that Part D medications are generally low cost so it would be reasonable to only include Part B medications in the cost measure.

This cost justification ignores the patient access and adherence concerns that accompany the relevant Part D drugs (detailed above). By leveling the playing field, this allows the physician to choose what is best for the patient.

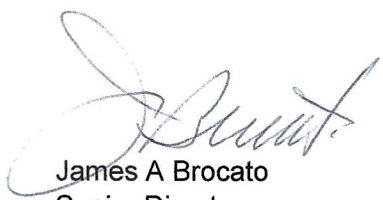
Therefore, if CMS does move forward with including Medicare Part B drugs like Dextenza in the revised Cataract Removal Measure, we recommend that CMS avoid an unlevel playing field by also including Medicare Part D drugs.

III. Conclusion

For the reasons detailed above, we recommend that CMS not include Part B drugs in the Cataract Removal Measure because doing so would not serve the purposes of the measure (improve patient care and reduce the cost to Medicare), but instead could have the opposite effects. Nonetheless, if CMS were to include Part B drugs in the Cataract Removal Measure, it must both make exceptions for the identified patients who cannot administer topical eye drops and also include Part D drugs.

Ocular greatly appreciates the opportunity to comment on the proposals related to the Cataract Removal Measure and reiterates its commitment to supporting policies that promote (and do not impede) beneficiary access to innovative treatments like Dextenza. If you have any questions about our comment letter or would like to discuss our comment in further detail, please contact me at (630) 292-6156 or jbrocato@ocutx.com.

Respectfully submitted,



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