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AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

President
Nick Mamalis, MD

Executive Director
Steve Speares

August 19, 2019

Elise Barringer
Designated Federal Official, HOP Panel
CMS/CM/HAPG/DOC
7500 Security Boulevard, C4-01-26
Baltimore, MD 21244-1850

RE: Request for Separate Payment Under Medicare Part B for FDA-Approved Drugs Administered in an ASC During Cataract Surgery that Have Post-Operative Indications

Dear Ms. Barringer:

I am Frank R. Burns, MD, an ophthalmologist who has been providing surgical and medical care to patients in Louisville, Kentucky, for more than 30 years. I currently serve on the Government Relations Committee of the American Society of Cataract and Refractive Surgery (ASCRS).

ASCRS is a medical specialty society representing nearly 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. I am also speaking today on behalf of the Ophthalmic Pharmaceutical Coalition led by ASCRS.*

Thank you for the opportunity to be here today to speak about a topic that has the potential to improve outcomes and reduce burden for beneficiaries: **Patient access to FDA-approved drugs administered at the beginning, during, or at the end of cataract surgery that have post-operative indications.**

ASCRS and the Ophthalmic Pharmaceutical Coalition are concerned that current packaging policies for surgical supplies in ASCs will have the unintended consequence of limiting patient access to new and innovative treatments administered during the time of surgery but are FDA-approved for post-operative indications, such as post-operative pain and inflammation or other sequela of the surgery. Currently, these drugs are considered a surgical supply and packaged into the facility fee once they come off pass-through status. As FDA-approved products come on to the market and eventually go off pass-through status, they are treated as a surgical supply and bundled into the facility fee. These drugs have FDA-approved indications for post-operative benefits and do not function as surgical supplies, so they should not be bundled into the ASC facility fee. ASCs, which typically operate on tight margins, will be unlikely to afford to offer these treatment options to patients if they are bundled into the facility fee.

Improved Outcomes and Reduced Patient Burdens

Cataract surgery is a highly successful procedure with extremely low complication rates. However, as surgeons always seeking means of providing even better care to our patients, recent advancements in cataract surgery include FDA-approved drugs administered during or at the end of cataract surgery that have post-operative indications to treat post-operative pain or inflammation and/or other sequela of the surgery. These drugs replace some or all of the eye drops patients must administer post-procedure and that are covered and reimbursed separately under Medicare Part D. Cataract surgery patients tend to be an older cohort of Medicare beneficiaries who may have difficulty administering their eye drops due to physical conditions, memory issues, or other comorbidities that may impact their abilities. If patients have limited ability to administer their own post-operative drops in the prescribed manner, they may experience pain, inflammation, and/or infection. While self-administered eyedrops may continue to be the best option for some patients, drugs administered during or right after cataract surgery have the potential to assist many beneficiaries in complying with post-operative regimens by reducing or replacing entirely their need for post-operative eyedrops.

Potential Access Issues Due to Inadequate ASC Reimbursement

Currently, CMS' packaging policy includes the cost of drugs and biologics that function as surgical supplies in the facility fee. We oppose CMS' broad interpretation of this policy that classifies drugs administered during the procedure as a surgical supply, despite the fact that they have an FDA-approved post-operative indication. We are concerned that when branded products on the market or in the pipeline for FDA approval go off pass-through status and are bundled into the facility fee, it will be impossible for Medicare beneficiaries to access these treatment options in an ASC. Without separate payment for these drugs, ASCs will not be in a financial position to offer patients the option to receive them. ASCs are already fiscally challenged because they receive only about half of the payment available to hospitals, yet the drug costs are the same.

In addition, this policy potentially stifles innovation by impeding the costly research and development of products currently being pursued by several companies that can deliver the medications otherwise necessary during the post-procedure period, including intracameral antibiotics, yet also be administered at the time of the cataract surgery.

CMS recognizes this challenge and there is precedent to pay separately under Part B for certain drugs in the ASC setting. As part of its ongoing efforts to combat the nation's opioid crisis, CMS finalized a policy in 2019 to pay separately for non-opioid pain management in the ASC because the cost of available non-opioid options may prevent ASCs from using the drug. ASCs will have the same challenges affording other FDA-approved medications with a post-operative indication as they do offering non-opioid pain options, and therefore, CMS should also provide separate payment under Part B for these drugs.

Requested Action

On behalf of ASCRS and the Ophthalmic Pharmaceutical Coalition, I urge CMS to modify its current packaging policy so that FDA-approved drugs administered at the time of cataract surgery with indications to treat or prevent post-operative issues are paid separately under Medicare Part B. As

mentioned previously, branded products recently approved or in the pipeline have the potential to improve patient compliance by reducing or eliminating the need for patient-administered post-operative eyedrops. ASCs will not be able to afford to provide these treatments if they are bundled into the facility fee.

Thank you again for the opportunity to provide input. If you have any questions or need additional information, please contact Nancey McCann, ASCRS director of government relations, at nmccann@ascrs.org or 703-591-2220.

Sincerely,

Frank R. Burns, MD
Member, ASCRS Government Relations Committee

*The Ophthalmic Pharmaceutical Coalition is made up of the following organizations: Allergan, Inc.; ASCRS; Eyepoint Pharmaceuticals, Inc.; Ocular Therapeutix, Inc.; Omeros Corporation; and the Outpatient Ophthalmic Surgery Society.