AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

President
Nick Mamalis, MD

Executive Director
Steve Speares

March 18, 2020

Francis J. Crosson, MD
Chairman
Medicare Payment Advisory Commission
425 I St, NW
Suite 701
Washington, DC 20001

Re: Separately payable drugs in the hospital outpatient prospective payment system

Dear Dr. Crosson,

On behalf of the American Society of Cataract and Refractive Surgery (ASCRS), a medical specialty society representing nearly 7,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care, thank you for the opportunity to provide feedback on a topic discussed at the March 2020 MedPAC public meeting, separately payable drugs in the hospital outpatient prospective payment system. Specifically, we:

- **Oppose efforts to bundle drugs administered during cataract surgery into the APC payment group. In fact, we urge CMS to make separate payment under Medicare Part B for FDA-approved drugs with a post-operative indication administered during cataract surgery in an ambulatory surgery center (ASC). Current innovation in cataract surgery is focused on developing treatments that have the potential to eliminate the need for post-operative eye drops separately covered and paid for under Medicare Part D, thereby improving outcomes through better patient compliance and reducing costs for both beneficiaries and the Medicare program. While these drugs have the potential for savings, manufacturers will be unwilling to bring them to market if there is no permanent payment pathway after the expiration of the initial pass-through period.**

ASCRS and the Ophthalmic Pharmaceutical Coalition—a group of stakeholder organizations and drug manufacturers led by ASCRS—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 that 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 APC rate paid under the Outpatient Prospective Payment System (OPPS) 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 APC rate paid under the OPPS. However, ophthalmic drugs with FDA-approved indications for post-operative benefits do not function as surgical supplies, so they should not be bundled into the APC rate. ASCs, which are paid at a much lower rate than hospital outpatient departments and typically operate on tight margins, cannot afford to offer these treatment options to patients if they are not paid for separately.

Improved Outcomes and Reduced Patient Burdens

Cataract surgery is a highly successful procedure with extremely low complication rates. However, 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 paid 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 Cost Savings to Beneficiaries and the Medicare Program

Most Medicare beneficiaries undergoing cataract surgery are prescribed post-operative drops that may come with significant costs depending on the patient's Part D plan, or lack thereof. While drugs administered during surgery must meet a certain price threshold to be paid on pass-through status when they come onto the market, it is likely that these treatments will cost significantly less than the post-operative drops covered under Part D, thereby reducing patients' out-of-pocket expenditures and overall costs to the Medicare program. Furthermore, the vast majority of cataract surgeries are performed in the lower-cost ASC setting, so potential savings from treatments administered during surgery would continue to contribute to the cost-effectiveness of cataract surgery.

Potential Access Issues Due to Inadequate ASC Payment

However, CMS' current packaging policy could prevent beneficiaries and Medicare from realizing these potential savings. During the pass-through period, CMS measures the utilization of the drug and, when the drug goes off pass-through status, adjusts the reimbursement level for the bundled facility fee based on the utilization data gathered and the formula. This results in a small increase in the APC payment, which recent experience with ophthalmic drugs coming off pass-through demonstrating that it has affected the use of the drugs in ASCs as these facilities cannot absorb these costs.

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 the trend will continue and when branded products on the market or in the pipeline for FDA approval go off pass-through status and are packaged into the APC rate, 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.

Concerns with MedPAC's Bundling Proposal

Current bundling of innovative drugs is already preventing ASCs from offering treatments to improve outcomes and reduce costs to beneficiaries and elsewhere in the Medicare program. Seeking additional opportunities to bundle drug costs may have further unintended consequences. MedPAC's presentation at the March meeting considers including criteria for clinical improvement before separate payment for a drug is permitted. We are concerned with how such criteria would be developed and administered. It would be impossible to develop guidelines that do not result in arbitrary designations. For example, for the drugs administered during cataract surgery with a post-operative indication, complication rates after cataract surgery are already low, so a regulator tasked with reviewing clinical improvement potential may not consider the improvements significant. However, when complications do arise, it is often because patients are not able to follow the post-operative regimen. Developing a system that takes all these factors into consideration—not to mention non-clinical benefits such as cost savings—will be impossible given the diversity of medical products on, or scheduled to come onto, the market.

Conclusion

While we understand that the commission seeks to encourage the efficient use of resources through increased use of bundled payments, in the case of FDA-approved drugs with a post-operative indication administered during cataract surgery, we believe CMS' current packaging policy and the Commission's desire for additional bundled payments will have the opposite effect. ASCs will not be able to afford to furnish these treatments as part of the APC group, thereby preventing improved outcomes and reduced spending. Without an assurance that facilities and physicians will be able to offer these branded products to patients, manufacturers will cease their innovation efforts in this area. **Given the potential limited access to drugs that may improve outcomes and reduce costs when they are bundled into the APC group payment, we recommend MedPAC develop more targeted strategies to reduce drug costs rather than focus on across-the-board solutions such as increased use of bundling.**

Thank you again for your consideration of this issue. If you have questions or would like to discuss further, please contact Nancey McCann, Director of Government Relations, at nmccann@ascrs.org or 703-591-2220.

Sincerely,

Nick Mamalis, MD
President, ASCRS