
Separate Payment under Medicare Part B for FDA-Approved Drugs with a Post-Operative Indication Administered During Cataract Surgery in ASCs

ASCRS and the Ophthalmic Pharmaceutical Coalition support separate payment under Medicare Part B for FDA-approved drugs with a post-operative indication administered at the time of surgery in Ambulatory Surgery Centers (ASCs).

Background

Current packaging policies for surgical supplies in the outpatient setting pose a potential 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 paid once they come off pass-through status. Pass-through status is a period of up to three years when manufacturers bring new, innovative drugs or devices to market and facilities are paid separately for using them. During this time, CMS collects utilization data on the new treatments and when the pass-through period expires, the data is used as factor in determining a new facility payment, and the cost of the drug is bundled into the facility fee.

CMS bundles drugs coming off pass-through into the facility fee because it considers them surgical supplies. However, new treatments administered during cataract surgery have FDA-approved indications for post-operative benefits and do not function as surgical supplies, so they should not be bundled into the facility fee. These drugs that replace some or all of the eye drops patients must administer post-procedure are covered and paid separately under Medicare Part D. ASCs, which typically operate on tight margins, will be unlikely to afford to offer these treatment options to patients if they are not paid for separately.

Impact on Ophthalmology

We are concerned that when branded products on the market or in the pipeline for FDA approval go off pass-through status and are packaged 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. These treatments have the potential to improve outcomes through better patient compliance. 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. Drugs administered during cataract surgery that take the place of post-operative drops address this issue.

ASCRS and Ophthalmic Pharmaceutical Coalition Advocacy

ASCRS formed and leads the Ophthalmic Pharmaceutical Coalition to advocate for separate payment for FDA-approved drugs with a post-operative indication administered at the time of cataract surgery in ASCs. We have provided comments to CMS urging it to provide separate payment in annual ASC payment rules and testified before CMS' Hospital Outpatient and ASC Payment Advisory Panel in support of this issue. In addition, we successfully advocated for bipartisan letters from the House and Senate to CMS requesting the agency review its payment policies related to these and other innovative treatments with an emphasis on ophthalmology.