December 22, 2023

Partnership for Quality Measurement
505 King Avenue
Columbus, OH 43201
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Via electronic delivery

RE: MUC 2023 – 201 - Cataract Removal with Intraocular Lens (IOL) Implantation

Dear Members of the 2023-2024 Pre-Rulemaking Measure Review (PRMR) Clinician Committee:

On behalf of the American Society of Cataract and Refractive Surgery (ASCRS), a medical surgical specialty society representing nearly 7,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care, we appreciate the opportunity to provide feedback on the potential revisions to MUC-2023-201, the Cataract Removal with Intraocular Lens (IOL) Implantation Cost Measure. ASCRS has been an active participant in the Cataract Cost Episode Measure TEP, as well as the reevaluation workgroup.

ASCRS continues to have many of the same concerns we outlined in our February 2023 comments. In addition, upon further reflection and research, we have some new concerns, as well.

Please find below our specific comments and recommendations:

Trigger Code - 66984

While the revised Cataract Removal with Intraocular Lens (IOL) Implantation Measure specifications do not include the additional trigger code (66982), we want to reiterate that we continue to support the use of CPT code 66984 as the only trigger for the cataract episode cost measure. As we have indicated previously, in order to compare surgeon costs fairly and validly, there must be a homogenous group of surgical cases to compare.

Including other trigger codes, such as complex cataract surgery, 66982, in this cost measure would not yield comparable data to measure a physician's resource use accurately. Patients undergoing cataract surgery that requires the use of the complex cataract code may suffer from a wide variety of ocular comorbidities or other non-ocular comorbidities, which could require varying levels of resource use depending on the condition. In addition, these

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patients often have complications requiring further surgery, such as a vitrectomy. To reiterate what was discussed during the initial review meeting the subsequent work group meetings, and our previous comments, complex cataract surgery may require additional supplies and increases the likelihood of potential complications, resulting in a range in value too significant to provide a homogenous patient group for a cost measure and should not be used as a trigger code.

As we have previously commented, ASCRS is also concerned that additional trigger codes and comorbidities would disproportionally affect small cataract practices. ASCRS members primarily practice in office-based settings of solo or small groups. Adding additional trigger codes would adversely impact smaller practices that do not do as many cataract procedures because it would only take one costly complex case to cause their Cost score to drop. Low volume cataract practices that provide care to patients with complex conditions would have greater exposure to receiving a penalty. In addition, some cataract surgeons do a majority of complex cases, and therefore, would be inappropriately penalized. It is also important to note that the majority of cataract cases are captured with 66984.

Removing Exclusions with Appropriate Risk Adjustment Methodology

While ASCRS, in conjunction with the workgroup discussion, initially agreed, with some skepticism, that the measure specifications could be updated to include patients with some of the ocular conditions and comorbidities that have been excluded with the proper and appropriate risk adjustment, we did express concern related to how exactly these codes would be risk adjusted and requested an explanation of the methodology.

However, even after the explanation and statistical analysis during the meeting with Acumen, ASCRS continues to have significant concerns regarding the inclusion of patients with any significant co-morbidities in the cataract episode cost measure. As we have indicated previously, we continue to question whether or not this is a valid risk-adjustment methodology and do not trust that it is possible to properly risk adjust for the majority of these patients with significant ocular conditions and comorbidities. Further, we do not trust that the algorithms described will properly risk adjust for the myriad of comorbidities and conditions that can be exacerbated as a result of the cataract surgery procedure through no fault of the surgeon. A foundational principle is to develop cost measures that are within the control of the physician to whom they will be attributed and to compare a homogeneous group.

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We remain concerned that CMS risks creating a system that encourages the care of uncomplicated cataract patients and discourages the care of the sickest, most complex cataract patients, which could not be coded for a complex cataract procedure 66982 – and therefore, excluded. This will result in these patients, whose care is more difficult and expensive, being at risk of losing timely access to care.

To reiterate, some cataract surgeons are in high-volume practices where they may avoid the problem of adverse risk selection, while others do not and may choose to see lower-risk patients. Choosing a course of treatment for a patient to not adversely impact a resource use score becomes a problematic, ethical dilemma for a physician who wants to uphold his or her sworn duties. Not only would this situation place physicians in an ethical quandary, the day-to-day task of monitoring the cost of care for each patient would add considerably to the already heavy regulatory burdens physicians face.

Therefore, we have identified a list of risk adjusted codes ASCRS believes should not be risk adjusted and continue to be excluded. Please click here to view:

https://ascrs.org/-/media/81da3965d25f4cd287b56ca2ef482ceb.ashx**.**

The codes highlighted in yellow should be EXCLUDED. The remaining codes highlighted in green are acceptable for risk adjustment.

Acumen's methodology document clearly states:

Services, and their Medicare costs, are assigned to an episode only when clinically related to the attributed clinician's role in managing patient care during the episode. …Unrelated services are not assigned to the episode. For example, the cost of care for a chronic condition that occurs during the episode but is not related to the clinical management of the patient relative to the cataract removal procedure with IOL implantation would not be assigned.

When thinking through which conditions should be included and excluded, we came back to the above statement to guide our thinking.

On the other hand, during the workgroup calls, an additional directive about the importance of including as many cases as possible in the measure was stated. Interestingly, this priority is not found in the methodology document. When these two principles (basically "quality" vs. "volume") were in conflict, the organizers of the workgroup gave preference to including as many cases as possible (volume), while we strongly give preference to "quality"--

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including only the cases that make the cost measure as fair, appropriate and transparent as possible.

Diagnosis/Conditions Added to Exclusions

The following Diagnosis/Conditions have never been included in the exclusions list, but after further review, we believe they were missed previously by the workgroup, and should now be added to correct the original omissions. The explanations are included below.

Herpes Virus

Surgery and the local trauma to ocular tissues related to the act of uncomplicated cataract surgery can reactivate the herpetic virus (HSV) in patients with latent disease. Reactivation can lead to out-of-control inflammation in some patients after surgery requiring referrals to corneal or uveitis specialists, as well as the PCP and/or a rheumatologist. Furthermore, patients can go to emergency rooms or urgent care offices, or need additional blood work or diagnostic testing, all of which will increase the costs, even though the initial surgery was uncomplicated.

B005.0 Herpesviral ocular disease, unspecified
B00.51 Herpesviral iridocyclitis
B00.52 Herpesviral keratitis
B00.53 Herpesviral conjunctivitis
B00.59 Other Herpesviral disease of the eye

Zoster Virus

Surgery and the local trauma to ocular tissues related to the act of uncomplicated cataract surgery can reactivate the varicella roster virus (VZV) in patients with latent disease. Reactivation can lead to out- of -control inflammation in some patients after surgery requiring referrals to corneal or uveitis specialists, as well as PCP and/or a rheumatologist. Furthermore, patients can end up in the emergency room or urgent care offices, all of which increase the cost, even though the initial surgery was uncomplicated.

B02.30 Zoster ocular disease, unspecified
B02.31 Zoster conjunctivitis
B02.32 Zoster iridocyclitis
B02.33 Zoster keratitis
B02.34 Zoster scleritis
B02.39 other herpes zoster eye disease

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Retinal Degenerations

Patients with peripheral retinal degenerations have a higher chance of retinal tears and detachments, even with uncomplicated cataract surgery. The additional office visits with a retina surgeon and additional treatments including laser retinopexy, pneumatic retinopexy, pars plana vitrectomy, or scleral buckling surgery would drive up the cost after surgery.

H33.3 Hereditary retinal degeneration
H35.5 Peripheral retinal degeneration with retinal break
H35.4 Peripheral retinal degeneration
H35.41 Lattice degeneration of retina

Anterior Scleritis

Surgery and the local trauma to ocular tissues related to the act of uncomplicated surgery can lead to anterior scleritis. Scleritis typically occurs in patients with underlying autoimmune diseases (sometimes prior to officially being diagnosed by the PCP). These patients tend to have significant inflammation and require visits to the PCP and rheumatologist (or urgent care/emergency room); additional blood work and diagnostic testing may also be needed. They are sometimes referred to a uveitis specialist to help with diagnosis and control of the underlying inflammation process. Other forms of scleritis have been placed on the exclusion list for these reasons, including posterior scleritis, brawny scleritis, and "other" scleritis. All forms of scleritis can be exacerbated at the time of uncomplicated cataract surgery, including anterior scleritis. We believe that anterior scleritis was overlooked.

H15.01 Anterior Scleritis
H15.011 OD
H15.012 OS
H15.013 Bilateral

Posterior Polar Cataracts

Posterior Polar Cataracts (officially called posterior subcapsular polar cataracts) are well documented to have higher risk and complication rates during cataract surgery. With higher vitrectomy rates, these patients often need second surgeries and/or additional treatment within

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the postop period for treatment of pressure-related and associated vireo-retinal sequelae.

H25.041 (OD) Posterior polar cataract
H25.042 (OS)
H25.043 (OU)

(Recurrent) Corneal Erosions

Patients with certain underlying corneal dystrophies or history of trauma are prone to RCE, which can require additional medical or surgical treatment, such as PRK, stromal micro puncture, and amniotic membrane placement during the post-op 90-day global window. Uncomplicated cataract surgery can exacerbate these conditions. In addition, preservatives in the post-operative drops may subject the cornea to increased risk of erosions and worsening of keratitis sicca after surgery.

H18.831 (OD). RCE
H18.832 (OS)
H18.833 (OU)

Punctate Keratitis

Uncomplicated cataract surgery can exacerbate keratitis. In addition, preservatives in the post-operative drops may subject the cornea to increase risk of punctate keratitis after surgery. Treatment for this diagnosis could include amniotic membrane placement.

H16.141 (OD) Punctate Keratitis
H16.142 (OS)
H16.143 (OU)

Neurotrophic Keratitis

Uncomplicated cataract surgery can exacerbate keratitis. In addition, preservatives in the post-operative drops may subject the cornea to increase risk of punctate keratitis after surgery. Treatment for this diagnosis could include amniotic membrane placement.

H16.231 (OD)
H16.232 (OS)
H16.233 (OU)

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Exposure Keratoconjunctivitis

Uncomplicated cataract surgery can exacerbate keratitis at the time of surgery. In addition, preservatives in the post-operative drops may subject the cornea to increased risk of exposure keratitis after surgery. Treatment for this diagnosis could include amniotic membranes placement.

H16.211 (OD)
H16.212 (OS)
H16.213 (OU)

Filamentary Keratitis

Uncomplicated cataract surgery can exacerbate keratitis. In addition, preservatives in the post-operative drops may subject the cornea to increase risk of punctate keratitis after surgery. Treatment for this diagnosis could include amniotic membrane placement.

H16.121 (OD)
H16.122 (OS)
H16.123 (OU)

Lagophthalmos

Patients with lagophthalmos typically have dry eyes due to corneal exposure issues. Uncomplicated cataract surgery can exacerbate keratitis. In addition, preservatives in the post-operative drops may subject the cornea to increase risk of punctate keratitis after surgery. Patients may need referral to an oculoplastics specialist. Treatment for this diagnosis could include amniotic membrane placement.

H02.2 Lagophthalmos
H02.20 Unspecified lagophthalmos
H02.201 RUL
H02.202 RLL
H02.203 OD unspecified lid
H02.204 LUL
H02.205 LLL
H02.206 OS Unspecified lid
H02.20A OD upper and lower lids
H02.20B OS upper and lower lids
H02.20C bilateral upper and lower lids

H02.21 Cicatricial Lagophthalmos

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H02.211 RUL
H02.212 RLL
H02.213 OD Unspecified lid
H02.214 LUL
H02.215 LLL
H02.216 OS Unspecified lid
H02.21A OD upper and lower lids
H02.21B OS upper and lower lids
H02.21C bilateral upper and lower lids

H02.22 Mechanical Lagophthalmos
H02.221 RUL
H02.222 RLL
H02.223 OD Unspecified lid
H02.224 LUL
H02.225 LLL
H02.226 OS Unspecified lid
H02.22A OD upper and lower lids
H02.22B OS upper and lower lids
H02.22C bilateral upper and lower lids

H02.23 Paralytic Lagophthalmos
H02.231 RUL
H02.232 RLL
H02.233 OD Unspecified lid
H02.234 LUL
H02.235 LLL
H02.236 OS unspecified lid
H02.23A OD upper and lower lids
H02.23B OS upper and lower lids
H02.23C bilateral upper and lower lids

Exophthalmic Conditions

These conditions are usually related to other underlying diseases. Exophthalmos can result in exposure to keratitis, which requires additional treatment and office visits.

H05.2 Exophthalmic Conditions
H05.20 unspecified exophthalmos
H05.21 displacement (lateral) of the globe
H05.211 OD
H05.212 OS
H05.213 bilateral

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H05.24 Constant exophthalmos
H05.241 OD
H05.242 OS
H05.243 bilateral
H15.0 Scleritis
H15.00 Unspecified scleritis
H15.001 OD
H15.002 OS
H15.003 Bilateral

Diagnosis/Conditions Previously Excluded that Should Continue to be Excluded

The following are diagnosis/conditions that were previously excluded and do not appear in either the excluded list or the risk adjusted list in the revised measure. They should continue to be excluded. The explanations are included below.

Psuedoexfoliation Glaucoma and Syndrome

There is an increased risk of complications during cataract surgery in patients with pseudoexfoliation. Not all patients will require iris hooks or iris retraction rings; therefore, these surgeries would be coded as 66984. Yet some of these patients may have zonular weakness and have higher rates of vitrectomy and other complications that require additional medical and surgical treatment. Vitreous loss is 5-10 times more common in these eyes. These patients are also at risk for later post operative complications, such as IOL/posterior bag dislocation which, depending on the severity, can happen during the 90-day global period. This will lead to additional office visits and referrals to retinal surgeons and/or surgeons who perform IOL fixation surgery.

H40.141 (OD) Pseudoexfoliation Glaucoma
H40.142 (OS)
H40.143 (OU)

Other Age-Related Cataracts

Not every patient with pseudoexfoliation has glaucoma. Patients with pseudoexfoliation without glaucoma are still at higher risk for complications during cataract surgery. According to the American Academy of Ophthalmology, the ICD -10 code for pseudoexfoliation of lens capsule is H25.89 other age-related cataracts. If doctors are coding this correctly, other age-related cataracts must be included in the exclusion list.

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H25.89 other age-related cataracts

Mature Cataracts

Cataract surgery on a severe, mature cataract is far more complex and riskier than an average cataract. Even though it is not coded at 66982, surgery on a severe cataract has a higher chance of complications, including corneal failure or vitreous prolapse, leading to the need for additional referrals and follow up surgery during the 90-day post op period. Mature cataract is also coded H25.89.

H25.89 other age-related cataracts.

Traumatic Cataracts

Due to the history of trauma resulting in cataracts, patients tend to have higher complication rates during surgery due to abnormal anatomy, scarring, limited visibility, and increased risk of inflammation. These patients are also at risk for higher post-op inflammation. Therefore, these patients should be excluded.

H26.101 (OD) Traumatic cataract
H26.102 (OS)
H26.103 (OU)

AMD – Wet and Dry

All patients with AMD are at higher risk for needing additional treatments and office visits after cataract surgery. That is why the anti-VEGF injections are excluded from the cost measure. HOWEVER, these patients still require retina specialist office visits and diagnostic testing (ie OCT, FA, etc.) that drives up the cost after surgery. ALL forms of AMD should be excluded. Dry AMD can convert to WET at any time, including during the 90-day post op period. Furthermore, AMD may be under-diagnosis at the time of cataract surgery, as these patient's dense cataracts may prevent adequate view on exam or OCT for proper diagnosis.

Dry (nonexudative) AMD early dry stage:
H35.3111 H35. 3121 H35.3131
Dry (nonexudative) AMD intermediate dry stage:
H35.3112 H35. 3122 H35.3132
Dry (nonexudative) AMD advanced atrophic w/o sub foveal involvement:
H35.3113 H35. 3123 H35.3133

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Dry (nonexudative) AMD advanced atrophic with sub foveal involvement:
H35.3114 H35. 3124 H35.3134

Wet (exudative) AMD w active choroidal neovascularization:
H35.3211 H35.3221 H35.3231
Wet (exudative) AMD w inactive choroidal neovascularization:
H35.3212 H35.3222 H35.3232
Wet (exudative) AMD w inactive scar:
H35.3213 H35.3223 H35.3233

Cost Measure Look-Back Rules

In the years since the cost measure was created, Medicare's rules for how soon the original office consult and the surgical date have been relaxed. The cost measure look-back rules should be relaxed to reflect this change. We suggest increasing the look-back period from 60 days to 180 days.

Service Assignment – Clinically Related Services

This revised cataract surgery episode cost measure adds the costs of additional clinically related services, such as durable medical equipment (DME), pre-operative testing, emergency department (ED) visits for ocular issues, and additional telehealth visits. While ASCRS believes it is fair to include these in the service assignments, we stress that these costs should be accounted for only when these services are absolutely related to the trigger code, 66984, and within the episode window.

Assigning Medicare Part B Medication Costs – Omidria and Dextenza

Pass-through status must be preserved as an unbiased method of accounting for the utilization of new and innovative drugs.

As ASCRS previously commented, while Omidria and Dextenza are no longer on pass-through, there may be new drugs coming onto the market with pass-through status in the future. Therefore, ASCRS wants to reiterate its opposition to including any pass-through drug in the cataract episode measure. As we have previously argued, including any pass-through drug in this cost measure defeats the purpose of pass-through status, which is to pay separately for new and innovative high-cost drugs as they are introduced into the marketplace, giving physicians time to become familiar with the new treatment option and its benefits. This time is used to provide unbiased utilization data, with no cost implications/penalties, which is ultimately used in the formula to update the APC payment once the drug comes off pass-through and is bundled into the facility payment. Including pass-through drugs in the cataract cost-episode measure risks influencing that data

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because physicians will choose not to use the drug based on its cost, rather than its clinical merits.

Dextenza and Omidria

The measure now includes Dextenza, as well as the previously included Omidria, even though the workgroup did not reach a consensus on whether the measure should include or exclude specific Part B drugs.

Dextenza and Omidria both have an FDA indication for reducing post operative pain and have been given a special payment status of non-opioid pain management drugs and are, therefore, paid separately in the ASC setting. They are both expensive medications that are under direct discretion/control of the surgeon to use.

Dextenza

As we previously commented and continue to maintain, given that Dextenza has the ability to reduce/eliminate the need for Medicare Part D postoperative topical corticosteroids, a class of mediation used routinely after cataract surgery, ASCRS does not support the inclusion of Dextenza into the Cataract Episode Measure and again, recommends this medication be excluded from the cost measure.

Omidria

However, as we have commented previously and still maintain, Omidria has an FDA indication for postoperative pain, but does not replace any medications that are routinely used after cataract surgery. Therefore, ASCRS continues to support the inclusion of this drug in the cost measure.

Medicare Part D Drugs Related to Cataract Surgery

ASCRS continues to oppose the inclusion of Medicare Part D drugs in the cataract episode-based cost measure because physicians cannot control their cost and, we therefore, support that this measure does not include them.

We continue to remain unconvinced that Acumen/CMS is able to standardize all Part D drug costs and accurately account for the varying costs beneficiaries pay for drugs based on their plan or even the pharmacy where they fill the prescription. As we discussed during our workgroup meeting and in our previous comments, other factors unrelated to the clinical merits of the drug, such as formulary design, pharmacy benefit managers (PBMs), and patient incentives including manufacturer's coupons, make it impossible for the surgeon to predict what drug is the most cost effective and what the patient will pay. **These many factors that impact the**

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price or availability of specific drugs are outside of the physician's control.

As a reminder, and discussed previously, there are currently FDA-approved, on-label Medicare Part B drugs administered during the time of surgery with post-operative indications for pain and inflammation, which replace the need for some Medicare Part D post-operative medicated eyedrops however, there are no FDA-approved drugs administered during surgery for post-operative infection control. In addition, there are off-label compounded drugs administered during cataract surgery that are also for post-operative pain, as well as for infection that are bundled into the facility payment. Consequently, cataract surgeons must prescribe patients some combination of drugs to treat post-operative pain, inflammation, and/or infection. While there are both branded and generic post-operative drops available, it is impossible for the surgeon to know what price a particular patient will pay based on the plan they have or the pharmacy where they fill the prescription.

Additionally, we are concerned that including Part D prescription drug costs in the cataract cost episode measure may inappropriately penalize physicians who select the most medically appropriate treatment for their patients. There are instances where an ophthalmologist would prescribe self-administered post-operative drops rather than administer a drug with a post-operative indication at the time of the surgery. For example, a patient may be allergic to an active ingredient in a drug that would be administered at the time of surgery. Since the patient is allergic to an ingredient in the medication, the ophthalmologist would not use it during surgery and instead, prescribe self-administered post-operative eye drops. It is essential that CMS recognize that the most appropriate methodology for determining cost should be flexible to allow for choice of a treatment option that is best for the patient and will lead to better outcomes.

Due to the factors discussed related to the clinical necessity of cataract surgeons prescribing post-operative eyedrops after surgery, and the inability of physicians to predict the cost of a drug based on the complex structure of the pharmaceutical market and the absence of transparency, they have no ability to control the costs of Medicare Part D drugs, and therefore, should not be included in the episode-based cost measure.

Methodology, Scoring and Feedback Process

While ASCRS is interested in continuing to collaborate on the cataract surgery cost episode measure and other future measures that focus on anterior segment procedures, we believe the MIPS scoring and feedback process needs to improve.

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As you are aware, as ASCRS members began to receive feedback on the cataract episode-based cost measure, for the first time, as part of the 2022 performance year/2024 payment year score, and many of them were concerned with their low scores. Initially, there were issues with duplicate services appearing in the patient-level data, which added to the confusion.

We participated in joint call with the AAO, as well as with the Center for Clinical Standards and Quality and Acumen staff to discuss our concerns and also focused on the fact that the patient-level data files lack the data required to improve measure performance. The two organizations also recommended the addition of date of service and rendering provider fields to future reports. It is clear that better education and meaningful feedback needs to be provided. We strongly recommend that before the cataract cost episode measure is applied for the 2023 performance year/2025 payment, the application of the measure be reviewed with the TEP so that any inconsistencies in service attribution are corrected.

Conclusion

We appreciate the opportunity to continue to provide input and additional comments.

If you have any questions or need additional information, please contact, Mark Cribben, ASCRS Director of Government Relations at mcribben@ascrs.org or Nancey McCann ASCRS GR Consultant at nmccann@ascrs.org.

Sincerely,

Parag Parekh, MD, MPA
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