



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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February 14, 2019

Seema Verma, MPH
Administrator

Demetrios Kouzoukas
Principal Deputy Administrator for Medicare and Director, Center for Medicare

Kate Goodrich, MD
Director, Center for Clinical Standards and Quality

Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Re: Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule

Dear Administrator Verma, Prin. Dy. Administrator Kouzoukas and Dr. Goodrich:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and 4,000 orthopaedic surgeons represented by the American Association of Hip and Knee Surgeons (AAHKS), we would like to thank you for the publication of the MLN Matters # SE19002 Article on [“Total Knee Arthroplasty \(TKA\) Removal from the Medicare Inpatient-Only \(IPO\) List and Application of the 2-Midnight Rule”](#). We also appreciate the opportunity to meet with you on February 25, 2019, to discuss this further. We appreciate the collegiality of the staff at the Center for Medicare and at the Center for Clinical Standards and Quality. Ahead of our scheduled meeting, we would like to highlight some on-going issues with the impact of TKA removal from the IPO list and provide comments on this MLN Matters article.

Once TKA removal from the IPO list went into effect on January 1, 2019, one of the unintended consequences of this policy change has been a lot of confusion on the part of a variety of stakeholders regarding how to interpret this new rule. We shared our concerns with your team through numerous phone calls, in-person meetings and a written letter dated February 28, 2018. In the meantime, AAOS and AAHKS also conducted extensive member education on this

topic including clinical criteria for outpatient TKAs.^{1,2} We have previously shared all our work in this area with your team that led the writing of this MLN Matters (# SE19002) article.

In response to the 2018 Medicare Hospital Outpatient Prospective Payment System Proposed Rule (CMS-1678-P), AAOS had commented (and we would like to reiterate) that

“We support the removal of TKA from the IPO list contingent upon several issues.

- *The determination of how to best provide adequate and timely care to a Medicare beneficiary should fall under the purview of the patient-surgeon relationship, as these are the individuals who shoulder the risk of these procedures.*
- *AAOS calls for clear criteria for surgical site selection. Not all ASCs nor all outpatient departments are the same.*
- *Another unintended consequence of forcing care into the outpatient setting becomes apparent when commercial payers follow CMS, the healthcare market leader. These payers will have considerable power to drive patient care to specific facilities and restrict patient access to ASCs based on cost alone.*
- *An outpatient TKA procedure would be appropriate only for carefully selected patients who are in excellent health, with no or limited medical comorbidities and sufficient caregiver support. It is important to note that the less invasive unicondylar arthroplasty, or partial knee replacement (CPT 27446), currently performed successfully in the outpatient setting, is not entirely like total knee arthroplasty. However, we have serious concerns with this model’s design and the application requirements that we discuss below.”*

Two-Midnight Rule Exception

The MLN Matters article (# SE19002) clarifies that if the expected need for an inpatient stay (i.e., defined as a need for two-midnights) is well documented on admission, early discharge is not penalized. Unfortunately, this is not well understood by many providers or hospital administrators. Prior experience with this rule has made many hospital reimbursement/compliance directors concerned that incorrect application of this rule may subject the hospitals and providers to financial penalties. Most orthopaedic surgeons had

¹ Yates AJ, Kerr JM, Fromison MI: The unintended impact of the removal of total knee arthroplasty from the Center for Medicare and Medicaid Services Inpatient-Only List. *J Arthroplasty* 2018;33:3602-6.

² American Association of Hip and Knee Surgeons: Outpatient Joint Replacement: Position Statement. Joint position statement on outpatient joint replacement. Available at: <http://www.aahks.org/position-statements/outpatient-joint-replacement/>. Accessed January 18, 2019.

always considered TKA a major surgical procedure for elderly patients and, hence, an obvious inpatient procedure requiring significant resources. They now face pressure to move the majority of TKAs to an outpatient designation. For patients, these changes may lead to confusion over cost sharing obligations. Patients may not realize, until it is too late and they receive a bill, that their TKA surgery has been billed as an outpatient procedure and that they are responsible for a higher out-of-pocket payment. Several of our patients have been left in this unfortunate situation.

To solve this issue, we recommend again that *TKAs be given an exception from Medicare's Two-Midnight Rule*. In the FY 2014 Medicare Inpatient and Long-term Care Hospital Prospective Payment System Final Rule, CMS stated that additional exceptions to the generally applicable two-midnight benchmark may be identified and acknowledged as “potential ‘rare and unusual’ circumstances under which an inpatient admission that is expected to span less than two midnights would nonetheless be appropriate for Medicare Part A payment”. In the 2016 Hospital Outpatient Prospective Payment System Final Rule, CMS had still only identified one “rare and unusual” exception (i.e., prolonged mechanical ventilation). However, it was stated that additional exceptions would be evaluated on a case-by-case basis. We believe that TKA should be given the same exception status as mechanical ventilation under the rare and unusual policy, to guide review by the Beneficiary and Family Centered Quality Improvement Organizations (BFCC-QIO), until more information is gathered. This will allow surgeons more flexibility while safely navigating the vast clinical space between outpatient and a two midnight stay for TKA patients.

Moreover, CMS expected, as stated clearly in the rule, that most TKA cases would remain inpatient. The lack of clarity surrounding acceptable justification for inpatient admission spanning fewer than two midnights has led to pressure on the surgeon to make outpatient the default setting for all TKAs. Those patients for whom one midnight may be sufficient, yet are clearly not acceptable outpatient candidates, fall into a gray area forcing outpatient status. When a standard status is expected by the overwhelming majority, the burden of proof should fall on the exception, not the standard.

Reduction of Burden on Clinicians

Currently, there is tremendous burden on orthopaedic surgeons to provide documentation to “prove” that a TKA patient needs inpatient care. In fact, the MLN Matters (# SE19002) article states that “2-Midnight Benchmark (helps guide contractor reviews of short stay hospital claims for Part A payment): Hospital claims are generally payable under Medicare Part A if the admitting practitioner reasonably expects the beneficiary to require medically necessary hospital care spanning 2 or more midnights and this expectation is supported by the medical

record documentation The case-by-case exception states that for hospital stays that are expected to span less than 2 midnights, an inpatient admission may be payable under Medicare Part A on a case-by-case or individualized basis if the medical record documentation supports the admitting physician/practitioner’s judgment...”. This article goes on to state that this is “based on complex medical factors including but not limited to

- Patient’s history, co-morbidities and current medical needs;
- Severity of signs and/or symptoms
- Risk of adverse events.”

While we appreciate CMS clarifying these criteria, the details are still nebulous. E.g., how many co-morbidities may be enough, how is severity defined and so on. While our position statements have sought to define site of care decision criteria and our surgeons already list comorbidities, Medicare Advantage and hospitals continue to question the surgeon’s clinical decision on the site of care and have increased documentation requirements. Again, the burden of justification should not lie with the operating surgeons.

In addition, we believe such additional documentation burden is in direct contradiction to Administrator Verma’s ‘Patients Over Paperwork’ initiative which we wholeheartedly support.

Risk-adjustment

We have stated in our Outpatient Joint Replacement position statement (referenced above) that social support and environmental factors (family or professional outpatient support) must be considered to determine if the outpatient setting is indeed the safest and most appropriate setting for a patient. Also, we recommend that a *“full discussion with the patient and family as to the risks and potential benefits of same-day discharge after hip and knee replacement be carried out.”* We believe that without socio-demographic considerations, patients, surgeons and hospitals in underserved communities will bear a disproportionate burden and unintended consequence of the TKA policy change.

We have also stated in this position statement that a *“critical program element is a team of medical staff capable and experienced in performing hip and knee arthroplasty in the outpatient setting whether in hospital or in ambulatory surgery center. The anesthesia team, the surgical team, and the recovery room staff should all be facile and experienced in outpatient early recovery discharge modalities that include adequate perioperative pain control, fluid resuscitation, early patient mobilization, and medical management.”* As you are aware, outpatient surgeries are assumed to be less resource intensive and hence reimbursed less. For

hospitals, making the outpatient setting the default for TKA surgeries implies less staff and resource allocation thereby violating one of the critical requirements for such surgeries.

Impact on Medicare Payment Models

Defaulting all TKA procedures to outpatient status is likely to impact the Comprehensive Care for Joint Replacement (CJR) and Bundled Payment for Care Improvement (BPCI) Advanced models. Contrary to CMS' expectation, more and more TKA cases are being pushed to the outpatient setting, thereby creating a situation in which most medically complex, high comorbid patients will remain inpatient as they are deemed too high risk not to hospitalize. Thus, these payment models will be left with medically complex patients skewing the overall demonstration results. The Innovation Center staff have assured us that they are reconsidering target pricing calculations based on the TKA decision. We urge you to expedite this process so that these payment model participants are not negatively impacted.

We would also request for a CPT code to trigger an outpatient BPCI Advanced episode. As removal of TKA from the IPO list rule was not contemplated within the design or historic pricing of BPCI Advanced, inclusion of outpatient TKAs in BPCI A seems a reasonable adjustment so that BPCI physicians may not be financially penalized for making site of care decisions in the spirit of the new policy.

Another alternative is to exclude BPCI Advanced TKAs from this new policy, e.g. all BPCI Advanced TKAs must stay inpatient, until clear and vetted evidenced-based patient selection criteria are established for qualifying Medicare beneficiaries as appropriate candidates for an outpatient TKA.

CMS could also release BPCI Advanced Physician Group participants from all downside risk for lower extremity joint replacements. In the absence of changes to the outpatient TKA policy and to ensure establishment of accurate pricing in BPCI Advanced, TKAs should be removed from baseline pricing in BPCI Advanced.

We have discussed these options in the past with the Payment Models Group at CMMI and we look forward to any data or other support that you may need to work on these changes.

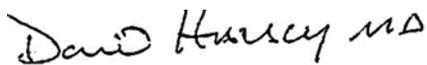
Medicare Advantage

This issue of wrongly defaulting TKA cases to the outpatient setting is especially concerning for surgeons and patients in Medicare Advantage (MA) plans across the country. The AAOS has heard several anecdotes from surgeons across teaching hospitals, community hospitals, urban

and rural hospitals that MA plans are requiring all TKA procedures to be done in the outpatient setting or otherwise denying claims. We have collected actual denial statements and have forwarded them to CMS staff working on Part C issues. For example, an 88-year old MA plan enrollee in Florida was denied an inpatient TKA procedure. This was subsequently reversed on a peer-to-peer appeal discussion, but it is a prime example of how elderly Medicare beneficiaries are at risk over unthoughtful denials. AAOS also engaged in a teleconference with appropriate CMS staff on this topic on February 28, 2018 and sent a formal written statement to you focused on MA. We expect that the MLN Matters article to clarify some of the confusion, but we request CMS to use its MA plan oversight authority to intervene and ensure that MA plan beneficiaries are not at an unfair disadvantage over their fee-for-service counterparts.

Thank you for your continued engagement on this issue. We believe that AAOS, AAHKS and CMS share the common objective of improved outcomes and patient safety and we can continue to work on these unintended consequences together. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,



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