AAHKS Position Statement: Removal of TKA from Inpatient Only List

Total Knee Arthroplasty Should be Considered, by Default, an Inpatient Procedure for Medicare Beneficiaries, Absent Evidence to the Contrary

From: Mark I. Froimson, MD, MBA, President, American Association of Hip and Knee Surgeons
Date: February 21, 2018
RE: TKA removal from IPO list
For: Information and Guidance to Members

During the American Association of Hip and Knee Surgeons (AAHKS) Legislative Retreat in Washington, D.C., from February 8-10, 2018 AAHKS leadership gathered and met with nearly 30 congressional offices. Among the issues discussed, consensus emerged that the current confusion surrounding the removal of total knee arthroplasty (TKA) from the inpatient only list compelled AAHKS to provide this position statement to assist providers and patients navigate this transition.

New Medicare Policy for TKA

In November 2017, the Center for Medicare and Medicaid Services (CMS) finalized the 2018 Medicare Outpatient Prospective Payment System[1] rule that removed total knee arthroplasty procedures from the Medicare inpatient-only (IPO) list of procedures. This action has already had significant and unexpected consequences.

The final rule was a response to emerging evidence in non-Medicare patients that there appears to be a healthy cohort suitable for TKA in an outpatient setting; it was also a concession to the expressed interest on the part of some orthopedic surgeons of extending this option to Medicare beneficiaries. Historically, the Medicare program covered knee replacement surgery only if it was performed on an inpatient basis. Through the final rule, CMS took a measured step towards allowing Medicare coverage for outpatient TKA surgeries by only allowing the procedure in outpatient facilities associated with a hospital. CMS did not allow the procedure to be moved to the free standing ambulatory surgery setting, indicating a desire to move slowly, presumably to ensure safety during this proposed transition. The final rule was clear in stating CMS's expectation was that the great majority of TKAs would continue to be provided in an inpatient setting.

Wide Confusion Over New Policy at the Provider Level

Unfortunately, the unintended consequence of this change has been an unprecedented amount of confusion on the part of a variety of stakeholders regarding how to interpret this new rule. Hospitals, surgeons, and payers are interpreting the rule from different perspectives and as such are each coming to very different conclusions. Further, there is no observed consistency in interpretation among hospitals and surgeons, yielding uncertainty about the freedom they have to prescribe the most clinically appropriate location for a patient's surgery. Of additional concern is the fact that many are reporting that Medicare Advantage plans are directing their networks to drive the majority of TKAs to outpatient status, despite clear evidence that that was not CMS's intent. This may be creating unsafe conditions for patients. As such, AAHKS offers this guidance to its members.

[1] 82 Fed. Reg. 52,356 (Nov. 13, 2017).

Interplay Between TKA and the "2 Midnight Rule"

The definition of outpatient procedure in Medicare parlance is not what many, including most beneficiaries, would understand it to be. For several years, CMS has utilized a rule called the "Two-Midnight Rule" to define outpatient status for all procedures not on the IPO list. CMS made TKA subject to the "Two-Midnight Rule" in conjunction with the decision to move TKA off the IPO list. According to the "Two-Midnight Rule," a hospital admission should be expected to span at least two midnights in order to be covered as an inpatient procedure. If it can be reliably expected that the patient will not require at least two midnights in the hospital, the "Two-Midnight Rule" suggests that the patient is considered an outpatient and is therefore subject to outpatient payment policies. Under prior guidance related to the "Two-Midnight Rule;" however, CMS also states that Medicare ***may*** treat some admissions spanning less than two midnights as inpatient procedures ***if*** the patient record contains documentation of medical need. Application of this guidance to TKA runs counter to CMS's stated intent. **CMS did not intend that each inpatient TKA, the current care standard, required such documentation of medical need. Rather, they expected, as stated clearly in the rule, that the vast majority of TKAs would remain inpatient. When a standard status is expected by the overwhelming majority, the burden of proof should fall on the exception, not the standard.**

This has been a source of great confusion for physicians and hospitals. 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. The result is that many hospital leadership teams have been very conservative in their interpretation and have directed their physicians to err on the side of outpatient designation – absent a clear standard.

This regulatory shift is now impacting thousands of orthopaedic surgeons who heretofore had considered this major surgical procedure for elderly patients an obvious inpatient procedure performed in hospital operating rooms, requiring significant resources. They now find that they are getting calls from C-suite and Utilization Review teams to avoid inpatient designation and face pressure to move the vast majority of TKAs to an outpatient designation. Patients also face changes in what many had assumed were inpatient procedures and which may lead to confusion over cost sharing obligations. This has been an overnight and baseless paradigm shift that requires examination and clarification.

Trend of TKA Clinical Advances

Since the inception of TKA, there have been many millions of patients who have been admitted to hospitals for their post-surgical care. These patients traditionally stayed for 3-5 days and were often discharged to an inpatient rehabilitation or skilled nursing setting. Until quite recently, the percent of patients that were institutionalized for over ten days, in hospital and in post-acute care, approached 50%. Patients who were more robust, had few medical comorbidities, and/or who had reliable social support were more likely to be discharged to home with home care.

A number of clinical advances have made the care of patients facing TKA safer and more expedient. These include, among others, better pain management, opioid sparing protocols, better blood management protocols, improved surgical techniques, improved patient preparation and selection for surgery, improved patient and family education and engagement, and better infection prevention strategies. Consequently, patients are now convalescing more quickly following TKA and are finding it easier to return to their homes more reliably. Rather than being away from home for 10-14 days, as in the recent past, many can receive resource intensive interventions that span one to three days as an inpatient and can then be ready and safe to continue their recovery in a non-clinical setting. This had been a great advance for patients and, as evidenced in the BPCI program, has saved considerable resources for CMS and the Medicare program.

Impact of an Outpatient Designation Remains Unknown

Great care, however, is needed before extrapolating from these advances in inpatient-anchored, resource-intensive care, as to how to move selected patients to an outpatient setting. In fact, the Medicare rule that allows for TKA to be done as an "outpatient procedure" provides no evidence that such a transition would be safe and without adverse consequence. Although there is some evidence on

how to risk stratify non-Medicare patients for ambulatory environments, these patients are quite different from the typical Medicare patient. They are, by definition, younger, and, by design, selected based on evolving evidence that remains under study. **In fact, the number of true outpatient TKA procedures remains quite small – by recent estimates, less than 5%.**

Another important outcome of this rule is that the surgeon bears the responsibility for the inpatient/outpatient designation, as stated in the preamble to the rule. Less appreciated is the lack of clarity surrounding acceptable justification for inpatient admission spanning fewer than two midnights. Pressure is being placed on the surgeon to make outpatient the default designation prior to surgery, before he/she is aware of any potential adverse surgical event, the degree of blood loss, the length of the procedure, or how the patient tolerates anesthesia. As a result of the final rule, the surgeon must admit the patient to the facility in order for the procedure to be considered an inpatient procedure. Those patients for whom one midnight may be sufficient, yet are clearly not acceptable outpatient candidates, fall into a gray area forcing outpatient status. It is unclear at this time that a surgeon has reliable criteria to predict that a given, elderly patient facing the stress of the surgery is suddenly, unlike the millions who preceded him, now suitable for treatment as an outpatient.

AAHKS Guidance to Members

As such, and after careful consideration of the evidence and the facts, and following a detailed conversation with the relevant CMS officials and governing agencies, AAHKS recommends to its members the following:

» Although TKA has been taken off the IPO list, *it is reasonable to expect that the vast majority of patients should be treated, by default, as qualifying for inpatient designation.* The physiology of patients did not change, nor did the standard of care, from December 2017 to January 2018.

This is consistent with CMS's own statements in 2018 Medicare Outpatient Prospective Payment System Final Rule of the impact of removing TKA from the IPO list. CMS stated that "the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgement made by the physician."[2] CMS also stated that the Medicare beneficiaries "who are able to receive this procedure safely on an outpatient basis . . . are a ***subset***," and that "we [CMS] do not expect a significant shift in TKA cases from the hospital inpatient setting to the hospital outpatient setting." [3]

» Therefore, all relevant parties agree that the burden of proof is on the surgeon to clearly state, not why this patient requires inpatient designation, but rather what criteria are present that suggest that inpatient resources are not expected to be utilized.

While it is possible to convert an outpatient admission to an inpatient admission, such a process takes additional surgeon time and creates an unplanned need for services and bed availability. Only when there is clarity that a patient is expected to be safely discharged within 24 hours should the surgeon designate the patient as an outpatient. A safe discharge is expected to occur when a patient has an acceptably low risk of developing life-threatening complications, including, confusion, delirium, fall, wound complication, bleeding, cardiovascular instability, urinary retention and ileus. Although current advanced care protocols have reduced the incidence of many of these adverse events, predicting which patient may experience one or more of these is generally not possible.

» Consequently, AAHKS would encourage its members to only utilize an outpatient designation for a patient when doing so does not pose the risk of making the occurrence of, or failure to detect, such an adverse event more likely.

It is expected that, at the present time, having little experience with treating TKA patients in outpatient departments, most of our members would continue to utilize the inpatient designation for the vast majority of their Medicare beneficiaries. This should remain the default designation and one that is

[2] 82 Fed. Reg. 52,523 (Nov. 13, 2017)
[3] 82 Fed. Reg. 52,524 (Nov. 13, 2017).

readily met through standard documentation whether the admission is one, two or three or more days. We believe that the intention of CMS supports an assumption of the appropriateness of an inpatient stay regardless of the expectation of a two-midnight stay.

Next Steps

We are currently working with CMS to pursue a resolution to this issue. Potential clarifications, guidance, or exceptions may take a number of forms. There are a number of additional considerations that must be carefully worked through as we consider the impact.

One includes the financial impact on patients and our duty to inform them of such. Will they be able to afford the potential increased patient financial responsibility conferred by this policy when their payment for events around their TKA move from Part A to Part B? Why would they agree to expedited discharge with decreased utilization of resources when such “engagement” results in a financial penalty to them because of time spent under observation status?

Our outreach with CMS will also address the unintended consequence that affects many of our members participating in episode based alternative payment models (APMs) that are based arounds DRG 469/470. Removing lower resource utilizing, healthier outpatients from the denominators for cost and quality performance metrics will impact most members’ ability to achieve quality goals and target pricing.

AAHKS wants, as we expect CMS does, what is best for our patients. Surgical and medical advances will continue to make this a dynamic conversation. We simply ask that the clinical and payment consequences be thoroughly examined and that we continue to allow total knee replacement admissions to default to approved inpatient stays regardless of discharge on post-op days one or two. This will allow for time to study the outcomes of total knee arthroplasty being removed from the IPO list.