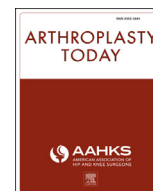




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White Paper

Total Knee Arthroplasty in Ambulatory Surgery Centers: The New Reality!

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ABSTRACT

By streamlining surgical care and eliminating postoperative hospitalization, the transition to ambulatory total knee arthroplasty (TKA) has the potential to improve efficiency and minimize the costs of care. However, practical, legal, and financial implications remain to be addressed. The Centers for Medicare and Medicaid Services has also yet to address concerns generated by the removal of TKA from the Inpatient-Only List and provide guidance on patient selection. Rolling out regulatory changes that impact high-volume procedures, such as TKA, in a short period of time and without appropriate feedback can only lead to further confusion. As surgeons, we are in a unique business model that requires us to constantly innovate to deliver high quality care, while also taking financial cuts as a result of our innovations.

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The removal of total knee arthroplasty (TKA) from the inpatient-only (IPO) list for Medicare beneficiaries in 2018 created significant confusion and administrative burden, with 91% of respondents in a November 2019 poll reporting continued difficulties [1,2]. While hospitals and surgeons cope with the unintended impact of this policy, the Centers for Medicare and Medicaid Services (CMS) has just moved a step further by adding TKA to the Ambulatory Surgery Center (ASC) covered surgical procedures (CSP) list [3]. With very limited guidance on patient selection, failure of CMS to address the concerns generated by the removal of TKA from the IPO list and implications related to physician ownerships in ASCs, the new CMS policy is surely set to pose added challenges.

Practical implications

The safety of outpatient TKA in the Medicare population remains to be established. While outpatient TKA has been shown to be comparable in immediate postoperative outcomes to inpatient TKA, it is

often performed in younger patients with more favorable comorbidity profiles than those observed in the Medicare population [4–7]. A few studies have proposed risk stratification tools for predicting outpatient stay as defined by CMS' Two-Midnight Rule in Medicare-aged patients [8,9], but the ideal Medicare patient to undergo outpatient TKA, and now ambulatory TKA, has not been defined.

CMS maintains that there is no expectation for all TKA procedures to be performed in the outpatient/ASC setting and that status determination is a complex medical decision that remains in the purview of the orthopedic surgeon [10]. Retaining the decision-making power places increased burden on the physician for documentation to support the level of necessary postoperative care. There are also concerns that TKAs performed at ASCs may pose a safety risk should significant intraoperative complications (eg, vascular injury, periprosthetic fractures, arrhythmias, and so on) occur. ASCs may not have the personnel or resources to immediately handle such complications. In addition, ASCs may not be equipped to handle unanticipated overnight stays in the event that discharge to home is not possible [11]. There are currently no minimum ASC requirements to guide written agreements for hospital transfers [12]. Therefore, it is critical for ASCs to develop well-defined protocols that not only address patient inclusion criteria but also contingency plans should major unanticipated complications or need for inpatient admission arise.

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Financial implications

There are 2 reimbursement portions for TKAs performed at ASCs: implants and service [3,13]. Payments for implant-related costs follow the same rates as the hospital Outpatient Prospective Payment System (OPPS), which is the reimbursement model for outpatient TKA. Payments for the service portion, however, are approximately 40% lower than the OPPS rates. CMS justifies the lower reimbursement rates for the service portion by the reduced overhead costs at ASCs [3]. Currently, the 2020 Medicare reimbursement for TKA under OPPS is \$11,900.71 and the reimbursement for TKAs performed at ASCs is \$8609.82 [3,13].

The low reimbursement rate for ambulatory TKA will likely trigger or incentivize other payers (ie, commercial) to shift more TKAs to ASCs. This may also increase competition among healthcare systems, with inpatient facilities or those not equipped to handle fast-track TKA to be affected the most in terms of loss of market share to ambulatory facilities. Even for hospitals that have ownership in ASCs, more procedures performed in the ambulatory setting would lead to decreased revenue for the same procedure.

There are additional financial implications to be considered. First, performing TKA at ASCs in the Medicare population requires thorough vetting of each patient's overall functional health status, complexity of the procedure, need for postoperative clinical or case management support, social/family support, discharge destination, and how these variables may impact anticipated length of stay [5]. Emerging reports show that while total physician work has remained unchanged over the past 5 years, a great deal of work has shifted to early phases in the episode of care [14]. For outpatient arthroplasty cases, care coordination and discharge planning that historically had occurred during inpatient admissions has to be conducted in the preoperative period to mitigate potential barriers for home discharge. Another component that is not accounted for in the reimbursement methodology is the need for close postoperative follow-up of patients discharged to home on the day of surgery [15,16]. For example, part of the success of outpatient TKA has been attributed to the utilization of nurse navigators who provide close communication and follow-up for patients [17]. The added work burden on the surgeon and costs for hiring nurse navigators are not accounted for in current reimbursement models.

Legal implications

Further complicating the picture, most ASCs are physician-owned [18]. Physicians who refer patients for TKA procedures at ASCs in which they have an ownership interest should be mindful of the Anti-Kickback statute (AKS). The AKS makes it a criminal offense to knowingly and willfully receive remuneration to induce or reward referrals for services payable by a federal health care program, such as Medicare or Medicaid [19]. The AKS, however, includes a number of safe harbors that protect certain arrangements from criminal and civil prosecution including a safe harbor for physician investments in ASCs [20]. To be protected by a safe harbor, an arrangement must satisfy all of the safe harbor's requirements. Compliance with a safe harbor is voluntary. Failure to comply with a safe harbor does not mean that an arrangement is by or in itself illegal, but that it will be subject to facts and circumstances analysis.

Moving forward

There are a few recommendations that can be made based on available data and lessons learned from the removal of TKA from the IPO list. These include the following:

1. Surgeons should not be pressured to shift TKAs to ASCs. Administrators are reminded that CMS acknowledges "there are a small number of less medically complex [Medicare] beneficiaries that could appropriately receive the TKA procedure in an ASC setting and physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations" [13].
2. In the absence of guidance from CMS, orthopedic groups are encouraged to develop conservative selection criteria that take into consideration medical comorbidities, body habitus, living environment, functional status, patient motivation, and anticipated length of stay.
3. Comprehensive interdisciplinary protocols emphasizing preoperative patient preparation, medical optimization, intraoperative efficiency, opioid-sparing anesthetic and analgesic techniques, blood preservation, rapid mobilization, and close postoperative follow-up are essential.
4. Same-day surgical procedures should be scheduled as early in the day as possible. Late-start cases should be avoided.
5. If there are any postoperative concerns regarding the safety of same-day discharge, surgeons should not hesitate to admit the patient with the appropriate documentation to justify the admission. However, surgeons are reminded that postoperative convenience care is not reimbursed by CMS or commercial payers.
6. ASCs should be prepared to handle unforeseen deviations from the expected course of care including perioperative complications and need for hospital admission. Standing agreements between ASCs and local hospitals to facilitate unexpected admissions will facilitate smooth transfers as needed.
7. ASCs should disclose financial interests or ownership by physicians to patients. ASCs also need to develop clear criteria delineating which patients are appropriate for ambulatory TKA to ensure appropriate referral patterns and compliance with federal fraud and abuse laws, including the AKS. Shared decision-making between the surgeon and the patient, along with informed consent and appropriate disclosure, should guide the most appropriate site of service.
8. In anticipation of future audits and policy changes, surgeons and hospitals should document the time spent on preoperative optimization and care coordination for TKAs performed at ASCs to help guide future reimbursement models.

In conclusion, by streamlining surgical care and eliminating postoperative hospitalization, the transition to ambulatory TKA has the potential to improve efficiency and minimize the costs of care, but questions regarding its safety and impact on physician work remain to be answered. CMS has also yet to address the concerns generated by the removal of TKA from the IPO list and provide clear guidance on patient selection criteria. Rolling out regulatory changes that impact high-volume procedures, such as TKA, in a short period of time and without appropriate feedback can only lead to further confusion. As surgeons, we are in a unique business model that requires us to constantly innovate to deliver high quality care, while also taking financial cuts as a result of our innovations. There is a need for innovative reimbursement systems that recognize and reward the increasing role that surgeons play in advancing value-based care.

Conflict of interest

James I. Huddleston reports royalties from Exactech; paid consultancy from Corin, Exactech, and ZimmerBiomet; a board member/committee appointments for AAHKS, Knee Society. Mohamad J. Halawi reports medical/orthopaedic publications editorial/

governing board for J Arthroplasty, Arthroplast and a board member/committee appointments for AAHKS Today The other author declares no potential conflict of interest.

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