**Evidence-based *Patient Selection Exclusionary Criteria* for OUTPATIENT TOTAL KNEE ARTHROPLASTY**

***APPROVED BY ORTHO GOVERNING COUNCIL FEB 20 2018***

# SCOPE:

These guidelines apply to patients at \_\_\_\_\_\_\_\_\_\_\_\_\_\_ who are insured through the Medicare Program, who are undergoing an elective total knee arthroplasty (TKA). Centers for Medicare & Medicaid Services (CMS) stated, on page 665: we expect providers to carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA procedure.

# PURPOSE:

The purpose of this ***patient selection exclusionary criteria*** is to provide evidence based guidance to clinical staff and other personnel on the proper procedures and requirements for all patients to receive services for the appropriate patient status based on regulations issued by CMS in 2017, page 663.

# GUIDELINES:

The patient status of every Medicare patient undergoing TKA will be determined prior to surgery by the performing surgeon based on the review of these guidelines. The patient status must be recorded in writing prior to the surgery, with the order dated and signed by the surgeon, or another physician or practitioner who will be involved in the care of the patient and has admitting privileges at the hospital.

CMS has designated TKA to be a surgery which is not required to be performed only as an inpatient as of January 1, 2018. The fact that TKA is not designated as inpatient only does not mean that it must be performed as outpatient, page 665.

CMS sates (page 665): “We continue to believe that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary’s individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary. We also reiterate our previous statement that the removal of any procedure from the Inpatient Only (IPO) list does not require the procedure to be performed only on an outpatient basis.”

When determining if a TKA should be performed as inpatient or outpatient, the physician/provider should consider many factors. Patients who meet any one or more of the following criteria shall be deemed appropriate for consideration as an inpatient admission:

1. Advanced age 70 or older (Krause, et al, 2018);
2. simultaneous bilateral TKA (Krause, et al, 2018);
3. surgery performed for fracture and orthopedic complexity (e.g. Bone loss, retained hardware) (Krause, et al, 2018);
4. uncontrolled (hemoglobin A1C >7.0) diabetes mellitus (type I or II) (Krause, et al, 2018);
5. BMI >30 (Krause, et al, 2018);
6. any bleeding disorders (Krause, et al, 2018);
7. American Society of Anesthesiologist (ASA) scores >2 (Krause, et al, 2018);
8. poorly controlled cardiac (e.g., heart failure, arrhythmia) or pulmonary (e.g. embolism, respiratory failure) (Krause, et al, 2018);
9. chronic opioid consumption (Krause, et al, 2018);
10. COPD (Krause, et al, 2018);
11. functional neurologic impairments (Krause, et al, 2018);
12. chronic or end-stage renal disease (Krause, et al, 2018);
13. oncologic disorder;
14. reduced cognitive pre-operative cognitive capacity (Krause, et al, 2018);
15. significant gait disturbance;
16. severe mobility disorders (use of assistive devices for ambulation);
17. non-ambulatory;
18. voiding difficulties or preoperative use of urologic medications and practical issues (Krause, et al, 2018);
19. history of MI; CHF; venous thromboembolism, cardiac arrhythmia, respiratory failure, or chronic pain requiring regular opioid medications (Krause, et al, 2018);
20. preoperative lymphocyte count less than 1500 cells/mm (Krause, et al, 2018);
21. albumin level < 3.5g/dL (Krause, et al, 2018);
22. transferrin levels <220 mg/dL (Krause, et al, 2018);
23. prealbumin levels < 22.5 mg/dL (Krause, et al, 2018);
24. hemoglobin level <13 g/dL (Krause, et al, 2018);
25. malnutrition (Krause, et al, 2018);
26. ETOH abuse or intravenous drug use (Krause, et al, 2018);
27. chronic liver disease (Krause, et al, 2018);
28. anticipation that patient will need SNF care at discharge (Krause, et al, 2018);
29. surgeon determines that a patient’s current living situation makes the patient a safety risk (e.g. living alone, living with a care giver unable to assist with ADLs, inability to access living, bathing and dining area of home) ; and
30. patient preference.
31. **SUPPORTIVE EVIDENCE:**
32. Patients over 75 years of age have been found to have a higher risk of post-operative falls, knee stiffness, pain, urinary retention and increased re-admission (Krause, et al, 2018).
33. BMI of 30 or greater have an increased rate of infection, odds ratio of 1.90, with 95% confidence interval (Krause, et al, 2018).
34. Patients with chronic kidney disease have double the risk of mortality and higher risk of post-operative adverse events (Krause, et al, 2018).
35. Patients with lower lymphocyte count have a three to five times higher frequency of a major wound complication (Krause, et al, 2018).
36. Patients with a hemoglobin of less than 13 g/dL are four to 5.6 times more likely to need a blood transfusion (Krause, et al, 2018).
37. Malnourished patients are five to seven times higher risk for developing a major wound complication (Krause, et al, 2018).
38. “Outpatient TKA are associated with a higher risk of post-operative complications including surgical site infection requiring irrigation and debridement and explantation of the prosthesis, stiffness requiring manipulation under anesthesia, component failure requiring revision due to noninfectious cause, and postoperative DVT” Arshi, et al., 2017,p. 1984
39. For stays for which the physician expects the patient to need less than 2 midnights of hospital care, an inpatient admission is payable under Medicare Part A on a case-by-case basis if the documentation in the medical record supports the admitting physician’s determination that the patient requires inpatient hospital care. This documentation and the physician’s admission decision are subject to medical review, which is discussed in greater detail below (80 FR 70541), page 666.
40. At this time, we expect that a significant number of Medicare beneficiaries will continue to receive treatment as an inpatient for TKA procedures, page 671.
41. We (CMS) do not expect a significant shift in TKA cases from the hospital inpatient setting to the hospital outpatient setting between January 1, 2018 (the effective date for the removal of TKA from the IPO list) and the current end dates of the performance periods for the BPCI and CJR models, September 30, 2018 and December 31, 2020, respectively page 671.
42. **UPDATES:**

This document will be updated on an ongoing basis, as there is scheduled future discussion between CMS and the American Academy of Orthopedic Surgeons and because we anticipate that as additional data from well-designed evidence-based studies become available, our practice may change.

**References:**

American Academy of Orthopedic Surgeons, (2015). Evidence-based clinical practice guideline.

Arshi, A., Leong, N., D’oro, A., Wang, C., Buser, Z., Wang, J., Jones, K., Petrigliano, F., & Soohoo, N. (2017). Outpatient total knee arthroplasty is associated with higher risk of perioperative complications. J Bone Joint Surg Am 99: p. 1978-86.

Courtney, P., Froimson, M., Meneghini, M., Lee, G., Della Valle, C. (2018*). Can total knee arthroplasty be performed safely as an outpatient in the Medicare population?* Journal of Arthroplasty, p. 1-4.

Department of Health and Human Services, Centers for Medicare & Medicaid Services, (2017). *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*; 42 CFR Parts 414, 416, and 419, [CMS-1678-FC], RIN: 0938-AT03, p. 1-1133.

Hirsch, R. (2018). *Sample policy for inpatient status – total knee replacement.* RAC University.

Krause, A., Sayeed, Z., El-Othmani, M., Pallekonda, V., Mihalko, W., & Saleh, K. (2018). *Outpatient Total Knee Arthroplasty: Are we there yet?* (Part 1). Orthop Clin N Am: 49, p. 1-6

Krause, A., Sayeed, Z., El-Othmani, M., Pallekonda, V., Mihalko, W., & Saleh, K. (2018). *Outpatient Total Knee Arthroplasty: Are we there yet?* (Part 2). Orthop Clin N Am: 49, p. 7-16.