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

MLN Matters Number: SE19002 Reissued
Related Change Request (CR) Number: N/A
Article Release Date: January 24, 2019
Effective Date: January 1, 2018
Related CR Transmittal Number: N/A
Implementation Date: N/A

Note: This article was reissued on January 24, 2019, to clarify information.

PROVIDER TYPE AFFECTED

This MLN Matters Special Edition Article is intended for hospital providers that submit hospital inpatient or outpatient claims for Total Knee Arthroplasty (TKA) procedures. The Two-Midnight Rule impacts acute-care hospitals, inpatient psychiatric facilities, long-term care hospitals (LTCHs), and Critical Access Hospitals (CAHs). CMS recognizes that such facilities may vary in their billing for TKAs.

CMS recognizes that a MLN article on the 2-Midnight Rule has already been published and can be found at the following link: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10080.pdf

This article is distinguished by its focus on TKA procedures and application of the 2-Midnight Rule now that this procedure has been removed from Medicare's inpatient-only (IPO) list.

*NOTE: Throughout this document the term "Provider" when used means "Hospital".

What You Need To Know

The Centers for Medicare & Medicaid Services (CMS) removed the Current Procedural Terminology (CPT) code describing TKA procedures from Medicare's Inpatient-Only List (IPO) effective January 2018. This allows TKA procedures to be performed on an *inpatient* or *outpatient* basis. In other words, it allows Medicare payment to be made to the hospital for TKA procedures regardless of whether a beneficiary is admitted to the hospital as an inpatient or as an outpatient, assuming all other criteria are met. This does not have any impact on CMS' 2-midnight policy.

CMS policy does not dictate a patient's hospital admission status and has no default determination on whether a TKA procedures should be done on an inpatient or outpatient basis.

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Rather, CMS continues its long-standing recognition that the decision to admit a patient as an inpatient is a complex medical decision, based on the physician's clinical expectation of how long hospital care is anticipated to be necessary, and should consider the individual beneficiary's unique clinical circumstances.

The Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) are contracted by CMS to review a sample of Medicare fee-for-service (FFS) short-stay inpatient claims (claims with hospital stays lasting less than 2 midnights after formal inpatient admission) for compliance with the 2-Midnight Rule.

BACKGROUND

The 2-Midnight Rule
Effective October 1, 2013, CMS finalized the 2-Midnight rule which directed how claims are to be reviewed by Medicare review contractors to determine the appropriateness of Medicare Part A payment. The regulation established two distinct but related medical review policies, the two midnight **presumption** and the two-midnight **benchmark**.

> **2-Midnight Presumption (helps guide contractor selection of claims for medical review):** Hospital claims with lengths of stay greater than 2 midnights after the formal admission are presumed to be reasonable and necessary for Medicare Part A payment. Although these claims may be submitted among a sample of cases received, the BFCC-QIOs generally will not focus their medical review efforts on stays spanning 2 or more midnights after formal inpatient admission, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the Two-Midnight presumption.
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> **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 time a beneficiary has spent receiving hospital care prior to inpatient admission will be considered when assessing whether this benchmark is met.

CMS revised the 2-Midnight Rule, effective January 2016 in the CY 2016 Hospital Outpatient Prospective Payment System (OPPS) CMS-1633-F to add the **Case-by-Case Exception**. 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 that the beneficiary required hospital inpatient care despite lack of a 2-midnight expectation 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

Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs)

BFCC-QIOs are tasked by CMS to review a sample of Medicare fee-for-service short-stay inpatient claims for compliance with the 2-Midnight Rule. CMS began using BFCC-QIOs, rather than Medicare Administrative Contractors (MAC) or Recovery Audit Contractors (RACs), to conduct the initial medical reviews of providers who submit claims for short stay inpatient admissions on October 1, 2015.

The focus of these reviews is also for BFCC-QIOs to educate admitting physicians/practitioners and providers about the Part A payment policy for inpatient admissions.

CMS instructs BFCC-QIOs to conduct routine analysis of hospital billing and target for review hospitals with high or increasing numbers of short inpatient stays that are potentially inappropriate under the 2-midnight policy.

TKAs, like any other condition or procedure not on the IPO list, are subject to medical review by CMS contractors. The review is based on documentation in the medical record that supports either the 2-Midnight Benchmark or the Case-by-Case Exception. It is important to note that CMS does NOT target condition or disease-specific claims, such as TKA procedures, for BFCC-QIO review.

BFCC-QIO reviewers look for documentation in the medical record that supports:

- the admitting physician/practitioner's reasonable expectation that the beneficiary will require medically necessary hospital services spanning 2 midnights or longer and admits the patient to the hospital based on that expectation

OR:

- the admitting physician/practitioner's judgment that the beneficiary required hospital care on an inpatient basis despite lack of a 2-midnight expectation 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.

The BFCC-QIO reviews the entire medical record for supporting documentation.

What does Removing TKA from the IPO list mean?

1. This **allows** TKA procedures to be paid by Medicare FFS when performed in **either** the hospital inpatient or hospital outpatient setting, assuming all other criteria are met.

2. This **allows** TKA short-stay inpatient claims (if chosen in a sample of claims) to be reviewed by the BFCC-QIOs for compliance with the 2-Midnight Benchmark or Case-by-Case exception (note that the two-year prohibition of RAC review for patient status continues to apply regardless of whether the case is performed on an inpatient or outpatient basis.)

NOTE: The cost-sharing amount the beneficiary is responsible for will differ based on whether the surgery is performed on an inpatient or outpatient basis (and will vary based on other factors such as geographic location).

What does Removing TKA from the IPO list NOT mean?

1. It does not mean that all TKAs must be performed on a hospital outpatient/observation basis nor does it mean that there is a presumption about where TKAs are performed.

2. It does not mean that TKA Short Stay inpatient claims are targeted for review by CMS.

NOTE: CMS has not made any pre-determinations on the number of patients receiving TKA procedures that should be treated as an inpatient or outpatient.

This MLN Matters article further clarifies and provides context for statements in the preamble for the CY 2018 OPPS final rule. In the CY 2018 OPPS final rule, CMS also prohibited Recovery Audit Contractor (RAC) patient status reviews for TKA procedures performed in the hospital inpatient setting for a period of two (2) years (CY 2018-2019).

Examples of TKA Cases and Rationale for Payment Determinations:

NOTE: The time a beneficiary spent as an outpatient before being admitted as an inpatient is considered during the medical review process for purposes of determining the appropriateness of Part A payment, but such time does not qualify as inpatient time. (See the Medicare Benefit Policy Manual, Chapter 1, Section 10, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c01.pdf for additional information regarding the formal order for inpatient admission.)

Case #1: Documentation Supports 2-Midnight Benchmark:

Dates of Service: On 1/6/18, patient was receiving hospital observation services; on 1/07/18, the physician order was written for inpatient admission; on 1/8/18, the patient was discharged home. (2 Midnights total; 1 Midnight after inpatient admission)

Case Summary: This 65-year-old female presented to the facility on January 6, 2018 for elective TKA surgery. She was placed in observation after receiving routine post-operative care.

She had a medical history of arthritis, diabetes mellitus, arrhythmia, sleep apnea, and chronic pain. The Physical Therapy (PT) progress notes from the morning on Post-op Day (POD) 1, indicated that the patient complained of feeling shaky and dizzy and was unable to complete her PT. The patient returned to her room, ate breakfast and her regular insulin dose was administered. Further nurse assessment noted that she remained light-headed. After a check of her blood sugar, the patient was found to be hypoglycemic and a snack was administered with improvement in her symptoms. However during afternoon PT session on POD 1, documentation in the medical record indicated that the patient again became shaky and complained of feeling hot. The patient was again returned to their room, sugars were assessed and the physician alerted—resulting in adjustments to her diabetic medications. The patient was admitted as an inpatient on 1/7/18 for continued monitoring and glucose stabilization. PT progress notes on the morning of POD 2 indicate the patient tolerated the session well, progressed as expected without other complaints. The patient was discharged 1/8/18.

Rationale for Approval: Medical management provided surgical repair, anesthesia administration, pre- and post-operative monitoring, pain and glucose management. No intraoperative complications were noted. On January 8, 2018, she was discharged home. Despite the lack of a 2 midnight stay after formal inpatient admission, the medical record documented symptoms during PT and two episodes of hypoglycemia, requiring adjustment of her insulin and close blood sugar monitoring post-op. This documentation provided a reasonable expectation, at the time the inpatient order was written, of medically appropriate hospital care spanning 2-Midnights.

Case #2: Medical Record Documentation Supports Case-by-Case Exception

Dates of Service: 02/12/2018 - 02/13/2018 (one midnight)

Case Summary: This 73-year-old male presented for elective total left knee replacement surgery on February 12, 2018, and was admitted to inpatient status the same day after developing post-operative bradycardia. He had a history of coronary artery disease, atrial fibrillation, complete heart block with pacemaker placement, diabetes, osteoarthritis, and hypertension. Medical management consisted of urgent evaluation by electrophysiology and correction of pacemaker malfunction, intravenous hydration, cardiac monitoring, laboratory testing, analgesics, antiemetics, anticoagulant, and IV antibiotic and home medications. On February 13, 2018 he was discharged to home.

Rationale for Approval: This was an elective admission for a TKA. The procedure was performed without complications, and the patient was quickly mobilized. His pain was controlled with oral pain medication soon after the procedure, however the patient demonstrated clinical decompensation of a chronic medical problem requiring urgent evaluation and treatment. The medical record documents that while this patient was previously physically active, due to the patient's extensive cardiac history with decompensation and need for urgent evaluation and treatment, it is reasonable to approve this case based upon patient history and comorbidities and current medical needs, severity of signs and symptoms, and presence of risk factors for an adverse event.

Case #3: Medical Record Documentation Did Not Support the 2-Midnight benchmark or the case by case exception:

Dates of Service: 03/6/18 - 03/07/18 (one midnight)

Case Summary: This 77 year-old female presented on March 6, 2018 for an elective TKA surgery and was admitted to inpatient status that same day. The patient had a history of gastroesophageal reflux disease. No other medical comorbidities were documented in the medical record. Medical management provided consisted of the surgical procedure of left TKA, pre- and post-operative monitoring, imaging, laboratory studies. Medications administered during this hospitalization included intravenous fluids, prophylactic antibiotics and post-op pain medication. The patient was discharged to her home on March 7, 2018. No potential intraoperative or potential post-operative complications were noted in the medical record.

Rationale: 77 year old presented for elective left TKA. Medical review is based on associated risk factors, comorbidities, and/or complications. The procedure was performed without any intraoperative complications. Patient comorbidities were minor and no adverse concerns were documented. The patient was monitored post operatively with good pain control, stable vital signs and was discharged the next day. The documentation did not support that hospital services were expected to span 2-midnights or more, nor did it support a case-by-case exception. There were no intra or post-operative complications documented in the medical record that supported inpatient status.

FREQUENTLY ASKED QUESTIONS

Question 1: Will CMS target TKA procedures for patient status review now that they are not on Medicare FFS IPO list?

Response 1: No. Claim selection is not condition or disease-specific. Sampling is done at the hospital level not at the claim level. Accordingly, TKA procedures are not targeted for review by CMS. CMS instructs BFCC-QIOs to conduct routine analysis of a sample of hospital claims with high or increasing numbers of inpatient stays less than 2-Midnights. When TKA or any type of claim is reviewed for Part A eligibility, BFCC-QIOs identify and educate the hospital on opportunities for improvement.

Question 2: Does removal of TKA from Medicare's FFS IPO list mean that this procedure should only be performed on a hospital outpatient basis?

Response 2: No. Removing a procedure from Medicare's FFS IPO list does not require the procedure to be performed on an outpatient basis. Rather, it allows the procedure to be performed in a hospital inpatient or hospital outpatient status.

Question 3: Who determines patient status as a hospital inpatient or outpatient?

Response 3: CMS continues its long-standing recognition that the decision to admit a patient as an inpatient is a complex medical decision, based on the physician's clinical expectation of how long hospital care is anticipated to be necessary, considering the individual beneficiary's unique clinical circumstances. CMS policy does not dictate patient status.

Question 4: What do BFCC-QIOs look for when evaluating a TKA or other short-stay inpatient claim, for compliance with the 2-Midnight Rule?

Response 4: BFCC-QIOs look for:

- documentation in the medical record that supports a reasonable expectation of medically necessary hospital services for 2 midnights or longer including all outpatient/observation and inpatient care time

OR

- documentation in the medical record that supports the admitting physician's determination that the patient required inpatient care despite the lack of a 2-midnight expectation based upon complex medical factors including but not limited to:
  - Patient's history, co-morbidities and current medical needs
  - Risk of adverse events
  - Severity of signs and symptoms

Question 5: Are there plans to remove other orthopedic inpatient surgical procedures from Medicare's FFS IPO list?

Response 5: Any future plans to remove orthopedic procedures from Medicare's FFS IPO will be communicated through the rulemaking process. This allows for stakeholder comments to be submitted and reviewed prior to release of CMS final rules.

ADDITIONAL INFORMATION

MLN Matters Article, MM10417, January 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS) Update with the removal of TKA from the IPO is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10417.pdf.

MLN Matters Article, MM10080, Clarifying Medical Review of Hospital Claims for Part A Payment, is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10080.pdf for additional information of the 2-midnight rule.

CMS-1633 is available at https://www.gpo.gov/fdsys/pkg/FR-2015-11-13/pdf/2015-27943.pdf. A fact sheet on the Two-Midnight Rule Fact Sheet is available at https://www.cms.gov/newsroom/fact-sheets/fact-sheet-two-midnight-rule-0.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
January 24, 2019	CMS reissued the article to clarify information.
January 11, 2019	CMS rescinded the article.
January 8, 2019	Initial article released.