EPSTEIN BECKER GREEN

EBG advisors

National Health Advisors

TKA, THA, and the 2 Midnight Rule:

Feb. 27, 2020

2016 – TKA IPO Timeline

CMS SOCIALIZING CONCEPT

- **CMS Position**
  - Soliciting input on whether TKA is appropriate for removal from IPO
- **AAHKS Response**
  - *"Most outpatient departments are not currently equipped to provide TKA to Medicare beneficiaries. Execution of outpatient TKA requires excellent patient selection and education, tailored anesthetic techniques, well done surgery, good medical care, and exceptional post-operative care coordination. Very few hospitals have executed all of these elements to date"*
  - *"AAHKS is not aware of any data or peer-reviewed literature to confirm the safety and efficacy of outpatient TKA in Medicare beneficiaries"*
  - *"In a setting **with excellent patient selection** and education, tailored anesthetic techniques, well done surgery, good medical care, and exceptional post-operative care coordination, it may be clinically appropriate for some **Medicare beneficiaries to have the option** of a TKA procedure as a hospital outpatient"*

2017 – TKA IPO Timeline

CMS PROPOSAL EFFECTIVE 2018

- **CMS Position**
  - Remove TKA from the IPO
- **AAHKS Response**
  - *"When surgeons are free from external pressures to make a judgment, in the best interests of the patient, on the appropriate site for surgery, [patient selection] criteria will be followed"*
  - *"There is a concern that commercial payers may interpret this CMS policy as invitation to implement coverage policies driving surgeries to lower cost facilities that may not be sufficiently prepared to handle the complexities or risks associated with some TKA procedures"*
  - *"CMS should make forcefully clear in the Final Rule that CMS expects that surgeons will make the ultimate patient-specific decision on site selection based on the level of patient selection and education, anesthetic techniques, medical care, and post-operative care coordination"*

2017 – TKA IPO Timeline

CMS PROPOSAL EFFECTIVE 2018

- **CMS Position**
  - *"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"*
  - *"There are a subset of Medicare beneficiaries with less medical complexity who are able to receive this procedure safely on a hospital outpatient basis"*
  - *"CMS does not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing [TKA] from the IPO list"*
- **No CMS analysis on how 2 midnight rule will impact TKAs admission status**
  - CMS suspends RAC review of TKA for 2 midnight rule violations through 2019

2018 – TKA IPO Timeline

IMPACT ON PATIENTS AND PROVIDERS

- **Anecdotal reports of . . .**
  - Hospitals making outpatient TKA default status
  - MA plans making outpatient TKA default status
  - Hospitals refusing to support case-by-case exceptions, as permitted under regulation
  - Outpatient TKAs removed from CJR, skewing patient mix and benchmarks
  - Hospitals, plans, surgeons confused by rules and exceptions under the 2 midnight rule

2018 – TKA IPO Timeline

PROPOSED REFINEMENTS

- **Mar. 2018 AAHKS letter to CMS Administration Seema Verma**
  - Hospitals and health plans are confused and not applying 2 midnight rule to TKA consistent with CMS guidance
- **Sept. 2018 AAHKS comment letter to HOPPS proposed rule**
  - Suspend, for 2 years, enforcement of 2 midnight rule for TKAs lasting longer than 24 hours
  - Revise program guidance and auditor guidelines to reflect a presumption of inpatient TKA status, requiring case-by-case exception for outpatient status if documented as clinically appropriate
  - CMS should use MLN and CMS Open Door Forums to clarify to hospitals and plans that case-by-case exception exists and that *"the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician"*

2019 – TKA IPO Timeline

ONE STEP FORWARD, TWO STEPS BACK

- **CMS releases TKA-specific on MLN guidance under the 2 midnight rule**
  - CMS leadership attributes MLN guidance to AAHKS request
  - CMS includes AAHKS language about physician judgment and role
  - BUT, included clinical case studies are completely unhelpful in clarifying case-by-case exceptions

- **KEPRO QIO audits of TKA admission status commence**
  - Intended to be educational corrections for providers, but unclear how QIOs are evaluating case-by-case exceptions

2019 – TKA IPO Timeline

MISSING CASE STUDIES OF CASE-BY-CASE EXCEPTIONS

- "Does the medical record support the admitting physician's determination that the patient required inpatient care despite not meeting the two midnight benchmark, based on complex medical factors such as:"
  - ***Patient history and comorbidities and current medical needs***
  - ***Severity of signs and symptoms***
  - ***Risk of an adverse event***
- MLN guidance includes only an example of a post-operative complication to justify inpatient status for an admission that lasted less than 2 midnights

2019 – TKA IPO Timeline

FEB. 25th AAHKS-AAOS MEETING WITH CMS

- **Met with CMS Center for Clinical Standards and Quality (CCSQ)**
  - Oversees QIO reviews
  - Drafted MLN guidance
- **Positive meeting and CCSQ welcomes input from AAHKS and AAOS on**
  - Clinical case studies for each case-by-case exception category
  - Social-support in the home factors that should influence admission status
  - Any other suggested edits to the MLN guidance
  - Examples of KEPRO denials that are unclear or contradictory
  - Examples of out-of-pocket charges to outpatient TKA patients
  - Should RAC review suspension be lifted in 2020 or extended?
  - Should THA be removed from IPO?

CMS – "Providers should adopt evidence-based patient selection protocols to appropriately identify [outpatient TKA] patients"

2019 – TKA IPO Timeline

MAY 2019 AAOS-AAHKS LETTER TO CMS ON GUIDANCE

- Add existing case-by-case exceptions policy to auditors' 2 midnight claims review guidelines
- Suspend auditor review of TJA claims for 2 midnight policy violations
- MA plans inappropriately denying coverage for inpatient TKA
- Proposed additions to MLN Guidance
  - Add clinical example of 2 midnight rule exception for "patient history and comorbidities"
  - Add clinical example of 2 midnight rule exception for "risk of adverse events"
  - Add guidance that providers should consider patient's social supports, home accessibility, and risk of adverse events

CMS Response to Letter Somewhat Responsive

DATED FEB. 18, 2020

- No response to our suggestions for MLN Guidance or auditor guidelines
- "MA plans can make medical necessity determinations so long as their coverage determinations are not more restrictive than coverage available to enrollees in Original Medicare." Referred our concerns to MA plan oversight
- CMS will use contractors (BFCC-QIOs) to continue to educate providers on 2 midnight policy elements
- RAC review of 2 midnight policy for TKA is suspended through 2020
- New CMS policy to suspend BFCC-QIO claims denials for procedures removed from the IPO list for 2 years following removal. QIOs will educate providers on proper claim submission during this period

AAHKS 2020 Poll on TJA IPO Removal

VALUABLE FEEDBACK FROM 417 RESPONDENTS

- Wide variation in physician scheduling of TJA patient – some leave it to hospital to change status if necessary
- More evidence of QIO reviews not aware of case-by-case exception policy
- Some hospitals and practices misinforming patients that they are responsible for 20% copay for outpatient TJA
- Patients are seeing higher out-of-pocket for outpatient pain meds (how much?)
- Many hospitals and practices unfamiliar with basic elements of 2 midnight rule policy, even facilities that should have years or experience
- Large demand for clear, simple guidelines on standards for inpatient admission

Next Steps

- Revisions to MLN Guidance for THA and TKA in ASCs
- Press CMS on whether QIOs are aware of, and educating providers on, case-by-case exceptions policy
- CMS will continue to push for societies to adopt evidence-based patient selection protocols for TJA length of stay