AAHKS
AMERICAN ASSOCIATION OF
HIP AND KNEE SURGEONS

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VIA REGULATIONS.GOV

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Centers for Medicare & Medicaid Services
CMS-4208-P
7500 Security Boulevard
Baltimore, MD 21244-8103

RE: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit

The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to submit the following comments on the proposed *Contract Year 2026 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit* ("Proposed Rule").

AAHKS is the foremost national specialty organization of more than 5,200 physicians with expertise in total joint arthroplasty (TJA) procedures. Many of our members conduct research in this area and are experts on the evidence-based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS is guided by four principles:

- Payment reform is most effective when physician-led;
- Reductions in physician reimbursement by public and private payers is the primary driver of provider consolidation;
- The burden of excessive physician reporting on metrics detracts from care; and
- Patient access, especially for high-risk patients, and physician incentives must remain a focus.

We respond to this Proposed Rule in the interest of ensuring effective and robust enforcement of utilization management (UM) and prior authorization regulations applicable to Medicare Advantage (MA) plans. Inappropriate and overly restrictive UM in MA has been identified by MedPAC as "a major source of administrative burden for many providers and can become a health risk for patients if policies affect the treatments that clinicians offer (e.g., step therapy requirements), inefficiencies in the process cause needed care to be delayed or abandoned, or poor decisions cause necessary care to be denied."

In response to these growing concerns, in 2023, CMS issued regulatory standards for MA plans, including the following:

- Clarify that MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare regulation;
- Establish that when coverage criteria are not fully established by NCDs or LCDs, MA organizations may create internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature made publicly available to CMS, enrollees, and providers; and
- Require all MA plans establish a UM Committee to review prior authorization policies annually and ensure consistency with Traditional Medicare's national and local coverage decisions and guidelines.

The 2026 Proposed Rule includes several provisions to build upon these prior efforts to curb "inappropriate prior authorization and other utilization management practices that unnecessarily limit access to care, create a system-wide burden, and negatively impact rural hospitals and other providers."[1] As our membership reports that MA plans continue to abuse UM and prior authorization to deny or delay medically necessary TJA in ways that do not apply to Traditional Medicare, we offer comments as follows.

I. Prohibited Internal Coverage Criteria – Sec. III.U.3.

Currently, MA plans may apply "internal coverage criteria" only when coverage under Traditional Medicare is not fully established. However, to improve compliance and ensure access to covered benefits, CMS proposes to prohibit the use of internal coverage criteria under two circumstances:

- The coverage criteria lack any clinical benefit, and therefore, exists solely to reduce utilization of the item or service; and
- The criteria are used automatically to deny coverage of basic benefits without an individual medical necessity determination.

These proposed prohibitions are absolutely necessary. Any coverage criterion must be related to determining medical necessity of the individual patient. CMS should use such a prohibition to take enforcement action against MA plans using internal coverage criterion, where the plan's evidence supporting the criterion is rooted in managing care to reduce utilization of an item or service to a less costly alternative without any clinical value to the patient.

[1] Medicare Payment Advisory Commission (MedPAC), Report to Congress: Provider Networks and Prior Authorization in Medicare Advantage (June 2024), https://www.medpac.gov/document/medpac-releases-june-2024-report-to-the-congress-medicare-and-the-health-care-delivery-system/.

These prohibitions should be used to act against plans with any coverage criterion that establishes a blanket policy to automatically deny access to a covered benefit when one circumstance is present in the patient records, without due consideration of the enrollee's medical history, physician's recommendations, clinical notes.

For example, an AAHKS member reports treating an obese male with knee osteoarthritis who needed a knee replacement. A prior authorization request was submitted with clinical history, failed conservative measures (NSAIDs, IA, PT, activity modification, weight loss), physical exam and radiographs all showing matching need for replacement. The plan denied authorization due to imaging not showing "at least moderate joint space narrowing." The denial was overturned after the ordering physician spent time securing a peer-to-peer call and explaining the situation to a reviewing physician. This suggests that the plan had a coverage criteria intended to deny authorization for a single reason ("joint space narrowing") without consideration of all other patient-specific factors included in the request.

We recommend further that CMS add another prohibition, barring internal coverage criteria that permits inpatient admission status only as an exception, without regard to the specific condition of the individual patient. The creeping proliferation of plan criteria authorizing procedures only on an outpatient basis, shifts the administrative burden of utilization management from the plan to the treating physician.

One of our members reports the experience of treating a 69-year old male with a need for a hip revision with arteriovenous malformation (AVM) collapsed femoral head, and a history of chronic kidney disease, coronary artery disease, alcohol abuse, Parkinson's, neuropathy, and diabetes, making him a high-risk for surgical complications and unlikely to be safely discharged within 36 hours. The physician booked the patient as an inpatient surgical admit. The plan's third-party organization reviewing vendor stated the procedure would not be covered unless it was booked as an outpatient procedure. Following a peer-to-peer call between the physician and the reviewer, inpatient status was approved.

In this case, the third-party organization's efforts should have been used to review the patient record and verify the medical necessity of an inpatient admission for the specific patient. Allowing plan coverage criteria that automatically presumes outpatient status, without regard to the actual patient record, accomplishes little more but taking physician time away from patient care to explain the medical necessity evidence present in the record.

II. Public Availability of Coverage Criteria – Sec. III.U.4.

CMS proposes to require MA plans to publicly display, on their website, a list of all items and services for which Internal Coverage Criteria may be applied to Part A or Part B benefits. The plan's Internal Coverage Criteria webpage would be displayed in a prominent manner and clearly identified in the footer of the website. The webpage must be easily available to the public in a machine-readable format, enabling third parties to examine UM practices.

Our members have been frustrated by opaque or hidden coverage criteria. For example, one of our members was treating a female patient with osteoarthritis in the hip who failed to see improvement overtime from conservative intervention measures, such as physical therapy (PT). The physician ordered a hip replacement which was denied by the plan's third-party organization reviewing vendor. After much time was lost, the physician secured a peer-to-peer review with a physician at the third-party organization and the denial was overturned. But the reviewer could never explain to the physician what the basis had been for the initial denial: history of smoking; BMI; duration of PT, other? Physicians cannot take a patient's coverage standards into account if those standards are not transparent.

Further, AAHKS supports requiring Internal Coverage Criteria to be reported to CMS by MA plans as part of their annual reporting requirements.

III. Clarifications Regarding Obligation to Cover Reasonable and Necessary Benefits: Reopening Decisions on Approved Hospital Inpatient Admissions – Sec. III.V.4

CMS reports it has seen previously approved inpatient hospital admissions later being inappropriately revised or rescinded by MA plans. CMS proposes that, if an MA organization approved an inpatient hospital admission, any additional clinical information obtained after the initial approval of admission cannot be used as new and material evidence to reopen the approval.

AAHKS supports this new rule. It is the experience of our members that MA plans wish to direct as many procedures as possible to the outpatient setting, without regard to the specific clinical status of the patient. We support any policies that limit plans' ability to deny or reopen approval for inpatient procedures. Certainly, once a patient has been approved to be admitted for a procedure as an inpatient, it is too late to force providers to deal with moving the patient or accepting a lower reimbursement. At this point, the attention of the facility and the physician should be on a successful procedure and recovery for the patient.

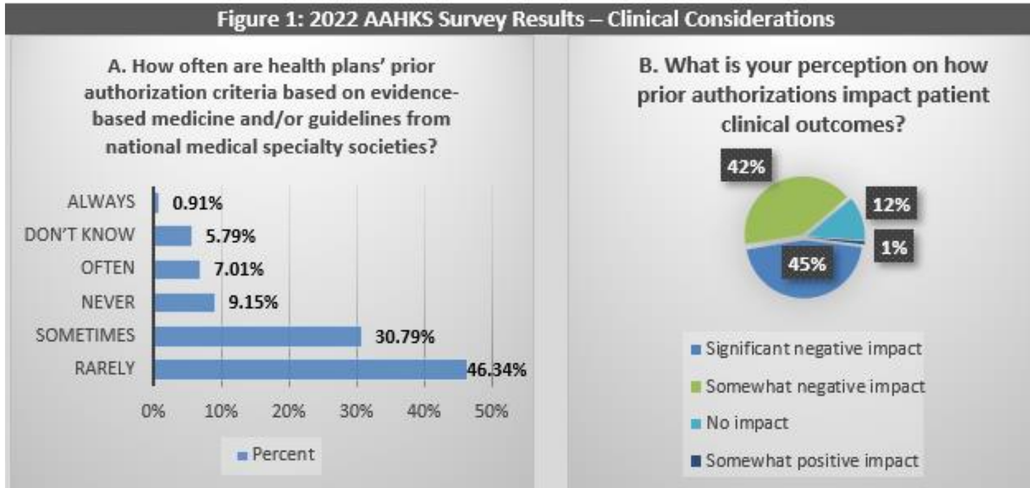
IV. Proposals to Further Limit Plan UM and Prior Authorization Practices Unrelated to Medical Necessity

a. AAHKS Member Experience Suggests Plan UM Practices and Policies Not Based on Medical Standards

AAHKS members report that many MA plans are abusing UM and prior authorization practices in a way that impairs quality care or outcomes. For example, fewer than 1% of respondents to a 2022 AAHKS Survey reported health payors always base prior authorization criteria on evidence-based medicine and/or guidelines from national medical specialty societies. A significant 46% of our respondents reported payors rarely used such data in prior authorization criteria. Approximately 87% of survey respondents perceive prior authorization of having a "significant negative impact" or a "somewhat negative impact" on clinical outcomes.

See Figure 1.

While these are internal survey results, they demonstrate the overall inconsistency and lack of confidence or transparency around UM and prior authorization standards.



b. <u>AAHKS Study Finds Major Plan Joint Replacement Coverage Policies Unsupported by Their Own Citations</u>

The following is an abstract from a pre-publication draft study (*Low-Level Evidence Used to Substantiate Insurance Coverage Policies for Knee and Hip Arthroplasty*) presented at the AAHKS Annual Meeting on November 10, 2024. The full study is attached at the end of this comment letter.

i. Introduction

In recent years, access to total knee arthroplasty (TKA) or total hip arthroplasty (THA) has become more regulated by commercial healthcare insurance policies that require specific criteria be met prior to authorizing surgery as medically necessary. The purpose of this study was to examine references from coverage policies to assess whether they justify the pre-surgery criteria mandated by insurance providers for approval of total joint arthroplasty (TJA) in patients with symptomatic knee and hip degenerative disease.

ii. Methods

The largest private commercial insurance providers in the United States were identified, of which nine had publicly accessible coverage policies for TKA and THA. Coverage criteria for procedural approval and respective references were retrieved. Three coverage criteria were identified: (1) diagnosis of osteoarthritis, (2) nonsurgical treatment (e.g. preoperative physical

therapy, nonsteroidal anti-inflammatories, etc.), and (3) exclusion criteria (e.g. BMI thresholds <40). Three reviewers graded references cited in coverage policies by level of evidence (LOE), type of reference and relationship to the three criteria groupings.

iii. Results

In total, out of 824 references, only 450 (54.6%) references were relevant to primary TKA and THA. Of the 824, 259 (31.4%) contained information pertinent to the diagnosis of osteoarthritis, 84 (10.19%) to nonsurgical treatment, and 107 (12.99%) applied to exclusion criteria. Of the 84 references relevant to nonsurgical treatment, only 16 (19.05%) had a LOE I-III. Among all references related to nonsurgical treatment, only four specifically tested the efficacy of nonoperative modalities, representing 0.49% of all references. However, only one had results that were applicable to the clinical management of end-stage osteoarthritic patients.

iv. Conclusion

Current criteria found in prior authorization policies for TKA and THA are unsubstantiated. Insurance companies that implement prior authorization criteria should be held to a standard in which recommendations are grounded in evidence-based medicine. This is currently not the case.

c. Continuing Audits of Plan UM and Prior Authorization Practices

We are pleased to learn that CMS UM audits were conducted throughout 2024 and will continue into 2025. As we understand that CMS is preparing to collect detailed information from initial coverage decisions and plan-level appeals, such as decision rationales for items, services, or diagnosis codes, we offer below our recommendations for MA plan data collection that will provide a better line of sight into UM and prior authorization practices. We offered these recommendations in November 2024 in response to *Information Collection: Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request* (CMS–10913).

1. *Require MA organizations to report at the plan-level rather than the contract-level.*
    - Plan level data would allow providers to use UM metrics in a more meaningful way to compare across MA plans.

2. *Instruct MA organizations to report more granular item and service-specific data.*
    - More granular data would enable stakeholders to use the UM data to better understand particular UM implications for certain items, services, settings and clinical decision criteria.
    - Further, this granular data could be helpful in identifying where and when policies such as "gold-carding" should be more widely adopted.

3. *Direct MA organizations to report additional data related to MA plans' UM decision-making processes including "the specific reason for denial" and the degree to which Artificial Intelligence or other algorithmic tools were used in the decision-making process.*

- A regulatory definition for "the specific reason for denial" and the inclusion of whether AI or other algorithmic tools were used in the decision-making process are key components of understanding any MA denials and how to properly address the denial and figure out an appropriate path forward with the patient.
- AAHKS agrees with CMS's statement in the 2023 MA Technical Final Rule that "[c]ommunicating all necessary information needed for the enrollee or provider to effectively appeal the decision, including the evidence used to support the internal coverage policy when applicable, is one of the purposes of the denial notice."

4. *Require MA organizations to report additional data related to the internal coverage criteria updates*
    - AAHKS appreciated earlier regulatory updates that provided clarity with regard to the overlap between Traditional Medicare coverage policies and also established more rigorous requirements for MA plans' internal coverage policies. AAHKS believes that in order for CMS and stakeholders to understand the impacts of such changes and to identify potential issues with MA plans' internal coverage criteria, CMS should require that MA organizations to report certain relevant data as part of the prior authorization reporting requirements imposed by the Advancing Interoperability and Improving Prior Authorization Processes Final Rule.

5. *Require MA organizations to report additional data related to Prior Authorization determinations involving site of service changes.*
    - Additional clarity on MA plans' practices of reimbursing a claim on an outpatient basis when a physician has ordered an inpatient procedure is needed to better plan and prepare to address patients' needs.

6. *Require MA organizations to report additional data related to the qualifications of plans' staff that review and make prior authorization determinations and to MA organizations' use of third parties to interpret and make PA determinations.*
    - Additional information regarding the providers or professionals reviewing MA plans' UM requests will better inform future rulemaking as CMS continues to refine the UM clinical criteria requirements.

7. *Standardize reporting across MA organizations through regulations, guidance, and/or implementation guides.*
    - Standardized reporting requirements would ensure patients' and providers' ability to access and use the reported UM aggregated metrics in a meaningful way.

8. *Facilitate use of the reported prior authorization data by posting reports to CMS' website.*
    - Allowing patients and providers the ability to meaningfully access and use aggregated reported data by requiring MA organizations' reports to be posted to

CMS' website and to be included in comparative data public reports is crucial for transparency and makes the process less burdensome.

9. *Require MA plans to make prior authorization coverage determination policies publicly available on MA organization websites.*
   - AAHKS specifically urges CMS to require MA plans to make internal coverage criteria publicly available and accessible on their plan website, or–at a minimum–to require MA plans to include a notification on the MA plan website that such coverage determination policies are available upon request.
   - AAHKS believes that without accessibility to MA organizations' internal coverage criteria, providers may still face the same administrative burdens with regard to MA plans' use of internal coverage criteria that predated the MA Technical Final Rule—particularly if such policies are behind paywalls or not otherwise available on an MA plan's website.

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AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at mzarski@aahks.org or Joshua Kerr at jkerr@aahks.org.

Sincerely,

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President

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cc: Cheri Rice, Acting Principal Deputy Administrator