

February 13, 2023

VIA REGULATIONS.GOV FILING

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 4201-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program and Medicare Prescription Drug Benefit Program* (hereinafter referred to as “proposed rule”).

AAHKS is the foremost national specialty organization of more than 4,600 physicians with expertise in total joint arthroplasty 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. As most of our services are scheduled elective surgeries, we have extensive experience with various payor utilization management and prior authorization practices. AAHKS is guided by three principles:

- Patient access, especially for high-risk patients, and physician incentives must remain a focus;
- Payment reform is most effective when physician-led; and
- The burden of excessive physician reporting on metrics detracts from care.

Our comments on the proposed rule are as follows:

I. Coverage Criteria for Basic Benefits (Sec. III.E.2)**a. MA Coverage and Payment Criteria that is No More Restrictive than Traditional Medicare Criteria**

CMS proposes new regulations to clarify existing policy that is not currently codified. Namely, that the scope of coverage of benefits in the Traditional Medicare program is applicable to MA plans in setting the scope of basic Medicare benefits that must be covered by the MA plan.

AAHKS Comment: We endorse this proposed codification of standards for MA coverage policy. MA plan limits on conditions of payment or coverage (such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), and other substantive conditions) for basic benefits should be no more restrictive than those under Traditional Medicare. The change will ensure clarity and transparency for providers and beneficiaries and will allow for more efficient use of plan and provider time in resolving coverage and payment questions. Stakeholders will know to focus their analysis and education on the coverage and payment standards of Traditional Medicare, rather than internal, proprietary, or external clinical criteria often used by MA plans which can be vague and subjective.

This means that MA plans may not deny coverage for basic Medicare benefits through medical necessity determinations based on coverage and benefit criteria not specified in Traditional Medicare. Not only will this ensure all Medicare beneficiaries, whether in MA or Traditional Medicare, receive the same access to basic benefits, it will ease administrative burdens for physicians by reducing the number of different coverage standards applicable to their patient population.

In some circumstances, NCDs or LCDs expressly include flexibility that allows coverage in circumstances beyond the specific coverage or non-coverage indications that are listed in the NCD or LCD, such as stating that a service may be covered when reasonable and necessary for the individual patient. We appreciate CMS' guidance in the preamble that it expects MA plans "to make medically necessary decisions in a manner *that most favorably provides access to services for beneficiaries.*"

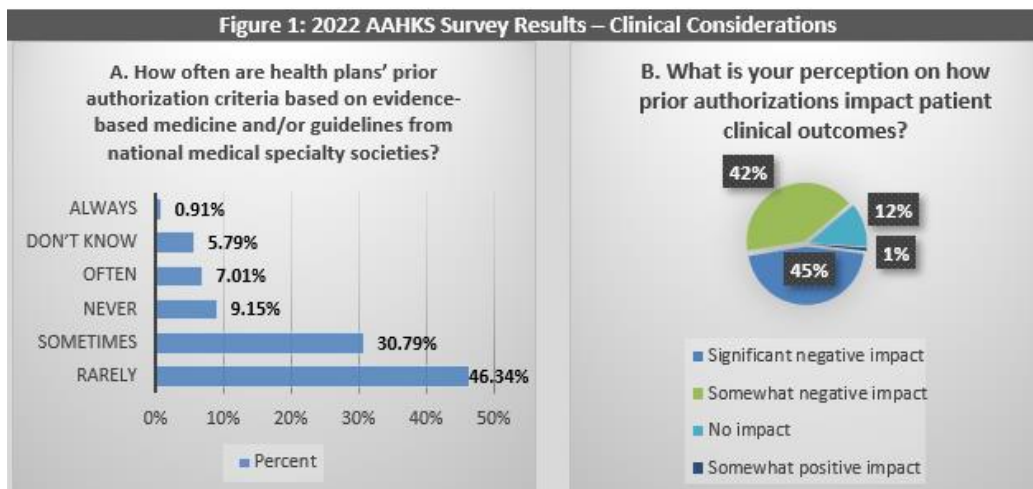
b. MA Coverage Criteria in the Absence of Traditional Medicare Coverage Criteria

CMS proposes that when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create "internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available." CMS proposes definitions for "widely used treatment guidelines" and "clinical literature".

AAHKS Comment: We strongly support this proposal which ensures that MA plan coverage policies are held to the highest objective and transparent standards. Requiring MA plans to provide publicly available information that discusses the factors they considered in making coverage criteria for medical necessity determinations will also lead to more efficient interactions between providers and plans over coverage standards. Providers, particularly medical societies, occasionally question or dispute the basis for coverage policies directly with a plan Medical Director. Much of the process is dedicated to trying to access and review the plan's coverage policy and the purported clinical literature that supports it. Requiring plans to make publicly available a summary of the evidence, list of the sources of evidence, and explanation of the rationale in internal coverage criteria will allow specialty societies to prioritize their time and

effort on only those coverage criteria that lack a strong basis in clinical literature or guidelines. Further, we believe MA plans, knowing their internal coverage criteria must be made public, will hold themselves to a higher standard of basing criteria on current, widely used treatment guidelines and clinical literature. For too long, our members have experienced too many MA plans denying services based on unpublished evidence or internal analyses.

Fewer than 1% of respondents to a 2022 AAHKS Survey stated 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 stated payors rarely used such data in prior authorization criteria. Approximately 87% of 2022 AAHKS 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 merely survey results, AAHKS believes these findings and the overall inconsistency and lack of confidence or transparency around utilization management (UM) and prior authorization standards.



We support CMS’ proposed definition of “current, widely-used treatment guidelines” as “those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions (such as referring to the Infectious Diseases Society of America for the Treatment of Clostridium Difficile) or to determine appropriate level of care (such as the American Society of Addiction Medicine Criteria for placement, continued stay, and transfer or discharge of patients with addiction and co-occurring conditions). This would also include AAHKS / American Academy of Orthopaedic Surgeons Clinical Practice Guidelines for *Osteoarthritis of the Knee*, *Osteoarthritis of the Hip*, *Surgical Management of Osteoarthritis of the Knee*, and AAHKS American College of Rheumatology *Indications for Total Hip and Knee Replacement*.

We support CMS’ proposed definition of “clinical literature” of high enough quality for the justification of internal coverage criteria. However, the highest level of evidence literature

available should be utilized when creating coverage determination policies. The proposed definition includes:

- (1) large, randomized controlled trials, (2) cohort studies, or (3) all-or-none studies with clear results . . .
- . . . published in a peer-reviewed journal, and
- specifically designed to answer the relevant clinical question,
or
- large systematic reviews or meta-analyses summarizing the literature of the specific clinical question . . .
- . . . published in a peer-reviewed journal . . .
- . . . with clear and consistent results.

We believe the first element of the definition should be “(1) large, randomized controlled trials, (2) large cohort or database studies, (3) case-control studies, or (4) well designed Level 2-3 studies, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question.”

Finally, we ask that CMS use the final rule preamble to explain how CMS will conduct oversight of MA plan compliance with these standards and what penalties plans will be subject to for violations. Will CMS adopt a method for providers to report MA plans that do not make the basis of their coverage criteria public? Or whose literature or guidelines do not meet the new definitions?

c. Medical Necessity Determinations and Options in Site of Service

Under current MA policy, when a Medicare-covered health care service can be delivered in more than one Medicare-covered way, or by more than one type of practitioner, an MA plan can choose how the covered services will be provided. CMS now proposes a “narrower policy” that allows MA plans to continue to choose who provides Medicare benefits through the creation of their contracted networks, but that limits MA plans’ ability to limit when and how covered benefits are furnished when Traditional Medicare will cover different provider types or settings.

AAHKS Comment: We strongly support the narrower scope of this policy. Joint replacement surgery can be performed in a number of settings (inpatient or outpatient acute care hospitals, ambulatory surgical center (ASC)). We believe that the decision of site of service for Medicare-covered procedures should be determined solely by the surgeon and patient based on clinical considerations. Our members have experienced a long history of frustrations from MA plans that will only cover joint replacement in the lowest cost site, regardless of clinical need. In some cases,

surgeon advocacy with the plan eventually leads to the clinically appropriate site of service being covered,¹ but plan policies that make the lowest-cost site of service the default should be ended.

This creates a corresponding need for CMS to require MA plan provider arrangements to specify to network providers whether, in such cases of multiple covered sites of service, providers will be reimbursed based on the actual site of service or the lower cost site that the MA plan would have preferred despite clinical need.

CMS should further be aware that while this new policy is welcome, its success will be limited by the clarity of Traditional Medicare guidance on coverage and payment when multiple sites of service are covered under the program. If Traditional Medicare covers joint replacement at inpatient and outpatient hospitals and ASCs, whom does CMS expect to select the most clinically appropriate site of service for the individual patient? It should be the physician and patient, but our members have extensive experience with hospitals and QIOs pushing joint replacement to the outpatient setting without an accurate understanding of the complete scope of Medicare coverage policy.

This confusion has been primarily experienced around surgical procedures that have recently been removed from the Medicare Inpatient Only (IPO) List, particularly in their interaction with CMS' 2-midnight rule for inpatient procedures. In numerous cases, some providers may have historically been performing procedures on the IPO list in which they have not had to justify or document the need for inpatient service over outpatient service. If and when a procedure is removed from the IPO list, it is subject to the 2-midnight rule, meaning that, regardless of the level of acuity or services provided, if the patient admission spans less than two midnights, Medicare will reimburse the service as an outpatient procedure. There are exceptions within the 2-midnight rule, but the experience of our members has been that hospital compliance departments, QIOs, and especially health plans, are unfamiliar with the exceptions.

We understand that the CMS Center for Clinical Standards and Quality (CCSQ) is developing new guidance for providers on the coverage, payment, and documentation issues for services that are removed from the IPO list, including the interaction with the 2-midnight rule. We urge CMS to speed the completion of this guidance which, in conjunction with CMS' proposed narrower policy on MA coverage standards, will ensure more patients are receiving care at the covered site of service that is determined to be most clinically appropriate by their providers.

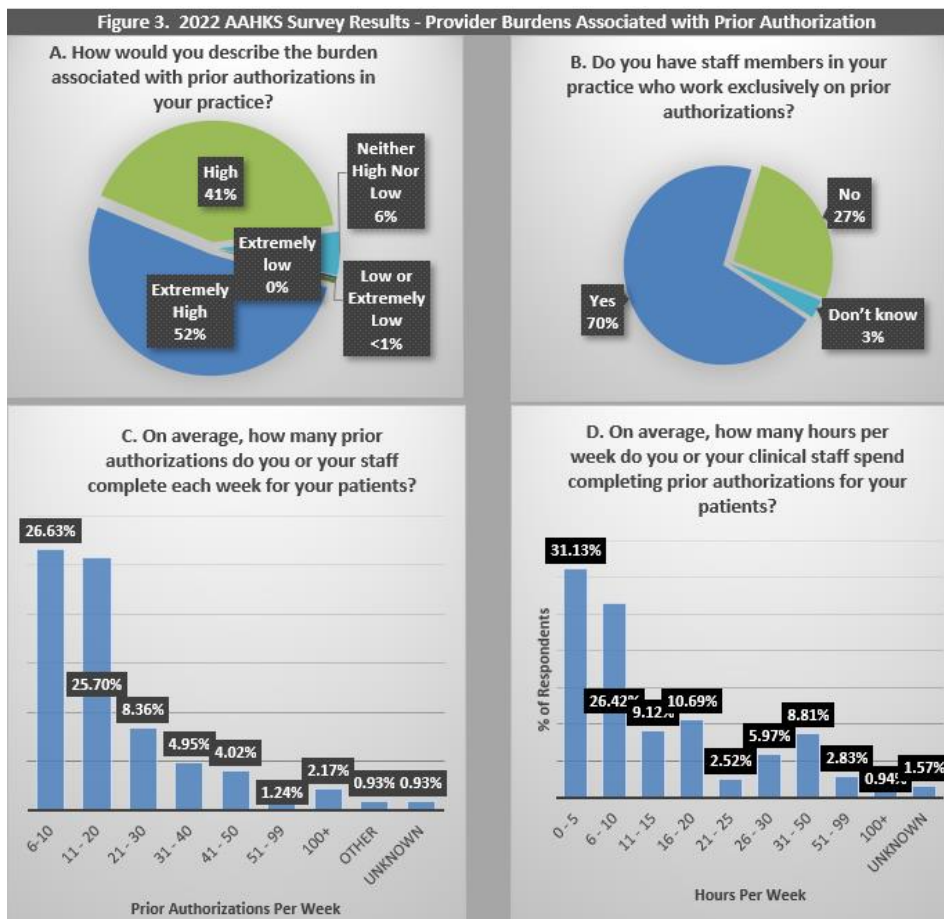
II. Appropriate Use of Prior Authorization (Sec. III.E.3)

CMS proposes to codify new regulatory requirements that prior authorization may only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary.

¹ AAHKS members are finalizing a study on insurance practices at one hospital which found that physicians succeed in appealing plan site-of-service determinations at a very low rate. We will share this study with CMS once it has been published later this year.

AAHKS Comment: We support this policy. It could be appropriate for an MA plan to use prior authorization before approving elective surgery to review the beneficiary’s medical history to verify that the surgery is medically necessary based Traditional Medicare standards. Yet, our members have experienced numerous instances of the prior authorization process being used to push an alternative, cheaper procedure on beneficiaries. This is a significant source of unnecessary physician burden. We also support the codification of the standard that when an enrollee or provider requests a pre-service determination and the plan approves this pre-service determination of coverage, the plan cannot later deny coverage or payment of this approval based on medical necessity.

Providers already face high administrative burdens when complying with current prior authorization requirements. Approximately 52% of respondents to the 2022 AAHKS Survey describe burdens associated with the prior authorization as being “extremely high,” while 42% of respondents described the burdens to be “high.” See Figure 3. Approximately 70% of respondents reported employing full-time staff dedicated exclusively to prior authorization.



III. Continuity of Care (Sec. III.E.4)

CMS proposes that MA plans must have, as part of their arrangements with contracted providers, policies for using prior authorization for basic benefits. These prior authorization policies must reflect that all approved prior authorizations must be valid for the duration of the entire approved prescribed or ordered course of treatment or service.

AAHKS Comment: We support this requirement. More upfront, transparent description of the scope and process of MA plan prior authorization policies will measurably reduce provider burden. Too much of our members’ time is spent away from patients, in correspondence with payers, trying to establish the nature of any delay in a positive coverage determination for a patient. We share CMS’ concern over MA plans that require repetitive prior approvals for needed services for enrollees that have a previously approved plan of care or are receiving ongoing treatments for a chronic condition. Repetitive prior approvals cause delays in receiving medically necessary care and create gaps in care.

Approximately 65% of respondents to a March 2022 poll of AAHKS reported determining whether certain treatments require prior authorization to be either “somewhat difficult” or “extremely difficult.” See Figure 2. Further concerning, approximately 95% of AAHKS respondents reported that the proportion of cases requiring prior authorization “increased significantly” or “increased somewhat” over the past five years.



IV. Utilization Management Committees (Sec. III.E.5)

CMS proposes requiring that MA plan UM committees must include a majority of members who are practicing physicians; include at least one practicing physician who is independent and free of conflict relative to the plan; include at least one practicing physician who is an expert regarding care of elderly or disabled individuals; and include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range of conditions are adequately considered in the development of the MA plan’s UM policies.

AAHKS Comment: We support this required UM committee membership as an important and helpful advance in the relevant expertise and independent perspective for UM policies. We

support the required inclusion of one expert in the care of the elderly. We also believe that CMS should require UM committees for MA plans to include a surgeon with specific expertise in total joint arthroplasty. We recognize that UM committees cannot be expected to include experts in clinical specialties, however, it is warranted in the case of total joint arthroplasty because this is both a high volume and high value procedure for MA plan beneficiaries. Generally, in considering what specific clinical expertise should be represented on an MA plan UM committee, prioritization should be given to fields where there is a high volume of procedures (leading to the frequent demand for expertise) as well as a high cost to procedures (leading perhaps to improper incentives by plans to disapprove coverage of procedures or direct them to lower cost settings).

V. Termination of Services in Post-Acute Care (Sec. III.E.6.a)

CMS seeks more information potential standards that should be applicable when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner and an MA plan can choose how the covered services will be provided. The reported anecdote of early termination of services in post-acute care settings by MA plans before the beneficiaries are healthy enough to return home is very similar to our member experiences with plans and hospitals pushing to discharge joint replacement patients before they are health enough to return home.

We endorse one potential future policy that CMS has identified: In the case of termination of services, enrollees and providers should receive information from the MA plan regarding the basis for termination of services (for example, the clinical rationale for termination of services) as part of the termination notice and without the enrollee having to request an appeal to a QIO. Another significant physician burden and inefficient waste of provider time is legwork and office work to determine a plan's rationale for termination of services.

VI. Gold Carding (Sec. III.E.6.b)

We are gratified that CMS encourages MA plans to adopt gold-carding programs that would allow providers to be exempt from prior authorization and provide more streamlined medical necessity review processes for providers who have demonstrated compliance with plan requirements. We, too, believe there is great promise in such programs. We are tracking the implementation of such-programs at the state level. Experience with these state laws may inform a future federal gold carding program for MA or other plans, but the need for national policy would be mooted if more plans adopted such programs of their own accord.

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

Sincerely,

A handwritten signature in black ink, appearing to read "B.D.S.", with a stylized flourish at the end.

Bryan D. Springer, MD
President

A handwritten signature in black ink, appearing to read "Michael J. Zarski", written in a cursive style.

Michael J. Zarski, JD
Executive Director

cc: Meena Seshamani, MD, PhD, Director, Center for Medicare
Liz Richter, Deputy Director, Center for Medicare
Ryan Howe, PhD, Deputy Director, Hospital and Ambulatory Policy Group, CM