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January 30, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications [CMS-4201-P]

Dear Administrator Brooks-Lasure,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 38,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease (AD), Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

A. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152)

The Centers for Medicare and Medicaid Services (CMS) is proposing to require MA organizations to develop and maintain procedures to offer digital health education to enrollees to improve access to medically necessary covered telehealth benefits. The AAN agrees with CMS that low digital health literacy, especially among populations experiencing health disparities, continues to impede telehealth access and worsen care gaps particularly among older adults, especially those with neurologic or cognitive disabilities. The AAN strongly believes that developing resources for improving digital literacy is key for ensuring equitable access to telehealth services for patients from underrepresented racial, ethnic, and socioeconomic populations.

CMS is also proposing to codify in regulation best practices for MA organizations to use in developing their provider directories in relation to

providers' cultural and linguistic capabilities. Specifically, CMS is proposing to require that MA organizations mirror Medicaid provider directory requirements by including information on each in-network provider's "cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office."[1] The AAN believes requiring MA plans to include language information in their provider directories may be helpful when a patient searches for a physician with the ability to communicate in the patient's native language. The AAN believes this requirement has the potential to make care more accessible for MA patients while reducing costs associated with interpreter services. Although this information is likely to be useful, the AAN is concerned with the potential establishment of additional reporting burdens. Additionally, the AAN requests clarification regarding how MA organizations will determine whether a particular language should be listed in the directory and whether there will be a requirement for a provider to be a certified translator, prior to having a particular language listed. The AAN also believes that CMS should consider the need for MA organizations to ensure directories are updated based on staff turnover.

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138)

The AAN greatly appreciates CMS' attention to addressing the growing burden associated with prior authorization (PA) in MA. Physicians in the United States complete an average of 41 PA requests every week, taking an average of 13 hours to process.[2] PA is one of the most time-consuming and expensive administrative requirements preventing physicians from spending more time with patients. Over 90% of clinicians reported that PA requirements have a negative impact on patient clinical outcomes and 82% of clinicians reported that issues associated with PA can lead to patients abandoning a recommended course of treatment.[3] Burdens associated with PA are often cited as a top concern among AAN members. The AAN supports policies that reduce the burdens associated with PA requirements and address the detrimental impacts that PA has on patient clinical outcomes.

In recent years, MA plans increasingly have used PA to reduce health care spending, substantially delaying medically necessary patient care and significantly increasing providers' administrative burden and related costs to comply with PA requirements. An August 2022 Issue Brief from the Kaiser Family Foundation found that 99% of MA Enrollees are in plans that require PA for some services.[4] The AAN was deeply disturbed by April 2022 findings from the Department of Health and Human Services Office of Inspector General relating to inappropriate PA denials. This report found that some PA requests were

[1] 87 Fed. Reg. at 79481
[2] AMA Prior Authorization (PA) Physician Survey. American Medical Association, 10 Feb. 2022, https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.
[3] Id.
[4] Freed, Meredith, et al. Medicare Advantage in 2022: Premiums, out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings. Kaiser Family Foundation, 8 Dec. 2022, https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings/.

denied by MA plans, even though the requested services met Medicare coverage guidelines.[5] In light of the growing enrollment of Medicare beneficiaries in MA plans, the increasing use of PA by MA plans, and the significant potential for PA to negatively impact patient clinical outcomes, the AAN believes that it is critical for CMS to engage in continual oversight of MA plans' use of PA to ensure that Medicare beneficiaries enrolled in MA plans have the same access to covered services as those covered under Medicare Fee-for-Service (FFS).

Coverage Criteria for Basic Benefits

The AAN strongly supports CMS' proposal to codify requirements so that "when an MA organization is making a coverage determination on a Medicare covered item or service, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies."[6] The AAN believes it is critical that MA beneficiaries maintain the same access to high-quality care as those beneficiaries in Medicare FFS. We note that we have previously urged CMS to establish closer oversight of MA plans' use of PA as well as the need for the agency to provide guidance to reduce PA for routine procedures and services. Additionally, the AAN appreciates CMS' proposal to ensure that "prior authorization should 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 or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care."[7] It is critical for CMS to note that historically physicians' services and procedures subject to PA are approved an overwhelming majority of the time. National data clearly indicates that for the vast majority of physicians' services and procedures subject to PA, and that no cases were denied for medical necessity.[8] Both of the proposed requirements are long overdue and necessary to ensure that MA plans are no longer inappropriately using PA to reduce health care spending. The AAN concurs with CMS that PA must not "be used to discriminate or direct enrollees away from certain types of services."[9]

The AAN urges CMS to reconsider its decision to decline to revise the agency's August 2018 decision that authorizes MA plans to use step therapy policies for Part B drugs under certain circumstances. Step therapy frequently delays or disrupts continuity of care and threatens outcomes for neurology patients. While CMS is correct that there frequently is "more than one drug that has demonstrated success in treating a certain disease or condition"[10] and that more than one drug or therapy might be generally considered appropriate for a particular neurologic condition, individual patient issues, the presence of comorbidities, potential drug-drug interactions, or patient intolerances may necessitate the selection of an alternative drug as the first course of treatment. Step therapy requirements

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[5] "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns about Beneficiary Access to Medically Necessary Care." Office of Inspector General, Department of Health and Human Services, 27 Apr. 2022, https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp?hero=mao-report-04-28-2022.
[6] 87 Fed. Reg. at 79500
[7] 87 Fed. Reg. at 79503
[8] National Level Summary Report. Evicore, https://www.evicore.com/-/media/files/evicore/footer-pages/national-level-summary-report-q1-2018.pdf?la=en.
[9] 87 Fed. Reg. at 79504
[10] 87 Fed. Reg. at 79500

often fail to recognize such considerations, resulting in delays in getting patients the right treatment at the right time. A patient's health care provider is in the best position to assess the patient's medical needs and select the most appropriate medication. Additionally, step therapy policies interfere with the patient–physician relationship, often resulting in delayed treatment, increased disease activity, disability, and in some cases irreversible disease progression. Step therapy requirements can also be administratively burdensome on clinicians and their staff as they help patients navigate complicated and often opaque coverage determination processes. Furthermore, payor exemption and appeals processes can be complicated and lengthy, making them onerous for busy physician practices and patients awaiting treatment.

Medical Necessity Determinations

CMS is proposing to codify in regulation long-standing guidance that medical necessity determinations are made based on "the medical necessity of plan-covered services based on coverage policies (this includes coverage criteria no more restrictive than traditional Medicare… where appropriate, involvement of the plan's medical director… and the enrollee's medical history (for example, diagnoses, conditions, functional status)), physician recommendations, and clinical notes."[11] The AAN supports this proposal and believes that codifying this requirement is necessary to ensure that MA organizations operate in alignment with existing guidance.

Continuity of Care

The AAN strongly supports CMS' proposal to require that "an approval granted through PA processes must be valid for the duration of a prescribed course of treatment and that plans are required to provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment switches to a new MA plan, switches from traditional Medicare to the approved course of an MA plan, or is new to Medicare."[12] The AAN requests clarification regarding instances in which a particular course of treatment is not subject to PA in traditional Medicare but is subject to PA requirements by an MA plan. The AAN strongly believes that this proposed requirement should be clarified so that MA plans must provide the proposed transition period for any ongoing course of treatment that had been covered under a traditional Medicare coverage policy, regardless of whether there was a PA requirement for that course of treatment in traditional Medicare.

The AAN also supports CMS' proposed definition of "course of treatment" to mean "a prescribed order or ordered course of treatment for a specific individual with a specific condition, as outlined and decided upon ahead of time, with the patient and provider."[13] These proposals are necessary to ensure that ongoing treatment is not disrupted by repetitive and burdensome PA requirements. To avoid adverse health outcomes, it is critical that patient care is not unnecessarily disrupted and that approvals run through the full course of treatment as determined by the provider.

[11] 87 Fed. Reg. at 79501
[12] 87 Fed. Reg. at 79454
[13] 87 Fed. Reg. at 79504

Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee (§ 422.137)

The AAN supports CMS' proposal to establish additional guardrails on the development and implementation of PA protocols in MA by requiring MA plans to establish a "Utilization Management (UM) Committee" to review all utilization management policies annually, including PA and that MA plans "may not use any UM policies for basic or supplemental benefits on or after January 1, 2024, unless those policies and procedures have been reviewed and approved by the UM committee."[14] Furthermore, the AAN concurs with CMS that any policy implemented by an MA plan should be consistent with current, traditional Medicare's coverage decisions and guidelines, and also must not be an unreasonable barrier to care.

To ensure that UM policies are adequately reviewed, the AAN supports CMS' proposal to "replace the requirement that practice and UM guidelines be based on reasonable medical evidence or a consensus of health care professionals in the particular field with a requirement that UM guidelines be based on current widely used treatment guidelines or clinical literature."[15] The AAN urges CMS to consider the need for transparency in this review process and urges the agency to consider the need for robust external stakeholder feedback prior to implementation of a new PA policy by a particular MA organization. Specifically, the AAN believes that MA organizations should be required to consult with relevant specialty societies to ensure that the MA organization is correctly interpreting any clinical practice guidelines that are cited as supporting the rationale for a particular PA policy. Absent a transparent process with an opportunity for stakeholder consultation, it is entirely possible that an MA organization may implement a PA protocol based on a flawed understanding of a particular clinical practice guideline. Additionally, the AAN supports the proposed requirement that the "committee must revise UM policies and procedures as necessary, and at least annually, to comply with the standards in the regulation, including removing requirements for UM for services and items that no longer warrant UM so that UM policies and procedures remain in compliance with current clinical guidelines."[16]

CMS is soliciting comments on recommendations regarding the UM Committee's composition. The AAN supports that the majority of the committee must be composed of practicing physicians representing a wide range of clinical specialties and believes that it is critical to ensure that there are representatives on MA organization's UM Committees that are free of conflict in relation to the MA organization itself. In addition, when developing policies pertaining to a specific item or service, it is critical that the UM Committee includes specialist representation with expertise in the use or medical need for that particular item or service. Absent this requirement, it is likely that the UM Committee will lack the expertise needed to determine whether a particular policy is in alignment with widely used treatment guidelines and literature.

H. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional With Expertise in the Field of Medicine Appropriate to the Requested

[14] 87 Fed. Reg. at 79505
[15] 87 Fed. Reg. at 79506
[16] Id.

Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629)

CMS is proposing to modify requirements with respect to "the expertise of the physician or other appropriate health care professional who must review an organization determination if the MA organization or applicable integrated plan (AIP), defined at § 422.561, expects to issue an adverse decision based on the initial review of the request."[17] CMS is proposing to modify this requirement so that the physician or other appropriate health care professional who conducts the review "must have expertise in the field of medicine that is appropriate for the item or service being requested before the MA organization or AIP issues an adverse organization determination decision."[18] The proposed standard of having "expertise in the field of medicine that is appropriate for the item or service being requested" is distinct from the existing standard that adverse decisions "must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision."[19] The AAN believes that the newly proposed standard is an improvement over the existing standard which has frequently led to adverse decisions being reviewed by health care professionals with minimal knowledge of the particular item or service being ordered. This has resulted in inappropriate denials, unnecessary delays in care, and adverse clinical outcomes.

Although this newly proposed standard is certainly an improvement and we concur with CMS that the proposal is likely to "enhance the overall decision-making process and the quality of the review" the AAN is disappointed that CMS will "not require the physician involved to be of the exact same specialty or sub-specialty as the treating physician."[20] The agency further notes that plans "will have discretion to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition."[21] CMS notes that in cases in which "there are few practitioners in a highly specialized field of medicine, a plan may not be able to retain the services of a physician of the same specialty or sub-specialty to review the organization determination."[22] While the AAN recognizes it may be difficult for MA organizations to retain the services of the wide variety of specialists and sub-specialists that would be needed to adequately review adverse determinations, it detrimentally impacts patient safety to have coverage determinations reviewed by health care professionals that lack the requisite knowledge, experience, and training of the relevant specialist or sub-specialist. The AAN strongly believes that MA cost savings should not be achieved by limiting patient access to necessary care. Rather than allowing MA organizations to risk beneficiary safety due to inadequate staffing, CMS should instead require that MA organizations retain the services of the necessary specialists and sub-specialists prior to implementing a particular utilization management policy. In cases in which a contracted specialist or sub-specialist has their contract with a particular MA organization terminated, and there is no appropriate

[17] 87 Fed. Reg. at 79509
[18] 87 Fed. Reg. at 79510
[19] Id.
[20] Id.
[21] Id.
[22] Id.

replacement in the same specialty or sub-specialty, the AAN believes that impacted PA requirements should be suspended until the MA organization can secure adequate staffing to review medical necessity decisions.

Conclusion

The AAN appreciates CMS' attention to addressing issues impacting MA beneficiaries' access to care, including PA burden. Reducing administrative burdens associated with PA is a top priority for the AAN. The AAN believes that reducing PA-related burdens will reduce costs and improve patient outcomes by allowing providers to focus more of their time on patient care, rather than administrative tasks. Please contact Matt Kerschner, the AAN's Director, Regulatory Affairs at mkerschner@aan.com or Max Linder, the AAN's Government Relations Manager at mlinder@aan.com with any questions or requests for additional information.

Sincerely,

Orly Avitzur, MD, MBA, FAAN
President, American Academy of Neurology