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April 1, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Request for Information on Medicare Advantage Data [CMS-4207-NC]

Dear Administrator Brooks-LaSure,

The American Academy of Neurology is the world's largest association of neurologists and neuroscience professionals, with over 40,000 members. The AAN's mission is to enhance member career fulfillment and promote brain health for all. A neurologist is a doctor with specialized training in diagnosing, treating and managing disorders of the brain and nervous system such as Alzheimer's disease, stroke, concussion, epilepsy, Parkinson's disease, multiple sclerosis, headache, amyotrophic lateral sclerosis, and migraine.

The AAN thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide feedback on the agency's Request for Information regarding Medicare Advantage Data, [89 Fed. Reg. 5907], (January 30, 2024) (RFI) and provide our views regarding common challenges and experiences in the Medicare Advantage (MA) program for which limited data are currently available. Although the appropriate collection and use of MA programmatic data is vital to the program's improvement and success, the data does not exist in isolation. In addition to considering the need for further transparency and more robust data collection, the AAN strongly urges the agency to consider additional reforms to the MA program aimed at promoting beneficiary access to care and improved health outcomes.

Request for Information

I. Prior Authorization

The AAN greatly appreciates CMS' attention to addressing the growing burden associated with prior authorization (PA) faced by both neurology patients and providers. Although critical reforms to how MA plans may

implement PA as a utilization management strategy were finalized in 2023[1] and 2024,[2] the AAN believes patients, providers, and researchers need access to additional data to fully understand how MA plans' usage of PA is impacting access to necessary care. The AAN shares the concerns for MA beneficiary access to care described by the HHS Office of Inspector General (OIG) in their report, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care.[3] As highlighted by the OIG report, although some denials are ultimately reversed by MA organizations, negative consequences from avoidable delays in medically necessary care persist. Critical delays in obtaining the best medicines and procedures for the best outcomes may ultimately lead to increased costs for the Medicare program and its beneficiaries and have negative impacts on health outcomes, particularly for patients with neurological disorders.

To ensure MA beneficiaries are not being deterred from receiving necessary neurologic care, the AAN believes it is appropriate for CMS to require MA plans to disaggregate at the service level all PA data that is required to be public under Medicare rules. As we have previously stated, the AAN believes that PA data must be disclosed on an individual service basis because disclosure on an aggregate basis will likely not include any information that both providers and patients could use when exploring different MA plans and thusly be virtually meaningless.[4] Moreover, we believe that, unless PA data is available on a service level, it will not be possible to focus efforts to reduce the potential disproportionate impact of PA on disabled and dual eligible enrollees to target the particular service lines requiring priority attention. We urge CMS to propose new service-level reporting requirements as soon as practicable.

In support of this effort, the AAN urges CMS to obtain from MA plans and to publish on the CMS website the complete PA and other data that MA plans are required to make public, including the recently proposed PA equity analysis data, if finalized. Publishing these data on a single governmental website will facilitate public access and enable Medicare beneficiaries, providers, and researchers to easily compare MA plans' PA practices. We also encourage a tracking system for adverse events, including hospitalization and death, related to PA. The AAN believes that to promote ease of understanding and analysis, data should be published as both a comprehensive machine-readable file with all items and services subject to PA and in a consumer-friendly format, wherein services subject to PA are described in plain language.

II. Artificial Intelligence

[1] 2024 Medicare Advantage and Part D Final Rule (CMS-4201-F) (Apr. 5, 2023), https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-final-rule-cms-4201-f.
[2] CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) (Jan. 17, 2024), https://www.cms.gov/priorities/key-initiatives/burden-reduction/policies-and-regulations/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f.
[3] "Some Medicare Advantage Organization Denial of Prior Authorization Requests Raise Concerns about Beneficiary Access to Medically Necessary Care," HHS Office of Inspector General, (Apr. 27, 2022) https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp.
[4] AAN Joins Comments on CMS 2025 Medicare Advantage Proposed Rule, (Jan. 5, 2024) chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.aan.com/siteassets/home-page/policy-and-guidelines/advocacy/comment-letters/20240105-rrc-comments-on-2025-ma-proposed-rule-d1095942.pdf.

Due to our dedication to advocating for access to high-quality neurologic care, the AAN is deeply disturbed by recent reports that MA plans are potentially using artificial intelligence (AI) tools to inappropriately deny MA beneficiaries claims.[5] To address this emerging issue, the AAN appreciates that CMS has released guidance clarifying MA plans' obligations concerning the use of AI in making coverage determinations.[6] We share CMS' stated concern that that "algorithms and many new artificial intelligence technologies can exacerbate discrimination and bias."[7] Further, we appreciate CMS' clarification that AI tools should only be used to ensure fidelity with the plan's publicly posted coverage criteria. The AAN notes that CMS specifies that it is "the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made."[8]

Given reports of potential non-compliance with CMS guidance and the lack of transparency concerning how these tools are being utilized by MA plans, as well as the clear potential for harm to Medicare beneficiaries, both through inappropriate denials and through the exacerbation of discrimination and bias, the AAN believes it is critical that CMS take expeditious action to promote transparency surrounding how MA plans are utilizing AI to support coverage decisions.

The AAN notes that the Office of the National Coordinator for Health Information Technology (ONC) recently issued proposals aimed at promoting transparency for AI and machine learning tools developed by health IT vendors that could potentially be integrated into the electronic health record.[9] ONC has proposed a framework aimed at ensuring that these tools are fair, appropriate, valid, effective, and safe, prior to such a tool being implemented in the EHR and potentially impacting patient care. The AAN recommends that CMS work with ONC on adapting this framework to ensure that similar transparency exists surrounding how AI tools used by MA plans are designed, developed, trained, and evaluated before they are implemented and impact coverage decisions to ensure that MA organizations are meeting their responsibility that such tools comply with all applicable rules for how coverage determinations may be made. Public reporting and transparency surrounding these factors will promote beneficiary understanding of how AI may impact access to care under a particular MA plan and to ensure that MA plans are not using AI to inappropriately deny or deter medically necessary care. Further, we recommend that while regulators work to define and address the roles and issues of AI in healthcare, beneficiaries will need reliable and timely access to a human-led appeals process.

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[5] "Humana Used Algorithm to Deny Care to Medicare Advantage Patients, Lawsuit Claims," HealthcareDive (Dec. 13, 2023), https://www.healthcaredive.com/news/humana-lawsuit-algorithm-medicare-advantage-deny-claims/702403/.

[6] "Frequently Asked Questions Related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)," CMS (Feb. 6, 2024), https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf.

[7] Id.

[8] Id.

[9] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, Office of the National Coordinator for Health Information Technology, https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.

III. Step Therapy

The AAN remains deeply concerned with CMS' decision to reverse previously existing protections against use of step therapy for Part B drugs in Medicare Advantage.[10] The AAN has repeatedly urged the agency to reinstate the September 17, 2012 HPMS memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services" and believes the allowance for step therapy for Part B drugs violates requirements that MA coverage policies must ensure beneficiaries have at minimum equal access to items and services covered under Medicare fee for service (FFS). AAN members report numerous instances of patient harm associated with step therapy protocols delaying patient access to care, leading to otherwise avoidable hospitalizations, disability, and death. The federal government encourages innovation and supports research into new therapies, and step therapy often denies Medicare beneficiaries of the most innovative and efficacious therapies with the fewest adverse effects. Fail-first policies are particularly detrimental in neurology, where a single stroke, relapse, or seizure can negatively change the course of a patient's entire life.

Absent a much-needed reversal on the prohibition, the AAN calls on CMS to implement robust reporting requirements to ensure that MA plans are meeting their obligations under the existing guidance, including the requirement to ensure that exception requests are addressed as quickly as possible, including meeting a 72-hour limit for expedited requests. Further, the AAN requests that CMS require plans to provide more transparency relating to how step therapy protocols are designed, including publicly reporting specifically on protocols that require patients to fail on multiple therapies before progressing to the therapy originally prescribed. Finally, the AAN urges CMS to strengthen disclosure requirements related to the design of step therapy protocols, noting that existing guidance does not define any process to which MA plans must adhere when developing step therapy requirements for Part B drugs, aside from disclosure of new requirements in the plan's annual notice of change and evidence of coverage documents.

IV. Data Transparency Surrounding Implementation of APIs

The AAN previously supported the development of Fast Healthcare Interoperability Resources (FHIR) application program interfaces (APIs) to improve patient and provider access to health data and to ensure data can flow when a patient transition between payers. The AAN appreciates CMS finalizing reporting requirements for MA plans related to patient use of the patient access API and believes the agency should consider further requirements to promote transparency surrounding the use of the payer-to-payer API.

The AAN notes that CMS did not finalize requirements that MA plans "review, consider, or honor the active PA decision of a patient's former payer" that was received via the payer-to-payer API. While we note that the CY 2024 MA and Part D final rule requires MA plans to provide a minimum 90-day transition period of coverage for an active course of treatment

[10] Seema Verma, "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage," (Aug. 7, 2018), www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.

when an enrollee enrolls in a new MA plan, these requirements do not address the need for submission of potentially duplicative information that has already been submitted via the payer-to-payer API once that transition period has ended and beneficiaries are subject to the new plan's PA requirements. The AAN urges CMS to consider additional reporting requirements for MA plans indicating how plans are utilizing data received through this API to reduce provider administrative burden and duplicative submission of data.

V. Health Equity

The AAN strongly supports efforts to promote health equity that allows providers and researchers to examine quality of care for a variety of populations, including, but not limited to, LGBTQ+, race and ethnicity, dual-eligible beneficiary status, disability, and rurality. Medicare Advantage is the dominant form of Medicare among Black, Hispanic, Asian, and Pacific Islander populations.[11] The AAN notes that available data indicates that "MA is more desirable among socioeconomically vulnerable populations including racial/ethnic minorities and those with lower income and lower education status."[12]

The AAN supports the proposed annual health equity analysis of utilization management policies and procedures proposed in the Contract Year 2025 Policy and Technical Changes for MA plans.[13] In addition to finalizing the health equity analysis, the AAN urges CMS to consider developing additional reporting requirements for MA plans to ensure that utilization management protocols are not discriminatory and that plans projected equity analysis is reflective of real-world impacts. Further, we recommend the chairs of MA Utilization Management committees be required to review a plan's PA process and certify that all policies are publicly available.

VI. Quality of Care

The AAN believes CMS should consider whether additional data are needed to better understand the reason that MA beneficiaries are more likely to switch to Medicare FFS in their last year of life. One important difference that a beneficiary may consider is that MA plans do not include hospice benefits. The AAN is deeply concerned by recent analysis from the Government Accountability Office indicating that "[h]igh rates of disenrollment from MA to join traditional Medicare fee-for-service may indicate issues with the quality of care, such as potential limitations accessing specialized care under some MA organizations' provider networks."[14]

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[11] Nancy Ochieng, et al., "Disparities in health Measures by Race and Ethnicity among Beneficiaries in Medicare Advantage: A Review of the Literature," KFF (Dec. 13, 2023), https://www.kff.org/report-section/disparities-in-health-measures-by-race-and-ethnicity-among-beneficiaries-in-medicare-advantage-report/.

[12] Scott Bilder, et al., "Harvard-Inovalon Medicare Study: Who Enrolls in Medicare Advantage vs. Medicare Fee-for-Service," Inovalon (Aug. 7, 2018), https://www.inovalon.com/wp-content/uploads/2023/06/Harvard-Inovalon-Medicare-Study.pdf.

[13] Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications, 88 Fed. Reg. 78,476 (Nov. 15, 2023) (to be codified at 42 C.F.R. 401).

[14] "Medicare Advantage: Continued Monitoring and Implementing GAO Recommendations Could Improve Oversight," GAO (June 28, 2022), https://www.gao.gov/products/gao-22-106026.

Data on why beneficiaries disenroll from MA may provide insight as to the causes of this shift, such as inadequacy of the specialty provider network, high-out-of-pocket costs, and/or elevated denial rates. For example, this data could be used to identify whether and when individuals or groups who experience higher out-of-pocket costs or multiple PA denials choose to change plans. Further analysis could show whether there are disruptions to the beneficiary's care and whether such disruptions have varying impacts across different demographic groups.

Conclusion

The AAN appreciates the opportunity to provide this response to the Request for Information. The AAN is committed to working with regulators to improve the MA program for our members and their patients, optimize data collection, and expand the use of data. Please contact Matt Kerschner, the AAN's Director, Regulatory Affairs and Policy at mkerschner@aan.com or Cale Coppage, the AAN's Senior Government Relations Manager at ccoppage@aan.com with any questions or requests for additional information.

Sincerely,

Carlayne E. Jackson, MD, FAAN
President, American Academy of Neurology