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January 27, 2025

Jeff Wu, JD, MBA
Office of the Administrator
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Submitted electronically via <http://www.regulations.gov>

Re: Medicare and Medicaid Programs: Contract Year 2026 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 (CMS-4208-P)

Dear Acting Administrator Wu:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Contract Year 2026 Policy and Technical Changes to the Medicare Advantage (MA) Program and Part D proposed rule.

ASH represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical (or non-malignant) conditions such as sickle cell disease (SCD), thalassemia, bone marrow failure, venous thromboembolism (VTE), and hemophilia. Hematologists have been pioneers in advancing the understanding and treatment of various hematologic diseases. Hematologists continue to be innovators in the fields of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients. Our mission is to foster high-quality care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders.

With these goals in mind, ASH appreciates the opportunity to comment on the proposed MA policies of importance to ASH members and the patients we serve. The proposed policies of interest to the Society include clarifications regarding the use of prior authorization, responsible integration and use of artificial intelligence (AI) technologies, and revised administrative policy for dually eligible enrollees. The Society has previously weighed in on improvements to prior authorization in Medicare Advantage plans, submitting comments on a proposed rule in [2023](#) and a CMS issued request for information in [2024](#).

Prior Authorization

CMS proposed several clarifications regarding the use of prior authorization (PA) to ensure that beneficiaries enrolled in MA plans have access to equitable, timely, and appropriate care. Many of these policies build on previous regulations, however for plan year 2026, CMS proposed new policy that MA plans must collect and make available PA data at the service level, as opposed to collecting PA data at the aggregate level. CMS will require MA plans to collect and share data at the service level to track the effect of PA and associated policies on individual services and procedures. The collected data will be used to determine if MA plans deny coverage for some services more than others.

ASH commends CMS for including policy clarifications on the use of prior authorization and supports the enhancements for transparency. We support the agency's policy to better identify patterns that may indicate increased denial rates for some services in comparison to others. While intended as a tool to ensure that care is medically necessary, meets certain standards, and controls costs, PA frequently creates barriers to patients accessing timely, medically necessary care. Members have shared many instances of CT scans, MRI scans, drugs, and treatment orders that are often denied on the first attempt of obtaining a prior authorization, to then have those same denials approved on appeal. The continual back and forth requires increased resources, delays patient care, and adds administrative burden to an already overburdened health care staff and provider workforce. Increased transparency on the approval and denial rates at the service level would support understanding for which services are the most administratively burdensome and time-consuming to access. This information would also support a similar understanding for the accessibility of services across specialties, identifying potential differences in approval and denial rates as well as turnaround times. The collected data will also provide information on possible needed improvements to PA processes to support patient access to care. ASH also supports the continuation of data collection at the aggregate level. Collection of aggregate data at the MA plan level continues to be important for transparency and supporting patient choice across MA plans. Aggregate data may also support MA plans to better understand the burden related to PA processes across the industry and improve the timeliness and accessibility of care. The Society strongly supports CMS' effort to collect and analyze PA data and improve process across Medicare Advantage and Part D plans.

Guardrails for the Use of Artificial Intelligence

The proposed rule also includes policies that will ensure responsible integration and use of artificial intelligence (AI) technologies. CMS proposes to revise regulatory language to ensure that when AI is used in any fashion, that AI must be used in a manner that preserves equitable access to MA services. In addition, the Agency proposes to require that AI tools used by MA plans must not impede access to medically necessary care or result in inequitable treatment for beneficiaries. And finally, the Agency proposes policy to ensure that the use of AI applications in utilization management and coverage decisions must adhere to patient-centered practices to avoid bias or unfair outcomes and cannot discriminate based on factors that are related to an enrollee's health status.

ASH supports the proposed policies to implement guardrails for the appropriate use of AI by MA plans to ensure access to timely and appropriate care. ASH has previously shared [comments](#) related to the use of technology and predictive models to support clinical care. In these comments, ASH emphasized the importance of transparency as to the types of data used in AI models, the frequency of data updates, and the underlying logic of predictive models and AI tools. Additionally, the Society cautions against a "one-size-fits-all" approach to building predictive models and AI tools, especially when they are used for complex or rare conditions commonly found in hematology. Several studies^{i,iii,iv} show significant and persistent disparities in medical care and health outcomes among patients across a range of blood disorders, underscoring the need for guardrails when AI tools are used in health care policy.

ASH has a longstanding commitment to supporting access to high-quality, clinically appropriate care and commends the agency for taking initiative to provide guardrails to prevent unintended barriers to care. ASH encourages CMS to continue monitoring the integration of AI tools used by MA plans and encourages the Agency to consider efforts to improve transparency on incorporated data elements, frequency of data updates, and logic of the AI models used for PA processes in MA plans. ASH supports the use of AI tools in the health care systems if the tools are used to ensure that appropriate care is delivered in a timely and patient-centric manner.

Improving Experiences for Dually Eligible Enrollees

Lastly, the rule addresses care improvements for dually eligible enrollees by proposing that a single identification (ID) card may be used for both Medicare and Medicaid, when those beneficiaries are dually enrolled. ASH supports this proposal and believes that a single ID card for dual eligible enrollees will support the integration of services across programs and reduce administrative burden. Additionally, the society supports the use of a single health risk assessment for dually eligible enrollees. Risk assessments are conducted for both Medicare and Medicaid beneficiaries, and the Society supports the use of one risk assessment for dually eligible enrollees. ASH believes that streamlining these activities will reduce administrative burden for providers, beneficiaries, and the Agency. We encourage CMS to develop educational materials and disseminate alerts to beneficiaries and providers to support continuous access to care for dually eligible beneficiaries and ensure coordination between Medicare, Medicaid, and plan providers as the single ID card and risk assessment policies are implemented.

ASH thanks CMS for the opportunity to share these comments on the CY 26 Policy and Technical Changes to the Medicare Advantage (MA) Program and Part D proposed rule. Should you have any questions or require further information, please contact ASH Manager for Health Care Access Policy, Carina Smith at casmith@hematology.org.

Sincerely,



Belinda Avalos, MD
President

ⁱ Ioannis Farmakis, Mary Cushman, Luca Valerio, Nikolaos Giannakoulas, Lukas Hobohm, Gregory Piazza, Stavros Konstantinides, Stefano Barco; Social Determinants of Health and Pulmonary Embolism Treatment and Mortality: The Nationwide Inpatient Sample. *Blood* 2022; 140 (Supplement 1): 343–344. doi: <https://doi.org/10.1182/blood-2022-166550>

ⁱⁱ Arushi Khurana, Raphael Mwangi, Loretta J. Nastoupil, Patrick M. Reagan, Umar Farooq, Jason T. Romancik, Timothy J. McDonnell, Shaun M Riska, Izidore S. Lossos, Brad S. Kahl, Peter Martin, Thomas E. Witzig, James R. Cerhan, Christopher R. Flowers, Matthew J. Maurer, Grzegorz S. Nowakowski; Evaluating the Impact of Lab-Based Eligibility Criteria By Race/Ethnicity in Frontline Clinical Trials for Diffuse Large B-Cell Lymphoma (DLBCL): A LEO Cohort Analysis. *Blood* 2022; 140 (Supplement 1): 2056–2058. doi: <https://doi.org/10.1182/blood-2022-169433>

ⁱⁱⁱ Warren Fingerhut, Stephanie Chinapen, Angela Katrichis, Caroline Carino, Eric Davis, Brian C. Shaffer, Christina Cho, Gunjan L. Shah, Juliet N. Barker; Analysis of 372 Adult Allograft Recipients Reveals Associations between Non-European Ancestry, Low Socioeconomic Status, and Receipt of HLA-Disparate Grafts. *Blood* 2022; 140 (Supplement 1): 313–314. doi: <https://doi.org/10.1182/blood-2022-168486>

^{iv} Molly Tokaz, Helen Baldomero, Andrew J Cowan, Wael Saber, Hildegard T. Greinix, Mickey Koh, Nicolaus Kröger, Mohamad Mohty, Sebastian Galeano, Shinichiro Okamoto, Nacem A. Chaudhri, Amado J Karduss, Fabio Ciceri, Vergilio Rensi Colturato, Selim Corbacioglu, Alaa M. Elhaddad, Lisa Force, Cristobal Augusto Frutos Ortiz, Andres Gomez-De Leon, Nada Hamad, Nelson Hamerschlak, Naya He, Aloysius YL Ho, Xiao-Jun Huang, Benjamin Jacobs, Heeje Kim, Minako Iida, Leslie E. Lehmann, Régis Peffault de Latour, Mary-Elizabeth M. Percival, Walid Rasheed, Kirk R. Schultz, Adriana Seber, Bor-Sheng Ko, Anderson Simone, Alok Srivastava, Jeff Szer, William A. Wood, Yoshihisa Kodera, Arnon Nagler, John A Snowden, Daniel J. Weisdorf, Jakob R. Passweg, Marcelo C Pasquini, Anna Sureda, Yoshiko Atsuta, Mahmoud Aljurf, Dietger Niederwieser, Martina Perdomo; An Analysis of the Worldwide Utilization of Hematopoietic Stem Cell Transplantation for Acute Myeloid Leukemia. *Blood* 2022; 140 (Supplement 1): 8146–8149. doi: <https://doi.org/10.1182/blood-2022-158338>