

2020

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October 1, 2020

Seema Verma Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1734-P P.O. Box 8016 Baltimore, MD 21244-8016

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

RE: Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule (CMS-1734-P)

Administrator Verma,

The American Society of Hematology (ASH) is pleased to offer comments on the proposed rule outlining revisions to the Medicare Physician Fee Schedule (PFS) for calendar year (CY) 2021.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

ASH offers comments on the following areas of the proposed rule, which are of particular importance to the Society's members:

- 1. Evaluation and Management Visits
- 2. CY2021 Conversion Factor
- 3. Telehealth and Other Services Involving Communications Technology
- 4. Proposal to Remove Selected National Coverage Determinations

Evaluation and Management Visits

ASH thanks the Centers for Medicare and Medicaid Services (CMS) for maintaining the changes to office/outpatient evaluation and management (E/M) services finalized in the CY2020 rulemaking and asks that the changes proposed in this rule be finalized and take effect on January 1, 2021. The Society strongly supports the agency's proposal to adopt the outpatient E/M code set as revised by the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel and valuations recommended by the AMA RVS Update Committee (RUC). ASH also supports the proposal to adopt the actual total times rather than the total times recommended by the RUC.

Specifically, ASH appreciates the meaningful increases for level 3, 4 and 5 visits, as this is significant for specialties, such as hematology, that frequently bill higher-level codes because of the complexity of the diseases and disorders treated. Patients with hematologic diseases and disorders frequently have a complex history and require extensive counseling, emotional support, and lengthy discussions related to goals of care. These diseases and disorders are often rare, such as porphyria, which affects many organ systems, and treatment may be unique to each patient. Additionally, many visits incorporate high-level interpretation and explanation to patients of associated lab and radiographic data as hematology diagnosis and treatment is closely aligned with lab results.

ASH also supports the documentation changes that accompany the revised outpatient E/M codes allowing providers to select the visit level and report these services by medical decision making (MDM) or time in accordance with the documentation requirements as revised by CPT. ASH is confident that these changes will meaningfully reduce the administrative burden of documenting these office visit services and appreciates CMS' efforts to work with the physician community to reduce burden without reducing reimbursement for complex office visit services.

Complexity Add-On Code

ASH appreciates that CMS continues to refine the new add-on code, GPC1X, but requests guidance on what documentation needs to be included when the code is used. As mentioned above, hematologic diseases and disorders are often very complex, and ASH believes this code will be frequently used by hematologists. GPC1X helps to capture the work required by specialists, such as hematologists, to maintain cognitive expertise, something that E/M codes have never successfully captured.

CY2021 Conversion Factor

ASH is concerned about the payment cuts resulting from budget neutrality requirements. The cuts are a major problem at any time but particularly when physicians are facing financial distress due to the COVID-19 pandemic. To mitigate the budget neutrality cuts, we strongly urge CMS and the Department of Health and Human Services (HHS) to utilize its authority under the public health emergency declaration. To preserve patient access to care and mitigate financial distress due to the pandemic, CMS and HHS can implement the office visit increases as planned while waiving budget neutrality requirements for the new Medicare office visit payment policy.

Telehealth and Other Services Involving Communications Technology

Physicians and patients alike have greatly benefited from the expanded telehealth services as a result of the declared Public Health Emergency (PHE). Permanent expansion of many of these services, however, will provide benefits beyond the PHE, especially for individuals living with chronic disease. Many hematologic diseases are rare and complex to manage. Patients may not have access to medical experts in their communities, and telehealth can help them receive appropriate care regardless of where they live. Furthermore, many patients travel great distances to see specialists, such as hematologists, particularly for follow-up visits to review lab tests or to discuss medication options, such as oral chemotherapy. Permanently expanding telehealth services would ease the burden on patients and allow them to continue care management remotely. ASH is aware that CMS does not have sole authority to make permanent what is outlined below, but the Society urges the agency to work with Congress to address these issues.

ASH is aware that CMS used waiver authority, in response to the PHE, to remove the geographic and site of service originating site restrictions placed on telehealth services. ASH urges CMS to work with Congress to permanently remove these restrictions to allow Medicare beneficiaries to utilize telehealth from their homes rather than require them to travel to specific sites. As mentioned above, many patients travel great distances to see specialists, including hematologists. Allowing patients to utilize telehealth from their home would ease the travel burden on patients and allow them to continue care management remotely.

Comment Solicitation on Continuation of Payment for Audio-only Visits

ASH appreciates CMS' recognition that audio-only telehealth services may continue to be beneficial to both patients and physicians beyond the public health emergency. ASH urges CMS to continue to cover and pay for the audio-only codes at the reimbursement levels set in the April 30, 2020 Interim Final Rule. ASH sees audio-only services as an important component of telehealth services and asks CMS to work with Congress to expand the telehealth benefit to allow for audio-only when patients do not have the infrastructure for video.

Video is not always an option – technology fails, bandwidth is not strong enough, and some elderly patients do not know how to access/utilize it. And while ASH appreciates CMS' offer to create new coding and payment similar to that of the virtual check-in, the Society strongly feels that the current audio-only codes are better suited for physicians and patients, have been widely utilized since coverage/payment was approved early in the PHE, and reflect the appropriate lengths of time and reimbursement (at the current rates during the PHE).

Supervision of Residents in Teaching Settings through Audio/Visual Real-Time Communications Technology

ASH supports making permanent the policy that the presence of a teaching physician during the key portion of a service furnished with the involvement of a resident can be met using audio/video real-time communications technology. This policy allows for greater flexibility and it may allow for subspecialists who are working remotely, including hematologists, to do this at other locations.

Virtual Teaching Physician Presence during Medicare Telehealth Services

Similarly, ASH supports making permanent the policy to allow Medicare to make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/visual real-time communications technology.

Proposal to Remove Selected National Coverage Determinations

ASH appreciates CMS' review of older national coverage determinations (NCD) and is in agreement on the removal of NCD #20.5 and #110.14, but strongly feels that NCD #190.3 remain in effect. Please see explanations below:

NCD #20.5 Extracorporeal Immunoadsorption (ECI) using Protein A Columns

ASH agrees with the removal of this NCD for the same reasons as provided by CMS – the policy is outdated.

NCD #110.14 Apheresis (Therapeutic Pheresis)

ASH supports the removal of this NCD because, as stated by the agency, it is outdated. ASH joined AABB and the American Society for Apheresis (ASFA) in 2015 to advocate that this NCD be retired because the NCD was outdated and did not accurately reflect advances in the discipline of Apheresis Medicine and its patient care applications. The Society, however, does have concerns that "contractor discretion" could be used to deny treatments and plans to work with other professional societies to educate the Medicare Administrative Contractors (MACs) on the intricacies of apheresis. ASH encourages CMS to direct the MACs to work with stakeholders, such as ASH, on this issue.

ASH disagrees with the removal of this NCD and refutes the rationale provided by CMS that the NCD has been replaced by the Next Generation Sequencing (NGS) policy. Cytogenetics and NGS are done concurrently; NGS is not a replacement of cytogenetics. NGS generally does not identify structural chromosomal rearrangements/alterations (i.e. monosomy 7), for which cytogenetics is the gold standard. Cytogenetic studies are still critical to diagnose disorders such as chronic myeloid leukemia as well as certain cytogenetic abnormalities in myelodysplastic syndromes. Both cytogenetics and NGS are done on bone marrow when testing for myeloid malignancies as they provide different information. ASH would be happy to connect CMS with clinical experts to further discuss this topic, if needed.

Thank you for the opportunity to provide comments on the Physician Fee Schedule proposed rule for CY 2021. The Society welcomes the opportunity to discuss these comments with you and your team at any time. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager, at lbrady@hematology.org or 716-361-2764 (cell).

Sincerely,

Stephanie J. Lee, MD, MPH

President