



# AMERICAN SOCIETY OF HEMATOLOGY

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September 1, 2022

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1770-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY at <https://www.regulations.gov>

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Dear Administrator Brooks-LaSure:

The American Society of Hematology is pleased to offer comments on the calendar year (CY) 2023 Medicare Physician Fee Schedule (MPFS) proposed rule. We appreciate the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on the provisions impacting our members.

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.

Specifically, ASH provides comments on the following provisions:

1. Evaluation and Management Services – Split (or Shared) Visits
2. Rebasing and Revising the Medicare Economic Index (MEI)
3. Payment for Medicare Telehealth Services
4. Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services
5. Quality Payment Program - Advancing Cancer Care MVP

## Evaluation and Management Services

### *Split (or Shared) Visits*

ASH appreciates CMS for proposing to delay, until January 1, 2024, the requirement

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that only the physician or qualified health provider (QHP) who spends more than half of the total time with the patient during a split/shared evaluation and management (E/M) visit can bill for the visit. The Society joins others in the medical community in urging CMS to allow physicians or QHPs to bill split or shared visits based on time or medical decision-making (MDM). ASH supports physician-led, team-based patient care and echoes the comments by the American Medical Association (AMA) in that patients benefit from the collaboration of physicians and QHPs who care for patients in hospitals, skilled nursing facilities, and other facilities where they work hand-in-hand. Billing based on the physician or QHP who performs more than 50% of the total time of the visit will disincentivize the continuation of these care relationships.

### **Rebasing and Revising the Medicare Economic Index (MEI)**

CMS is proposing to utilize data collected by the U.S. Census Bureau rather than the AMA data, which comes from the 2006 Physician Practice Information (PPI) Survey, to inform the Medical Economic Index (MEI). The MEI has long served as a measure of practice cost inflation and a mechanism to determine the proportion of payments attributed to physician practices costs. CMS is concerned that the 2006 PPI Survey is outdated and is proposing to use Census Bureau data instead. There are concerns, however, that this proposal would result in significant redistribution within physician payments. ASH again supports the comments by the AMA in asking that CMS pause consideration of other sources of cost data for use in the MEI and that the agency work with the AMA on the new data collection effort to ensure consistency and reliability in physician payment.

### **Payment for Medicare Telehealth Services**

ASH strongly supports the implementation of the provisions included in the Consolidated Appropriations Act of 2022 which extended certain telehealth flexibilities allowed under the COVID-19 public health emergency (PHE) for an additional 151 days after the end of the PHE. Specifically, ASH is pleased that the telephone E/M codes (99441-99443) are included in the 151-day extension. The Society, however, would like to see these codes in addition to the other telehealth flexibilities, including the waiving of the geographic and site of service restrictions, be made permanent, beyond the 151-day extension.

The telehealth flexibilities expanded under the COVID-19 pandemic have hugely benefited the patient and provider communities. 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 chemotherapies. Many physicians continue to contract COVID-19 and while they are unable to treat patients in the office, many are well enough to conduct telehealth visits. And in addition to COVID-19, the medical community is now also concerned about other infectious diseases, such as Monkeypox. Permanently expanding telehealth services would ease the burden on patients and allow them to continue care management remotely, in a more efficient and safe manner.

The telephone-only codes have been particularly beneficial. Video is not always an option for many patients – technology fails, bandwidth is not strong enough, elderly patients do not know how to access/utilize it. Additionally, many times, the oral conversation between a physician and a patient is the key component (rather than visually seeing the patient), especially for patients with blood diseases. ASH requests that coverage and equitable payment for audio-only telehealth services is maintained beyond the PHE.

### **Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services**

ASH is pleased to see that CMS included in the proposed rule a request for information on expanding Medicare Parts A and B coverage for dental services. The Society requests that the funding source to cover the dental services should be separate from and without impact on the Medicare Physician Payment Schedule. Dental services are a key component to treating many hematologic diseases and disorders, including sickle cell disease, hemophilia, and many blood cancers, such as acute myeloid leukemia, acute lymphocytic leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia, and multiple myeloma.

Specifically, CMS is seeking comment on clinical scenarios where the dental services may be inextricably linked and substantially related and integral to the clinical success of other covered medical services. There are a number of examples related to hematology and in many cases dental services are performed as part of a comprehensive workup prior to initiation of a specific therapy or treatment:

- It is standard of care that patients undergo a comprehensive dental evaluation with appropriate follow-up if they are going to have hematopoietic stem cell transplantation (HSCT) – a common procedure for treatment of malignant and non-malignant blood diseases. Side effects of the HSCT frequently occur in the oral cavity. Improper oral preparation of the patient prior to transplant can cause or exacerbate these complications.<sup>1,2</sup> Additionally, lack of dental care can delay transplants and cause issues with weight loss and poor healing post-therapy due to inability or discomfort with eating.
- A comprehensive dental evaluation is also standard for individuals undergoing chimeric antigen receptor (CAR) T-cell therapy.
- Any patient undergoing chemotherapy for treatment of a blood cancer should receive dental care prior to beginning treatment as patients become neutropenic after starting chemotherapy, increasing the risk of oral abscesses. The goal is to prevent dental issues/oral infections from occurring when the patient has low blood counts and is at high risk for complications.
- Individuals undergoing treatment for multiple myeloma receive bisphosphonates, which according to National Comprehensive Cancer Network (NCCN) guidelines, should be paired with a baseline dental exam.<sup>3</sup> All patients on bisphosphonates should undergo dental examinations every 6 months and about 10% of them will develop osteonecrosis of the jaw, which requires intervention and treatment by oral surgeons.
- Dental services are a necessary component of comprehensive care for people with hemophilia. Periodic dental care reduces not only the risk of gingival bleeding, but also the risk of untreated dental caries necessitating tooth extraction, which in a 70 kg patient requires clotting factor treatment costing approximately \$3,000 per day for 1-3 days.

Quality and consistent dental care is also a critical component of caring for individuals with sickle cell disease (SCD). Studies have shown that among individuals having a sickle cell crisis, those with dental infections were 72% more likely to be admitted to the hospital compared to those without dental infections. Based on preliminary data from this analysis, prevention of dental infection among individuals with SCD could result in an estimated cost saving of \$2.5 million dollars per year.<sup>4</sup> There is also literature detailing increased dental caries and periodontal disease in people with SCD.<sup>5</sup> Additionally, hydroxyurea, which is proven to reduce morbidity and mortality for individuals living with SCD, has also been shown to cause oral cavity mucosal lesions, including pain, burning sensation, and teeth decay.<sup>6,7</sup> Unfortunately, many individuals living with SCD lose a number of teeth, which greatly limits nutrition, general well-being, and overall quality of life.

CMS is also seeking comment on what professional services, including, but not limited to dental services, may occur during and prior to the patient's hospitalization or procedure requiring hospitalization.

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<sup>1</sup> Boguslawska-Kapala A, Halaburda K, Rusyan E, Gołabek H, Strużycka I. Oral health of adult patients undergoing hematopoietic cell transplantation. Pre-transplant assessment and care. *Ann Hematol.* 2017 Jul;96(7):1135-1145. doi: 10.1007/s00277-017-2932-y. Epub 2017 Feb 13. PMID: 28194493; PMCID: PMC5486807.

<sup>2</sup> Elad S, Raber-Durlacher JE, Brennan MT, Saunders DP, Mank AP, Zadik Y, Quinn B, Epstein JB, Blijlevens NM, Waltimo T, Passweg JR, Correa ME, Dahllöf G, Garming-Legert KU, Logan RM, Potting CM, Shapira MY, Soga Y, Stringer J, Stokman MA, Vokurka S, Wallhult E, Yarom N, Jensen SB. Basic oral care for hematology-oncology patients and hematopoietic stem cell transplantation recipients: a position paper from the joint task force of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) and the European Society for Blood and Marrow Transplantation (EBMT). *Support Care Cancer.* 2015 Jan;23(1):223-36. doi: 10.1007/s00520-014-2378-x. Epub 2014 Sep 5. PMID: 25189149; PMCID: PMC4328129.

<sup>3</sup> National Comprehensive Cancer Network. [https://www.nccn.org/professionals/physician\\_gls/pdf/myeloma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf).

<sup>4</sup> Laurence B, Haywood C Jr, Lanzkron S. Dental infections increase the likelihood of hospital admissions among adult patients with sickle cell disease. *Community Dent Health.* 2013 Sep;30(3):168-72. PMID: 24151791; PMCID: PMC4115243.

<sup>5</sup> Kakkar M, Holderle K, Sheth M, Arany S, Schiff L, Planerova A. Orofacial Manifestation and Dental Management of Sickle Cell Disease: A Scoping Review. *Anemia.* 2021 Oct 22;2021:5556708. doi: 10.1155/2021/5556708. PMID: 34721900; PMCID: PMC8556080.

<sup>6</sup> Antonioli, E., Guglielmelli, P., Pieri, L., Finazzi, M., Rumi, E., Martinelli, V., Vianelli, N., Luigia Randi, M., Bertozzi, I., De Stefano, V., Za, T., Rossi, E., Ruggeri, M., Elli, E., Cacciola, R., Cacciola, E., Pogliani, E., Rodeghiero, F., Baccarani, M., Passamonti, F., Finazzi, G., Rambaldi, A., Bosi, A., Cazzola, M., Barbui, T., Vannucchi, A.M. and (2012), Hydroxyurea-related toxicity in 3,411 patients with Ph<sup>-</sup>negative MPN. *Am. J. Hematol.*, 87: 552-554. <https://doi.org/10.1002/ajh.23160>

<sup>7</sup> Maha Badawi, Soulafa Almazroa, Fatima Azher, Fatin Alsayes, Hydroxyurea-induced oral ulceration, *Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology*, 10.1016/j.oooo.2015.09.006, 120, 6, (e232- e234), (2015).

- For individuals undergoing bone marrow transplant or CAR T-cell therapy, access and coverage of dental services is critical, but there are a number of other services that are beneficial to the success of the procedure, such as:
  - Geriatric assessments, which can include physical therapy/occupational therapy referrals, and/or consultation with a dietician;
  - Pre-transplant assessment, which includes a psychologist appointment and financial counseling; and,
  - Smoking cessation.

ASH would be happy to meet with CMS to discuss what is outlined above and provide greater detail on how dental services are critical to the success of many common therapies for treatment of hematologic diseases and disorders.

## Quality Payment Program

### *Advancing Cancer Care MVP*

ASH appreciates the efforts taken by CMS to streamline the reporting requirements under the Merit-based Incentive Payment System (MIPS) program and is pleased to see a MIPS Value Pathway (MVP), the Advancing Cancer Care MVP, which is applicable to clinicians who treat patients within the practice of oncology and hematology. In general, ASH is pleased with this MVP, but the Society would like to highlight that of the 11 MIPS quality metrics only four are relevant to hematology and they are quite general. While these improvement activities are applicable to all patients with cancer including hematologic malignancies, additional quality metrics developed by CMS in concert with ASH that are more focused on the care of patients with hematologic conditions would be welcome. Lastly, ASH would like to note that there has been a move away from depression screening towards distress screening, so the Society does question the inclusion of Q134, *Preventive Care and Screening: Screening for Depression and Follow-up Plan*. Distress screening is a more comprehensive, complex and broad assessment of a patient's needs, including psychological (i.e., cognitive, behavioral, emotional), social, spiritual, and/or physical needs. Research has suggested that distress screening is more likely to lead to a supportive intervention than depression screening alone.<sup>8</sup> ASH would be happy to serve as a resource as CMS continues to update and create MVPs.

In closing, the Society thanks CMS for the opportunity to provide input on the proposed 2023 MPFS rule. Please reach out to ASH Chief Policy Officer, Suzanne Leous (sleous@hematology.org), with any questions or clarifications regarding our comments.

Sincerely,



Jane N. Winter, MD  
President

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<sup>8</sup> Valerie Pracilio Csik, Emma Hannan, Lauren Waldman, Greg D. Garber, and Brooke Worster. Analysis of the likelihood of depression versus distress screening to identify need for intervention. DOI: 10.1200/JCO.2022.40.16\_suppl.1544 Journal of Clinical Oncology 40, no. 16\_suppl (June 01, 2022) 1544-1544.