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February 09, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-185

Re: Dental Services Recommendations for CY 2025 Medicare Physician Payment Fee Schedule

Dear Administrator Brooks-LaSure:
The American Society of Hematology (ASH) appreciates the opportunity to submit recommendations for additional clinical treatment scenarios in which dental services are inextricably linked to other Medicare covered services for sickle cell disease (SCD) and other hematologic disorders for consideration for coverage and payment in the Calendar Year (CY) 2025 Medicare Physician Payment Fee Schedule (MPFS) 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 SCD, 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 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.

Providing appropriate and timely dental care is a crucial component for the successful treatment of many hematologic diseases including SCD, hemophilia, and many blood cancers, such as acute myeloid leukemia, acute lymphoblastic leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia, and multiple myeloma. ASH applauds the Agency's progress in expanding coverage for dental services inextricably linked to chemotherapy, CAR T-Cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy), all when used in the treatment of cancer.

While ASH acknowledges that under this statute CMS has the authority to expand coverage for dental services only when they are *inextricably linked and substantially related and integral to the clinical success of other covered medical services*, ASH believes that CMS will find that this test is met as oral health care is essential to the success of treatments for individuals with 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.[1] 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.[2]

**Bone Marrow and Hematopoietic Stem Cell Transplantation**

ASH was pleased to see in the CY 2023 MPFS, that CMS finalized coverage and payment of dental services performed as part of a comprehensive workup *prior* to organ transplantation (including bone marrow or hematopoietic stem cell transplantation (HSCT). They are integral to the clinical success of certain of these covered medical services.

As CMS has recognized, it is standard of care that patients undergo a comprehensive dental evaluation with appropriate follow-up if they are going to have HSCT – a common procedure for treatment of malignant and non-malignant blood diseases, including SCD. 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.[3,4] Additionally, lack of dental care prior to transplant can delay transplantation, and lack of dental care post-HSCT can cause issues with weight loss and poor healing due to inability or discomfort with eating.

The Society requests that in the CY 2025 MPFS, CMS consider coverage and payment of dental services to those performed *following* organ transplantations (including bone marrow or hematopoietic stem cell transplantations). Maintenance of oral hygiene after HSCT minimizes the severity of oral and dental infections, which is important because chronic graft versus host disease (cGVHD) is common following allogeneic HSCT (used to treat blood diseases such as acute myeloid leukemia) and bone marrow replacement treatment (used to treat blood diseases such as leukemias, lymphomas, and aplastic anemia).[5,6,7] Oral manifestations of cGVHD include mucosal changes, xerostomia, and rampant caries. Frequent dental evaluation of patients with cGVHD is critical because of the increased rate of dental caries associated with this disease; furthermore, gingivitis and periodontal disease should

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[1] 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.

[2] 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.

[3] Bogusławska-Kapała A, Hałaburda K, Rusyan E, Gołąbek 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.

[4] 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.

[5] Elad S, Zadik Y, Zeevi I, Miyazaki A, de Figueiredo MA, Or R. Oral cancer in patients after hematopoietic stem-cell transplantation: long-term follow-up suggests an increased risk for recurrence. Transplantation. 2010 Dec 15;90(11):1243-4. doi: 10.1097/TP.0b013e3181f9caaa. PMID: 21119507.

[6] 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.

[7] Schubert, M.M., Correa, M.E.P. and Peterson, D.E. (2015). Oral Complications of Hematopoietic Cell Transplantation. In Thomas' Hematopoietic Cell Transplantation (eds S.J. Forman, R.S. Negrin, J.H. Antin and F.R. Appelbaum). doi: 10.1002/9781118416426.ch101

be monitored and managed appropriately to avoid additional infection.[8] Multiple extractions without replacement therapy leaves patients with a poor capacity to eat and may negatively impact the success of the transplant and quality of life.[9,10,11]

ASH would like to thank the agency for considering and including our comments on previous MPFS proposed rules on dental services for patients with SCD. As the new and innovative cell and gene therapies for SCD demonstrate, there have been several recent breakthroughs in the practice of hematology in which dental services are important for the success of the clinical treatment. Additionally, as the cell and gene therapies become more widely available and the data matures, ASH recommends including cell and gene therapy as a clinical treatment scenario for future consideration for the coverage of dental services.

The Society appreciates the opportunity to share additional comments related to Medicare coverage and payment for dental services; ASH will provide a separate attachment with the references cited in this letter for ease of reference. Please use ASH Manager for Health Care Access Policy, Carina Smith (*casmith@hematology.org* or 202-292-0264), as your point of contact if you have any questions or if we can provide additional information.

Sincerely,

Mohandas Narla, DSc
President

Mary-Elizabeth M. Percival, MD
Chair, Committee on Practice

CC:

Laura Ashbaugh, Center for Medicare, Hospital and Ambulatory Policy Group, Division of Practitioner Services
Erick Carrera, Center for Medicare, Hospital and Ambulatory Policy Group, Division of Practitioner Services
Zehra Hussain, Center for Medicare, Hospital and Ambulatory Policy Group, Division of Practitioner Services

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[8] Tomblyn M, Chiller T, Einsele H, Gress R, Sepkowitz K, Storek J, Wingard JR, Young JA, Boeckh MJ; Center for International Blood and Marrow Research; National Marrow Donor program; European Blood and Marrow Transplant Group; American Society of Blood and Marrow Transplantation; Canadian Blood and Marrow Transplant Group; Infectious Diseases Society of America; Society for Healthcare Epidemiology of America; Association of Medical Microbiology and Infectious Disease Canada; Centers for Disease Control and Prevention. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global perspective. Biol Blood Marrow Transplant. 2009 Oct;15(10):1143-238. doi: 10.1016/j.bbmt.2009.06.019. Erratum in: Biol Blood Marrow Transplant. 2010 Feb;16(2):294. Boeckh, Michael A [corrected to Boeckh, Michael J]. PMID: 19747629; PMCID: PMC3103296.

[9] Etebarian A, Mirshamsi H, Sadeghi HS, Hemmati F. Oral rehabilitation in a patient with sclerotic-phenotype chronic graft versus host disease: a case report. Quintessence Int. 2019;50(3):208-213. doi: 10.3290/j.qi.a41973. PMID: 30773573.

**[10]** Mahn, Douglas H. Simultaneous Extractions, Implant Placement, and Immediate Loading With Hybrid Prosthesis in Patient With Chronic Graft-Versus-Host Disease. Clinical Advanced in Periodontics. 30 August 2018. https://doi.org/10.1002/cap.10037

[11] Bogusławska-Kapała A, Halaburda K, Rusyan E, Gołąbek 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.