



American Society for
Transplantation and Cellular Therapy

February 10, 2023

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

SUBMITTED ELECTRONICALLY

RE: Requests for Dental Coverage Inextricably Linked to Medical Care, CY 2024 MPFS Recommendations

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following additional comments and references in relation to dental services, as requested in the CY 2023 Physician Fee Schedule Final Rule.

The ASTCT is a professional membership association of more than 3,000 physicians, scientists, and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current FDA approvals for chimeric antigen receptor T-cell (CAR-T) therapy.

For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases. ASTCT members very much rely on team care for the complex cancers and other disorders requiring hematopoietic stem cell transplants (HSCTs) and newer cell therapies like CAR-T.

If CMS has any questions regarding these comments, please contact Alycia Maloney, the ASTCT's Director of Government Relations, at amaloney@astct.org.

A handwritten signature in black ink, appearing to read "B Sandmaier", with a long horizontal flourish extending to the right.

Brenda Sandmaier, M.D.
ASTCT President, 2022-2023

I. Confirmation of timeline for dental coverage during Hematopoietic Stem Cell Transplant (HSCT) episodes of care.

ASTCT applauds CMS for confirming that HSCT is a type of organ transplant and that the clinical success of HSCT is “inextricably linked” to the availability of dental care for these patients:

We appreciate the commenters’ feedback regarding the scope of organ transplant as it applies to Medicare Parts A and B payment for dental services that are inextricably linked to, and substantially related and integral to the clinical success of certain covered medical services. We agree with the evidence commenters provided regarding the inextricable link between dental services and hematopoietic stem cell and bone marrow transplantation as consistent with the other organ transplants, particularly with regard to the risk of infection for patients requiring all of these organ transplants.

In response to comments, we are clarifying that Medicare payment may be made under Parts A and B for dental or oral services prior to organ transplants, which for the purposes of this policy includes scenarios where the patient receives an organ transplant, including a bone marrow or hematopoietic stem cell transplant. We also recognize that term “organ transplant” may not be considered to include bone marrow or hematopoietic stem cell transplants in all contexts, and note that Medicare payment policies for organ procurement organizations or other payment policies may be applied differently for the purposes of paying for bone marrow and stem cell transplantations. 87 FR 69677-78

The ASTCT is seeking clarification that this coverage extends to dental care needed during and immediately after the HSCT episode of care. Due to the potential occurrence of graft-versus-host-disease (GVHD) in the post-transplant period, transplant patients are at heightened risk of dental-related infections that may have devastating effects if not treated in a timely manner. These complications can emerge at any point during the transplant episode of care and may have delayed onset throughout the first-year post-transplant.¹ Additional references can be found in Appendix I, at the end of this letter.

The ASTCT asks that CMS clarify that the timeframe for which dental coverage applies to HSCT patients includes the pre-transplant, transplant and immediate post-transplant (up to 1 year after the date of HSCT) periods for patients with either acute or chronic GVHD.

II. Request to provide coverage for dental care services to patients receiving Chimeric Antigen Receptor T-cell (CAR-T) therapy

The ASTCT asks that CMS extend coverage for dental care to Medicare beneficiaries receiving CAR-T therapy, as those episodes of care require high-dose chemotherapy and other lymphodepletion methodologies, as the risks associated with these regimens mirror those with HSCT. CMS notes the necessary inclusion of this step in the administration of CAR-T in National Coverage Determination (NCD) 110.24.² This request is based on the same scientific evidence that

¹ S. Elad, Oral Graft-Versus-Host Disease: A Pictorial Review and Guide for Dental Practitioners; *International Dental Journal*; Volume 71, Issue 1, February 2021, Pages 9-20. <https://doi.org/10.1111/idj.12584>

² CMS, National Coverage Determination 110.24: Chimeric Antigen Receptor (CAR) T-cell Therapy.

<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374&bc=CAAAAAAAAAAAAA>



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substantiates the HSCT request; the primary difference is that patients receive autologous CAR-T cell therapy instead of an infusion of autologous or allogeneic stem cells. A selected set of references to support this request is provided in the attached Appendix II.

ASTCT asks that CMS cover dental care intrinsically related to and contemporaneous with CAR-T, due to the required lymphodepletion regimen.

For reference purposes, we are including our comments as submitted in September 2023 in response to the CY 2023 Physician Fee Schedule Proposed Rule:

Medicare Coverage of Dental Care

ASTCT very much appreciates CMS' proposal to pay for oral health care that is medically necessary according to accepted standards of practice and that is reasonable, necessary, integral, and prudent to the management and/or treatment of a covered medical condition and/or for prevention of a medical complication from oral/dental pathologies.

ASTCT members have been experiencing challenges in finding dental care for underinsured Medicare patients. Additionally, our members routinely interact with patients for whom the side effects of oncology care has negatively affected their dentition and have noted that the lack of Medicare coverage results in challenges maintaining their oral health.

It is very important that proper oral care be provided before and after transplant and cellular immunotherapy treatment. To give perspective, we offer a few real-life case examples.

- Case 1: A patient with progressive disease came to a transplant/cellular therapy center with Medicare and out-of-state Medicaid as a secondary payer. An oral medicine evaluation determined that the patient needed a full mouth extraction because his teeth were non-restorable, putting him at increased risk for complication during and after treatment. The patient's Medicaid insurance did not cover these services in the state where the transplant was to occur and the patient was unable to afford the time or financial expense of postponing his immunotherapy and travelling home for the dental care. Without Medicare payment as an option, the treating clinician was forced to reach out to a private dental office that specializes in treating medically complex patients and ask if it would be willing to perform needed dental care services under charity care.
- Case 2: A stem cell transplant patient was seen as part of a routine pre-transplant oral health evaluation. The oral medicine evaluation determined that three fillings were needed to decrease risk of dental infection during transplant. The patient was inaccurately informed by his insurance representative that all services related to his transplant were covered by Medicare and, based on this information, proceeded with treatment. The patient (understandably) assumed the dental services were covered and, therefore, did not pay the statement received for the fillings afterwards, resulting in the account and this patient facing medical debt and collections. The transplant center social work staff and the treating oral medicine clinician were then tasked with working to help the patient identify options for financial assistance.
- Case 3: A post-transplant patient with graft-versus-host-disease (GVHD) was found to need extensive dental services, including fillings and extractions. These services are necessary to maintain oral health, proper nutrition, and reduce short- and long-term infection risk due to immunosuppression related to treating the patient's GVHD. The patient asked if there was any

way that Medicare would cover some costs of his dental treatment since the services are directly related to history of transplant, which is a covered service ([NCD 110.23](#)). The center reached out to the Senior Health Insurance Benefits Assistance (SHIBA) office with this question on behalf of the patient and was informed (direct quote): “I found some information on the *Medicare.gov* website under [Medicare Dental Coverage](#), specific to the *Statutory Dental Exclusion*. I also checked an authoritative resource we often use, the [Center for Medicare Advocacy](#) and found the [Legal Memorandum: Statutory Authority Exists for Medicare to Cover Medically Necessary Oral Health Care](#), which stipulates that “*medically necessary oral health care*” refers to care that, according to accepted standards of practice, is reasonable, necessary, integral, and prudent to the **management and/or treatment of a covered medical condition**, and/or for prevention of a medical complication from oral/dental pathologies. It appears that Medicare may cover the certain dental needs if it can be determined they resulted from cancer treatment(s).” This representative worked with the patient to make case for dental coverage with the MAC, but failed. The patient paid out-of-pocket for his post-transplant dental needs.

These real-life, recent examples are only a sample of the cases our membership see regularly in which the lack of coverage and payment for dental care necessary for cancer treatment is detrimental to beneficiaries.

Below, we offer answers to some of the questions CMS posed to further assist the agency with its consideration of reimbursement for oral and dental care in support of medical treatment.

How should CMS define “medically necessary” dental services?

ASTCT believes the definition identified by the SHIBA representative is a good starting point: “medically necessary oral health care” refers to care that, according to accepted standards of practice, is reasonable, necessary, integral, and prudent to the **management and/or treatment of a covered medical condition**, and/or for prevention of a medical complication from oral/dental pathologies.”

Specific to ASTCT membership, multiple references exist in the National Comprehensive Cancer Centers’ (NCCN) clinical guidelines,³ the National Institute for Dental and Craniofacial Research,⁴ and in several multi-society clinical practice recommendations.⁵

What are examples of medical services where oral/dental care is integral to the success and outcome of the treatment?

Dental examination and stabilization (i.e., resolution of current concerns) are considered a standard of care in HSCT since any patients who are on immunosuppressives while receiving chemotherapy and radiation will need dental/oral stabilization care pre-transplant and continued care post-transplant. This represents the majority of the HSCT patient population. Patients at risk for GVHD (i.e., those with an unrelated and/or mismatched donor) are particularly in need.

³ NCCN Guidelines for Survivorship, Prevention and Treatment of Cancer-Related Infections, and Hematopoietic Cell Transplantation. https://www.nccn.org/guidelines/category_1

⁴ Elad, S., Raber-Durlacher, J.E., Brennan, M.T. et al., 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* 23, 223–236 (2015). doi.org/10.1007/s00520-014-2378-x

⁵ NIDCR website: <https://www.nidcr.nih.gov/health-info/cancer-treatments>

Specific needs include:

- Extraction of teeth to treat deep caries, pulpal/periapical infection, vertical root fracture, and severe periodontal disease;
- Root canal therapy to treat deep caries, pulpal/periapical infection, or cracked tooth syndrome;
- Root canal retreat or extraction to treat previously root-canal-treated teeth with evidence of residual or recurrent periapical infection;
- Dental evaluation and restorations (e.g., fillings, buildups) and/or silver diamond fluoride therapy to treat dental caries that poses risk for pulpal infection during this period OR that would put tooth at risk for future extraction in patients treated with antiresorptive therapy to prevent medication-related osteonecrosis of the jaw (MRONJ);
- Root canal therapy and decoronectomy to stabilize teeth that are not candidates for extraction or restoration in patients treated with antiresorptive therapy;
- Scaling and root planing for patients with active periodontal disease;
- Extraction or operculectomy to treat pericoronitis or partially impacted third molars; and
- Partial dentures or complete dentures in isolated cases, if required for nutrition.

Two additional clinical scenario examples are:

- Immunotherapy-related mucositis (IRM): IRM may require biopsy and often requires compounded topical steroids or tacrolimus rinse to adequately manage.
- Immune-related salivary gland dysfunction (e.g., chronic GVHD, immunotherapy-related, etc.): immune-mediated salivary dysfunction, analogous to Sjogren Syndrome, that can lead to rapid, progressive dental caries if not actively treated and/or prevented. Indicated treatments include prescription fluoride toothpaste, supervised fluoride varnish, silver diamond fluoride, dental restorations in early stages for prevention, caries treatment and root canal therapy, and extraction in advanced cases. Removable partial dentures, complete dentures, and implants/crowns to replace extracted teeth in severe cases. Sialagogue therapy with pilocarpine or cevimeline is also critical for comfort/quality of life and decay prevention.

What are ways to establish a process to identify additional dental services that are linked to the clinical success of other covered medical services?

We offer the following suggestions:

- 1) Establish a modifier by which the clinician attests to the medical necessity of the oral/dental services, which enables the MACs to do periodic and focused reviews. CMS could review MAC decision-making to provide feedback and encourage similarity across MACs.
- 2) Consider the use of a prior authorization process, with an option for expedited review.
- 3) Recognize all clinician types for oral/dental care services. For example, whenever patients present to emergency departments with oral pain, the hospital and emergency physician must perform a medical screening examination to rule out systemic infection or other high-risk issues. It is important that these medical screening examinations be covered and paid to both the facility and professional, even if the final diagnosis is a dental cavity with a referral to a dentist.
- 4) Cover both planned and emergency care for patients who meet the medical necessity categories (i.e., receiving oncology care), due to the sometimes urgent/emergent nature of problem identification across a variety of care settings and locations.
- 5) Establish cross-MAC consistency in coverage of dental services via memos and audits of MAC decision-making on this issue. Beneficiaries need consistent access regardless of geographic location.

Appendix I: References to Support Dental Coverage Throughout the HSCT Episode of Care

- American Dental Association (ADA), Cancer Therapies and Dental Considerations, Chicago (IL): ADA, 2022.
 - <https://www.ada.org/resources/research/science-and-research-institute/oral-health-topics/cancer-therapies-and-dental-considerations>
- Centers for Disease Control and Prevention (CDC), Guidelines for Preventing Opportunistic Infections Among Hematopoietic Stem Cell Transplant Recipients Recommendations of CDC, the Infectious Disease Society of America, and the American Society of Blood and Marrow Transplantation, Atlanta (GA): CDC, 2000.
 - <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4910a1.htm>
- Majhail NS, Rizzo JD, Lee SJ, et al. Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation; Center for International Blood and Marrow Transplant Research (CIBMTR), American Society for Blood and Marrow Transplantation (ASBMT), European Group for Blood and Marrow Transplantation (EBMT), Asia-Pacific Blood and Marrow Transplantation Group (APBMT), Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ), East Mediterranean Blood and Marrow Transplantation Group (EMBMT) and Sociedade Brasileira de Transplante de Medula Ossea (SBTMO). Co-published in Biol Blood Marrow Transplant, 2012; 18(3): 348-371; Bone Marrow Transplant, 2012; 47(3): 337-341; and Hematol Oncol Stem Cell Ther, 2012; 5(1): 1-30.
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- Georgakopoulou E, Stebbing J, Scully C. Targeted cancer therapies: Oral health care implications. J Am Dent Assoc 2018;149(2):100-11
 - https://www.ebmt.org/sites/default/files/2019-01/2019_Book_TheEBMTHandbook.pdf
- Guideline on dental management of pediatric patients receiving chemotherapy, hematopoietic cell transplantation, and/or radiation (2008). Pediatr Dent 30 (7 Suppl):219-225
 - Link: https://www.aapd.org/assets/1/7/G_Chemo1.PDF
- Hansen HJ, Estilo C, Owosho A, Solano AK, Randazzo J, Huryn J, Yom SK. Dental status and risk of odontogenic complication in patients undergoing hematopoietic stem cell transplant. Support Care Cancer. 2021 Apr;29(4):2231-2238. doi: 10.1007/s00520-020-05733-1. Epub 2020 Sep 8. PMID: 32901321; PMCID: PMC8432266.
- Majhail NS, Rizzo JD, Lee SJ, Aljurf M, Atsuta Y, Bonfim C, Burns LJ, Chaudhri N, Davies S, Okamoto S, Seber A, Socie G, Szer J, Van Lint MT, Wingard JR, Tichelli A; Center for International Blood and Marrow Transplant Research; American Society for Blood and Marrow Transplantation; European Group for Blood and Marrow Transplantation; Asia-Pacific Blood and

- Marrow Transplantation Group; Bone Marrow Transplant Society of Australia and New Zealand; East Mediterranean Blood and Marrow Transplantation Group; Sociedade Brasileira de Transplante de Medula Ossea. Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation. *Bone Marrow Transplant*. 2012 Mar;47(3):337-41. doi: 10.1038/bmt.2012.5. PMID: 22395764; PMCID: PMC3393084.
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Appendix II: References to Support Dental Coverage for CAR-T based on Required Lymphodepletion

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 - [CellularTherapyDentalForm.pdf \(umich.edu\)](#)
- Guideline on dental management of pediatric patients receiving chemotherapy, hematopoietic cell transplantation, and/or radiation. *Pediatr Dent*, 2008; 30(7 Suppl):219–225
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