



American Society for  
Transplantation and Cellular Therapy

September 6, 2022

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

*SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV*

RE: CMS–1770–P Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit comments on the CY 2023 Physician Fee Schedule Proposed 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. Therefore, we are pleased to comment on the agency’s request for information on shared/split E/M services in facilities and coverage and payment for dental care.

If CMS has any questions regarding these comments, please contact Alycia Maloney, the ASTCT’s Director of Government Relations, at [amaloney@astct.org](mailto:amaloney@astct.org).

A handwritten signature in black ink, appearing to read "B Sandmaier". The signature is fluid and cursive, with a long horizontal line extending to the right.

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



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### ***Other Evaluation and Management (E/M) Changes and Shared/Split Services***

ASTCT appreciates that both the AMA and CMS have worked to make changes for “all other E/M” code descriptors and documentation elements for implementation in calendar year (CY) 2023. We support CMS adopting the AMA other E/M changes and urge CMS to continue to work with AMA such that HCPCS level II codes are no longer needed for E/M prolonged services.

With these changes, CMS continues to uphold the intent of the Administrative Simplification Act (ASA) to reduce administrative burden by applying standard code sets and definitions to all providers and payers. **ASTCT asks that CMS adopt the other E/M AMA/CPT code changes and the AMA documentation guidelines for reporting the codes on claims, and further requests that CMS fully retire the 1995/1997 documentation guidelines.**

In last year’s rule, CMS clarified that the concept of shared/split outpatient E/M services is applicable in the facility setting only. CMS also finalized the definition of a shared/split visit in a new section at 42 CFR § 415.140—enabling the clinician who furnished the history, exam, medical decision making (MDM) components, or more than half of the total visit time (the summation of the distinct time spent by each physician and non-physician provider (NPP)) to bill the E/M service for 2022. CMS also finalized using half the total visit time as the sole criteria for defining the substantive portion of the visit to determine the billing provider in CY 2023. In this proposed rule, CMS proposes to retain the 2022 policy for CY 2023 and asks for comments concerning the best method to define the substantive portion of a shared/split visit.

As ASTCT commented last year, we believe that, if MDM is performed by a physician in the shared/split visit, then—by definition—the physician should be considered to be the clinician who furnished the “substantial portion” of the visit. Since MDM involves work such as modifications to the plan of care for the patient and evaluating risk, physicians contribute to a level of work based on their expertise and scope that goes beyond simply counting the time furnished during the visit. Specialists such as transplant physicians have—by definition—specialized knowledge and experience and, thus, will contribute more overall to the MDM component when they furnish this component in a visit, in comparison to the NPP involved.

**Therefore, we recommend that, when medical decision-making is used to select the E/M level for a shared/split visit and the physician documentation supports physician contribution to medical decision making, then the physician should be considered as the one who furnished the substantial portion and will be the one to bill for the visit.** We believe this will appropriately recognize the physician effort involved in MDM as part of a shared/split visit.

### ***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.



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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,<sup>1</sup> the National Institute for Dental and Craniofacial Research,<sup>2</sup> and in several multi-society clinical practice recommendations.<sup>3</sup>

*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.

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 sliver 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);

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<sup>1</sup> NCCN Guidelines for Survivorship, Prevention and Treatment of Cancer-Related Infections, and Hematopoietic Cell Transplantation. [https://www.nccn.org/guidelines/category\\_1](https://www.nccn.org/guidelines/category_1)

<sup>2</sup> 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](https://doi.org/10.1007/s00520-014-2378-x)

<sup>3</sup> NIDCR website: <https://www.nidcr.nih.gov/health-info/cancer-treatments>

- 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.

### **Conclusion**

Once again, the ASTCT thanks CMS for the opportunity to comment. Please contact Alycia Maloney, ASTCT's Director of Government Relations, at [amaloney@astct.org](mailto:amaloney@astct.org), for any further questions or to discuss these issues.