



Judith Haber, PhD, APRN, FAAN
Executive Director
Professor Emerita

Oral Health Nursing Education and
Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

September 6, 2023

Submitted electronically via:

[https://www.regulations.gov/commenton/
CMS-2023-0121-1282](https://www.regulations.gov/commenton/CMS-2023-0121-1282)

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS-1770-P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2024 Physician Fee Schedule Proposed Rule

Dear Administrator Brooks-LaSure:

The Oral Health Nursing Education and Practice (OHNEP) program appreciates the opportunity to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the proposals and request for information on Medicare Parts A and B Payment for Dental Services in the CY 2023 Physician Fee Schedule Proposed Rule.

INTRODUCTION

By way of brief background, the OHNEP program is a national nursing initiative funded by the CareQuest Institute, that for the past 12 years has focused on advancing oral health equity for populations across the lifespan. Our objective is to integrate oral health with overall health in undergraduate and graduate nursing programs and as a standard of care in clinical settings. As the largest component of the healthcare workforce, the nursing profession is making a significant contribution to advancing medical-dental integration in academic and clinical settings, especially for populations bearing a disproportionate burden of chronic health problems and poor oral health.

Along with hundreds of medical, nursing, dental, patient, and consumer advocacy organizations, we deeply appreciate the Administration's work to create a more equitable healthcare delivery system through expanded clarification of Medicare payment for medically necessary oral and dental treatment. The importance of this undertaking cannot be overemphasized, as it will have a direct and meaningful impact on the lives of millions of Medicare beneficiaries.



Judith Haber, PhD, APRN, FAAN
Executive Director
Professor Emerita

Oral Health Nursing Education and
Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

For that reason, we wish to applaud the Biden Administration and the exemplary team at the Center for Medicare and Medicaid Services (CMS), as well as the many Members of Congress who actively urged CMS to further clarify the Medicare program's payment of medically necessary oral and dental services. With nearly two-thirds of each year's cancer diagnoses suffered by Americans aged 65 and older, the proposed clarification of Medicare payment policy to include cancer treatment services is vital to numerous beneficiaries and their families.

By further clarifying Medicare payment of medically necessary dental treatment services for beneficiaries with cancer, CMS is charting an important course to improved outcomes and lower costs. CMS' proposal will help ensure that older adults have access to the medically necessary oral care they need. The progress it makes towards more equitable health care for people who rely on Medicare for their health insurance demonstrates that CMS heard stakeholders' request for more transparency on how to effectively seek additional payment clarification, and what it has provided will be of tremendous help.

As a result, we wish to comment on the proposed payment clarification for cancer treatment services as well as express our perspective on the other important issues raised in this proposed rule.

COMMENTS

In response to the Administration's solicitation of public comments, OHNEP wishes to address the following issues: Medicare payment clarification related to covered cancer treatment, that is, chemotherapy and radiation therapy services and cancer treatment-related dental diagnostic and treatment services that are inextricably connected to clinical outcomes.

Medicare payment clarification related to covered cancer treatment and radiation therapy services.

Cancers, including leukemias, lymphomas, and solid tumors (and tumors/lesions of the oral cavity and oropharynx), are the second leading cause of death in the United States after heart disease. In 2020, an estimated 1,603,804 persons were newly diagnosed with cancer and 602,347 died. In the U.S., cancer is diagnosed more frequently in men than women. Advancing age is the number one risk factor for cancer; and more than two thirds of all new cancers are diagnosed among adults aged 60 years and older. As the number of adults living to old age increases, so will the number of new cancer cases (CDC, 2021).



Judith Haber, PhD, APRN, FAAN
Executive Director
Professor Emerita

Oral Health Nursing Education and
Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

National expenditures in 2018 for cancer care in the U.S. were \$150.8 billion. (National Cancer Institute, 2020). Costs will increase as the population ages, more people are diagnosed with cancer, and as new and more expensive treatments become the standard of care (American Cancer Society, 2022; National Cancer Institute, 2020).

While cancer affects all populations nationwide, social, geographic, and economic inequities are present. Cancer health equity is negatively affected by low income, low health literacy, inaccessible transportation to screening and treatment sites, and/or lack of insurance. People who do not have reliable access to health care are also more likely to be diagnosed with late-stage cancer that might have been treated more effectively if diagnosed at an earlier stage. Further, African Americans have higher cancer death rates than all other racial ethnic groups (National Cancer Institute, 2020).

There is a close association between cancer and oral disease. Moreover, there is an inextricable relationship between immunosuppression related to chemotherapy and radiation cancer treatments, the need for dental services before during, and following treatment, and increased risk for co-morbidities and negative clinical outcomes. There are many manifestations of cancer treatment and its side effects in the oral cavity, especially for older adults. Oral pathogens and inflammation, for example, escalate risk for immunosuppression-related side effects of cancer treatment that are local in the oral cavity or are systemic (Archarya, Geist, Powell and Torres-Urquidy, 2019; Keefe and Bateman, 2019). Coordinated, collaborative care, including dental care, is crucial before during and after cancer care to maximize clinical outcomes, decrease cost, and improve quality of life and patient experience (Triple Aim). Major cancer treatment modalities, besides surgery, cause immunosuppression and include, but are not limited to chemotherapy, radiation, and stem cell and bone marrow transplants. Adjuvant therapy agents interrupt cell metabolism, inhibit cell division, and cause cell death to rapidly proliferating cancer cells and healthy, normal cells in bone marrow, mucosal cells in the digestive tract (including the oral cavity) and hair follicle cells. The results are bone marrow suppression, and immunosuppression with systemic and oral side effects (Archarya, Geist, Powell and Torres-Urquidy, 2019; Parisi and Glick, 2003, Keefe and Bateman, 2019).

A significant concern, especially for older adults, is that immunosuppression increases the potential for sepsis and risk for infections like mucositis, both of which increase the risk for morbidity and mortality. Oral pathogens are commonly isolated in chemotherapy-induced neutropenic fever and sepsis. Other serious oral complications related to chemotherapy and/or radiation include oral bleeding, candidiasis, salivary changes, xerostomia, dysgeusia and medically related osteonecrosis of the jaw (MRONJ). Oral health problems related to poor oral hygiene, tooth decay, and periodontal disease present at the time of diagnosis, or during

treatment or recovery escalate the risk for treatment-related systemic side effects and complications like sepsis and mucositis that increase resource utilization and cost (Paoli et al., 2018; Phonsuphot, Chimruang and Intapa, 2021).

Chemotherapy and radiation are standard therapeutic modalities for patients with solid tumor and blood cancers. Both can weaken the immune system during and for months after cancer treatment is completed (Dellwo, 2021). Chemotherapy, whether administered intravenously, by injection or in pill form, has a cytotoxic systemic treatment, affecting fast-growing tumor cells. Because chemotherapy is unable to differentiate cancer cells from other cells, it affects other body systems, most notably bone marrow cells so that it cannot produce a sufficient number of disease-fighting immune-system cells. Low white blood cell counts, that is, neutropenia, can result.

Chemotherapy is associated with serious immunosuppression-related oral and systemic side effects including mucositis, oral bleeding, candidiasis, salivary changes and sepsis. Radiation therapy also can permanently damage tissue and put patients at risk for oral complications, including xerostomia, mucositis, trismus, severe tooth decay, dysphagia, dysgeusia, and medication-related osteonecrosis of the jaw (MRONJ), the latter of which is also a regular consequence of high-dose bisphosphonate treatment for breast cancer and antiangiogenic therapies to treat multiple myeloma. Radiation therapy also can have an immunosuppressive effect that increases risk for systemic co-morbidities, including sepsis and other serious infections associated with increased morbidity and mortality.

Radiation, although usually not systemic, also has a powerful cytotoxic effect (Kaur and Asea, 2012). It is targeted directly at the tumor or tumor bed. Radiation may have a less damaging on the immune system because it is not systemic. However, radiation does have to travel through areas of healthy cells to get to the tumor, so that those and nearby cells can be affected. Depending on where the tumor is located, radiation may directly damage the immune system. Radiation aimed at the skeletal system or bone marrow can affect the bone marrow similar to the effect of chemotherapy causing neutropenia (Kaur and Asea, 2012). Radiation near the axilla following treatment of a solid breast cancer tumor, can damage lymph nodes which are part of the immune system, leading to risk of infection in the arm and lymphedema (Wei, Lu et al, 2021). Patients with a diagnosis of leukemia, lymphoma, or multiple myeloma scheduled for a stem cell or, bone marrow transplant receive total body radiation (TBI) prior to the transplant (conditioning process). The TBI causes neutropenia and related immunosuppression. Because the radiation conditioning process kills stem cells, patients are temporarily unable to replace the neutrophils that fight infection. As such, older adults are at extremely high risk for oral and systemic infections Finally, after chemo and radiation are completed, a person's immune system

stays suppressed for up to a year (MSKCC,2023). Radiation-induced neutropenia can have a negative effect on overall survival on treatment of solid tumors including cervical (Cao, Yan, Bai, and Gu, 2023), lung, colon, and pancreas (Pim, Kroese, et al., 2021; Kapoor, Collins et al, 2020), head and neck cancer (Dai, Tian, Shui, Li, Wei, 2022)

When cancer spreads, metastatic disease, the whole body may need radiation that causes immunosuppression related neutropenia, a reduction in the body's ability to fight off infections that may lead to sepsis and death. Individuals with metastatic disease who receive 2nd line chemo and/or radiation treatment to reduce tumor size or growth and/or for symptom management (i.e., pain) may experience ongoing immunosuppression and increased risk of local and/or systemic infection.

Sepsis is life-threatening organ dysfunction due to a dysregulated host response to infection (Singer, Deutschman, and Seymour, 2016). Sepsis can delay and/or disrupt cancer therapy, and reduce survival (Riley, Glenny, Worthington, Littlewood, Mauleffinch, Clarkson, McCabe, 2017). Cancer patients are estimated to account for 16.4% of sepsis cases per 1,000 people and are 10 times more likely to develop sepsis than non-cancer patients (Archarya, 2019; Gudiol, Puig, Cuervo, Carratala, 2021). The mortality rate for cancer patients who develop sepsis is 20-40%, and two thirds of sepsis cases occur in people over 60 years of age.

Mucositis is a painful side effect of chemotherapy and/or radiation in which the lining of the digestive system (including the mouth) becomes inflamed, often seen as sores and ulcers in the mouth (NCI, 2020). It occurs in ~40% of patients having chemotherapy; up to 90% of patients with head and neck cancer developed mucositis in the mouth and digestive system (Phonsuphot, et al., 2021).

Elting and Chang (2019), report that the incremental cost of oral mucositis among patients receiving radiation therapy is approximately \$5,000-30,000 and \$3,700 per cycle among patients receiving chemotherapy. The incremental cost of mucositis-related hospitalization among stem cell transplants may exceed \$70,000 per patient. Ongoing management of xerostomia is reported to cost \$40-200 per month (Elting and Chang, 2019).

The primary drivers of cost are hospitalizations, rehospitalizations, parenteral and enteral feedings, febrile neutropenia, and chronic use of interventions like sialagogues. Cancer patients who develop sepsis and/or septic shock, represent a disproportionately high burden in terms of hospital utilization, intensity of resource use, and excess cost of ~\$30,000 per patient, and are estimated to double cancer care costs (Tew et al., 2021).

Medication-related osteonecrosis of the jaw (MRONJ) is a significant oral complication in cancer patients being treated with antiresorptive (IV bisphosphonates) and antiangiogenic medications. Estimates for conservative management of MRONJ are reported to range from \$35,000 to a high of \$70,000 (Elting and Chang, 2019). Clinical manifestations include pain, fistulas, and exposed and extensive destruction of jawbone. Treatment for MRONJ ranges from palliative to intensive hyperbaric oxygen and surgical removal of necrotic jawbone.

A study conducted by Owosho and colleagues (2018) at Memorial Sloan Kettering Cancer Center (MSKCC) among >2000 patients treated for cancer, reported a twelve-fold decrease in the incidence of MRONJ for patients who had pre-treatment dental exams and removal of all dental decay in comparison to those who had no dental pretreatment. These findings are supported by data from other studies (Diopoulos, 2009, Ripamonti, 2009, Bonacina, 2011, Bramanti, 2014). The MSKCC evidence provided support for MSKCC's implementation of a pre-treatment dental care protocol with follow up dental care every three months for 24 months.

It is for the above reasons that we applaud CMS for proposing to clarify Medicare payment for medically necessary dental treatment services that are inextricably linked to covered cancer treatment services. Specifically, we propose that the final Physician Fee Schedule for 2023 encompass:

- Dental and oral examinations performed as part of a comprehensive workup for Medicare beneficiaries with cancer prior to the administration of chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and high-dose bone-modifying agents (antiresorptive therapy).
- Dental and oral examinations performed as part of a comprehensive workup for Medicare beneficiaries with cancer prior to the administration of **radiation therapy**.
- Diagnostic and treatment services (which may include imaging, anesthesia, operating room use, and other ancillary services) to eliminate oral or dental infection prior to or concurrent with the administration of **radiation therapy for the duration of cancer-related immunosuppression**.
- Diagnostic and treatment services (which may include imaging, anesthesia, operating room use, and other ancillary services) to eliminate oral or dental infection prior to or concurrent with the administration of chemotherapy, CAR T-cell therapy, and high-dose bone-modifying agents and for the duration of cancer-related immunosuppression.



Judith Haber, PhD, APRN, FAAN
Executive Director
Professor Emerita

Oral Health Nursing Education and
Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

- Dental and oral examinations as well as diagnostic and treatment services for beneficiaries receiving Medicare-covered treatment for head and neck cancer, whether primary or metastatic, regardless of site of origin, and regardless of initial modality of treatment.

We urge CMS to finalize the proposed payment clarifications for these diagnostic and treatment services due to the crucially important clinical needs they meet and the outcomes improvement they will make possible for beneficiaries battling primary and metastatic disease. In addition, we urge inclusion of appropriate Medicare payment clarification for cancer treatment-related diagnostic and treatment services, such as imaging, anesthesia, and operating room use. Last but by no means least, we urge clarification of Medicare payment for medically necessary dental treatment services that are inextricably linked to **radiation therapy**.

Conclusion

Thank you for this opportunity to provide comments about the Administration's proposal to expand the scope of medically necessary oral and dental services that are eligible for the Medicare program's payment clarification. Improving oral health will improve health, health equity, and quality of life for many of this nation's most underserved seniors. As a result, we stand ready to serve as a continuing resource to CMS as continuing progress is made for a healthier and more equitable America. We also wish to assist in any way needed as the Agency undertakes educational outreach to expand awareness across the dental care community of this vital progress it is making a reality.

If you have additional questions regarding these matters and the comments offered herein, please contact Judith Haber, PhD, APRN, FAAN, jh33@nyu.edu, 203-249-4699.

Sincerely,

A handwritten signature in black ink that reads 'Judith Haber' in a cursive script.

Judith Haber, PhD, APRN, FAAN
Professor Emerita and Executive Director
Oral Health Nursing Education and Practice (OHNEP) Program

References:

1. Acharya, A. Geist, S.-M. R. Y., Powell, V. & Torres-Urquidy, M.H. (2019). Chapter 3: An environmental scan of the various oral-systemic contact points. In Acharya, A. Powell, V., Torres-Urquidy, M.H., Posteraro, R.H., & Thyvalikakath, T.P. (Eds.), *Integration of medical and dental care and patient data* (2nd ed., pp.35-46).
2. American Cancer Society. (2022). *Cancer facts and figures*. Retrieved August 15, 2023 from <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf>.
3. Bonacina R, Mariani U, Villa F, Villa A. Preventive strategies and clinical implications for bisphosphonate-related osteonecrosis of the jaw: a review of 282 patients. *J Can Dent Assoc*. 2011;77:b147. PMID: 22129778
4. Bramati, A., Girelli, S., Farina, G., Dazzani, M. C., Torri, V., Moretti, A., Piva, S., Dimaiuta, M., & La Verde, N. (2015). Prospective, mono-institutional study of the impact of a systematic prevention program on incidence and outcome of osteonecrosis of the jaw in patients treated with bisphosphonates for bone metastases. *Journal of bone and mineral metabolism*, 33(1), 119–124. <https://doi.org/10.1007/s00774-014-0566-x>
5. Cao, H., Yan, H., Bai, S, Gu, B. (2023). Radiation-Induced Lymphopenia and the Survival of Women with Cervical Cancer: A Meta-Analysis. *Journal of Obstetrics and Gynaecology*. 43(1): 1-10. <https://doi.org/10.1080/01443615.2023.2194991>
6. Center for Disease Control (CDC). (2020). *Cancer Data and Statistics*. Retrieved August 15, 2023 from <https://www.cdc.gov/cancer/dcpc>.
7. Dai, D., Tian, Q., Shui, Y., Li, J., Wei, Q. (2022). The Impact of Radiation Induced Lymphopenia in the Prognosis of Head and Neck Cancer: A Systematic Review and Meta-Analysis. *Radiotherapy and Oncology*. 168: 28-36. <https://doi.org/10.1016/j.radonc.2022.01.003>.
8. Damen, P.J.J., Kroese, T.E., van Hillegersberg, R. et al. (2021). The Influence of Severe-Radiation-Induced Lymphopenia on Overall Survival in Solid Tumors: A Systematic Review and Meta-Analysis. *International Journal of Radiation Oncology*. 111 (4): 936-948. <https://doi.org/10.1016/j.ijrobp.2021.07.1695>.
9. Dellwo, A. (2021). How Do Chemo and Radiation Affect the Immune System? *Very Well Health*. Retrieved August 15, 2023, from <https://www.verywellhealth.com/how-strong-is-your-immune-system-after-chemo-and-radiotherapy-affect-the-immune-system?>

10. Dimopoulos MA, Kastiris E, Bamia C, et al. Reduction of osteonecrosis of the jaw (ONJ) after implementation of preventive measures in patients with multiple myeloma treated with zoledronic acid. *Ann Oncol.* 2009;20:117-120. <https://doi.org/10.1093/annonc/mdn554>.
11. Elting, L.S. & Chang, Y. (2019). Costs of oral complications of cancer therapies: estimates and a blueprint for future study. *Journal of the National Cancer Institute*, 53, 116-123. <https://doi.org/10.1093/jncimonographs/lgz010>.
12. Gudiol C., Albasanz-Puig, A., Cuervo, G., & C, K., et al. arratalà, J. (2021). Understanding and managing sepsis in patients with cancer in the era of antimicrobial resistance. *Frontiers in Medicine*, op8, 636547. <https://doi.org/10.3389/fmed.2021.636547>.
13. Ishimaru, M., Matsui, H., Ono, S., Hagiwara, Y., Morita, K., & Yasunaga, H. (2018). Preoperative oral care and effect on postoperative complications after major cancer surgery. *British Journal of Surgery*, 105(12), 1688-1696. <https://doi.org/10.1002/bjs.10915>.
14. Kapoor, V., Collins, A., Griffith, K., et al. (2020). Radiation Induces Iatrogenic Immunosuppression by Indirectly Affecting Hematopoiesis in Bone Marrow. *Oncotarget*. 11(19): 1681-1690. <https://doi.org/10.18632/oncotarget.27564>.
15. Kaur, P. and Asea, A. (2012). Radiation-induced Effects and the Immune System in Cancer. 9. Dellwo, A. (2022). How Do Chemo and Radiation Affect the Immune System. Retrieved August 15, 2023, from *Frontiers in Oncology*. 2:1-21. <https://doi.org/10.3389/fonc.2012.00191>.
16. Keefe, D.M. Keefe and Bateman, E.H. (2019). Potential Successes and Challenges of Targeted Cancer Therapies. *Research Frontiers: Oral Toxicities of Cancer Therapies*. 2019 (53): 25-29. <https://doi.org/10.1093/jncimonographs/lgz008>.
17. Memorial Sloan Kettering Cancer Center (2023). Allogenic Stem Cell Transplant: A Guide for Patients and Caregivers. Retrieved August 15, 2023, from <https://www.mskcc.org/cancer-care/patient-education/allogenic-stem-cell-transplantation>.
18. National Cancer Institute. (2020, September 25). *Cancer statistics*. Retrieved August 3, 2022, from <https://www.cancer.gov/about-cancer/understanding/statistics>.
19. National Cancer Institute. (March 28, 2022). *Cancer disparities*. Retrieved August 3, 2022, from <https://www.cancer.gov/about-cancer/understanding/disparities>.
20. Owosho AA, Liang STY, Sax AZ, Wu K, Yom SK, Huryn JM, Estilo CL. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2018 May;125(5):440-445. <https://doi.org/10.1016/j.oooo.2018.02.003>.

21. Paoli, C.J., Reynolds, M.A., Sinha, M., et al. (2018). Epidemiology and costs of sepsis in the United States—an analysis based on timing of diagnosis and severity level. *Critical Care Medicine*, 46, 1889. PMID:30048332.
22. Parisi, E.P. & Glick, M.G. (2003). Immune suppression and considerations for dental care. *The Dental Clinics of North America*, 47, 709-731. [https://doi.org/10.1016/S0011-8532\(03\)00038-7](https://doi.org/10.1016/S0011-8532(03)00038-7).
23. Phongsuphot, K., Chimruang, J., Intapa, C. (2021). Incidence and Severity of Oral Mucositis in Adult and Elderly Cancer Patients After Receiving Chemotherapy in Uttaradit Hospital. *CM Dental Journal* 42(1):159-172. <https://www.verywellhealth.com/how-strong-is-your-immune-system-after-chemo-and-radiotherapy>.
24. Riley, P., Glenny, A., Worthington, H.V., Littlewood, A., Fernandez-Mauleffinch, L., Clarkson, J.E., McCabe, M.G. (2017) Interventions for preventing oral mucositis in patients with cancer receiving treatment: Cytokines and growth factors. *Cochrane Database of Systematic Reviews* 2017 Nov 28: 11(11):CD011990, <https://doi.org/10.1002/14651858CD011990.pub2>.
25. Ripamonti CI, Maniezzo M, Campa T, et al. Decreased occurrence of osteonecrosis of the jaw after implementation of dental preventive measures in solid tumour patients with bone metastases treated with bisphosphonates. The experience of the National Cancer Institute of Milan. *Ann Oncol*. 2009;20:137-145. <https://doi.org/10.1093/annonc/mdn526>.
26. Saito, H., Watanabe, Y., Sato, K., Kkawa, H., Yoshida, Y., Katakura, A., Takayama, S and Saito, Michio (2014). Effects of professional oral healthcare on reducing risk of chemotherapy-induced oral mucositis. *Support Care Cancer*, 22(11): 2935-2940. <https://doi.org/10.1007/s00520-014-2282-4>.
27. Singer, M, Deutschman, C.S., Seymour, C.W., et al. (2016). The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA*. 315(8): 801-810. <https://doi.org/10.1001.2016.0287./jama>.
28. Tew, M., Dalziel, K., Thursky, K., Krahn, M., Abrahamayan, L., Morris, A.M., & Clarke, P. (2021). Excess cost of care associated with sepsis in cancer patients: Results from a population-based case-control matched cohort. *PLoS ONE*, 16(8), e0255107. <https://doi.org/10.1371/journal.pone.0255107>.
29. Wei, X., Li, F., Jin, S., et al. (2021). Developing and Validating a Prediction Model for Lymphedema Detection in Breast Cancer Survivors. *European Journal of Oncology Nursing*. <https://doi.org/10.1016/jeon.2021.102023>.