



American Association of Oral and Maxillofacial Surgeons

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Dental Recommendations for CY 2025 Review

Submitted via MedicarePhysicianFeeSchedule@cms.hhs.gov

Re: Dental Recommendations for CY 2025 Review

Dear Sir/Madam:

The American Association of Oral and Maxillofacial Surgeons (AAOMS) represents more than 9,000 oral and maxillofacial surgeons (OMSs) in the United States. OMSs specialize in the diagnosis and treatment of disease, injury and defects of both hard and soft tissues of the mouth, face and jaws. Oral and maxillofacial surgery is a surgical specialty of dentistry and one of the few dental specialties whose members routinely perform Medicare-covered procedures. As such, our members have extensive experience with the Medicare program.

AAOMS recognizes the Centers for Medicare & Medicaid Services' (CMS) initiative to extend Medicare coverage for necessary dental services that address oral and dental complications in patients following the direct treatment of head and neck cancer. Patients frequently present with complications extending three years or more post-treatment, not only for head and neck cancers but also for other cancer types. Additionally, a comparable trend may be seen in patients experiencing complications following anti-resorptive drug therapy, for non-cancer-related conditions.

In light of these findings, we offer further information and literature to assist CMS in its evaluation of dental service provisions during the post-treatment period for head and neck cancer patients, including evidence to support the extension of coverage for specific dental services up to five years for those who have received radiotherapy. Coverage may also be extended to include dental services for complications arising from bisphosphonate therapy, which is used in the management of both cancerous and non-cancerous conditions. This expanded coverage for certain dental services is crucial for addressing the broader spectrum of oral health complications associated with various Medicare-covered treatments.

Establishment of a minimum coverage duration of two years for necessary dental services in the post-treatment period for head and neck cancer, extended to a minimum of five years following radiotherapy

As noted previously, AAOMS supports CMS' decision to extend Medicare coverage for certain dental services to address oral or dental complications following the direct treatment of head and neck cancer

(HNC). We also appreciate CMS' consideration of the comprehensive research and evidence from stakeholders, in shaping this policy. This action reflects the agency's dedication to a policy-making process that is both evidence-based and collaborative.

We acknowledge CMS' assessment, as informed by evidence from various commenters, that most oral complications following HNC treatment are likely to occur within the first 24 months after completing direct treatment. However, **we interpret the current evidence and literature as supporting the provision of Medicare coverage for a minimum of two years, with the understanding that some patients may require dental or oral healthcare beyond this period due to delayed or late-onset complications.**

It's important to recognize that the timeline for the emergence of oral or dental complications post-treatment is not uniformly linear and can significantly vary among patients. For instance, a patient who has received radiation therapy to the head or neck may still face a considerable risk for osteoradionecrosis of the jaw (ORN) even a decade after treatment, especially if dental extractions or other invasive oral surgical procedures are required. While the risks for “de novo” or spontaneous ORN and other common oral toxicities might have a specific time frame for what is considered typical in terms of manifestation, the actual occurrence of these complications can vary widely. This variability may be influenced, at least in part, by the unique healthcare needs of the individual patient.

Patients who have undergone treatment for HNC are perpetually at risk for oral or dental complications, although their specific risk significantly vary based on the treatment modality employed. For instance, radiation therapy, with its unique mechanism of injury, tends to cause specific types of oral complications, such as xerostomia (dry mouth), mucositis, osteoradionecrosis and an increased risk of dental caries, due to its direct impact on salivary glands and oral mucosa¹. In contrast, chemotherapeutic modalities, with different mechanisms, often lead to a distinct set of complications, including alterations in taste, increased susceptibility to oral infections and mucosal sensitivity².

As noted in previous comments, radiotherapy plays a significant role in the treatment of head and neck cancer with approximately 80 percent of all HNC patients receiving radiotherapy at least once during the course of their disease³. Osteoradionecrosis or ORN is a recognized late toxicity in patients who have received radiotherapy for head and neck malignancies⁴. Therefore, CMS may wish to consider extending coverage for specific dental services in the post-treatment period for these patients. **There is evidence**

¹ Sroussi, H.Y., Epstein, J.B., Bensouda, R.J., Saunders, D.P., Lalla, R.V., Migliorati, C.A., Heavilin, N. and Zumsteg, Z.S. (2017). Common oral complications of head and neck cancer radiation therapy: mucositis, infections, saliva change, fibrosis, sensory dysfunctions, dental caries, periodontal disease, and osteoradionecrosis. *Cancer Medicine*, 6(12). 298-2931. <http://doi.org/10.1002/cam4.1221>

² PDQ® Supportive and Palliative Care Editorial Board. PDQ Oral Complications of Chemotherapy and Head/Neck Radiation. Bethesda, MD: National Cancer Institute. Updated October 21, 2022. Available at: <https://www.cancer.gov/about-cancer/treatment/side-effects/mouth-throat/oral-complications-hp-pdq>. Accessed January 30, 2024. [PMID: 26389320]

³ Strojan, P., Hutcheson, K.A., Eisbruch, A., Beitler, J.J., Langendijk, J.A., Lee, A.W.M., Corry, J., Mendenhall, W.M., Smee, R., Rinaldo, A. and Ferlito, A. (2017). Treatment of late sequelae after radiotherapy for head and neck cancer. *Cancer Treatment Reviews*, 59. 79-92. <https://dx.doi.org/10.1016/j.ctrv.2017.07.003>

⁴ Caparrotti, F., Huang, S.H., Lu, L., Bratman, S.V., Ringash, J., Bayley, A., Cho, J., Giuliani, M., Kim, J., Waldron, J., Hansen, A., Tong, L., Xu, W., O'Sullivan, B., Wood, R., Goldstein, D. and Hope, A. (2017). Osteoradionecrosis of the mandible in patients with oropharyngeal carcinoma treated with intensity-modulated radiotherapy. *Cancer*, 123(19). 3691-3700. <http://doi.org/10.1002/cncr.30803>

to support Medicare coverage for dental services necessary to address oral or dental complications arising from radiotherapy, extending for a minimum of five years post direct treatment. The five-year time frame for post-radiation complications, especially osteoradionecrosis, is based on an understanding of the delayed onset of radiation-related complications.

Specifically, Caparrotti et al.⁴ studied 1,196 patients with oropharyngeal carcinoma, finding that, although the incidence of ORN is relatively low among patients treated with intensity-modulated radiotherapy (IMRT), it escalates over time. Specifically, the study reports an actuarial rate of ORN of 3 percent at one year, 5 percent at three years and 7 percent at five years post-treatment. Given that oropharyngeal carcinoma is the most prevalent site for squamous cell malignancy in the head and neck region⁴, and IMRT is the standard form of treatment⁴, the long-term impact on the mandible is significant. These effects may not become apparent until several years after treatment, as Caparrotti et al. have indicated.

This evidence supports a more extended coverage timeframe than initially proposed by CMS. A five-year minimum coverage period is more aligned with the literature's findings, reflecting the typical progression and risk factors associated with these complications.

Establishment of a minimum coverage duration of two years for necessary dental services in the post-treatment period for cancer patients treated with anti-resorptive therapy, including bone-modifying agents

As noted previously, AAOMS supports CMS' 2024 initiative to cover dental services necessary for the identification, diagnosis and treatment of oral or dental infections before or during Medicare-covered anti-resorptive therapy for cancer patients. However, it is important to acknowledge that medication-related osteonecrosis of the jaw (MRONJ), a serious and debilitating condition, is a known risk associated with anti-resorptive therapy, including the use of bone-modifying agents⁵. This therapy, often used in the management of cancer, can interfere with the bone remodeling process, potentially leading to the death of bone tissue in the jaw⁵. MRONJ often manifests as pain, swelling, infection and exposed bone in the jaw area⁵.

In consultation with our panel of experts, we have identified clinical evidence suggesting a potential for delayed onset of MRONJ in certain cancer patients. Oral and maxillofacial surgeons have observed cases where patients sought treatment for dental complications up to three years post-treatment, especially in those with multiple myeloma and metastatic bone lesions. This is supported by a prospective cohort study which found that the risk of zoledronic acid, a bisphosphonate derivative, causing osteonecrosis of the jaw in people with cancer in their bones increases in the years following treatment⁶. Specifically, one percent after a year of being on the drug, two percent after two years and three percent after three years.

⁵ American Association of Oral and Maxillofacial Surgeons. (2022). Medication-related osteonecrosis of the Jaw-2022 update (position paper). Available at: https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/mronj_position_paper.pdf

This observation aligns with findings from Van Poznak et al.⁶, a prospective cohort study of 3,491 people. The study revealed an increasing risk of osteonecrosis of the jaw associated with zoledronic acid, a bisphosphonate derivative, in patients with bone-involved cancers. Specifically, the cumulative incidence was found to be about 1 percent after one year of medication use, 2 percent after two years and approximately 3 percent after three years. We note this study is not specific to HNC but rather includes patients with bone metastases from a solid tumor, multiple myeloma and other malignant neoplasms for which IV bisphosphonate has clinical indications in the treatment of metastatic bone disease. Van Poznak et al. identified the predominant cancer types in their study as breast, prostate and lung, with 423 participants (12.1 percent) categorized as having “other neoplasms.” The authors concluded that the risk of MRONJ increases over time post-treatment and is influenced by several factors, including the patient’s oral health, the type of cancer and the frequency of dosing. This highlights the multifactorial nature of MRONJ risk, underscoring the importance of individualized assessment and management, as well as an extended window of Medicare coverage for cancer patients receiving anti-resorptive therapy, including treatment with bone-modifying agents.

For cancer patients undergoing dental extractions or similar invasive oral surgeries post-treatment, a systematic literature review by Schwech et al.⁷ highlights a significantly elevated risk of developing MRONJ. Specifically, the review indicates that patients treated with high-dose bisphosphonate and denosumab face a risk nearly five times higher of developing MRONJ following tooth extraction. Furthermore, the study notes that the occurrence of MRONJ can manifest up to three years after the extraction.

The development of MRONJ becomes increasingly likely with prolonged exposure to anti-resorptive therapies. Notably, the impact of bisphosphonate medications can linger for an extended period. Furthermore, concomitant medical issues and their associated treatments can intensify these risks over time. **Current literature supports the extension of Medicare coverage to include certain dental services furnished post-anti-resorptive therapy, when used in the treatment of cancer for at least two years following treatment.** CMS may consider this coverage be maintained for at least two years post-treatment to adequately address the potential delayed onset and progression of MRONJ in cancer patients treated with anti-resorptive therapy, including bone-modifying agents.

Extension of Medicare coverage at a minimum duration of two years for dental services post-anti-resorptive therapy in non-cancer patients

AAOMS recognizes the significant strides CMS has made towards covering dental services to address oral or dental complications in the context of anti-resorptive therapy for cancer patients. The literature supports extending this consideration to non-cancer patients undergoing similar treatments. MRONJ, a critical concern linked with anti-resorptive therapies including bone-modifying agents, poses risks irrespective of the underlying condition – cancerous or non-cancerous.

⁶ Van Poznak, C.H., Unger, J.M., Darke, A.K., Moinpour, C., Bagramian, R.A., Schubert, M.M., Hansen, L.K., Floyd, J.D., Dakhil, S.R., Lew, D.L., Wade, J.L., Fisch, M.J., Henry, L., Hershman, D.L., and Gralow, J. (2021). Association of osteonecrosis of the jaw with zoledronic acid treatment for bone metastases in patients with cancer. *JAMA Oncology*, 7(2). 246-254. <http://doi.org/10.1001/jamaoncol.2020.6353>

⁷ Schwech, N., Nilsson, J., and Gabre, P. (2023). Incidence and risk factors for medication-related osteonecrosis after tooth extraction in cancer patients – A systematic review. *Clinical and Experimental Dental Research*, 9(1). 55-65. <http://doi.org/10.1002/cre2.698>

Clinical evidence and expert consultations suggest that the delayed onset of MRONJ is not exclusive to cancer therapies. In other words, MRONJ can occur irrespective of the underlying condition for which the medication is prescribed. The risk factors, such as prolonged exposure to bisphosphonates and accompanying medical treatments, are also prevalent in non-cancer patients receiving anti-resorptive therapy. This is corroborated by studies like those conducted by Van Poznak et al.⁶ and Schwech et al.⁷, which, although focused on cancer patients, provide insight into the extended risk period for MRONJ associated with bisphosphonate use.

However, we recognize the risk associated with MRONJ development is statistically higher in cancer patients than non-cancer patients⁵. While Schwech et al. underscores that cancer patients treated with high-dose bisphosphonate and denosumab face a statistically higher risk of developing MRONJ following dental extractions, it is essential to recognize that the severity of this condition in non-cancer patients can be equally significant. The occurrence of MRONJ, as indicated by Schwech et al., can manifest up to three years post-extraction, highlighting the prolonged risk period irrespective of the underlying medical condition.

This acknowledgment suggests similar dental and oral treatment approaches for both cancer and non-cancer patients affected by MRONJ. Despite the variance in statistical risk, the potential severity and impact on quality of life in non-cancer patients may warrant the same level of attention and access to comprehensive dental care as provided to those with cancer. Therefore, CMS may wish to consider a uniform approach in extending Medicare coverage for necessary dental services post-treatment for all patients at risk of MRONJ, regardless of their cancer status.

Given the shared risk profile between cancer and non-cancer patients treated with these therapies, CMS may consider a similar extension of Medicare coverage for necessary dental services post-treatment. Specifically, CMS may consider extending coverage for dental services necessary to address oral or dental complications post-anti-resorptive therapy, including bone-modifying agents, for a minimum duration of two years for non-cancer patients, aligning with the proposed coverage for cancer patients. This approach ensures a comprehensive and equitable treatment plan for all individuals at risk of MRONJ, regardless of their primary diagnosis.

Lastly, there is an inextricable risk of the development for severe dental and oral complications, such as ORN/MRONJ, in patients who have undergone the specific treatments for which Medicare has permitted coverage and payment for linked dental services. Once patients receive these treatments, they are perpetually at risk for developing such complications.

The provision of dental services is not merely adjunct but is fundamentally linked to the management of the Medicare-covered medical condition. However, the manifestation of dental or oral complications following these medically invasive procedures often occurs outside the immediate treatment window. This delayed onset may call for reconsideration or reassessment of the current Medicare coverage to ensure that it aligns with the long-term healthcare needs of these patients.

Thank you for your consideration of these comments. Please contact Patricia Serpico, AAOMS Director of Health Policy, Quality & Reimbursement, with any questions at 800-822-6637, ext. 4394 or pserpico@aaoms.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark A. Egbert, DDS, FACS'.

Mark A. Egbert, DDS, FACS
AAOMS President

A handwritten signature in black ink, appearing to read 'Adam S. Pitts, DDS, MD, FACS'.

Adam S. Pitts, DDS, MD, FACS
Chair, AAOMS Committee on Healthcare Policy, Coding & Reimbursement