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American Association of Oral and Maxillofacial Surgeons

9700 W. Bryn Mawr Ave.
Rosemont, IL 60018-5701

847-678-6200
800-822-6637
fax 847-678-6286

AAOMS.org

Paul J. Schwartz, DMD
President

Karin Wittich, CAE
Executive Director

January 30, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Dental Recommendations for CY 2024 Review

Submitted via MedicarePhysicianFeeSchedule@cms.hhs.gov

Re: Dental Recommendations for CY 2024 Review

Dear Sir/Madam:

The American Association of Oral and Maxillofacial Surgeons (AAOMS) appreciates the opportunity to recommend additional clinical scenarios for CMS' consideration of medically necessary dental services in advance of the CY 2024 Medicare Physician Fee Schedule Proposed Rule.

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 supports CMS' efforts to ensure access to medically necessary dental services for scenarios in which such services are both clinically advisable to eliminate a dental/oral infection and integral to overall clinical success. The AAOMS Committee on Healthcare Policy, Coding and Reimbursement has developed the following recommendations based on current standards of care for patients presenting with diagnoses related to head and neck cancer or medication-related osteonecrosis of the jaw as well as those requiring total joint replacements and cardiovascular surgery. We hope to work with CMS on the recommendation of medically necessary dental services.

Recommendations for additional clinical scenarios for CY 2024

Head and neck cancer: Consideration of Medicare payment for post-radiation dental services

Head and neck cancer (HNC) represents approximately 6 percent of all malignancies, with over 500,000 new cases diagnosed worldwide each year[1]. Radiotherapy continues to play a significant role in the treatment of HNC, with approximately 80 percent of all HNC patients receiving radiotherapy at least once during the course of their disease[2]. Oral complications related to HNC treatment, whether chemotherapy, radiotherapy or combination treatment with concurrent systemic agents are well documented[2,3]. Oral toxicities resulting from HNC treatment include, but are not limited to oral

mucositis, hyposalivation, dysphagia, osteoradionecrosis and radiation-related caries [2,3,4,5,6]. These oral toxicities may be acute (developing during active treatment) or late onset (manifesting several months after treatment is complete) with some latent complications of radiotherapy linked to permanent tissue damage[2,7]. In addition, current data show approximately 30 percent of HNC patients develop radiation caries within 12 months following completion of radiotherapy[1].

Outside of the deterioration of dental and periodontal health, the management of long-term chronic effects of radiotherapy, such as mucosal pain and recurrent infection, salivary gland dysfunction and osteoradionecrosis contribute significantly to disease burden and national health care costs as the economic consequences of preventing and managing oral complications of cancer therapy can be substantial[8,9].For example, incremental costs for the conservative management of osteoradionecrosis ranges between approximately $4,000-$35,000 and between $5,000-$30,000 for management of oral mucositis in cancer patients undergoing radiotherapy[9]. Elting & Chang attribute this high cost both to the resource-intensive settings in which management of oral complications typically takes place and the complex needs of cancer patients including enteral and parenteral feedings, febrile neutropenia and frequency hospitalizations[8].

The National Cancer Institute recommends that dental and oral health professionals be considered part of the cancer care team[10]. This recommendation is supported by contemporary scientific literature which indicates that effective management of the complex oral health needs of HNC patients requires a multidisciplinary approach that includes dental specialists and other oral health professionals[10,11,12]. In general, medical standards of cancer care include routine follow-up, supplemental or secondary treatments for symptom management and long-term management of overall health. It stands to reason that oral and dental care should be incorporated into clinical cancer care protocols for pre-, intra- and post-treatment, especially for diagnoses or therapies known to cause oral complications, whether acute or chronic. Access to medically necessary dental services post radiation may positively impact patient quality of life and mitigate some of the resource-intensive treatment of advanced oral sequalae of HNC.

AAOMS supports CMS' decision to allow Medicare Parts A and B payment for a dental or oral examination performed as part of a comprehensive workup, as well as the medically necessary diagnostic and treatment services to eliminate an existing or potential oral or dental infection, prior to or contemporaneously with Medicare-covered treatments for head and neck cancer (HNC) beginning in CY 2024. However, **we encourage CMS to consider the expansion of Medicare coverage to include medically necessary dental services occurring postradiotherapy for beneficiaries with a diagnosis of head and neck cancer.**

Head and neck cancer: AAOMS comments on definition and policy scope

In the CY 2023 Medicare Physician Fee Schedule Final Rule, CMS indicated a possible need to further refine and/or clarify certain aspects of CY 2024 policy changes regarding HNC, including the term "head and neck cancer" itself. AAOMS agrees with CMS that this term encompasses several conditions that often require multimodal therapies, and we do not believe this is inappropriate or unclear.

HNC statistics indicate the majority of cancers of the head and neck region are squamous cell carcinomas originating in the mucosal surfaces of the oral cavity, pharynx and larynx[7]. HNC may also arise in the salivary glands or paranasal sinuses and nasal cavity, although these manifestations are less common[7]. HNC typically originates within one of these primary sites although occasionally, it is secondary in nature[7,13]. There is clinical evidence that HNC can be locally advanced or metastatic[7,13].

Broadly speaking however, whether primary squamous cell carcinoma, metastatic or metachronous, clinical diagnostic and therapeutic approaches for HNC remain fundamentally similar[13]. As outlined above, treatment modalities for HNC have been historically linked to both acute and chronic oral toxicities which may cause damage to bony structures, tissues and salivary glands, both directly and indirectly. Therefore, regardless of the anatomical structure the cancer originates in or metastasizes to, HNC-related diagnoses will inevitably involve therapies that require the management of oral or dental sequelae.

AAOMS supports coverage for a dental or oral examination performed as part of a comprehensive workup, as well as the medically necessary diagnostic and treatment services to eliminate an existing or potential oral or dental infection, prior to or contemporaneously with Medicare-covered treatments for head and neck cancer whether primary or metastatic, regardless of where the cancer originated. Specifically, AAOMS encourages CMS to consider expanding this policy to include medically necessary dental services rendered post-radiation. AAOMS would be pleased to provide additional information and/or guidance on the post radiation period, upon request.

Medication-related osteonecrosis of the jaw

Medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of antiresorptive and/or antiangiogenic drug therapy. The medications associated with MRONJ, including bisphosphonates and denosumab are commonly prescribed in the management of certain cancer-related conditions, metabolic bone diseases and osteoporosis[14]. The link between osteonecrosis of the jaw and these medications has been long-studied, however proving causality of any medication-related complication is challenging from an epidemiologic perspective. MRONJ is a rare entity, multifactorial in nature, and patients with the same clinical presentation exist who have not been exposed to an antiresorptive medication[14].

To estimate the risk for medications associated with MRONJ, the primary parameter to be considered is the therapeutic indication for treatment (e.g., malignancy or osteoporosis/osteopenia). The data suggest that antiresorptive medications, such as bisphosphonates, denosumab and certain antiangiogenics are associated with an increased risk for developing MRONJ[14]. The risk of MRONJ is considerably higher in the malignancy group (<5%) than in the osteoporosis group (<0.05%). The current literature reaffirms that the risk of MRONJ is significantly greater in cancer patients receiving antiresorptive therapy compared to patients receiving antiresorptive therapy for osteoporosis[14]. We note that current data are insufficient to identify other medications as risk factors for developing MRONJ[14]. However, given the poly-pharmaceutical management of cancer patients, combined with the fact that cancer and immunosuppression are risk factors for MRONJ without exposure to antiresorptive agents, identifying a single medication as being the etiologic agent for MRONJ seems unlikely in case reports or mini-case series.

The prevalence of MRONJ within populations exposed to the medications listed above has not been found to be statistically significant[15] and, from a clinical standpoint, prevention of MRONJ is the gold standard. However, for those patients diagnosed with MRONJ, management of the complication may include both medical and surgical therapies[14,15]. Certain services, such as debridement of necrotic bone, sequestration or segmental or marginal resection of the jaws are historically considered for payment under Medicare, when deemed medically necessary. However, other integrally related dental services which may include, but are not limited to tooth extractions, alveoloplasty and removal of exostosis

generally are not. Inherently, current Medicare coverage limitations may work to exacerbate existing barriers in accessing medically necessary and essential dental services in the treatment of osteonecrosis and in the management of certain malignancies and metastatic bone disease.

As such, **AAOMS encourages CMS to consider coverage for dental or oral examinations as part of a comprehensive workup, as well as the medically necessary diagnostic and treatment services to eliminate an oral or dental infection for Medicare beneficiaries diagnosed and being treated for medication-related osteonecrosis of the jaw.**

Total joint arthroplasty

Literature and scientific data on the effects of perioperative oral/dental health on patient outcomes following total joint replacement is mixed. An industry-wide consensus on pre-surgical dental protocols for orthopedic surgery has yet to be reached. However, AAOMS believes there is evidence that supports the provision of perioperative dental examination and diagnostic and therapeutic services prior to total joint replacement surgery, specifically primary total hip (THA) and knee (TKA) arthroplasty. According to Young et al., the most consequential and costly postoperative complication is peri-prosthetic joint infection, which continues to be the leading cause of chronic postsurgical pain and functional limitation[16]. Peri-prosthetic joint infections increase burden on the health care system[16]. In fact, there is data that shows peri-prosthetic joint infections nearly triple the cost of a total joint arthroplasty procedure[17].

The goal with peri-operative oral and dental management is to eliminate oral flora bacteremia that may occur post joint replacement procedure that may colonize and infect the prosthetic joint. The bacteremia can be spontaneous with patients that have advanced periodontal disease with large bacterial bioload. Bacteremia can also be caused by invasive dentoalveolar procedures, such as tooth extraction performed soon after the arthroplasty procedure. Therefore, identification of patients who may fall into this category would be highly beneficial to prevent postoperative complications such as infection. Such pre-operative diagnostic and therapeutic management would promote more rapid healing and quicker rehabilitation, particularly if an unexpected dental procedure could be avoided in the early postoperative phase. Of particular concern is the fact that oral health disparities disproportionately affect members of racial or ethnic minority groups, most pronounced in populations aged 65 and older[16]. In this age group, approximately 19 percent of patients are edentulous and more than half present with moderate to severe periodontal disease[16]. Given the prevalence of total joint arthroplasty in the Medicare population, this is significant.

As such, **AAOMS encourages CMS to consider coverage for dental or oral examinations as part of a comprehensive workup, as well as the medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to or contemporaneously with total joint arthroplasty procedures.**

Cardiac surgery

Similar to total joint arthroplasty procedures, there lacks consensus in the scientific literature on prophylactic dental diagnostic and surgical treatment prior to cardiovascular surgery. The current standard of care does not absolutely require dental evaluation prior to certain cardiac procedures, which may in part be because such procedures are often more urgent or emergent, rather than elective. Nonetheless, compelling scientific evidence exists to expand Medicare coverage to include dental/oral examinations and necessary treatments to identify and eradicate dental/oral infection prior to, or

contemporaneously with certain cardiac procedures, as cited by CMS in the CY 2023 Medicare Physician Fee Schedule Final Rule and finalized for CY 2023.

As expressed in previous comments, AAOMS supports CMS' decision to allow Medicare Parts A and B payment for a dental or oral examination performed as part of a comprehensive workup, as well as the medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to or contemporaneously with cardiac valve replacement or valvuloplasty procedures.

Much of the scientific literature is inconclusive as to whether pre-operative dental treatments impact postoperative surgical outcomes in cardiovascular surgery, including cardiac valve procedures[18]. However, a systematic literature review by Cotti et al. found that, based on expert opinion there is general agreement on the need for screening and treatment or oral/dental infections in patients who are to undergo cardiac surgery, although no standardized clinical guidelines or protocols exist to outline the screening process, in terms of both dental treatment options and timing of such procedures in relation to the planned cardiac intervention[19]. The authors convened an expert panel (including cardiologists, cardiac surgeons and dental specialists) to disseminate current data and establish a consensus on early screening and resolution of dental or periodontal infections prior to cardiac surgery[19]. This process resulted in standardized protocol for evaluating oral infections and dental treatments for cardiac patients to be used in the interventional preparation phase by both dental and cardiac teams[19]. The authors note however, the lack of scientific evidence on the risk-to-benefit ratio for perioperative dental treatment in patients undergoing cardiovascular surgery[19]. Specifically, Cotti et al. highlights the need for communication and care coordination between medical and dental providers and care teams in determining the most appropriate treatment protocols for complex cardiac patients [19]. We find this systematic and detailed approach to perioperative dental treatment compelling in relation to patients requiring cardiovascular surgery.

As such, **AAOMS encourages CMS to consider extending Medicare coverage to include all cardiovascular procedures, as the mitigation of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures.**

Recommendations of CDT©[1] codes that describe medically necessary dental services

In general, the dental services being recommended for CMS' consideration are those routinely performed in the management of patients presenting with certain oral and maxillofacial pathology, such as cellulitis and abscess of the face, mouth and/or neck; inflammatory conditions of the jaws including osteoradionecrosis; osteomyelitis; drug-induced osteonecrosis; and all other oral sequelae of cancer treatment. The recommended dental services also include those routinely performed for patients requiring total joint arthroplasty or cardiovascular surgery, when deemed clinically appropriate.

These recommendations are meant to provide a framework of the types of dental services that may be clinically advisable in relation to the above listed clinical scenarios. We wish to clarify that, not all services may be appropriate in every circumstance. For example, a patient undergoing bisphosphonate

[1] *CDT© is a registered trademark of the American Dental Association*

drug therapy may be at higher risk of developing osteonecrosis of the jaw, the onset of which may be triggered by invasive dentoalveolar surgery such as tooth extraction. Therefore, AAOMS believes that clinical discretion and care coordination between the dental or oral health specialist and the medical physician, as indicated by CMS is essential to ensure the clinical appropriateness of dental treatment in any given clinical scenario.

The following dental diagnostic and therapeutic services are recommended for CMS' consideration of Medicare payment for CY 2024 for the clinical scenarios previously described:

- **Clinical oral evaluations, where essential for detection of dental/oral infection, as described by CDT© codes D0140, D0150, D0160, D0180, D9310, D9410, and D9420**

  Many of the patients captured in the clinical scenarios thus far described have significant health issues and often present with comorbidities that impact treatment and disease management. Many of these evaluations are lengthy and require information and coordination between several physicians or other qualified health care professionals.

- **Extractions and/or coronectomy, when indicated for eradication of dental/oral infection as described by CDT© codes D7140, D7210, D7220, D7230, D7240, D7241, D7250, and D7251.**

  Extractions should be performed when indicated, specifically for teeth that cannot be managed with non-surgical treatment. Medicare coverage considerations should include D7220, D7230 and D7240 as periodontal pockets can be involved in certain pathologies.

- **Alveoloplasty or ridge preparation procedures as described by CDT©^ codes D7310, D7311, D7320 and D7321.**

  There are clinical scenarios in which an alveoloplasty is required in conjunction with extractions as a preventative measure to reduce the risk of postoperative infection as well as to facilitate future normal function with/without prosthesis placement. If alveolar anatomy is large and may prevent intubation, this may be considered medically necessary. Specific to head and neck cancer patients, such services may be required if the patient presents with chronic ulcerations of the oral cavity.

- **Excision of bone tissue, including exostosis and torus palatinus/mandibularis as described by CDT© codes D7471, D7472, D7473 and D7485.**

  These services may also be considered preventive, in certain circumstances to reduce the risk of postoperative infection. In other clinical scenarios, such services may be required to facilitate prosthesis placement ensuring adequacy of function and nutrition, which is vital to healing from any invasive dental surgical procedure.

- **Excision of benign soft tissue lesions as described by CDT© codes D7410, D7411, D7412**.

  If identified as part of a comprehensive oral examination or workup, these procedures may aid in the determination of the disease process and facilitate appropriate treatment planning.

- **Excision of benign intra-osseous lesions as described by CDT© codes D7450, D7451, D7460, D7461.**

  Similar to benign soft tissue lesions as outlined, there are clinical scenarios in which these procedures aid in the determination of the disease process, as well as facilitate appropriate treatment planning.

- **Surgical incision and drainage procedures as described by CDT© codes D7510, D7511, D7520 and D7521.**

  Under certain circumstances, these procedures are medically necessary as an active infection would preclude other dental surgical services, in addition to posing a significant threat to the patient's airway, depending on severity of the infection. Additionally, these procedures aid in establishing a basis for patient health and prevent further bacterial dissemination through the bloodstream.

- **Periodontal and the partial ostectomy/sequestrectomy for removal of non-vital bone as described by CDT© codes D4355 and D7550, respectively.**

  These procedures help to establish a healthy tissue baseline, as well as decrease the bioload of bacteria in patients presenting with advanced periodontal disease.

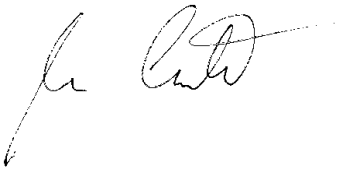
- **Surgical removal of foreign body from mucosa, skin, subcutaneous alveolar tissue or the musculoskeletal system as described by CDT© codes D7530 and D7540.**

  Primarily, these procedures are required for the elimination or eradication of disease and/or infection.

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

Sincerely,

Paul J. Schwartz, DMD
AAOMS President



Joshua E. Everts, DDS, MD, FACS
Chair, AAOMS Committee on Healthcare Policy, Coding & Reimbursement

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