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### American Association of Oral and Maxillofacial Surgeons

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September 5, 2023

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1784-P P.O. Box 8016 Baltimore, MD 21244-8016

Submitted online via <u>www.regulations.gov</u>

Re: File Code CMS-1784-P Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies

Dear Administrator Brooks-LaSure:

The American Association of Oral and Maxillofacial Surgeons (AAOMS) represents more than 9,000 oral and maxillofacial surgeons (OMSs) in the United States. AAOMS commends CMS on efforts to improve access to high-quality and affordable health care, specifically, the proposals aimed at ensuring Medicare beneficiaries have access to medically necessary and essential dental services. We appreciate the opportunity to comment on the proposed 2024 revisions to the Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies, published in the August 7, 2023, Federal Register (Vol. 88, No. 150, pages 52262-53197).

#### CY 2024 Medicare Physician Fee Schedule rate setting and conversion factor

Medicare providers stand to face another round of significant payment cuts beginning January 1, 2024. In the proposed rule, CMS estimates that the CY 2024 Medicare Physician Fee Schedule (MPFS) conversion factor — the basic starting point for calculating Medicare payments — will be \$32.7476, representing nearly a 3.4 percent decrease from the \$33.8872 CF for 2023.

The Medicare payment system has been devalued through recurring and drastic payment cuts year after year. CMS's proposal fails to account for the economic factors that have dramatically increased practice costs in the past year. The CY 2024 MPFS proposed rule jeopardizes the already-strained financial stability of many physician practices, especially small independent practices. **AAOMS urges CMS and HHS not to finalize the proposed payment cuts and to work with Congress to fundamentally reform the MPFS to ensure reimbursement stability for Medicare providers moving forward.** 

## <u>Proposals and request for information on Medicare Parts A and B payment for dental services</u>

Dental services linked to Medicare-covered cancer treatments

Oral and maxillofacial surgery is the surgical specialty of dentistry and one of the few dental specialties whose members perform Medicare-covered procedures that range from the removal of cancerous tumors in the mouth/jaw area and the extraction of infected teeth to preparing a patient's jaw for radiation cancer treatment to repairing tissue or bones in the facial area following trauma. As such, our members have extensive experience with the Medicare program.

AAOMS supports efforts to expand Medicare coverage for certain oral and maxillofacial surgery services<sup>1</sup> that the association considers to be "medically necessary" or "essential" because they are integral in the management of certain acute conditions. We believe such services include the evaluation and definitive treatment of infections of the head and neck prior to, or concurrently with certain therapies used to treat cancer.

AAOMS appreciates CMS's consideration of the serious, dental related complications — specifically medication-related osteonecrosis of the jaw (MRONJ) — that can result from certain immunosuppressive cancer treatments, such as high-dose antiresorptive and/or antiangiogenic drug therapy. The data suggest that antiresorptive medications, such as bisphosphonates, denosumab and certain antiangiogenics are associated with an increased risk for developing MRONJ², which can complicate cancer treatment and lead to reduced survival rates post-treatment³.

As CMS has acknowledged, patients with existing dental disease pose the greatest risk for developing MRONJ secondary to bone-modifying therapy<sup>3</sup>. From a clinical standpoint, prevention of MRONJ is the gold standard and AAOMS has long emphasized<sup>2</sup> the importance of a multidisciplinary, coordinated approach that includes pretreatment dental management in minimizing the risk of MRONJ. As such, AAOMS supports CMS's proposal to expand Medicare coverage and payment for dental examinations prior to, as well as diagnostic and treatment services to eliminate an oral or dental infection prior to or at the same time as, the administration of high-dose bone modifying agents. AAOMS further supports the expansion of similar coverage of dental diagnostic and therapeutic services, furnished prior to or concurrently with other Medicare-covered cancer treatments including chemotherapy and chimeric antigen receptor (CAR) T-cell therapy.

Consistent with the policy changes finalized in the CY 2023 Medicare Physician Fee Schedule final rule<sup>4</sup>, **AAOMS supports CMS's proposal to allow Medicare payment for services that are ancillary to, or provided in conjunction with, covered dental services such as X-rays, administration of anesthesia, use of the operating room and other facility services for the above listed clinical scenarios.** AAOMS continues to believe such services represent necessary diagnostic, clinical and procedural considerations that must be determined by the surgeon on a case-by-case basis.

Proposal to clarify coverage and payment for dental services linked to covered treatment of head and neck cancer

AAOMS wishes to commend CMS on its proposal to clarify coverage and payment for medically necessary dental services linked to Medicare-covered treatments for head and neck cancer (HNC). As noted, the term "head and neck cancer" refers to a group of cancers that originate in various

areas of the head and neck, with the mucosal surfaces of the oral cavity, pharynx and larynx being most common<sup>5</sup>. These cancers are often grouped together because they share common risk factors, symptoms and treatment approaches.

Clinical evidence supports that HNC may be locally advanced or metastatic<sup>5,6</sup>. Although, as acknowledged by CMS diagnostic and therapeutic treatment approaches to HNC remain fundamentally similar whether primary, metastatic or metachronous<sup>6</sup>.

As such, AAOMS supports CMS's proposal to clarify that Medicare payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as for the medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to the initiation of, or during, treatments for head and neck cancer, whether primary or metastatic, regardless of site of origin, and regardless of initial modality of treatment.

Request to consider Medicare payment for post-radiation dental services

AAOMS reiterates its request for CMS to consider coverage for certain post-radiation dental services linked to HNC. As noted in previous comments, radiotherapy plays 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<sup>7</sup>.

Oral toxicities related to HNC treatment, whether radiotherapy, chemotherapy or combination treatment with concurrent systemic agents are well documented and include, but are not limited to, mucositis, hyposalivation, dysphagia, osteoradionecrosis and radiation-related caries<sup>7,8,9,10,11</sup>. 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<sup>5,7</sup> as well as damage to bony structures, tissues and salivary glands. In addition, current data show approximately 30 percent of HNC patients develop radiation caries within 12 months following completion of radiotherapy<sup>12</sup>.

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<sup>13,14</sup>. 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<sup>14</sup>. 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<sup>14</sup>.

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. 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. As such, AAOMS encourages 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.

Consideration of dental services prior to radiation therapy in the treatment of head and neck cancer as inextricably linked

As noted above, radiation therapy or radiotherapy remains a standard form of treatment for many tumors of the head and neck region<sup>7,15</sup>. Oral complications, as well as potential damage to the hard and soft tissues of the head and neck resulting from cancer treatment — including radiotherapy — are well documented.

Radiotherapy can lead to a decrease in cellular proliferation rate, apoptosis<sup>15</sup> and neutropenia<sup>16</sup>, all of which may significantly increase the patient's susceptibility to illness and infection<sup>16</sup> during treatment and in the post-radiation period. Although, exactly how radiotherapy affects the immune system may be dependent on several factors, including total radiation dose, the part of the body being irradiated, how much of the body is being treated and whether radiation is administered in conjunction with chemotherapy<sup>16</sup>. Clinical evidence indicates the cell-damaging properties of radiation therapy are nonspecific<sup>15</sup>, meaning cells and tissues in and around the treatment area can be affected. For HNC, this may include the oral mucosa, salivary glands, maxillary and mandibular bone, teeth and/or masticatory muscles<sup>15</sup>.

In general, pre-radiation dental treatment aims to eliminate or prevent infection and to minimize the risk and/or severity of radiation-related oral toxicities including oral mucositis, oropharyngeal candidiasis, xerostomia and radiation-related caries<sup>17</sup>. In addition, this dental treatment may also include necessary oral surgery (extraction(s) and/or preprosthetic surgery) done prior to the exposure to high dose radiotherapy. This would help avoid the potential healing difficulties that have been well documented related to the reduced blood supply that results in the irradiated areas. While some of the side effects of radiotherapy cannot be avoided, there is some research to suggest pre-radiation dental management may be a factor in mitigating the risk of developing serious complications, such as osteoradionecrosis<sup>15,18,19</sup>.

We note it has been a longstanding CMS policy<sup>20</sup> to permit Medicare payment for extractions done to prepare the jaw for radiation treatment of neoplastic disease. However, pre-radiation dental treatment protocols vary<sup>17</sup> and invasive procedures such as tooth extraction may not be indicated<sup>21</sup> for certain patients, depending on several factors including, but not limited to, planned radiation schedule, dosage and the type of radiotherapy to be administered. It stands to reason that, in such cases there may be other diagnostic and therapeutic dental services necessary to identify, diagnose and treatment an oral or dental infection that may be more appropriate. A 2022 systematic review and meta-analysis<sup>22</sup> found only weak correlation between pre-radiation tooth extractions and increased risk for osteoradionecrosis development however, it is still the case that invasive surgical procedures to eliminate or prevent dental/oral infections prior to initiating radiotherapy may not be clinically indicated in certain circumstances.

As such, AAOMS encourages CMS to extend coverage to examinations, as well as other diagnostic and therapeutic dental services furnished to identify, diagnose and treat oral or dental infections prior to the initiation of Medicare-covered radiation treatments for head and neck cancer.

Request to align coverage and payment policies to include ASCs

AAOMS continues to believe that access to procedures described above, as well as those finalized under the Medicare Physician Fee Schedule CY 2023 final rule is often critical to successful outcomes for patients with certain acute conditions. As OMSs routinely evaluate and safely treat patients ranging in complexity across a variety of care settings, AAOMS supports Medicare coverage of these services in either the inpatient or outpatient hospital setting.

Under the CY 2024 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule<sup>23</sup>, CMS has proposed to assign 229 dental procedure codes to clinical Ambulatory Payment Classifications (APCs). This would allow hospital outpatient departments to receive facility payment for dental services that meet Medicare coverage and payment criteria, if finalized. We believe this proposal supports CMS's dental coverage policies finalized in the CY 2023 MPFS final rule, as well as those outlined in the CY 2024 MPFS proposed rule.

In the CY 2024 OPPS/ASC CMS proposed rule, CMS further proposes to add 26 dental surgical services to the ASC Covered Procedures List, identifying them as safe to perform and payable by Medicare in the ASC setting. **AAOMS encourages CMS to align the coverage and payment policies under the MPFS with these proposals.** 

As it stands, dental services performed to identify, diagnose and treat oral or dental infections prior to or contemporaneously with Medicare covered organ transplant surgery, cardiac valve replacement and valvuloplasty procedures, as well as covered treatments for head and neck cancer beginning in 2024 and the proposals outlined in the 2024 MPFS proposed rule, Medicare coverage is limited to hospital inpatient and outpatient settings. Services to eliminate an oral or dental infection may include, but are not limited to, the extraction of teeth, intraoral and extraoral incision and drainage procedures and partial ostectomy/sequestrectomy for removal of non-vital bone, all of which are surgical procedures CMS proposes to allow payment when furnished in the ASC, providing all Medicare coverage and payment criteria are met. Permitting Medicare payment in the ASC for inextricably linked and medically necessary dental surgical services furnished to identify, diagnose and treatment oral or dental infections prior to, or at the same time as, select covered medical procedures would help to ensure the consistent application of Medicare dental coverage and payment policies across care settings.

Further, we believe that ASCs have the potential to mitigate many of the external pressures that currently act as barriers in access to care. The lack of and/or limited hospital-based OR access is exacerbated by ongoing medical staffing shortages and industry-wide inflation. Other challenges exist for patients unable to access hospital facilities because of geographic or transportation limitations. Indeed, industry research indicates the health care system as a whole benefits when procedures migrate to less costly care settings. As such, AAOMS encourages CMS to align coverage policies under the MPFS and the ASC payment system to allow Medicare coverage and payment for dental surgical services to identify, diagnose and treat oral or dental infections, when inextricably linked to the clinical scenarios finalized in the 2023 MPFS final rule and those proposed in the 2024 MPFS proposed rule.

#### Additional clinical scenarios for dental services integral to other covered medical services

AAOMS appreciates CMS's acknowledgement of our Association's recommendations related to Medicare coverage and payment for select dental services linked to other covered cardiovascular procedures and total joint arthroplasties. We recognize that CMS holds the view that the existing clinical evidence and scientific literature do not substantiate the inherent connection between these primary surgical procedures and dental services aimed at eradicating an oral/dental infection. AAOMS will continue to explore whether there is new or alternative evidence related to these clinical scenarios to support the inextricable linkage with select dental services.

### Request for information on the implementation of payment policies for dental services

Medicare denial to support third-party primary payment

In the proposed rule, CMS seeks comment on the "informal practice" of dental professionals submitting a dental claim to Medicare for the purpose of obtaining a denial so that another carrier or third-party payer may issue primary payment. Given the dental surgical nature of many oral and maxillofacial procedures, OMSs routinely submit claims to both dental and medical carriers, as appropriate. The need to produce a denial for non-covered services is particularly impactful for cases that involve both types of plans.

According to Section 950 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) <sup>24</sup>, prohibits secondary or supplemental group plans from requiring dental providers to file claims for services excluded from coverage under §1862(a)(12) of the Social Security Act. We note that MMA does not preclude a group plan from requiring such a determination in cases involving, or appearing to involve inpatient dental services, or other dental services that may be covered by Medicare. However, there are many dental services and clinical scenarios for which Medicare payment is not permitted and therefore MMA may apply.

AAOMS is aware that some dental insurance carriers routinely require a denial or adverse determination from a medical carrier — which may include Medicare — for certain dental services or codes. AAOMS opposes this practice. This process can be administratively burdensome to dental providers, create significant delays in claims reimbursement and may be confusing or frustrating to patients. Therefore, it may not be so much as an informal practice but rather a requirement for dental claims adjudication, under certain circumstances.

When submitting dental services to Medicare for purposes of a denial, CMS notes the appropriate HCPCS modifier(s) must be included on the dental claim form to indicate the billing practitioner does not believe Medicare payment is warranted. We wish to clarify that neither the 2019 (current) version of the ADA Dental Claim form, nor the version slated to take effect Jan. 1, 2024, include a box or field for HCPCS modifier use. AAOMS in not aware of any medical carriers that currently accept the dental claim form, therefore when a medical denial must be obtained for a dental service, the CMS-1500 form (or ANSI ASC X12N 837P electronic transaction) is typically used.

Contractor pricing and data to inform appropriate payment for dental services

AAOMS continues to support CMS's proposal to retain carrier pricing methodology for the dental services for which payment is currently made under the MPFS, as well as for those dental services that may be paid under the CMS proposals beginning in CY 2024.

Additionally, we support suggestions that certain publicly available data sources, such as FAIR Health may provide meaningful cost and utilization data to inform appropriate payment for dental services. Specifically, the FAIR Health database includes<sup>25</sup> claims data for services rendered in all areas of the U.S., which could aid Medical Administrative Contractors in determining dental payment rates that appropriately account for geographic variation.

MPFS payment indicators for CDT<sup>©1</sup> codes

AAOMS commends CMS for the guidance issued to local Medicare contractors in June to revise the RVU file that applied MPFS payment indicators to CDT® codes. We reiterate comments submitted by the ADA on behalf of all dental specialties that multiple procedure reductions and other payment reductions applicable to covered CPT®2 codes should not apply to CDT® codes or dental services. Primarily, this is because the global surgery concept does not apply to CDT®.

According to Chapter 1 of the National Correct Coding Initiative Policy Manual<sup>26</sup>, the rationale for the multiple surgery payment reduction stems, in part from code valuation in relation to the global period:

"Most medical and surgical procedures include pre-procedure, intra-procedure, and post-procedure work. When multiple procedures are performed at the same patient encounter, there is often overlap of the pre-procedure and post-procedure work. Payment methodologies for surgical procedures account for the overlap of the pre-procedure and post-procedure work."

Unlike CPT codes, where surveys are used to establish RVU's as well as parameters to refine global periods, there is no survey data that establishes what comprises pre-service and post-operative services that may arise as a consequence of a primary dental procedure, or the duration (e.g., number of postoperative visits) of a reasonable period that could be designated as a global period.

AAOMS continues to believe that, lacking structured survey data to inform the existence of overlap in pre- and post-procedure physician work, it is inappropriate to apply payment reductions based on such parameters to CDT<sup>©</sup> codes.

# AMA RUC as the entity best positioned to provide resource inputs for physician work and practice expense

Lastly, AAOMS offers support for the current AMA/Specialty Society RVS Update Committee (RUC) process and mirrors the sentiment of many in the healthcare industry that AMA RUC is the entity best positioned to provide accurate, relevant resource data to support physician work and practice expense valuations.

The RUC process is robust and transparent. AAOMS believes it plays a significant role in determining the relative value of medical procedures and services. We support the RUC process and acknowledge the physicians and healthcare practitioners representing over 100 specialty societies and disciplines who continue to dedicate their time and clinical expertise to the RUC process.

 $<sup>^1</sup>$  CDT $^\odot$  is a registered trademark of the American Dental Association.

<sup>&</sup>lt;sup>2</sup> CPT<sup>©</sup> is a registered trademark of the American Medical Association.

Thank you for your consideration of these comments. Please contact Patricia Serpico, AAOMS Director of Health Policy, Quality and Reimbursement, with any questions at 800-822-6637, ext. 4394 or <a href="mailto:pserpico@aaoms.org">pserpico@aaoms.org</a>.

Sincerely,

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Joshua E. Everts, DDS, MD, FACS

Chair, AAOMS Committee on Healthcare Policy, Coding & Reimbursement

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