Center for
Medicare Advocacy
Advancing Access to Medicare and Health Care

Submitted Electronically via www.regulations.gov

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

Re: Dental Payment Policies in the CY 2024 Physician Fee Schedule Proposed Rule (CMS-1784-P)

Dear Administrator Brooks-LaSure:

The Center for Medicare Advocacy (the Center) is a national, non-profit law organization that works to ensure access to Medicare, health equity, and quality healthcare. The organization provides education, legal assistance, research and analysis on behalf of older people and people with disabilities, particularly those with long-term conditions. The Center's policy positions are based on its experience assisting thousands of individuals and their families with Medicare coverage and appeal issues. Additionally, the Center provides individual legal representation and, when necessary, challenges patterns and practices that inappropriately deny access to Medicare and necessary care. We appreciate the opportunity to submit these comments.

As an advocacy organization, the Center receives calls and emails on a daily basis from Medicare beneficiaries across the country. For decades now, the absence of coverage for medically related dental care has been one of the pressing problems that we most frequently hear about. The individuals who contact us experience high risks to their health and health care treatment, as well as very compromised quality of life because they cannot readily afford this dental care.

The Center reiterates its praise of the current Administration and the team at Centers for Medicare & Medicaid Services (CMS) for their diligent efforts to improve treatment outcomes for Medicare beneficiaries who require medically essential dental care. We appreciate last year's clarification by CMS that Medicare payment may be made for dental services that are inextricably linked to, and substantially related and integral to the clinical success of a covered medical service. We commend the agency's revision of the regulation at 42 C.F.R. § 411.15(i)(3)(i) to permit payment for necessary diagnostic and treatment services to eliminate dental infections in the context of Medicare-covered organ transplant, cardiac valve replacement, and valvuloplasty procedures. We now applaud CMS' current proposal to recognize payment for dental services that are integral to certain additional clinical treatments.

A. Dental Services Inextricably Linked to Certain Cancer Treatments

The Center strongly urges CMS to finalize its proposal to allow payment for dental services that are inextricably linked to chemotherapies, CAR T-Cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of any type of

cancer. Careful dental management is imperative for patients experiencing immunosuppression and the toxic effects of these critical therapies. We have spoken to individuals who likely could have benefited from such management in the course of treatment for lymphoma and cancer of the prostate, thyroid, breast, colon, anus, vocal chords, and other cancers. We have also heard from Medicare beneficiaries who urgently required but could scarcely afford treatment to eliminate oral infections as a precondition to receiving lifesaving cancer treatment. If finalized and effectively implemented, CMS' proposed policy will be of enormous help to such patients in the future.

It is more often the case, though, that we hear from patients who, in the aftermath of successful chemotherapy, radiation, and bisphosphonate therapies, are suffering severe dental and oral side effects. They typically report of how all of their teeth began breaking off in jagged pieces, of painful inflammation and sores erupting throughout their mouth, and of developing frequent oral infections that became resistant to antibiotics over time, spreading into their bloodstream and to other tissues and organs in their body. Tales of lost employment, multiple hospital stays, speech impairment, inability to chew food, drastic weight loss, electrolyte imbalance, malnutrition, and need for parenteral nutrition also figure into their stories. While some of these individuals did not have the benefit of dental care before initiating or contemporaneously with cancer treatment, some reported that their oral health had been fine prior to and their oral hygiene impeccable during cancer treatment. We therefore urge CMS to consider whether payment may appropriately be made in certain instances when dental care is clinically advised and justified in the post-treatment phase of cancer.

Moreover, we encourage CMS' consideration of radiation therapy in the treatment of cancer more broadly and not just in conjunction with chemotherapy. On rare occasions, the Center hears from patients requiring dental treatment in relation to radiation treatment alone -- usually post-surgical dissection of head and neck cancer. But we have also heard from patients who suffered devastating dental complications in the treatment of other cancers (e.g., thyroid) with surgery and radiation alone.

There are studies concluding that periodontal examination and therapy are even recommended prior to surgical treatment of certain cancers. *See, e.g.,* Jia C, Luan Y, Li X, Zhang X, Li C. Effects of periodontitis on postoperative pneumonia in patients with lung and esophageal cancer, *Thorac. Cancer.* 2021 Mar; 12(6); 768-774. doi: 10.1111/1759-7714.13828. (Periodontitis is an important predisposing factor for post-operative pneumonia after open thoracotomy, and periodontal treatment is associated with a lower incidence of pneumonia following lung and esophageal cancer surgery); Nishikawa M, Honda M, Kimura R, et al. Clinical impact of periodontal disease on postoperative complications in gastrointestinal cancer patients. *Int. J. Clin. Oncol.* 2019 Dec; 24(12): 1558-1564. doi: 10.1007/s10147-019-01513-y. (Periodontal disease is an independent risk factor for infectious complications after gastrointestinal cancer surgery). Such studies suggest that addressing dental infections even at the surgical stage could help avoid health complications that may ostensibly delay or otherwise hamper subsequent stages of cancer treatment.

Although we cannot provide the supporting medical evidence requested by CMS, we encourage the agency's consideration of whether dental services may be inextricably linked to the clinical success of other immunotherapies that may have a similar lymphodepleting component as CAR-T cell therapies.

B. Dental Services Integral to Covered Cardiac Interventions

The Center has gotten calls from cardiac patients who urgently required treatment to address dental infections before their surgeons would agree to operate. We therefore urge CMS to permit payment for dental screenings and, when clinically justified, medically necessary dental treatment that a patient may need in order to undergo, or to avoid complicating or compromising the following covered cardiac procedures.

- CPT 33206, 33207, 33208 (pacemaker insertion or replacement)
- CPT 33249 (insertion or replacement of ICD - implantable cardioverter defibrillator)
- CPT 33361-33364 (transcatheter aortic valve replacement)
- CPT 33405 (surgical procedure on aortic valve)
- CPT 33430 (mitral valve replacement)
- CPT 33894 (endovascular stent repair)
- CPT 33975, 33990, 33991, 33995 (cardiac assist procedures)
- CPT 37236, 37237 (endovascular stent placement)
- DRG 218 (cardiac valve and other major cardiothoracic procedures)
- DRG 222-227 (cardiac defibrillator implant)
- DRG 242-244 (cardiac pacemaker implant)
- DRG 266-267 (endovascular cardiac valve replacement)
- DRG 319-320 (other endovascular cardiac valve procedures)

Dental treatment will certainly not be integral to the success of a covered cardiac intervention in every case. The determination of whether an individual patient's diagnosed dental issues risk compromising the outcome of the particular cardiac procedure will depend on various factors particular to the patient and to the procedure. Further, because dentally-sourced infections can cause serious complications at the site of intracardiac or intravascular stents and devices even after the surgical procedure, we urge CMS to extend payment, when clinically advised and justified, to dental treatment following the cardiac procedure.

C. Dental Services Inextricably Linked to Treatment for Head and Neck Cancer

We fully support CMS' proposal to clarify that Medicare Parts A and B payment may be made for examination and medically necessary diagnostic and treatment services to eliminate oral or dental infection prior to the initiation of, or during, treatments for head and neck cancer, whether primary or metastatic, regardless of the site of origin, and regardless of initial modality of treatment. Respectfully, we ask CMS to adopt a definition of "during" or "contemporaneously with" that recognizes the patient-specific clinical decisions in head and neck cancer treatment, while adhering to the agency's interpretation of its authority under the Medicare statute. The

following case example illustrates why dental services may be integral to the clinical success of a course of treatment for head and neck cancer that has technically ended:

The Center recently heard from a beneficiary who was diagnosed with sinus cancer at the end of 2022. The oncology team determined that the best course of action for this patient was immediate surgical removal of his tumors followed by prompt initiation of chemotherapy and radiation. No time could be spared for a dental examination and treatment, nor would it have been clinically advisable while he was immunosuppressed. Shortly after the completion of chemotherapy and radiation this February, most of the patient's teeth began to break off above the gumline. He is in considerable pain and can no longer chew food. While tooth extractions normally would have been appropriate (and covered by Medicare) prior to chemo and radiation, they are contraindicated now, six months post-treatment, due to risk of bone loss from radiation. He must instead have root canals, the cost of which will nearly deplete his and his wife's retirement savings. Without the recommended dental treatment, however, he is susceptible to ongoing infections and inflammation, complicating his successful recovery from cancer and increasing the risk of relapse.

For patients like this beneficiary, a definition of "during" or "contemporaneously with" that encompasses a clinically-recognized recovery phase for targeted head and neck cancer treatment would advance the goals of the Medicare program without violating the statutory dental exclusion.

D. Dental Services Possibly Inextricably Linked to Other Covered Services

We greatly appreciate CMS' commitment to considering whether dental services may be inextricably linked to additional Medicare-covered services and evaluating clinical evidence that may support such a linkage. Over the years, we have heard from Medicare beneficiaries who urgently required dental care in order to prevent continuing complications of and most optimally treat their underlying diseases and medical conditions. These have included severe COPD, uncontrolled diabetes, epilepsy, Sjogren's disease, lupus, rheumatoid arthritis, chronic kidney disease, Ludwig's angina, and retroperitoneal fibrosis. Dental services certainly would not be inextricably linked to the successful treatment of these conditions in *every* case. But for these particular individuals, their oral pathologies needed to be addressed because they were clinically determined to be a highly exacerbating factor in the progression and treatment outcome of their medical conditions.

Many of the individuals who contact us have been prescribed therapies with immune-suppressing and dental side effects, such as certain bone-modifying agents, corticosteroids, and anticonvulsant medications. Quite a number of the individuals who have an autoimmune disorder as their primary diagnosis, are also afflicted with other autoimmune disorders – sometimes several. Incidentally, we have observed that many of them are women and racial minorities. The combined impact of their conditions and prescribed treatments on their health have made dental treatment an urgent component of their care, but one they cannot readily afford.

We underscore the comment made by our colleagues at FamiliesUSA that "Increasing access to and affordability of dental and oral health services that improve the outcomes of Medicare-covered services related to each of these conditions is an important health equity issue. People who rely on Medicare to treat these conditions should not be unable to afford dental and oral health care that might lead to better disease management and health outcomes."

E. Implementation of Payment for "Inextricably Linked" Dental Services

The Center understands that several pieces must align in order for Medicare patients to actually access the dental services that are inextricably linked to their covered medical treatments. We also understand that while CMS may be able to guide or influence some of those pieces, the agency does not control all of the pieces. That said, we urge CMS to utilize all available vehicles within its means to educate relevant providers about the payment policy, address concerns and uncertainties they may have about the policy, and encourage dentists to enroll in Medicare.

We created surveys that were recently distributed by The Organization for Donation and Transplant Professionals (NATCO), the American Association of Hospital Dentists (AAHD), and the Special Care Dentistry Association (SCDA) to their members. The surveys are designed to gauge the knowledge that transplant centers and hospital and special care dentists have concerning the dental payment clarification and to gather input from these providers that could help inform implementation of the policy. Preliminary results of the surveys reflect that less than half of the respondents are aware of the clarification and learned of it through advocacy and professional organizations (e.g., ADA, SCDA).

Even those providers who know about the payment clarification still have questions about what dental care could be covered, at what stage of their patients' medical treatment, and how to code the services and bill Medicare correctly. They are very hesitant to inform or advise their patients without a better understanding of the policy, its particulars and logistics. One transplant provider suggested that information could be disseminated through the United Network for Organ Sharing (UNOS), which sends policy updates to transplant centers and patients. Dentists and transplant providers alike are interested in obtaining clearer directions (something akin to a roadmap) on how to properly submit claims and what can be expected in terms of reimbursement. Some hospital dentists are dissuaded by the challenges they already encounter in trying to bill Medicare for covered oral and maxillofacial surgical (OMFS) procedures, including frequent denials by fiscal intermediaries, time-consuming appeals, and low reimbursement.

Some transplant centers say it would be helpful to know of the local Medicare-participating dentists to whom they could refer their patients. Transplant centers have no prior experience in billing Medicare for dental services as a part of a transplant procedure. It would be entirely novel for them to make arrangements to reimburse a non-participating dentist to furnish care to their transplant candidate/patient. Some asked if this would entail billing directly to Medicare for their patient's dental services, or through their Medicare Cost Report (Kidney Acquisition).

The concept of obtaining payment directly from a patient's medical provider is likewise novel to most dentists, even though medical-dental care coordination is nothing new. As such, there is understandable apprehension and reluctance to attempt such arrangements for Medicare patients.

Having more comprehensive information and guidance that provides assurance of a predictable outcome may help encourage these providers to facilitate or provide care to eligible patients. Several respondents wanted to know if any transplant programs or dentists have had success yet in getting this care paid for their patients.

On a separate implementation topic, the Center believes it is crucial that Medicare Advantage plans fully understand the payment clarification and that they must pay for medically-integral dental services in addition to any supplemental dental benefits they offer. This information should be included in the dental benefits section of their annual Evidence of Coverage (EOC). Moreover, plans should make sure that their customer service representatives have scripts and protocols in order to furnish accurate information about medically-integral dental services to enrollees and providers. If an enrollee may qualify for payment of medically-integral dental services, the plan should help them to locate care from an appropriate dentist.

Responding to CMS' query about whether "inextricably linked" dental services should be provided in federally qualified health centers (FQHCs), we feel that they should, as FQHCs serve a significant number of dual eligibles. Concerning dual eligibles, the Center also believes Medicare could require that state agreements with MA organizations offering Dual Eligible-Special Needs Plans (D-SNP) do more to ensure care and benefit coordination for their enrollees. This is particularly important for dual eligibles in states that include fairly comprehensive adult dental benefits in their Medicaid plans. For instance, it could be required that D-SNP plans inform their enrollees of in-network dentists who also participate in Medicaid. An enrollee could maximize their benefits by obtaining care from such a provider, and significantly reduce their out-of-pocket liability. This would enhance the care and coverage that dual eligibles receive whether they require routine or medically-integral dental care.

We further believe that greater outreach and education should be made to Medicaid-participating dentists and dental programs about the Medicare dental clarification. Encouraging these providers to enroll in Medicare could facilitate care for dual eligibles and reimbursement for those providers.

Conclusion

Thank you for the opportunity to submit these comments. For additional information, please contact David Lipschutz, Associate Director at DLipschutz@medicareadvocacy.org, or Kata Kertesz, Senior Policy Attorney at KKertesz@medicareadvocacy.org, both at (202)293-5760. For additional information concerning the medically necessary oral health comments, please contact Wey-Wey Kwok at (860) 456-7790 or wkwok@medicareadvocacy.org.