



September 11, 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 Consortium for Medically Necessary Oral Health Coverage 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 2024 Physician Fee Schedule Proposed Rule.

INTRODUCTION

By way of brief background, the Consortium for Medically Necessary Oral Health Coverage is a leading consensus-building alliance of more than 240 dental, medical, patient, and consumer organizations (please see the Consortium's Community Statement, which is attached to this submission and is also posted at www.OralHealthConsortium.org). 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.

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 improve patient access to needed care by clarifying 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. We also wish to note the important perspectives of leading authorities across the medical community. As excerpted below, strong clinical consensus exists about the importance of medically necessary oral and dental care:

American Academy of Neurology:

“[P]oor dental hygiene increases likelihood of bacterial endocarditis and worsens stroke outcomes in all subtypes due to an increased inflammatory burden.”

American Association of Clinical Endocrinology:

“[U]ntreated periodontal disease makes it more difficult to control diabetes, leading to the dreaded diabetic microvascular and macrovascular complications.”

American Association of Hip and Knee Surgeons:

“Best practices for our surgeons include a dental evaluation in patients at risk prior to arthroplasty. This is particularly important for the poor and disenfranchised. A dental infection is also disastrous in the post-operative patients; prompt evaluation of oral infection is critical in patients after surgery.”

American College of Cardiology:

“The data linking dental infections to increased risk of cardiovascular disease is clear. Severe dental infections can compromise cardiac conditions.”

American College of Emergency Physicians:

“[N]umerous instances of emergency department visits and hospitalizations for an array of medical problems have a dental condition as an underlying cause. For example, dental infections may be the source of the bacteria responsible for an infected cardiac or orthopedic prosthesis and sepsis.”

American College of Gastroenterology:

“Urgent dental care is sometimes necessary before patients can undergo treatment for gastrointestinal diseases, including inflammatory bowel diseases and Hepatitis C virus. It is important for patients with these chronic diseases to receive dental care and avoid any delay in treatment.”

American College of Physicians:

“Dental problems, particularly dental infections, pose a major problem for patients with cardiac valvular disease, patients who are immunosuppressed by virtue of underlying disease or immunosuppressive medications, patients with various types of prostheses, and patients who are at risk of aspiration. The implications of dental disease in such patients extend well beyond their oral disease, with potentially life-threatening complications if the dental problems are not treated.”

American College of Rheumatology:

“It is vital for patients to receive appropriate dental evaluation and prompt treatment so they can continue their immune suppressant medications.”

American Diabetes Association:

“[U]ntreated periodontal disease makes it more difficult to control blood glucose and is associated with increased risk of diabetes complications, including kidney failure and cardiovascular disease. People with diabetes are more likely to need medical procedures such as cardiac surgery or kidney transplantation [which] may have to be delayed due dental problems.”

American Nephrology Nurses Association

“[W]e urge CMS to consider that dental health is a determinant of health for those with end-stage renal disease. There is a plethora of research to support this conclusion and studies have shown that adults with end-stage renal disease (ESRD) tend to have more severe oral disease than the general population, leading to increased mortality.”

American Psychiatric Association:

“[M]any are treated long term with psychotropic medications that may reduce resistance to infection. Without appropriate dental care, these individuals are at increased risk for septicemias, endocarditis and other potentially threatening conditions.”

American Society of Clinical Oncology:

“Untreated dental disease in patients about to undergo chemotherapy regimens that carry the risk of hematologic toxicity, especially leucopenia, may be a cause of fatal sepsis.” Additionally, “[e]xpert consensus panels have recommended dental assessment prior to the use of intravenous bisphosphonates.”

American Society of Transplant Surgeons:

“Untreated dental problems can become deadly once a patient is immunosuppressed, so good dental care is a critical part of preparation for transplant.”

American Thoracic Society:

“Bacterial biofilms between teeth harbor pathogens that, when aspirated, can increase susceptibility or complicate the management of pulmonary diseases such as pneumonia, bronchitis, and chronic obstructive pulmonary disease (COPD). The risk is greater in immune-compromised individuals.”

Association of Oncology Social Work:

“Dental treatment must precede many life-saving chemotherapeutic cancer interventions.”

Kidney Care Partners

“Access to dental services not only is important for dialysis patients as part of their ability to access kidney transplants, but also to access cardiovascular procedures given that many dialysis patients also live with serious, chronic cardiovascular conditions, and to reduce the risk of systemic infections developing from an oral source.”

National Association of Community Health Centers

“Medicare’s lack of dental coverage ...exacerbates underlying racial, geographic and disability-related health and wealth disparities; improved Medicare coverage for medically necessary dental care would help millions of people get healthy without having to make impossible financial tradeoffs and would mitigate some of these health inequities.”

National Interprofessional Initiative on Oral Health

“NIIOH applauds CMS for considering dental coverage related to a variety of clinical scenarios, including certain surgical procedures, transplants, cancer treatments, diabetes and other chronic disease management, immunosuppression, heart disease treatments and other circumstances. Emerging evidence documents the bidirectional relationship between oral health and other chronic health conditions. There is strong legal consensus supporting the actions CMS has proposed, as well as adding coverage for additional medical scenarios that CMS is considering.”

National Multiple Sclerosis Society

“[I]ndividuals living with MS are at increased risk of infection development and complications from oral pathogens. Coverage of dental examinations and treatments is unquestionably needed for beneficiaries requiring long-term use of immunosuppressing medications to help manage MS.”

North American Transplant Coordinators Organization

“Serious and aggressive infections, regardless of location --- including the teeth and periodontium --- risk serious complications among immunosuppressed transplant recipients. And the danger intensifies among older adults whose immune systems can be weakened by aging (immunosenescence).”

Oral Health Nursing Education and Practice Program

“[N]urses are witness to the impact of poor oral health and lack of a Medicare dental benefit on the health care outcomes and quality of life for older adults with chronic conditions including, but not limited to diabetes, cardiovascular, and respiratory conditions. Of particular note is the relationship of poor oral health and increased risk for serious co-morbidities and complications for conditions like, cancer, solid organ transplants, and autoimmune diseases, which may prevent, delay, as well as interrupt treatment and/or reduce likelihood of optimal clinical outcomes.”

Renal Physicians Association:

“[P]oor dental health can compromise the ability of ESRD patients to achieve good medical outcomes due to its impact on serum albumin levels and glucose control.”

Sepsis Alliance

“An infection in the mouth that forms as a result of surgery or even just routine dental cleaning and scaling should, like all infections, be treated as quickly as possible to reduce the risk of complications, including sepsis. This is especially important for individuals who are immunosuppressed because of disease (Diabetes, Leukemia, HIV, Chronic Kidney Disease), pharmaceuticals (cancer chemotherapies, biologics for management of autoimmune diseases), and/or natural aging (immunosenescence).”

Society for Transplant Social Workers:

“Untreated dental problems can become deadly once a patient is immunosuppressed, so good dental care is a critical part of preparation for transplant.”

Society for Vascular Surgery:

“We encourage all vascular patients, but especially those who have had or intend to have arterial stents or grafts placed, to undergo appropriate dental care to avoid these potentially devastating vascular complications.”

The Gerontological Society of America:

“Given the many serious potential complications from poor oral health and the already formidable challenges in obtaining dental care as we age, it is vital that access to medically necessary dental services be available.”

The Society of Thoracic Surgeons:

“[C]ardiothoracic surgeons often find that their patients have primary bacterial endocarditis or, worse, prosthetic valve endocarditis secondary to neglected dental health and chronic dental abscesses. These are life-threatening situations that could be prevented if Medicare would cover medically necessary oral/dental health therapies.”

COMMENTS

In response to the Agency's solicitation of public comments, we wish to address the following issues:

1. Medicare Payment Clarification Related to Covered Cancer Treatment and Radiation Therapy
 2. Medicare Payment Clarification Related to Certain Covered Cardiac Medical Services
 3. Discussion in Response to the Agency's Solicitation for Comments on Diabetes
 4. Inextricable Linkage of Dental Services to Other Covered Services
 5. Implementation of Payment for Inextricably Linked Dental Services
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1. Medicare Payment Clarification Related to Covered Cancer Treatment and Radiation Therapy

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 1,806,590 persons were newly diagnosed with cancer and 606,520 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).

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. 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 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.

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.

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, 2022). 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, the draft Physician Fee Schedule for 2024 proposes payment clarification for:

- 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.
- 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.

2. Medicare Payment Clarification Related to Certain Covered Cardiac Medical Services

Since the late 1980s, a large number of epidemiological investigations describe an association between periodontal disease (PD) and cardiovascular diseases (CVD) and stroke, two of the most common and costly chronic diseases that are mostly the result of atherosclerosis (Sanz et al., 2020)¹. PD, CVD and stroke are greatly influenced (and possibly dependent upon) chronic inflammatory mechanisms. A recent umbrella review (Peruzzi et al., 2022)² summarized the associations between cardiovascular and periodontal disease. The evidence supports the epidemiological association of PD and CVD and ischemic stroke. As CVD and stroke are clearly influenced by inflammation, and as treatment of PD would reduce both oral and systemic inflammation, it is logical to assume that treatment of PD would reduce overall inflammatory burden and hence the risk of CVD and ischemic stroke. Such findings have been reported for persons with cardiovascular diseases (Jeffcoat et al., 2014¹⁰, Borah et al, 2022³); however, the body of evidence is not as robust as it is for diabetes mellitus.

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.

As a result of these considerations, we applaud CMS for exploring this important issue and urge inclusion in the Final Rule of Medicare payment clarification related to certain covered cardiac medical services where the risk of infection posed to beneficiaries is similar to that associated with cardiac valve replacement or valvuloplasty.

3. Discussion in Response to the Agency's Solicitation for Comments on Diabetes

Diabetes Mellitus (DM) is a metabolic disorder characterized by abnormal glucose metabolism. This common chronic disease affects more than 11% of the adult population in the United States, with a marked increase in prevalence in persons 65 years and older (26.4%). The sequelae of diabetes include nephropathy (the major reason for renal transplants in the U.S.), retinopathy (the major reason for blindness in adults in the U.S.), cardiovascular disease, other vascular disorders, and neuropathy. The total cost of diabetes-related care in the United States has been estimated to be \$327 billion (Centers for Disease Control and Prevention, 2022).

There is a close association of diabetes and oral diseases. Oral manifestations of DM in the oral cavity include periodontitis, Candida infection, dry mouth, and decay affecting the roots of the teeth. Indeed, DM is the only recognized chronic disorder that is a risk factor for periodontitis. The relationship between DM and periodontitis is bidirectional, as periodontitis has been shown to be a risk factor for poor metabolic control in persons with DM (Lamster, 2014).

For patients with DM and periodontitis, provision of preventive dental care/conservative periodontal treatment leads to a statistically and clinically significant reduction in glycated hemoglobin (HbA1c), a key measure of metabolic control, and an established risk marker for clinical complications of DM. The reduction in HbA1c was 0.4-0.5% over 3 to 12 months. This was ascribed to the removal of the periodontal biofilm, reduction in the oral bacterial challenge and reduction in the resultant periodontal inflammation. This conclusion was published in a Cochrane Review (Simpson et al. 2022). Of importance, the authors of this review stated that further studies are unlikely to change the conclusion.

Additionally, large database analyses show that conservative periodontal treatment is associated with improved health outcomes and reduced healthcare costs. Such findings have been reported in Jeffcoat et al. (2014), Nasseh et al. (2016), Smits et al. (2020), Lamster et al. (2021), Lamster et al. (2022), and Borah et al. (2022). While the differing design of these analyses reported somewhat different outcomes, each of the studies found reduced utilization, and lower costs. The Santa Fe Group performed an analysis of the effect of preventive dental care/conservative periodontal treatment on total health care costs for persons with DM as identified in the referenced studies. There was a 19% reduction in these costs, which were realized primarily in in-patient/hospital expenditures.

An essential component of diabetes treatment is a well-balanced diet high in fruits, vegetables, and unrefined grains, and low in refined carbohydrates and saturated fats. An intact natural or restored dentition (≥ 20 teeth in occlusion) is associated with improved intake of fruits and vegetables, and maintenance of an intact dentition depends on adequate preventive and restorative dental care. Thus, preventive and restorative dental care fosters a healthy diet that is key to diabetes treatment.

While we understand CMS is not proposing payment clarification at this time, we applaud the Agency for soliciting comments on this important issue. We are also grateful to the Agency for providing highly valued guidance in the proposed rule:

Commenters, submitters, and other interested parties have urged us to consider the importance of access to oral health care for people with chronic auto-immune conditions, and other chronic disease conditions, such as, but not limited to, diabetes... We urge interested parties to consider the circumstances under which dental services are inextricably linked to specific covered services (not diagnoses) used to treat patients with auto-immune conditions or other chronic conditions, supported by clinical evidence.

We are in the process of exploring specific diabetes-related covered services for which the provision of inextricably linked dental care is associated with improved outcomes and reduced cost. We look forward to presenting our findings in nominations that we will file by February 10, 2024, for your consideration.

4. Inextricable Linkage of Dental Services 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. Numerous Medicare beneficiaries urgently require dental care in order to prevent continuing complications of and most optimally treat underlying diseases and medical conditions, including severe chronic obstructive pulmonary disease (COPD), uncontrolled diabetes, epilepsy, Sjogren's disease, lupus, rheumatoid arthritis, chronic kidney disease, Ludwig's angina, and retroperitoneal fibrosis. While dental services are not inextricably linked to the successful treatment of these conditions in every case, for many beneficiaries, oral pathologies must be addressed when they were clinically determined to be a highly exacerbating factor in the progression and treatment of their medical conditions.

Many such individuals are prescribed therapies with immune-suppressing and dental side effects, such as certain bone-modifying agents, corticosteroids, and anticonvulsant medications. Those who have an autoimmune disorder as their primary diagnosis are also afflicted with other autoimmune disorders and routinely more than one. Many such patients are women and/or members of ethnic or racial minority populations, and a concerning share of them are unable to afford the combined cost of their conditions, prescribed treatments, and urgently needed dental treatment.

As a result, we concur with the perspective offered 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."

5. Implementation of Payment for Inextricably Linked Dental Services

We join with other leading organizations in the oral health community in urging CMS to do everything it can to educate providers about Medicare's updated payment policy, address concerns and uncertainties they may have, and encourage dentists to enroll in Medicare. Surveys created by the Center for Medicare Advocacy (CMA) and distributed by the Organization for Donation and Transplant Professionals (NATCO), the American Association of Hospital Dentists (AAHD), and the Special Care Dentistry Association (SCDA) found that less than half of all respondents are aware of Medicare's payment clarification and learned of it through advocacy and professional organizations.

Among providers who know about the payment clarification, many 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 understandably hesitant to inform or advise their patients without a better understanding of the policy, its particulars, and logistics. 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, and transplant centers indicated a desire to know of local Medicare-participating dentists to whom they could refer their patients.

Another opportunity for awareness-building relates to the Medicare Advantage (MA) program. MA plans need to 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 join with other community leaders in believing that they should, as FQHCs serve a significant number of dual eligibles. Medicare could also 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. 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 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 Eric Berger at ericsberger@outlook.com or 804-405-7600.

Sincerely,



Eric S. Berger

Attachment: Community Statement on Medicare Coverage for Medically Necessary Oral and Dental Health Therapies

- ¹ Sanz M, Del Castillo AM, Jepsen S, Gonzalez-Juanatey JR, D'Aiuto F, Bouchard P, Chapple I, Dietrich T, Gotsman I, Graziani F, Herrera D, Loos B, Madianos P, Michel JB, Perel P, Pieske B, Shapira L, Shechter M, Tonetti M, Vlachopoulos C, Wimmer G. Periodontitis and Cardiovascular Diseases. Consensus Report. *Glob Heart*. 2020 Feb 3;15(1):1. doi: 10.5334/gh.400. PMID: 32489774; PMCID: PMC7218770.
- ² Peruzzi M, Covi K, Saccucci M, Pingitore A, Saade W, Sciarra L, Cristalli MP, Miraldi F, Frati G, Cavarretta E. Current knowledge on the association between cardiovascular and periodontal disease: an umbrella review. *Minerva Cardiol Angiol*. 2022 Mar 25. doi: 10.23736/S2724-5683.22.06022-7. Epub ahead of print. PMID: 35332749.
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Resources related to Cancer discussion above:

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