

September 6, 2022

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: CMS-2022-0113-1871 CY 2023 Physician Fee Schedule Proposed Rule**  
Submitted electronically via <https://www.regulations.gov/commenton/CMS-2022-0113-1871>

Dear Administrator Brooks-LaSure:

The Gerontological Society of America (GSA) 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 2023 Physician Fee Schedule Proposed Rule.

## INTRODUCTION

GSA honors aging across the lifespan and is the nation's oldest and largest interdisciplinary organization devoted to research, education, and practice in the field of aging. The principal mission of the Society — and its 5,400+ members — is to cultivate excellence in interdisciplinary aging research and education to advance innovations in practice and policy. We encourage interdisciplinary research collaboration and communication. We routinely convene stakeholders to discuss issues of importance and make recommendations to address the specific needs of older adults.

GSA members contribute the evidence base as it relates to the importance of oral health as an essential element of healthy aging. We have a long-standing commitment to oral health, which includes multiple collaborations over several years. Guided by our [Oral Health Workgroup](#), we work to increase awareness of appropriate oral care and strengthen the impact that all members of healthcare and caregiver teams have to ensure good oral care for older people. Additionally, **GSA's Oral Health Interest Group**, is an interdisciplinary network that provides an active opportunity for persons interested in the issue of oral health to meet and exchange, information and resources.

Starting in 2016, GSA's Oral Health Initiative published and actively disseminated several papers including a white paper from an interprofessional convening that included more than 20 aging and oral health national organizations entitled "[Interprofessional Solutions for Improving Oral Health in Older Adults: Addressing Access Barriers, Creating Oral Health Champions](#)." We developed and published two *What's Hot* newsletters addressing oral health issues: "[Oral Health: An Essential Element of Healthy Aging](#)" in 2017 and "[Interrelationships Between Nutrition and Oral Health in Older Adults](#)" in 2020.

Along with hundreds of medical, dental, patient, and consumer advocacy organizations, we deeply appreciate the Administration's proposal to create a more equitable healthcare delivery system through expanded coverage of medically necessary oral and dental treatment because of the direct and meaningful impact this coverage will have in the lives of tens of millions of Medicare beneficiaries.

It is well established that chronic diseases disproportionately impact Medicare beneficiaries and impose a substantial cost on the federal government. It is also well established that untreated oral microbial infections are closely linked to a wide range of costly chronic conditions. In addition, oral diseases have been documented by researchers and medical specialty societies as precluding, delaying, and even jeopardizing a broad range of essential medical procedures.

Until now, most Medicare beneficiaries have been unable to receive oral and dental care even when medically necessary. Instead, Medicare coverage historically extended to the treatment of all microbial infections *except* for those relating to the teeth and periodontium. We believe there is no medical justification for this exclusion: medically necessary oral and dental care is integral to the management of numerous diseases and medical conditions, and the lack of such care heightens the risk of costly complications while increasing the financial burden on Medicare, beneficiaries, and taxpayers.

We are pleased to note that our perspective is shared by a broad cross-section of the medical community. Indeed, strong clinical consensus exists about the need for medically necessary oral and dental care. Below, for example, please find a sampling of statements by leading clinical authorities:

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 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 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 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.”

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.”

As a result of these important facts and clinical perspectives, we wish to applaud the Administration for its proposal to meaningfully broaden reimbursement for medically necessary services and to create an important opportunity for stakeholders to suggest other clinical scenarios where coverage of medically necessary oral and dental services may be appropriate.

## COMMENTS

In response to the Administration’s solicitation of public comments, GSA wishes to address the following issues:

1. Dental Services Integral to Covered Medical Services Which Result in Improved Patient Outcomes
2. Coverage to Prevent Infection: Transplant-related Surgical Procedures and Immune Suppression
3. Administrative and Procedural Issues
4. Legal Analysis of “Inextricably Linked” Standard
5. Legal Analysis of Integral Dental Treatment Coverage

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### **1. Dental Services Integral to Covered Medical Services Which Result in Improved Patient Outcomes**

The CDC reports that persons with certain chronic non-communicable diseases (NCDs) are more likely to have severe oral disease, especially periodontal disease<sup>iv</sup>. Although there is an extensive list of NCDs to which oral diseases are linked, we will focus only on those with the most evidence, and with the greatest opportunity for improvements in population health and health equity, and associated cost avoidance. These linkages are based on data from clinical trials, laboratory studies of biological mechanisms, retrospective studies from large insurance data sets, best practice protocols advocated by both clinical care centers and private insurance companies, and treatment paradigms recommended over many years by professional clinical societies and associations. Three important examples of NCDs that can be improved with supportive dental care follow.

#### **1.1 Preventive Dentistry and Health Outcomes for Persons with Diabetes**

Diabetes mellitus 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)<sup>v</sup>.

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. 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)<sup>vi</sup>.

Clinical studies have demonstrated treatment of periodontitis is associated with improvement in metabolic control. Specifically, conservative periodontal treatment is associated with a reduction in

glycated hemoglobin of 0.4-0.5%. This is due to a removal of the periodontal biofilm which reduces the bacterial challenge, and the resulting reduction in periodontal inflammation<sup>vii</sup>.

As a logical follow-up to these studies, analyses of large databases show that access to conservative periodontal treatment/preventive dental care is associated with improved health outcomes and reduced healthcare costs. The initial study examined these relationships for several chronic diseases (Jeffcoat et al., 2014)<sup>viii</sup>. As additional studies were published, the focus has been almost exclusively on this relationship for persons with DM.

A study using the Truven Health MarketScan Research Databases estimated the relationship between periodontal treatment and both health care costs and utilization (Nasseh et al., 2016)<sup>ix</sup>. After deducting the cost of the dental service for the first two years of the study, the two-year savings in the 3<sup>rd</sup> and 4<sup>th</sup> years was \$1328 for patients who did not begin a diabetes-associated drug regimen.

A subsequent publication from the Netherlands found a similar result (Smits et al., 2020)<sup>x</sup>. Data were from the Achmea Health Database; individuals who were continuously enrolled for a 7-year period were included in the analyses. Enrollees with diabetes that either received periodontal treatment, or did not, were compared. For individuals who did receive periodontal care, the diabetes-related health costs were 12 euros less per quarter. While this reduction may seem small, the quarterly diabetes-related costs were only 30 euros per quarter.

A study of health care use and costs of enrollees in the New York State Medicaid program examined the relationship between preventive dental care, health outcomes and cost (Lamster et al., 2021)<sup>xi</sup>. This report used electronic health records of more than 500,000 individuals who were continuously enrolled in the program for 3 years. Enrollees who accessed preventive dental services in the first 2 years had a 9% reduction in hospitalizations and a total adjusted health cost reduction of \$354/year. Further, there was an incremental reduction in utilization and costs when enrollees had additional preventive visits. However, health care savings were reduced or not observed if the enrollees required an extraction or endodontic (root canal) treatment, indicative of advanced oral infection.

As compared to what was seen for the entire cohort, a subsequent analysis of the New York State Medicaid database only considered enrollees with diabetes and observed both greater reduction in utilization and costs for enrollees accessing preventive care versus enrollees with diabetes who did not access such care (Lamster et al., 2022)<sup>xii</sup>. In fact, there was an 11% reduction in hospitalizations, and a reduction in total adjusted healthcare costs of \$881/year. In this and the previous study, the outcomes were adjusted for 15 variables in the database, including general health status and a well-person visit to a medical provider.

A study of the association of preventive dental services and healthcare outcomes for persons with diabetes and cardiovascular disease used the Arkansas BlueCross and BlueShield database from 2014 to 2018 (Borah et al., 2022)<sup>xiii</sup>. Enrollees were in a plan that provided both medical and dental benefits. Accessing preventive dental care resulted in an annual savings of between \$515 and \$574 for enrollees with diabetes, and between \$866 and \$1718 for enrollees with diabetes and cardiovascular disease. The greatest savings were seen for hospitalizations.

### **Recommendation**

Data from different populations in the United States, the Netherlands, and U.S. public and private insurance systems show that access to preventive dental care and conservative nonsurgical periodontal treatment (where indicated) are associated with improved health outcomes and reduced healthcare costs for persons with diabetes. Considering the importance of containment of health care costs in the United States, these data offer a novel approach to both improving oral health and general health, while

reducing healthcare expenditures. Thus, we recommend inclusion of preventive dental care (dental prophylaxes) and conservative (non-surgical) periodontal treatment (as needed) for all persons with diabetes to reduce infections and inflammation.

## **1.2. Pneumonia and chronic lung disease**

Poor oral health is associated with lung infections such as Ventilator Associated Pneumonia (VAP) (Scannapieco 1999)<sup>xiv</sup> and Aspiration Associated Pneumonia (AP) (Scannapieco 2021)<sup>xv</sup>. Genetic epidemiologic studies show that the organisms causing pneumonia are very often genetically identical pathogens isolated from the teeth of intubated patients diagnosed with VAP (Heo et al. 2008)<sup>xvi</sup>. Systematic reviews have documented that improved oral hygiene in the hospital and nursing home setting reduces the risk of pneumonia (Sjogren et al. 2016)<sup>xvii</sup>, Zhao et al. 2020<sup>xviii</sup>, Liang et al. 2021<sup>xix</sup>).

Recently Non-Ventilator Hospital Acquired Pneumonia (NVHAP) was recognized as a significant cause of hospital-acquired infection, and oral care is now considered an important component of interventions to prevent this costly infection (Scannapieco et al., 2022)<sup>xx</sup>. Further, a study of Medicaid enrollees who receive preventive dental treatment in the 12 months prior, or periodontal therapy in the six months prior to a hospitalization, have a reduced risk for NVHAP (Baker et al. 2022)<sup>xxi</sup>. These findings are consistent with previous research on the relationship between oral health and the risk for lower airway infection.

A related association between oral health and lung disease has been documented for Chronic Obstructive Pulmonary Disease (COPD). While the primary driver of COPD is chronic long-term tobacco smoking, evidence points to the impact of poor oral hygiene and periodontal disease as exacerbators of COPD progression. Studies show that reduced lung function is associated with severity of periodontal disease (Scannapieco and Ho 2001<sup>xxii</sup>; Offenbacher et al. 2012<sup>xxiii</sup>) and a number of clinical trials support the notion that periodontal therapy in the form of scaling and root planning and improved oral hygiene can reduce the risk of COPD progression (Kelly et al. 2021)<sup>xxiv</sup>.

Estimates suggest that a single case of VAP incurs additional treatment costs of \$28000- \$40,000<sup>xxv,xxvi</sup>. In the United States, total costs incurred to treat preventable cases of VAP thus results in unnecessary spending. Alternatively, the cost of providing simple mechanical oral care for hospital patients at bedside requires simple materials that cost a few dollars per day, plus time spent by providers. Cost-benefit calculations argue that provision of oral care to prevent pneumonia in hospitals and nursing homes would result in substantial overall healthcare cost savings (Munro and Baker, 2018; Munro et al., 2018; Sekiya et al., 2021).<sup>xxvii,xxviii,xxix</sup>

### **Recommendation**

We recommend inclusion of preventive oral hygiene, prophylaxes and non-surgical periodontal treatment in the form of scaling and root planing on a regular basis for persons with chronic lung diseases, and daily oral hygiene care for ADL dependent persons in hospitals, assisted living, long-term care facilities and on home care. Further, there is evidence that receipt of preventive dental services before hospitalization is associated with lower rates of pneumonia in the hospital (Garcia et al., 2009).<sup>xxx</sup> CMS should consider support for dental preventive services before admission to the hospital for elective surgical or other procedures.

## **1.3 Preventive dental care and cardiovascular diseases.**

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)<sup>xxxi</sup>. PD, CVD and stroke are greatly influenced (and possibly dependent upon) chronic inflammatory mechanisms. A

recent umbrella review (Peruzzi et al., 2022)<sup>xxxii</sup> 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., 2014<sup>10</sup>, Borah et al, 2022<sup>xxxiii</sup>); however, the body of evidence is not as robust as it is for diabetes mellitus.

There is some evidence that periodontal treatment decreases surrogate risk factors for CVD, including reductions of C-reactive protein, TNF $\alpha$  and IL-6, plus LDL and reductions in hypertension, a major risk factor for CVD and stroke (Zhou, et al., 2013<sup>xxxiv</sup>; Teixeira, et al., 2020)<sup>xxxv</sup>. However, no large randomized controlled trials have been conducted to evaluate the effect of periodontal treatment on CVD risk. Thus, preventive dental treatment including tooth cleaning and oral hygiene improvement *may* decrease overall inflammatory challenge that is considered a risk factor for CVD and stroke.

## **Recommendation**

CMS may consider limiting coverage to high-risk groups such as persons with diabetes, obesity, and physical impairments, and consider a CMMI initiative (using extant data from Medicare Advantage, for example) to determine whether the cost savings noted by Borah et al. (2022)<sup>xxxvi</sup> are replicated in the Medicare setting.

## **2. Coverage to Prevent Infection: Transplant-related Surgical Procedures and Immune Suppression**

### **2.1. Prior to and during chemotherapy for cancer, and other instances of long-term immunosuppression**

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; more than two thirds of all new cancers are diagnosed among adults aged 60 years and older, i.e., the Medicare population. As the number of adults living to old age increases, so will the number of new cancer cases (CDC, 2021)<sup>xxxvii</sup>.

National expenditures in 2018 for cancer care in the U.S. were \$150.8 billion. (National Cancer Institute, 2020)<sup>xxxviii</sup>. 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)<sup>xxxix, xl</sup>.

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. Blacks/African Americans have higher cancer death rates than all other racial ethnic groups (National Cancer Institute, 2020)<sup>xli</sup>.

There is a close association of cancer and oral disease. There are many manifestations of cancer treatment and its side effects in the oral cavity, especially for older adults. Medicare provides coverage for treatment of medical services but does not provide a dental benefit for older adults, not even in

medically necessary cases like cancer. 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, immunotherapy, 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)<sup>xlii,xliii,xliv</sup>.

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. Sepsis is life-threatening organ dysfunction due to a dysregulated host response to infection (Singer, Deutschman, and Seymour, 2016)<sup>xlv</sup>. Sepsis can disrupt cancer therapy, and delay and reduce survival (Riley, Glenny, Worthington, Littlewood, Mauleffinch, Clarkson, McCabe, 2017)<sup>xlvi</sup>. Cancer patients are estimated to account for 16.4% of sepsis cases per 1000 people and are 10-times more likely to develop sepsis than non-cancer patients (Archarya, 2019; Gudiol, Puig, Cuervo, Carratala, 2021)<sup>xlvii,xlviii</sup>. The mortality rate for cancer patients who develop sepsis is 20-40%. Two thirds of sepsis cases occur in people over 60.

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)<sup>xlix</sup>. 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)<sup>l</sup>.

Oral pathogens are commonly isolated in chemotherapy-induced neutropenic fever and sepsis. Other serious oral complications 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 side effects and complications like mucositis and sepsis that increase resource utilization and cost (Paoli et al., 2018; Phonsuphot, Chimruang and Intapa, 2021)<sup>li,lii</sup>.

Elting and Chang (2019)<sup>liii</sup>, report that the incremental cost of oral mucositis among patients receiving radiation therapy is approximately \$5,000-30,000 and \$3700 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)<sup>liv</sup>. 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)<sup>lv</sup>.

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)<sup>lvi</sup>. Clinical manifestations include pain, fistulas, and exposed and extensive destruction of jaw bone. Treatment for MRONJ ranges from palliative to intensive hyperbaric oxygen and surgical removal of necrotic jawbone.

A study conducted by Owosho and colleagues (2018)<sup>lvii</sup> 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)<sup>lviii,lix,lx,lxi</sup>. 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.

## Recommendation

We recommend that preventive dental care, oral hygiene care, and dental treatments to eliminate oral infection (see paragraph below for a list of appropriate codes) are medically necessary in cancer therapy (Archayra, 2019; Parisi and Glick, 2003; Ishimaru et al, 2018; Saito, Watanabe, Sato, Ikawa, Yoshida, Katakura, Takayama and Sato, 2014)<sup>lxii,lxiii,lxiv,lxv</sup>. There are increased risks for compromising clinical outcomes and increasing the cost burden of cancer care when treatment plans do not include dental screening, preventive dental care, and dental procedures that precede chemotherapy, radiation, and bone marrow transplants. Dental care should be included before and when critically necessary during treatment and continued as ongoing oral health care until immunosuppression is resolved (Riley, Glenny, Worthington, et al., 2018; Ishimaru, Matsui, Ono et al., 2018; Saito, Watanabe, Sato et al., 2014)<sup>lxvi,lxvii,lxviii</sup>. Since ~66% of cancer occurs in older adults, these additional costs and poor clinical outcomes have a significant negative effect on CMS costs.

We further recommend that CMS provide a medically necessary dental benefit for preventive, diagnostic, periodontal, caries removal, extractions, and management of oral side effects of cancer treatment in both inpatient or community settings and cover reconstruction essential to *restoring capacity to eat, drink, and swallow to maintain nutrition and overall health*. The evidence supports that this dental benefit should begin prior to beginning cancer therapy and continue as appropriate during treatment and continue post-treatment until immunosuppression ends, infections are resolved, and restorative interventions when indicated are completed.

(The appropriate CDT codes for consideration are D0120, D0140, D0150, D0210, D0230, D0270, D0272, D0273, D0274, D0277, D0330, D1110, D1206, D1208, D4341, D4342, D4346, D4355 and D4910. We estimate the monthly pmpm costs of this care per affected and dentally adherent person at \$36.17.<sup>lxix</sup> Implementation logic regarding fragmentation/bundling, integral procedures and allowable contemporaneous procedures is available upon request.)

## 2.2 Transplant surgery and during the post-surgical immunosuppression

By 2021, more than 40,000 solid organ transplants occurred annually in the United States<sup>lxx</sup>. Age is no longer a contraindication to transplantation. Nearly 25% of people on solid organ transplant waitlists are 65 years of age and older (Hemmersbach-Miller, et. al., 2021)<sup>lxxi</sup>. These lifesaving procedures include, but are not limited to the kidney, lung, heart, liver, and pancreas. People with chronic conditions like end stage renal disease (ESRD), severe diabetes, advanced heart or lung disease, and liver disease are candidates for transplants that replace their damaged solid organs (Parisi and Glick 2019)<sup>lxxii</sup>. The five-year survival rate for single solid organ transplants is > 70% for kidney, liver, and pancreas transplants (Hanrahan, Israni and Danovitch, 2021; Gil et al., 2018; Shyr et al., 2021)<sup>lxxiii,lxxiv,lxxv</sup>. Life-threatening infections related to the weakened immune systems of older adults (immunosenescence) and transplant-related immunosuppression are serious complications of transplantation. Older adults are at increased risk for infectious complications following solid organ transplants (Hemmersbach-Miller, et. al., 2021).

Kidney transplant patients have additional concerns related to being on dialysis where they develop significant co-morbid conditions like portal hypertension. Moreover, evidence shows that oral disease is prevalent in the renal dialysis community; up to 50% of individuals in dialysis units have less than

standard dental care and unsatisfactory oral health status. Most dental care is performed on an emergency basis, thereby supporting that there is often longstanding oral disease prior to transplantation that may be a barrier to having this life and cost saving treatment<sup>lxxxvi</sup>. Oral health is also important for clinical outcomes prior to and after heart transplantation. Gruter and Brand (2020)<sup>lxxxvii</sup> reported that patients who underwent heart transplant and followed an immunosuppression regimen, had a higher risk of gingival hyperplasia, periodontitis, Candida infections, xerostomia, and a 4.3 times higher chance of developing oral malignancies in comparison to healthy individuals. Persons with end stage liver disease have comorbid conditions, including dental infections that can postpone being listed for a transplant (Guggenheimer, et. al., 2007)<sup>lxxxviii</sup>. Åberg and colleagues (2014)<sup>lxxxix</sup> reported that one of the last clearances presented to their Liver Transplant Board is the oral health status of the transplant candidate. Their findings reveal that multiple tooth extractions, a surrogate marker of dental infections, was significantly associated with reduced time from diagnosis of liver disease to need for liver transplantation ( $p=0.02$ ).

High rates of poor oral health, including periodontal disease and xerostomia, are risk factors for compromising successful transplant outcomes. Infection is a risk factor for poor prognosis, and associated with malnutrition, wasting syndrome and increased levels of local and systemic inflammation. Transplant patients typically take multiple medications involving long-term use of immunosuppressive drugs, as well as multiple medications for co-morbidities like diabetes and cardiovascular disease. Schonfeld and colleagues (2019)<sup>lxxx</sup> provide evidence that screening for and treatment of oral inflammation and infections, including decay (extractions, fillings), gingivitis, and periodontitis (scaling and root planing), must begin pre-transplantation and continue as appropriate post-transplantation, after 3-6 months, to prevent sepsis and organ rejection until immunosuppression is resolved. But for dental problems being resolved and/or stabilized, thereby lowering the risk for Infection and sepsis pre-transplant, this medical/surgical procedure may not be able to proceed.

### **Recommendation**

We recommend that candidates for solid organ transplants be required to have a dental assessment/screening for and treatment of decay and infections like periodontal disease prior to and following transplant surgery that potentially compromise the outcomes of surgery (including organ rejection).

### **3. Administrative and Procedural Issues**

Coding: We are in favor of using extant EHR coding systems such as ICD10 and CDT codes for treatment. Of note is that both have been mandated for dental care in the Veterans Health Administration (VA) since the mid-1990s. Moreover, VA has developed common ICD code lists (~10 most common diagnoses used per treatment) to link to dental treatments.<sup>lxxxi</sup>

Location of Treatment: CMS sought comments on the best location of treatment to be provided. We recommend that treatment be provided in outpatient facilities, when appropriate and inpatient facilities as necessary. Treatments may also be provided in assisted living and private residences as needed and appropriate.

### **Coverage standard for medically necessary services.**

From pages 445-6: “For example, after further review, we believe that if a patient requiring an organ transplant has an oral infection, the success of that transplant could be compromised if the infection is not properly diagnosed and treated prior to the transplant surgery. Without an oral or dental examination to identify such an infection, and the necessary treatment, such as restorative dental services, to eradicate it prior to the transplant procedure, the patient’s ability to accept the organ

transplant could be seriously complicated or compromised. Examples of restorative dental services to eradicate infection could include: extractions (removal of the entire infection, such as pulling of teeth - for example, CDT D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as fillings - for example, CDT D2000-2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planning – for example, CDT D4000-4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal - for example, CDT D3000-3999).”

At present, patients with ESRD and potential kidney transplant are covered under Medicare Advantage, most often a plan called D-SNP, which is a combination Medicare-Medicaid plan that includes many patients under the age of 65.

There is insufficient research to support appropriateness and cost effectiveness of restorations and root canals as preventive measures in these populations. Other questions around implementation are appropriate. Will these services have the same deductible and co-payments limits as the rest of Medicare? How will the fee schedule be determined to maximize participation? In many states, Medicare Advantage networks with their lower reimbursement include no more than 25% of private practice dentists.

### **Recommendation**

Lamster, et al.<sup>lxxxii</sup> or Borah, et al.<sup>lxxxiii</sup> provide the framework for appropriate medically-related dental coverage. The only difference is coverage for extractions. There would need to be language referring to “integral components” of procedures to prevent unexpected billing to patients. When restorative and endodontics are included, costs would increase by 3x to 5x based on Lamster and proprietary data.

Oral cancer exams (D0431) should be considered an integral component of clinical exams (D0120-D0150). The appropriate CDT codes for consideration are D0120, D0140, D0150, D0210, D0230, D0270, D0272, D0273, D0274, D0277, D0330, D1110, D1206, D1208, D4341, D4342, D4346, D4355 and D4910. Extraction codes D7140, D7210, D7250 and D7251 merit inclusion based on the findings in Lamster, et al., 2022<sup>lxxxiv</sup>. Implementation logic regarding fragmentation/bundling, integral procedures and allowable contemporaneous procedures is available upon request.

### **Coverage of dental services for care management services.**

There may be value in adopting some Medicare Advantage protocols. Current Medicare Advantage coverage of dental procedures ranges from preventive only to comprehensive. However, CMS defines comprehensive as at least one of each of the following services: exam, cleaning, x-rays, Fluoride treatment, and other CDT code OR one of each of the following services per year: non-routine, diagnostic, restorative, endodontic, periodontic, extraction and “others”. This definition is not consumer friendly and is the source of many patient complaints. Some coverage plans bypass procedure-based limitations and provide the patient with an annual allowance.

Some Medicare Advantage plans include a network of dentists similar to a dental HMO for cost containment and there are no benefits available outside the network. Often, PPO networks contain fewer dentists compared to traditional PPOs. Very few Medicare Advantage plans pay more than 75% of UCR. There are access to care concerns about all options.

### **Recommendations**

1. Medically necessary dental care should increase access to needed oral health care and allow the patient to keep one’s own dentist.

2. Reimbursements levels should be at the 70%-85% of UCR<sup>lxxxv</sup> as determined by Fair Health fees. There may be concerns the higher fees are too costly. Of note is that the fees used by Borah, et al.<sup>lxxxvi</sup> resulted in significant healthcare cost savings.
3. CMS must consider that many technical and invasive procedures will be outside the scope of the proposed Medicare coverage. The use of multiple dentists may be counterproductive and result in increased time and cost to the patient.

### **Future payment models**

CMS will reap the greatest value when dentists have patients who have the highest compliance with preventive dentistry. Rewarding dentists for providing preventive services is the most efficient method of creating a risk sharing arrangement when total healthcare costs are outside of their control.

The proposed rule has the potential impact of adding more than 200,000 dental clinicians to the CMS rolls who have been siloed off from current patient protection protocols because of the exclusion of oral health care from Medicare. In Medicare Advantage plans, dentists are considered “Downstream Entities”, but they are required to meet the same requirements as providers who are in-plan providers with Medicare. Will dentists be credentialed in the same manner as physicians and other health care professionals? How quickly will CMS be able to promulgate and implement rules for credentialing dentists? How will this impact dentists who are currently DME providers to CMS? What are the rules for non-covered services and balance billing? Does CMS have the capacity and training to perform FWA evaluations for dental care?

### **Recommendation**

CMS create an Advisory Panel of medical and dental third-party payers with NCQA dental credentialing and FWA analysis experience. This group should include dental clinicians who are knowledgeable in caring for older adults, understand the value of the dental team in oral health prevention and the importance of integrating oral health into overall health care.

### **Benefits Coordination**

For patients receiving limited dental benefits through Medicare A and B, insurance companies will need to create a “wrap around” individual policy or they may elect to continue with the current offerings. There is no difficulty either from an administrative or actuarial standpoint when rules concerning the underlying coverage are provided in a timely manner. A basic federal employee plan known as FEHB is administered by Blues or Elevance Health (Anthem) in most states and has additional coverage or a wraparound commercially available insurance plan by GEHA and others known as FEDVIP<sup>lxxxvii</sup>. From the insurance company perspective, multiple options will still be made available to Medicare recipients. Dental offices that participate with insurance plans are used to submitting to secondary carriers.

### **Recommendation**

Any benefit changes to dental coverage must be published by March 31 of the preceding year to allow Medigap or “wrap around” plans to evaluate and file with the individual states in a timely manner.

## **4. Legal Analysis of “Inextricably Linked” Standard**

We strongly support CMS’ proposal to clarify and codify its interpretation of section 1862(a)(12) of the Act to recognize Medicare payment for dental services that are essential to certain covered medical services. For decades, the cost of dental care has hindered Medicare beneficiaries from being able to safely undergo important medical treatments. Historically under-resourced populations have faced disproportionate barriers in affording medically related dental care. The agency’s proposal paves the

way toward ameliorating disparities in access to critical health services and bringing Medicare's dental coverage policy up to date with clinical standards of care.

We have concern, though, about the proposed wording of the legal standard exempting from the statutory exclusion "[d]ental services that are *inextricably linked* to, and substantially related and integral to the clinical success of, a certain covered medical service[.]" (emphasis added) We anticipate that uncertainty about the meaning of the phrase "inextricably linked to" could lead to inconsistent decisions on claims, appeals, and prior authorizations, and create frustrations for patients, medical providers, and adjudicators alike.

Oxford Languages defines the term "inextricably" to mean "in a way that is impossible to disentangle or separate." Merriam-Webster defines "inextricable" as "forming a maze or tangle from which it is impossible to get free." The phrase "inextricably linked" thus connotes an absolute inseparability and could be unduly restrictive if employed as a coverage standard without guiding criteria. In evaluating whether a dental service is inextricably linked to a medical service, a contractor might incorrectly deny coverage if the two services could, as a practical matter, ever be considered independently. Another contractor might construe the standard as a temporal one, akin to the current "same time/same dentist" rule requiring that the two services be furnished simultaneously. This would not align with the fact that Medicare payment is allowed in some scenarios where dental services are performed separate from the covered medical service (e.g., extraction of teeth to prepare the jaw for radiation treatment, oral or dental exam prior to kidney transplant). A legal standard that raises ambiguity or inconsistency would demand further clarification from the agency in the future.

The policy goals of CMS' proposal can be effectively achieved just by narrowly tailoring payment to dental services that are "substantially related and integral to the clinical success of certain covered medical services." This is a rigorous, yet clearer and workable, standard that contractors, plans, and adjudicators can apply in analyzing claims. They will be able to determine, without speculation, if a claim meets this requirement based on whether the clinical evidence demonstrates that the standard of care for a covered medical treatment necessitates dental clearance, or the provision of ancillary dental services, or appropriate measures to address dental infections and other oral problems, to avoid undue risk and promote a positive outcome.

## **5. Legal Analysis of Integral Dental Treatment Coverage**

We commend CMS's recognition that there may be clinical scenarios where the ongoing disease management of a patient receiving medically necessary care may have an improved outcome or see a clinical benefit from the performance of dental services. We believe there are situations in which dental services should be considered so integral to the standard of care for an otherwise covered medical service that the statutory payment preclusion does not apply. Prime examples are where rampant, untreated periodontal disease is complicating the management of a patient's diabetes, or recurrent aspiration or nosocomial pneumonia is seeding from oral periodontopathic bacteria. Access to targeted dental care can help prevent the adverse personal and fiscal consequences in these examples, and the statute does not bar Medicare payment for such care.

Medicare's foot care policy offers a precedent here. Section 1862(a)(13) of the Act unambiguously excludes payment for routine foot care. Nevertheless, there is longstanding policy guidance allowing payment for routine foot care determined to be a necessary and integral part of otherwise covered services (e.g., diagnosis and treatment of ulcers, wounds, or infections), or where an individual has an underlying systemic medical condition (i.e., metabolic, neurologic, and peripheral vascular diseases) that has caused severe circulatory problems or diminished sensation in the individual's legs or feet. Applying

similar authority and clinical justification, CMS could duly cover certain dental treatments integral to the standard of care for patients presenting with certain underlying medical conditions and clinical findings.

### **Conclusion**

Thank you for this opportunity to provide comments about the Administration's proposal to deliver much-needed coverage of medically necessary oral and dental treatment. 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.

If you have additional questions regarding these matters and the comments offered herein, please contact Patricia M. D'Antonio, Vice President, Policy and Professional Affairs at [pdantonio@geron.org](mailto:pdantonio@geron.org) or 202-587-5880.

Sincerely,

A handwritten signature in cursive script that reads "James C. Appleby".

James C. Appleby, BSPHarm, MPH, ScD (Hon)  
Chief Executive Officer

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