



August 30, 2022

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1779-P
P.O. Box 8016
Baltimore, MD 21244-8016
Submitted electronically to: <http://www.regulations.gov>
Re: CMS-1770-P (Section II.L.)

To Administrator Brooks-LaSure:

The Oral Health Nursing Education and Practice Program (OHNEP) is pleased to provide the Centers for Medicare & Medicaid Services (CMS) comments on the proposals and request for information on Medicare Parts A and B Payment for Dental (Section II.L.) in the proposed rule on Medicare and Medicaid Programs: CY2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies, Medicare Shared Savings Program Requirements, etc. (CMS-1770-P).

The Oral Health Nursing Education and Practice (OHNEP) Program is a unique national initiative that aims to enhance the nursing profession's interprofessional role in oral health and its links to overall health in both academic and clinical settings. Funded by the CareQuest Institute for Oral Health, the OHNEP program aims to integrate interprofessional oral health content and competencies for the nation's 4.2 million nurses in undergraduate and graduate nursing programs through faculty and preceptor development, curriculum integration, and establishment of "best practices" in clinical settings.

The OHNEP Program recognizes that oral health has a significant impact on the overall health and well-being of individuals across their lifespan yet, all too often, forgotten as an essential part of overall health. Among older adults, 47% of whom have no dental insurance, the burden of oral disease is most significantly borne by those who are members of racially and ethnically diverse, poor, and under resourced communities (Freed et al., 2021). Poor oral health for older adults is associated with pain, loss of teeth, poor nutrition, infection, increased risk for systemic conditions and related complications associated with serious morbidity and mortality. The aging of the US population, coupled with the increasing number of adults retaining their teeth and who

have one or more chronic conditions with an oral-systemic connection, creates an unprecedented need for oral health care among older adults, highlighting the need for improving the population health of older adults by authorizing a Medically Necessary Medicare Dental Benefit.

We thank CMS for its willingness to consider revision of the now restrictive definition of medically necessary dental coverage to support a dental benefit for those conditions where the provision of dental services is “inextricably linked to the clinical success of an otherwise covered medical service” and, as such, significantly and integrally related to that primary medical service and delivered in both inpatient and community settings.

As a nurse-led national initiative that has engaged nursing students, faculty, administrators, and practicing clinicians, the OHNEP program is in a unique position to respond to the considered revision for a medically necessary dental benefit for older adults. Registered Nurses (RN), Nurse Practitioners (NP), and Midwives (CNM) are on the frontlines 24/7 of settings where older adults access healthcare in primary and specialty care, hospitals, long term care, as well as home settings. Across these clinical settings, nurses 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. The related increased costs are a burden to Medicare that could be reduced with preventive dental care before, during, and following treatment as appropriate.

Non-Communicable Chronic Conditions

Diabetes. The CDC reports that people with specific non-communicable diseases (NCDs) are more likely to have clinical outcomes that are impacted by severe oral disease, especially periodontal disease (Parker et al., 2020). Diabetes (DM), a metabolic disorder characterized by abnormal glucose metabolism, affects >11% of the population with a marked increase in prevalence (~27%) in persons 65 and older. Physicians, Nurse Practitioners, Registered Nurses, and Physician Assistants provide medical management of DM in primary, specialty, acute, and other clinical settings and understand the bi-directional relationship between effective glycemic control and prophylactic oral health care that contribute to preventing the complications of diabetes and poor glycemic control including nephropathy, neuropathy, retinopathy, and amputation (Lamster, 2014). The total cost of diabetes-related care in the United States has been estimated at \$327 billion (Centers for Disease Control and Prevention, 2022). There is a close association of DM and oral diseases. Manifestations in the oral cavity include periodontitis (gum disease), Candida infections, xerostomia (dry mouth), and decay affecting the roots of the teeth and increased potential for tooth loss. DM is the

only recognized chronic disorder that is a risk factor for periodontitis. It is important to note that the relationship between DM and periodontitis is bi-directional, as periodontitis has been shown to be a risk factor for poor metabolic control in persons with DM (Lamster, 2014).

Findings from clinical studies reveal that treatment of periodontitis is associated with improvement in glycemic control. Specifically, conservative periodontal treatment is associated with a reduction in HgA1c of 0.4-0.5%. This is due to the removal of periodontal biofilm which reduces the bacterial burden and the resulting reduction in periodontal inflammation (Simpson et al., 2022). Additional analyses of large data bases show that access to conservative periodontal treatment/preventive dental care is associated with improved health outcomes and reduced healthcare costs (Jeffcoat et al., 2014; Nasseh et al., 2016; Lamster et al., 2021). The most recent study by Borah and colleagues (2022), investigating the association of preventive dental care and health outcomes for persons with DM and cardiovascular disease, used the Arkansas BlueCross and BlueShield database from 2014-2018. 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 reduction in hospitalizations.

The OHNEP program recommends inclusion of preventive dental care and conservative (non-surgical) periodontal treatment as needed for persons with DM to reduce inflammation and infections, thereby contributing to improvement in health outcomes and cost avoidance/savings in health care utilization/resources.

Respiratory Conditions. Poor oral health is associated with respiratory infections like pneumonia. Pneumonia the #1 cause of hospital acquired infections and especially common in older adults (Munro et al., 2021). Epidemiological studies show that organisms causing pneumonia are identical pathogens to those isolated from the teeth of intubated patients with ventilator acquired pneumonia (VAP) (Heo et al., 2008). Data from systematic reviews support that improved oral hygiene in hospital and nursing home settings reduces the risk of pneumonia (Sjogren et al., 2016; Zhao et al., 2020; Liang et al., 2021). Oral hygiene protocols administered in hospital intensive care settings is most often provided by the nursing staff.

Non-ventilator hospital acquired pneumonia (NV-HAP) has been recognized as a significant, but largely preventable cause of hospital acquired infections. NV-HAP comprises 60% of the cases of hospital-acquired pneumonia (Munro et al., 2021). NVHAP accounts for over \$3 billion in healthcare costs annually in the U.S. (Munro, et al., 2022). In acute care settings, there is a body of evidence on the role of oral care for NV-HAP prevention. A Veterans' Health Administration (VHA) interprofessional team, led by nurse researchers, have scaled a nursing staff administered oral hygiene protocol across the VHA system to 155 hospitals and long-term-care facilities, where

they have demonstrated NV-HAP reductions up to 92% with significant related cost avoidance (Munro & Baker, 2019).

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 supports the impact of poor oral hygiene and periodontal disease as exacerbators of COPD progression. Findings of studies reveal that reduced lung function is associated with severity of periodontal disease (Scannapieco & Ho, 2001; Sanz et al., 2020) a number of clinical trials support that periodontal therapy in the form of scaling and root planning can reduce the risk of COPD progression (Kelly et al., 2021).

Estimates suggest that a single case of VAP incurs additional treatment costs of \$28-\$40,000 (Giuliano et al., 2018; Agency for Healthcare Research and Quality, 2017). Alternatively, consider the cost of providing preventive oral hygiene resources for hospital and long-term care patients at the bedside that cost a few dollars per day, plus time to implement an oral hygiene protocol as a reportable quality improvement indicator as a NVHAP reduction and cost savings/avoidance strategy (Munro & Baker, 2018; Munro et al., 2021; Sekiya et al., 2021).

The OHNEP program recommends inclusion of preventive dental care, including oral hygiene protocols, for older adults at risk for pneumonia, especially prior to hospitalization, surgery, and in long term care settings. We also recommend as preventive dental care and conservative (non-surgical) periodontal treatment as needed for persons with COPD to reduce inflammation and infections, thereby contributing to improvement in health outcomes and cost avoidance/savings in health care utilization/resources.

Immunosuppression

Cancer. 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).

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).

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 available in hospital and community settings, 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 (Acharya et al., 2019; Parisi & Glick, 2003; Keefe & 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. Sepsis can disrupt cancer therapy, and delay and reduce survival (Riley et al., 2017). Cancer patients are estimated to account for 16.4% of sepsis cases per 1000 people and are ten times more likely to develop sepsis than non-cancer patients (Acharya et al., 2019; Gudiol et al., 2021). The mortality rate for cancer patients who develop sepsis is 20-40%. Two thirds of sepsis cases occur in people over 60.

Physicians and nurses, as well as other members of the oncology team, care for patients who experience the complications and side effects of their cancer treatment. Oral pathogens are commonly isolated in potentially life-threatening chemotherapy-induced neutropenic fever and sepsis. Mucositis, a painful side effect of chemotherapy and/or radiation, affects the oral cavity and digestive tract, and involves inflammation, as well as painful sores and ulcers in the mouth and throughout the digestive tract. 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 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 & 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).

Preventive dental care, oral hygiene care, and dental treatments to eliminate oral infection are medically necessary in cancer therapy (Acharya et al., 2019; Parisi & Glick, 2003; Ishimaru et al., 2018; Saito et al., 2014). For example, a study conducted by Owosho and colleagues (2018) at Memorial Sloan Kettering Cancer Center (MSKCC) with >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 (Dimopoulos, 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.

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 et al., 2018; Ishimaru et al., 2018; Saito et al., 2014). Since ~66% of cancer occurs in older adults, these additional costs and poor clinical outcomes have a significant negative effect on CMS costs.

The OHNEP program recommends 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.

Transplantation. 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). These lifesaving procedures include, but are not limited to the kidney, lung, heart, liver, and pancreas. Nurses provide care for people with chronic conditions like end stage renal disease (ESRD), severe diabetes, advanced heart or

lung disease, and liver disease who are candidates for transplants that replace their damaged solid organs (Parisi & Glick, 2019). They understand how poor oral health, including decay and gum disease, negatively impact optimal clinical outcomes. The five-year survival rate for single solid organ transplants is > 70% for kidney, liver, and pancreas transplants (Hanrahan et al., 2021; Gil et al., 2018; Shyr et al., 2021). 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 (Provenzano, 2005).

Oral health is also important for clinical outcomes prior to and after heart transplantation. Gruter and Brand (2020) 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). Åberg and colleagues (2014) reported that one of the last clearances presented to their Liver Transplant Board is the oral health status of the transplant candidate.

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) 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.

The OHNEP program recommends 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).

Conclusion

Thank you for the opportunity to provide comments about the Administration's proposal to provide medically necessary oral and dental Medicare coverage. While the nursing profession will not be providing the dental care, we can contribute to implementing oral hygiene assessment and intervention protocols, promoting lifestyle changes, and improving oral health literacy. Improving oral health will improve overall health for older adults, quality of life, and health equity for our nation's seniors. The OHNEP program is confident that the proposed implementation of a medically necessary dental benefit will lower overall healthcare costs and make an important contribution to improving health outcomes for older adults, especially those with targeted NCDs, cancer, and in need of organ transplantation. The Oral Health Nursing Education and Practice (OHNEP) program is available to serve as a clinical resource as continuing progress is made as, together, we collaborate on improving the oral health and overall health of America's older adults.

Very truly yours,

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