

August 29, 2022 Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1770-P P.O. Box 8016 Baltimore, MD 21244-8016

Submitted electronically to: http://www.regulations.gov

Re: CMS-1770-P (Section II.L.)

TO WHOM IT MAY CONCERN:

The Santa Fe Group (SFG) (https://santafegroup.org/) 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).

INTRODUCTION:

The Santa Fe Group is a 501 (c)(3), action-oriented think tank with a passion to improve lives through oral health. Since its inception 25 years ago, the SFG has been instrumental as a neutral convener, communicator, connector and catalyst to move the needle on critical issues such as oral cancer, dental education reform, children's oral health, improved primary care access, the importance of linking medical and dental health systems, and most recently, expanding oral healthcare for our nation's seniors.

We thank CMS for its willingness to consider revision of the now restrictive definition of medically necessary dental coverage. The SFG has worked in various capacities with the CMS, other federal agencies, and like-minded groups to support the inclusion of medically necessary dental treatment in Medicare parts A and B for nearly seven years. The SFG agrees with CMS that there are many instances where dental services are "inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are substantially related and integral to that primary medical service". We suggest that coverage in the circumstances below will improve population health and health equity in America, as many of the chronic medical conditions included are unequally distributed among medically and dentally underserved individuals.

Despite the progress made in reducing dental disease and edentulism in older adults, inequities remain in access to oral health care and health outcomes related to race, ethnicity, residence, socioeconomic level, gender identity, and sexual orientation. Such inequities diminish health and quality of life. Poor oral health has consequences for health, consequences that are often more significant for Black, Hispanic, and AI/AN individuals. For example, people with periodontal disease (PD) — also called gum disease — are 28% more likely to suffer a first-time heart attack than persons without this condition¹. Further, while white adults over the age of 18 are more likely to have heart disease, Black adults are more likely to die of heart disease². Black, and Hispanic Americans and AI are also more likely to have severe PD^{3,4}. Treating PD in people with diabetes is "particularly important" because successfully managing PD is linked with successfully managing blood sugar levels. Because diabetes rates are higher in AI/AN, Black, and Hispanic communities than in white communities, untreated PD is likely to result in greater harm for these communities⁵.

1. Periodontitis Increases the Risk of a First Myocardial Infarction | Circulation (ahajournals.org)

4. Nelson RG, Schlossman M, Budding LM, et al. Periodontal Disease and NIDDM in Pima Indians. Diabetes Care 13:836-40, 1990.

^{2.} Racial and Ethnic Disparities in Heart Disease (cdc.gov)

^{3.} National Institutes of Health. Oral Health in America: Advances and Challenges. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Institute of Dental and Craniofacial Research, 2021. Pp.3B3-5.

^{5.} L Casanova, F J Hughes, P M Preshaw, Diabetes and periodontal disease: a two-way relationship, Br Dent J. 2014 Oct;217(8):433-7. doi: 10.1038/ sj.bdj.2014.907.

The cost of oral health care remains a significant barrier to equitable access to care and improved oral health. According to the Social Security Administration, among elderly beneficiaries:

- 37% of men and 42% of women receive half or more of their income from Social Security, and
- 12% of men and 15% of women rely on Social Security for 90% or more of their income⁶.

Medicare Parts A and B traditionally do not cover routine dental services; Medicare Advantage dental benefits vary greatly by plan. Nearly 24 million Medicare beneficiaries lack critical oral health coverage, and 76.5 million adult Americans lack dental coverage overall. Many older adults did not receive regular dental services when they were younger and as a result experience more dental disease and need more extensive treatment to maintain their oral health. Among all Medicare and Medicare Advantage recipients, at least 75% of total dental costs were paid out of pocket, adding strain to household budgets for people on fixed incomes⁷.

All Americans should receive regular dental care to prevent oral health problems from developing and affecting general health. When cost, lack of transportation, or other barriers lead people to postpone care, oral infections are likely to worsen and become more difficult and costly to treat. Similarly, because of delays in care, cancers of the mouth and throat might not be diagnosed until these conditions become more dangerous. Untreated and active dental disease inequitably affects the general health outcomes of several chronic diseases leading to increased morbidity and costs.

In considering what changes to make in the delivery of medically necessary dental care in Medicare, CMS can benefit from the many studies and prospective actions of the private health care insurance sector. Insurance studies and industry practices strongly suggest that provision of dental care, especially the elimination of oral infections, can lower total healthcare costs significantly. This cost savings is realized almost entirely by fewer and shorter hospitalizations for chronic, non-communicable diseases like diabetes, respiratory infections and heart disease.^{8,9,10,11}

CMS seeks criteria to use in determination of medical necessity. SFG favors the use of the triple aims criteria for guidance, i.e., coverage of dental problems and procedures that are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are substantially related and integral to that primary medical service. Further, covered dental services should improve one or more of the triple aims: patient experience, cost, and clinical outcomes.

Santa Fe Group recognizes that CMS is interested in feedback on whether there are circumstances - such as diabetes - where the ongoing disease management of the patient receiving a medically necessary treatment may have an improved outcome or see a clinical benefit from the performance of dental services. Thus, the first category, and the one with the greatest potential impact on health and cost avoidance, addresses Dental Services Integral to Covered Medical Services Which Can Result in Improved Patient Outcomes, especially diabetes. The second category is coverage to prevent infection prior to and during the recovery from cancer and transplant surgical procedures and before and during immune suppression. A final section addresses administrative matters as requested.

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 disease¹². Although there is an extensive list of NCDs to which oral diseases are linked, the SFG 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

- Nasseh K, Vujicic M, Glick M. The relationship between periodontal interventions and healthcare costs and utilization: Evidence from an integrated dental, medical, and pharmacy commercial claims database. Health Econ. 2017;26:519–527. http://onlinelibrary.wiley.com/doi/10.1002/hec.3316/epdf. Accessed June 1, 2016.
- 11. Avalere Health LLC. Evaluation of Cost Savings Associated with Periodontal Disease Treatment Benefit. Memo to Pacific Dental Services Foundation. January 4, 2016. Accessed August 30, 2017. http://pdsfoundation.org/downloads/Avalere_Health_Estimated_Impact_of_Medicare_Periodontal_Coverage.pdf.
- 12. ParkerML, Thornton-EvansG, WeiL,GriffinSO. Prevalence of and Changes in Tooth Loss Among Adults Aged ≥50 Years with Selected Chronic Conditions United States, 1999–2004 and 2011–2016. MMWR 2020;69:21.

^{6.} Fast Facts & Figures About Social Security, 2021 (ssa.gov)

^{7.} The Glaring Scope of Racial Disparities in Oral Health | CareQuest Institute for Oral Health

^{8.} United Healthcare. Medical Dental Integration Study 2013. http://www.uhc.com/content/dam/uhcdotcom/en/Private%20Label%20Administrators/100-12683%20Bridge2Health_Study_Dental_Final.pdf. Accessed June 1, 2016.

^{9.} Cigna. Improved Health and Lower Medical Costs: Why Good Dental Care is Important. 2010. https://www.cigna.com/assets/docs/life-wall-library/ Whygooddentalcareisimportant_whitepaper.pdf. Accessed June 1, 2016.

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 sequalae 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)¹³.

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)¹⁴.

Clinical studies have demonstrated that 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 inflammation¹⁵.

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)¹⁶. 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)¹⁷. After deducting the cost of the dental service for the first two years of the study, the two-year savings in the 3rd and 4th 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)¹⁸. 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)¹⁹. 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

^{13.} Centers for Disease Control and Prevention. National Diabetes Statistics Report website.https://www.cdc.gov/diabetes/data/statistics-report/index. html. accessed 8/3/2022.

^{14.} Lamster IB. Diabetes Mellitus and Oral Health: An Interprofessional Approach. 2014. John Wiley & Sons, Inc. Ames, Iowa.

Simpson TC, Clarkson JE, Worthington HV, MacDonald L, Weldon JC, Needleman I, Iheozor-Ejiofor Z, Wild SH, Qureshi A, Walker A, Patel VA, Boyers D, Twigg J. Treatment of periodontitis for glycaemic control in people with diabetes mellitus. Cochrane Database of Systematic Reviews 2022, Issue 4. Art. No.: CD004714. DOI: 10.1002/14651858.CD004714.pub4.

^{16.} Jeffcoat MK, Jeffcoat RL, Gladowski PA, Bramson JB and Blum JJ. Impact of periodontal therapy on general health. Evidence from insurance data for five systemic diseases. American Journal of Preventive Medicine 2014;47(2):166-174.

^{17.} Nasseh K, Vujicic, M and Glick, M. The relationship between periodontal interventions and health care costs and utilization. Evidence from an integrated dental, medical and pharmacy commercial database. Health Affairs 2016. doi:10.1002/hec.3316.

Smits KPJ, Listl S, Plachokova AS, Van der Gallen O and Kalmus O. Effect of periodontal treatment on diabetes-related costs: a retrospective study. BMJ Open Diabetes Research & Care 2020. doi:10.1136/bmjdrc-2020—001666.

^{19.} Lamster I, Malloy KP, DiMura PM, Cheng B, Wagner VL, Matson J, Proj A, Xi Y, Abel SN and Alfano MC. Dental services and health outcomes in the New York State Medicaid program. Journal of Dental Research 2021; 100 (9): 928-934.

care versus enrollees with diabetes who did not access such care (Lamster et. al., 2022)²⁰. 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)²¹. 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, SFG recommends 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)²² and Aspiration Associated Pneumonia (AP) (Scannapieco 2021)²³. 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)²⁴. Systematic reviews have documented that improved oral hygiene in the hospital and nursing home setting reduces the risk of pneumonia (Sjogren et al. 2016²⁵, Zhao et al. 2020²⁶, Liang et al. 2021²⁷).

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)²⁸. 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)²⁹. 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 2001³⁰; Offenbacher et al. 2012³¹) and a

^{20.} Lamster I, Malloy KP, DiMura PM, Cheng B, Wagner VL, Matson J, Proj A, Xi Y. Abel SN and Alfano MC. Preventive dental care is associated with improved health care outcomes and reduced costs for Medicaid members with diabetes. Frontiers in Dental Medicine, 2022 (in press).

Borah.BJ, Brotman SG, Dholakia R, Dvoroznak S, Jansen MT, Murphy EA and Naessens JM. Association between preventive dental care and healthcare cost for enrollees with diabetes or coronary heart disease: 5-year experience. Compendium 2022; 43 (3):130-139.

^{22.} Scannapieco, F. A. (1999). "Role of oral bacteria in respiratory infection." J Periodontol 70(7): 793-802.

^{23.} Scannapieco, F. A. (2021). "Poor Oral Health in the Etiology and Prevention of Aspiration Pneumonia." Dent Clin North Am 65(2): 307-321.

^{24.} Heo, S. M., E. M. Haase, A. J. Lesse, S. R. Gill and F. A. Scannapieco (2008). "Genetic relationships between respiratory pathogens isolated from dental plaque and bronchoalveolar lavage fluid from patients in the intensive care unit undergoing mechanical ventilation." Clin Infect Dis 47(12): 1562-1570.

^{25.} Sjogren, P., I. Wardh, M. Zimmerman, A. Almstahl and M. Wikstrom (2016). "Oral Care and Mortality in Older Adults with Pneumonia in Hospitals or Nursing Homes: Systematic Review and Meta-Analysis." J Am Geriatr Soc 64(10): 2109-2115.

^{26.} Zhao, T., X. Wu, Q. Zhang, C. Li, H. V. Worthington and F. Hua (2020). "Oral hygiene care for critically ill patients to prevent ventilator-associated pneumonia." Cochrane Database Syst Rev 12: CD008367.

^{27.} Liang, S., X. Zhang, Y. Hu, J. Yang and K. Li (2021). "Association between perioperative chlorhexidine oral care and postoperative pneumonia in non-cardiac surgical patients: A systematic review and meta-analysis." Surgery 170(5): 1418-1431.

^{28.} Scannapieco, F. A., K. K. Giuliano and D. Baker (2022). "Oral health status and the etiology and prevention of nonventilator hospital-associated pneumonia." Periodontol 2000 89(1): 51-58.

^{29.} Baker, D., K. K. Giuliano, M. Thakkar-Samtani, F. A. Scannapieco, M. Glick, M. I. Restrepo, L. J. Heaton and J. Frantsve-Hawley (2022). "The association between accessing dental services and nonventilator hospital-acquired pneumonia among 2019 Medicaid beneficiaries." Infect Control Hosp Epidemiol: 1-3.

^{30.} Scannapieco, F. A. and A. W. Ho (2001). "Potential associations between chronic respiratory disease and periodontal disease: analysis of National Health and Nutrition Examination Survey III." J Periodontol 72(1): 50-56.

^{31.} Offenbacher, S., J. D. Beck, S. P. Barros, R. Y. Suruki and Z. G. Loewy (2012). "Obstructive airway disease and edentulism in the atherosclerosis risk in communities (ARIC) study." BMJ Open 2(6).

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)³².

Estimates suggest that a single case of VAP incurs additional treatment costs of \$28000- \$40,000^{33,34}. In the United States, total costs incurred to treat preventable cases of VAP thus results in hundreds of millions of excess 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).^{35,36,37}

RECOMMENDATION

SFG recommends inclusion of preventive oral hygiene, prophylaxes and non-surgical periodontal treatment 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)³⁸.

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)³⁹. PD, CVD and stroke are greatly influenced (and possibly dependent upon) chronic inflammatory mechanisms. A recent umbrella review (Peruzzi et al., 2022)⁴⁰ 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., 2014¹⁶, Borah et al, 2022⁴¹); 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 α and IL-6, plus LDL and reductions in hypertension, a major risk factor for CVD and stroke (Zhou, et al., 2013⁴²; Teixeira, et al., 2020)⁴³. However, in contrast to the outcomes data for diabetes, the body of evidence is not as robust on 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)⁴⁴ are replicated in the Medicare setting.

- 32. Kelly, N., L. Winning, C. Irwin, F. T. Lundy, D. Linden, L. McGarvey, G. J. Linden and I. A. El Karim (2021). "Periodontal status and chronic obstructive pulmonary disease (COPD) exacerbations: a systematic review." BMC Oral Health 21(1): 425.
- 33. Giuliano, K. K., Baker, D., & Quinn, B. (2018). The epidemiology of nonventilator hospital-acquired pneumonia in the United States. American Journal of Infection Control, 46(3), 322–327. doi:10.1016/j.ajic.2017.09.005.
- 34. AHRQ. Estimating the Additional Hospital Inpatient Cost and Mortality Associated With Selected Hospital-Acquired Conditions. https://www.ahrq.gov/hai/pfp/haccost2017-results.html.
- 35. Munro and Baker, 2018) Appl Nurs Res. 2018 Dec;44:48-53. doi:10.1016/j.apnr.2018.09.004. Epub 2018 Sep 19.
- 36. Munro et al. Infection Control & Hospital Epidemiology (2021), 1-6 doi:10.1017.
- 37. Sekiya et al. Int J Environ Res Public Health . 2021 Jul 13;18(14):7453).
- 38. Garcia, Robert & Jendresky, Linda & Colbert, Larry & Bailey, Althea & Zaman, Mohammed & Majumder, Mujbur. (2009). Reducing Ventilator-Associated Pneumonia Through Advanced Oral-Dental Care: A 48-Month Study. American journal of critical care: an official publication, American Association of Critical-Care Nurses. 18. 523-32. 10.4037/ajcc2009311.
- 39. 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.
- 40. 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.
- 41. Borah.BJ, Brotman SG, Dholakia R, Dvoroznak S, Jansen MT, Murphy EA and Naessens JM. Association between preventive dental care and healthcare cost for enrollees with diabetes or coronary heart disease: 5-year experience. Compendium 2022; 43 (3):130-139.
- 42. Zhou SY, Duan XQ, Hu R, Ouyang XY. Effect of non-surgical periodontal therapy on serum levels of TNF-a, IL-6 and C-reactive protein in periodontitis subjects with stable coronary heart disease. Chin J Dent Res. 2013;16(2):145-51. PMID: 24436950.
- 43. Teixeira FCF, Marin-Leon L, Gomes EP, PedrÃo AMN, Pereira ADC, Francisco PMSB. Relationship between periodontitis and subclinical risk indicators for chronic non-communicable diseases. Braz Oral Res. 2020 Jun 19;34:e058. doi: 10.1590/1807-3107bor-2020.vol34.0058. PMID: 32578801.

2. Coverage to prevent infection prior to and during recovery from cancer and transplant-related surgical procedures and before/during 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)⁴⁵.

National expenditures in 2018 for cancer care in the U.S. were \$150.8 billion. (National Cancer Institute, 2020)⁴⁶. 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)^{47,48}.

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)⁴⁹.

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)^{50,51,52}.

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)⁵³. Sepsis can disrupt cancer therapy, and delay and reduce survival (Riley, Glenny, Worthington, Littlewood, Mauleffinch, Clarkson,

^{44.} Borah.BJ, Brotman SG, Dholakia R, Dvoroznak S, Jansen MT, Murphy EA and Naessens JM. Association between preventive dental care and healthcare cost for enrollees with diabetes or coronary heart disease: 5-year experience. Compendium 2022; 43 (3):130-139.

^{45.} Centers for Disease Control and Prevention. (2021, September 3). *Cancer prevention during older adulthood*. Retrieved August 3, 2022 from https://www.cdc.gov/cancer/dcpc/prevention/older-adulthood.htm.

^{46.} National Cancer Institute. (2020, September 25). Cancer statistics. Retrieved August 3, 2022, from https://www.cancer.gov/about-cancer/understanding/statistics.

^{47.} American Cancer Society. (2022). Cancer facts and figures. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf

^{48.} National Cancer Institute. (2020, September 25). Cancer statistics. Retrieved August 3, 2022, from https://www.cancer.gov/about-cancer/understanding/statistics.

^{49.} National Cancer Institute. (2020, September 25). Cancer statistics. Retrieved August 3, 2022, from https://www.cancer.gov/about-cancer/understanding/statistics

^{50.} Acharya, A. Geist, S.-M. R. Y., Powell, V. & Torres-Urquidy, M.H. (2019). Chapter 3: An environmental scan of the various oral-systemic contact points. In Acharya, A. Powell, V., Torres-Urquidy, M.H., Posteraro, R.H., & Thyvalikakath, T.P. (Eds.), *Integration of medical and dental care and patient data* (2nd ed., pp.35-46).

^{51.} Parisi, E.P. & Glick, M.G. (2003). Immune suppression and considerations for dental care. *The Dental Clinics of North America*, 47, 709-731. doi: 10.1016/S0011-8532(03)00038-7.

^{52.} Keefe, D.M.and Bateman, E.H. (2019). Potential Successes and Challenges of Targeted Cancer Therapies. *Research Frontiers: Oral Toxicities of Cancer Therapies*. 2019 (53): 25-29.

^{53.} Singer, M., Deutschman, C.S., Seymour, C.W. et al. (2016). The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA*. 315 (8): 801-810. doi: 10.1001/jama.2016.0287.

McCabe, 2017)⁵⁴. 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)^{55,56}. 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)⁵⁷. 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)⁵⁸.

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)^{59,60}.

Elting and Chang (2019)⁶¹, 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)⁶². The primary drivers of cost are hospitalizations, 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)⁶³.

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)⁶⁴. 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)⁶⁵ 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

- 54. Riley, P., Glenny, A., Worthington, H.V., Littlewood, A., Fernandez-Mauleffinch, L., Clarkson, J.E., McCabe, M.G. (2017) Interventions for preventing oral mucositis in patients with cancer receiving treatment: Cytokines and growth factors. *Cochrane Database of Systematic Reviews* 2017 Nov 28: 11(11):CD011990, doi: 10.1002/14651858CD01990.pub2.
- 55. Acharya, A. Geist, S.-M. R. Y., Powell, V. & Torres-Urquidy, M.H. (2019). Chapter 3: An environmental scan of the various oral-systemic contact points. In Acharya, A. Powell, V., Torres-Urquidy, M.H., Posteraro, R.H., & Thyvalikakath, T.P. (Eds.), *Integration of medical and dental care and patient data* (2nd ed., pp.35-46).
- 56. Gudiol, C., Albasanz-Puig, A., Cuervo, G., & Carratalà, J. (2021). Understanding and managing sepsis in patients with cancer in the era of antimicrobial resistance. Frontiers in medicine, 8, 636547. https://doi.org/10.3389/fmed.2021.636547.
- 57. National Cancer Institute. (March 28, 2022). Cancer disparities. Retrieved August 3, 2022, from https://www.cancer.gov/about-cancer/understanding/ disparities.
- 58. Phongsuphot, K., Chimruang, J., Intapa, C. (2021). Incidence and Severity of Oral Mucositis in Adult and Elderly Cancer Patients After Receiving Chemotherapy in Uttaradit Hospital. *CM Dental Journal* 42(1):159-172'
- 59. Paoli, C.J., Reynolds, M.A., Sinha, M., et al. (2018). Epidemiology and costs of sepsis in the United States—an analysis based on timing of diagnosis and severity level. *Critical Care Medicine*, 46, 1889. pmid:30048332.
- 60. Phongsuphot, K., Chimruang, J., Intapa, C. (2021). Incidence and Severity of Oral Mucositis in Adult and Elderly Cancer Patients After Receiving Chemotherapy in Uttaradit Hospital. *CM Dental Journal* 42(1):159-172.
- 61. Elting, L.S. & Chang, Y. (2019). Costs of oral complications of cancer therapies: estimates and a blueprint for future study. *Journal of the National Cancer Institute*, 53, 116-123. doi: 10.1093/jncimonographs/lgz010
- 62. Elting, L.S. & Chang, Y. (2019). Costs of oral complications of cancer therapies: estimates and a blueprint for future study. *Journal of the National Cancer Institute*, 53, 116-123. doi: 10.1093/jncimonographs/lgz010
- 63. Tew, M., Dalziel, K., Thursky, K., Krahn, M., Abrahamayan, L., Morris, A.M., & Clarke, P. (2021). Excess cost of care associated with sepsis in cancer patients: Results from a population-based case-control matched cohort. *PLoS ONE*, 16(8), e0255107. doi: 10.1371/journal.pone.0255107.
- 64. Elting, L.S. & Chang, Y. (2019). Costs of oral complications of cancer therapies: estimates and a blueprint for future study. *Journal of the National Cancer Institute*, 53, 116-123. doi: 10.1093/jncimonographs/lgz010.
- 65. Owosho AA, Liang STY, Sax AZ, Wu K, Yom SK, Huryn JM, Estilo CL. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2018 May;125(5):440-445. doi: 10.1016/j.oooo.2018.02.003. Epub 2018 Feb 14. PMID: 29580668; PMCID: PMC7518027.

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)^{66,67,68,69}. 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:

SFG recommends 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)^{70,71,72,73}. 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)^{74,75,76}. Since ~66% of cancer occurs in older adults, these additional costs and poor clinical outcomes have a significant negative effect on CMS costs.

SFG further 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.

(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. SFG estimates the monthly pmpm costs of this care per affected and dentally adherent person at \$36.17. 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 (newsroom@unos.org)⁷⁸. Age is no longer a contraindication to transplantation. Nearly 25% of people on solid organ transplant waitlists are 65

- 67. Ripamonti CI, Maniezzo M, Campa T, et al. Decreased occurrenceof osteonecrosis of the jaw after implementation of dental preventive measures in solid tumour patients with bone metastases treated with bisphosphonates. The experience of the National Cancer Institute of Milan. *Ann Oncol.* 2009;20:137-145.
- 68. Bonacina R, Mariani U, Villa F, Villa A. Preventive strategies and clinical implications for bisphosphonate-related osteonecrosis of the jaw: a review of 282 patients. J Can Dent Assoc. 2011;77:b147.
- 69. Bramati A, Girelli S, Farina G, et al. Prospective, mono-institutional study of the impact of a systematic prevention program on incidence and outcome of osteonecrosis of the jaw in patients treated with bisphosphonates for bone metastases. *J Bone Miner Metab*.2015;33:119-12.
- 70. Acharya, A. Geist, S.-M. R. Y., Powell, V. & Torres-Urquidy, M.H. (2019). Chapter 3: An environmental scan of the various oral-systemic contact points. In Acharya, A. Powell, V., Torres-Urquidy, M.H., Posteraro, R.H., & Thyvalikakath, T.P. (Eds.), *Integration of medical and dental care and patient data* (2nd ed., pp.35-46).
- 71. Parisi, E.P. & Glick, M.G. (2003). Immune suppression and considerations for dental care. *The Dental Clinics of North America*, 47, 709-731. doi: 10.1016/S0011-8532(03)00038-7.
- 72. Ishimaru, M., Matsui, H., Ono, S., Hagiwara, Y., Morita, K., & Yasunaga, H. (2018). Preoperative oral care and effect on postoperative complications after major cancer surgery. *British Journal of Surgery*, 105(12), 1688-1696. doi: 10.1002/bjs.10915.
- 73. Saito, H., Watanabe, Y., Sato, K., Kkawa, H., Yoshida, Y., Katakura, A., Takayama, S and Sato, Michio (2014). Effects of professional oral healthcare on reducing risk of chemotherapy-induced oral mucositis. *Support Care Cancer*, 22(11): 2935-2940. Doi: 10.1007/s00520-014-2282-4.
- 74. Riley, P., Glenny, A., Worthington, H.V., Littlewood, A., Fernandez-Mauleffinch, L., Clarkson, J.E., McCabe, M.G. (2017) Interventions for preventing oral mucositis in patients with cancer receiving treatment: Cytokines and growth factors. *Cochrane Database of Systematic Reviews* 2017Nov 28: 11(11):CD011990, doi: 10.1002/14651858CD01990.pub2.
- 75. Ishimaru, M., Matsui, H., Ono, S., Hagiwara, Y., Morita, K., & Yasunaga, H. (2018). Preoperative oral care and effect on postoperative complications after major cancer surgery. *British Journal of Surgery*, 105(12), 1688-1696. doi: 10.1002/bjs.10915.
- 76. Saito, H., Watanabe, Y., Sato, K., Kkawa, H., Yoshida, Y., Katakura, A., Takayama, S and Sato, Michio (2014). Effects of professional oral healthcare on reducing risk of chemotherapy-induced oral mucositis. *Support Care Cancer*, 22(11): 2935-2940. Doi: 10.1007/s00520-014-2282-4.
- 77. Jones JA, Monopoli M. Designing a new payment model for oral care in seniors. *Compendium* 2017; 38 (9): 622-629. PMID: 28972386. With Addendum dated 9/14/21: 2021 Santa Fe Group Updated Plan and Cost Estimates for Medicare Part B Dental Coverage. Available at https://santafegroup.org/news/medicare/2021-santa-fe-group-updated-plan-and-cost-estimates-for-medicare-part-b-dental-coverage/
- 78. UNOS Newsroom. (2021, August 5). U.S. on pace to top 40,000 transplants in a single year for first time. https://unos.org/news/on-pace-for-40000-transplants-record/

^{66.} Dimopoulos MA, Kastritis E, Bamia C, et al. Reduction of osteonecrosis of the jaw (ONJ) after implementation of preventive measures in patients with multiple myeloma treated with zoledronicacid. *Ann Oncol.* 2009;20:117-120.

years of age and older (Hemmersbach-Miller, Wolfe, and Schmader, 2021)⁷⁹. 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)⁸⁰. 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)^{81,82,83}. 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, Wolfe, and Schmader, 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 treatment⁸⁴. Oral health is also important for clinical outcomes prior to and after heart transplantation. Gruter and Brand (2020)⁸⁵ 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, Eghtesad, Close, Shay, and Fung, 2007)⁸⁶. Åberg and colleagues (2014)⁸⁷ 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)⁸⁸ 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.

SFG RECOMMENDATION

The Santa Fe Group 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).

3. Administrative comments:

Coding: SFG is in favor of using extant EHR coding systems such as ICD10 and CDT codes for treatment. Of note is that

- 79. Hemmersbach-Miller, M., Wolfe, C.R., Schmader, K.E. (2019). Solid organ transplantation in older adults. Infectious and other age-related considerations. *OBM Transplant*, 3(1). doi: 10.21926/obm.transplant.1901046
- Parisi, E.P. & Glick, M.G. (2003). Immune suppression and considerations for dental care. *The Dental Clinics of North America*, 47, 709-731. doi: 10.1016/S0011-8532(03)00038-7.
- Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-term survival after kidney transplantation. The New England Journal of Medicine, 385, 729-743. doi: 10.1056/NEJMra2014530.
- Gil, E., Kim, J.M., Jeon, K., Park, H., Kang, D., Cho, J., Suh, G.Y., & Park, J. (2018). Recipient age and mortality after liver transplantation: a populationbased cohort study. *Transplantation*, 102(12), 2025-2032. doi: 10.1097/TP.00000000002246.
- 83. Shyr, B.U., Shyr, B.S., Chen, S.C., Shyr, Y.M., & Wang, S.E. (2021). Inferior survival outcomes of pancreas transplant alone in uremic patients. *Scientific Reports*, 11, 21073. doi: 10.1038/s41598-021-00621-y.
- 84. https://www.scsp.net/articles/the-importance-of-dental-care-for-transplant-recipients
- 85. Gruter, M.O. and Brand, H.S. (2020). Oral Health Complications After a Heart Transplant: A Review. *British Dental Journal*. 228(3): 177-182. doi: 10.1038/s41415-020-1244-0.
- Guggenheimer, J., Eghtesad, B., Close, J.M., Shay, C., Fung, J. (2007). Dental Health Status of Liver Transplant s. *Liver Transplant*. 13(2): 280-286. Doi:10.1002/It.201038.
- 87. Åberg, F., Helenius-Hietala, J., Meurman, J., & Isoniemi, H. Association between dental infections and the clinical course of chronic liver disease. *Hepatology Research* 2014; 44(3), 349-353. doi: 10.1111/hepr.12126.
- Schonfeld, E.A. & Brown, R.S. (2019). Genetic causes of liver disease: when to suspect a genetic etiology, initial lab testing, and the basics of management. *Medical Clinics of North America*, 103(6), 991-1003. doi: 10.1016/j.mcna.2019.07.003.

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.⁸⁹

Location of treatment: CMS sought comments on the best location of treatment to be provided. SFG recommends 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, 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 tooth as root canal - for example, CDT D3000-3999)."

SFG Comments: 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.

SFG RECOMMENDATION

Lamster, et al.⁹⁰ or Borah, et al.⁹¹ 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., 2022⁹². 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.

^{89.} Gibson G, Wehler C, Jurasic MM. Providing Effective Dental Care for an Ageing Population. IDJ 2022;72:S39-43. Contact david.stanczyk@va.gov for details.

^{90.} Lamster I, Malloy KP, DiMura PM, Cheng B, Wagner VL, Matson J, Proj A, Xi Y. Abel SN and Alfano MC. Preventive dental care is associated with improved health care outcomes and reduced costs for Medicaid members with diabetes. *Frontiers in Dental Medicine*, 2022 (in press).

^{91.} Borah.BJ, Brotman SG, Dholakia R, Dvoroznak S, Jansen MT, Murphy EA and Naessens JM. Association between preventive dental care and healthcare cost for enrollees with diabetes or coronary heart disease: 5-year experience. *Compendium* 2022; 43 (3):130-139.

^{92.} Lamster I, Malloy KP, DiMura PM, Cheng B, Wagner VL, Matson J, Proj A, Xi Y, Abel SN and Alfano MC. Dental services and health outcomes in the New York State Medicaid program. *Journal of Dental Research* 2021; 100 (9): 928-934.

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.

SFG 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 UCR⁹³ 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.⁹⁴ 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 FEDVIP⁹⁵. 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 by CMS 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.

93. Jones JA, Monopoli M. Designing a new payment model for oral care in seniors. *Compendium* 2017; 38 (9): 622-629. PMID: 28972386. With Addendum dated 9/14/21: 2021 Santa Fe Group Updated Plan and Cost Estimates for Medicare Part B Dental Coverage. Available at https://santafegroup.org/news/medicare/2021-santa-fe-group-updated-plan-and-cost-estimates-for-medicare-part-b-dental-coverage/

^{94.} Borah.BJ, Brotman SG, Dholakia R, Dvoroznak S, Jansen MT, Murphy EA and Naessens JM. Association between preventive dental care and healthcare cost for enrollees with diabetes or coronary heart disease: 5-year experience. *Compendium* 2022; 43 (3):130-139.

^{95.} https://www.opm.gov/healthcare-insurance/healthcare/ and https://www.opm.gov/frequently-asked-questions/search/?cid=f308fb49-6413-4849-8191-181ed4b4329f

CONCLUSION

The Santa Fe Group thanks the CMS for their willingness to consider issues related to medically necessary dental care. We appreciate the opportunity to provide comments about these proposed rules and have provided evidence to demonstrate how patients could benefit from this change. Improving oral health will improve health, health equity, and quality of life for some of this nation's most underserved seniors. Thank you for your consideration!

Sincerely,

Leusa A Dolan

Terri Dolan, President, Santa Fe Group https://santafegroup.org/

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