

BY ELECTRONIC MAIL: MedicarePhysicianFeeSchedule@cms.hhs.gov

February 2, 2024

The Honorable Chiquita Brooks-LaSure Centers for Medicare and Medicaid Services Attention: CMS–1770–F 7500 Security Boulevard P.O. Box 8016 Baltimore, MD 21244-8016

Re: Nominations of Dental Services for Medicare Coverage

Dear Administrator Brooks-LaSure:

On behalf of the Santa Fe Group, (<u>https://santafegroup.org</u>), we are pleased to nominate this clarification of payment policy for dental services that are inextricably linked and substantially related and integral to the clinical success of covered medical services used for the treatment of Medicare beneficiaries with diabetes.

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 26 years ago, the Santa Fe Group has served as a neutral convener, communicator, connector, and catalyst to move the needle on critical issues such as oral cancer, dental education, 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 are also a proud member of the Consortium for Medically Necessary Oral Health Coverage, which is a diverse

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†Deceased

partnership of more than 240 organizations that are united in undertaking educational, community-building, and advocacy efforts to secure Medicare coverage of medically necessary oral and dental treatment.

The Administration's clarification of Medicare payment policy for medically necessary oral and dental care holds the promise of having a direct and meaningful impact in the lives of millions of Medicare beneficiaries. Equally meaningful is the Administration's creation of the annual nominations process, which enables stakeholders "to identify for consideration and review submissions of additional dental services that are inextricably linked and substantially related and integral to the clinical success of other covered medical services."

We value the opportunity to nominate clinical scenarios for consideration. As a result, we take very seriously the guidance provided in the Physician Fee Schedule for 2024 to focus nominations on treatment of covered medical services for which medically necessary care is most appropriate and suitable. Specifically, the rule stated: "We urge interested parties to consider the circumstances under which dental services are inextricably linked to specific covered services (not diagnoses) used to treat patients..."

Towards that end, we are pleased to present herein the Santa Fe Group's nomination of dental services that are inextricably linked to covered medical services upon which beneficiaries with diabetes depend. As detailed below, the delivery of appropriate dental services in accordance with clinical guidelines and standard of care is substantially related and integral to the optimal outcome of covered medical services. Clinical studies document that treatment of oral infections, such as periodontitis and related inflammation, meaningfully improves the treatment and management of diabetes. By contrast, the absence of treatment of chronic dental infections complicates covered medical treatment for the management of diabetes and exacerbates insulin resistance, worsens glycemic control, and other diabetes related complications.

Key Background Issues

As detailed in this nomination, a recent Cochrane Collaboration systematic review of 35 studies found that preventive dental care and conservative periodontal treatment is associated with a reduction in glycated hemoglobin (HbA1c) of 0.43 - 0.50% over 3 to 12 months.¹ This marked reduction is due to the removal of the biofilm, with a resulting reduction in the local inflammatory response. This also reduces the systemic inflammatory burden, which in turn will affect blood glucose levels. Since there is a documented inextricable link between HbA1c, reflective of longer-term effective management of blood glucose levels, and clinical complications, reducing oral and dental disease when medically necessary is therefore essential to the treatment of diabetes and related conditions.

Indeed, the Cochrane authors described the above clinical outcome related to preventive dental care, conservative periodontal treatment, and reduction in HbA1c, as statistically and clinically significant. It was also found to be comparable to what is seen when a second hypoglycemic agent is added to metformin for patients with diabetes who are managed with oral medication (Simpson, 2022). Underscoring the confidence of this finding, the authors additionally stated that "further trials evaluating no treatment *vs* usual care are unlikely to change this conclusion."

Moreover, numerous basic and clinical studies point to the contributions of oral diseases to inflammation in persons with diabetes, which puts them at risk for micro- and macrovascular complications including retinopathy, nephropathy, neuropathy, cardiovascular diseases, and stroke. Further, there is a documented reduction in hospitalizations in persons with diabetes who receive conservative periodontal treatment. For this reason, such treatment is recommended by American Diabetes Association Clinical Guidelines and is supported by the American Association of Clinical Endocrinologists, among other notable stakeholders. Nevertheless, a substantial portion of the Medicare population continues to lack access to medically necessary dental treatment.

Central to this finding is the bi-directional relationship between diabetes and dental conditions, as well as the pathophysiology of inflammation related to periodontal disease and diabetes.² Diabetes is a chronic condition in which the body has a problem processing glucose from carbohydrates in

food. This causes chronically high levels of blood sugar which triggers the body's inflammatory response and, over time, type II diabetes (T2D) causes ongoing inflammation throughout the body. As T2D develops, cells become less responsive to insulin and the resulting insulin resistance increases blood glucose and the systemic inflammatory burden, as well. This is crucially important because inflammation plays a central role in the pathophysiology of T2D, its associated metabolic abnormalities, and a broad range of related chronic illnesses.

Fortunately, reciprocal management of glycemic control and periodontal disease decreases risk for and actual cases and severity of diabetes and periodontal disease. As but one important example, medical management of diabetic glycemic control may also involve less medication if inflammation related to periodontal risk and disease is minimized. As determined by clinical analyses discussed below, medically necessary treatment improves outcomes and reduces hospitalization as well as the utilization of other health care resources.

Covered Medical Services Related to Recommended Payment Clarification

This nomination focuses on dental services that are inextricably linked to, and substantially related and integral to the clinical success of, the following covered medical services upon which beneficiaries with diabetes depend: (listed in numerical order)

- CPT 36901-36906: Dialysis circuit procedures
- CPT 82947: Chemistry procedures, blood glucose testing
- CPT 83036: Hemoglobin A1C testing
- CPT 90935, 90937, 90940: Hemodialysis procedures
- CPT 90961: Physician or other qualified healthcare professional visits for ESRD
- CPT 90989-90999: Other dialysis procedures
- CPT 92227-92229: Diabetic retinopathy screening
- CPT 99091: Collection and interpretation of physiologic data
- CPT 99202-99215: Evaluation and Management (E/M) Services
- CPT 99211: Office visit for an established patient
- CPT 99487: Complex chronic care management services
- CPT 99490-99491: Chronic care management services
- CPT 99497: Remote physiologic monitoring services

- CPT 99605-99607: Medication Management
- CPT 99802-99804: Assessment, Intervention, Face to Face (F2F)
- DRG 637: Hospitalization for diabetes with major complications
- G0108: Diabetes Self-Management Training
- G0109: Group Diabetes Self-Management Training
- G0270: Nutrition Therapy
- G0466: FQHC visit new patient
- G0467: FQHC visit established patient

The Bidirectional Relationship Between Oral Disease and Diabetes Mellitus

The relationship between oral diseases and diabetes mellitus is complex and bidirectional. Diabetes increases the risk and severity of oral diseases, such as periodontitis (gum inflammation and bone loss), tooth loss, dry mouth, and oral fungal infections. Additionally, oral diseases are documented as affecting blood glucose control and contributing to the development of diabetes complications, such as retinopathy, nephropathy, cardiovascular disease, and neuropathy.

Specific clinical examples of this bidirectional relationship include the following:

- Inflammation plays a key role in the pathophysiology of T2D and its associated metabolic abnormalities. Periodontitis impairs blood glucose control in persons with diabetes by increasing the local levels of inflammatory mediators in their blood, such as interleukin-1 beta (IL-1β), tumor necrosis factor alpha (TNF-α). Those mediators contribute to systemic inflammation and interfere with insulin binding, increasing insulin resistance, ultimately resulting in increased risk of clinical complications of diabetes. Periodontitis thereby complicates diabetes management.
- Diabetes reduces saliva production, causing dry mouth which further increases the risk of dental caries and oral fungal infections.
- Additionally, diabetes affects the healing of oral tissues after dental procedures or injuries and is associated with the increased risk of post-operative complications, such as infection, bleeding, and delayed wound healing.

• Last but by no means least, studies have shown that individuals with diabetes and periodontitis who suffer from poor dental health face a markedly higher risk of morbidity (i.e., retinopathy, nephropathy, cardiovascular disease, macrovascular disease (stroke and cardiovascular disease), and neuropathy) and mortality.

The importance of reducing HbA1c cannot be understated because of the link between glycemic control and the occurrence of complications of diabetes. For example, in the Diabetes Control and Complications Trial, intensive therapy over thirty years resulted in lower HbA1c and fewer major cardiovascular outcomes, including nonfatal myocardial infarction, stroke, or cardiovascular death, among others.

Further, the DCCT/EDIC found a reduction of both microvascular (retinopathy, nephropathy, neuropathy) and macrovascular complications of diabetes when glycemic control was maintained at near normal concentrations.³ Thus, dental treatment (e.g., preventive dental treatment and periodontal care) that facilitates the reduction of HbA1c is highly beneficial in the management of persons with diabetes.

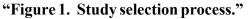
In sum, the bidirectional relationship between oral disease and diabetes is evidenced in numerous clinical scenarios that directly impact beneficiaries' health and utilization of health care resources.

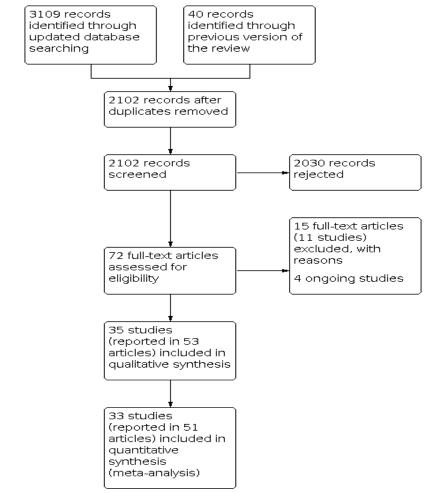
The Pathophysiology Link between Diabetes and Dental Disease: Periodontitis and Diabetes

It is well established that diabetes exacerbates periodontitis. Periodontitis affects local and systemic inflammation, contributing to poor metabolic control in people with diabetes. The primary underlying mechanism is the hyperinflammatory state found in both conditions. In the oral cavity, frank suppuration indicative of periodontal abscesses is seen , ultimately resulting in tooth loss. Persons with diabetes are at increased risk for tooth loss, which interferes with consumption of a healthy, fiber-rich diet.

As summarized above, a Cochrane Collaboration review of 35 studies found that preventive dental care and conservative periodontal treatment is associated with a reduction in glycated hemoglobin (HbA1c) of 0.43 - 0.50% over 3 to 12 months¹. The Cochrane review included randomized controlled trials (RCTs) of persons age 16 and over with both periodontitis and diabetes mellitus. It included both type 1 and T2D. The relevant interventions included scaling and root planning (removal of the biofilm below the gumline), with or without surgical treatment, antimicrobial or other drug therapy, supragingival (above the gumline) scaling, and oral hygiene instructions in order to assess changes in HbA1c over periods ranging from 3 to 12 months.

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Treatment of periodontitis for glycaemic control in people with diabetes mellitus

# Studies	Time	Ν	Mean difference	95%CI	Favors treatment
34	3-4 months	1309	-0.43	-0.59, -0.28	+
13	6 months	793	-0.30	-0.52, -0.08	+
1	12 months	133	-0.5	-0.55, -0.55	+

Over the periods of 3-4 months, 6 months, and 12 months, the Cochrane Review identified the following findings in HbA1c, which summarize the detail offered on pp. 18-20 of the Review:

Thus, evidence from a variety of RCTs indicates that preventive dental care and/or conservative periodontal treatment is a medically necessary dental service and is a component of comprehensive management of persons with diabetes. Further, multiple studies from the United States and other countries show that provision of preventive dental care and/or conservative periodontal treatment to persons with diabetes is associated with improved outcomes, reduced incidence of diabetes-related complications, and lower utilization of healthcare resources. The greatest effect was seen for hospital visits and in-patient services. This effect is exposure related, as increased frequency of preventive visits was associated with a proportionately greater reduction in health care utilization.⁴ Those studies followed patients over multiple years.

In cross-sectional studies, periodontitis was shown to co-occur with medical complications of diabetes. However, studies show that periodontal changes can precede other complications of diabetes. Children and adolescents with early-stage diabetes demonstrated increased gingival inflammation and loss of gingival soft tissue as compared to an age-matched control group without diabetes. These changes occurred before retinopathy or nephropathy had developed.⁵ Further, in a longitudinal study of persons with diabetes, comparing those with and without periodontitis, the cohort with periodontitis at the start of the monitoring period were at increased risk for subsequent development of clinical complications.

Clinical and public health experts have similarly underscored the importance of oral treatment in treating people with diabetes. The following excerpts from the letters in the Appendix illuminate this point:

"Dental services are often integral to the successful care and management of individuals with diabetes. That is because oral disease and diabetes are closely connected. For example, diabetes is documented as increasing the risk and severity of oral diseases, such as periodontitis, tooth loss, dry mouth, and oral infections. Similarly, oral diseases are documented as affecting blood glucose control and contributing to the development of diabetes complications, such as cardiovascular disease and kidney disease. As a result, indeed, ensuring that chronic dental infections are treated will protect beneficiaries with diabetes from suffering insulin resistance, worsened glycemic control, and other complications. Also, as a researcher studying vascular disease in diabetes, both the laboratory and clinical literature have clearly list periodontal disease and the development of atherosclerosis."

Ira Goldberg, MD, Director Division of Endocrinology Diabetes and Metabolism, NYU Langone Medical Center

"There is no question that dental services are often integral to the successful care and management of individuals with diabetes. That is because oral disease and diabetes are closely connected. For example, patients living with diabetes are documented to be at an increased risk and severity of oral diseases, such as periodontitis, tooth loss, dry mouth, and oral infections. Similarly, oral diseases are documented as affecting insulin sensitivity and blood glucose control which contribute to the development of diabetes complications, such as cardiovascular disease and kidney disease. As a result, ensuring that chronic dental infections are diagnosed and treated will protect beneficiaries with diabetes from suffering insulin resistance, worsened glycemic control, and other complications."

Robert H. Eckel, MD Professor of Medicine, Emeritus University of Colorado Anschutz Medical Campus Past President of the American Heart Association "[T]he diagnosis and treatment of dental infections is proven effective in protecting beneficiaries with diabetes, resulting in reduced hospitalizations... With a substantial portion of the Medicare population currently lacking access to medically necessary dental treatment, your efforts hold the promise of making a direct and meaningful impact in the lives of millions of Medicare beneficiaries."

Steven G. Ullmann, PhD Professor, Department of Health Management and Policy Director, Center for Health Management and Policy Special Assistant to the Provost Donna E. Shalala, PhD Trustee Professor Former Secretary of Health and and Human Services

How Treatment Guidelines Support Medically Necessary Dental Care for Medicare Recipients with Diabetes

Diabetes affects over 28.7 million children and adults and is the seventh leading cause of death in the United States. The prevalence of diagnosed diabetes increased from 10.3% in 2001-2004 to 13.2% in 2017-2022 and is projected to grow. Diabetes is a highly prevalent health condition in the aging population. Over 25% of people over the age of 65 have diabetes; 50% of older adults meet the criteria for pre-diabetes; and, the number of older adults living with T2D is expected to increase rapidly in the coming decades.⁶

As noted, the relationship between oral diseases and diabetes mellitus is complex and bidirectional. The American Diabetes Association 2023 Standards of Care (El Sayed et al., 2023) emphasize the importance of Comprehensive Medical Evaluation and Assessment of Co-morbidities in the provision of Person-Centered Collaborative Care. The Standards of Care (P. 549, section 4.2), state that: "people with diabetes can benefit from a coordinated multidisciplinary team that may include and is not limited to diabetes care and education specialists, primary care and subspecialty clinicians, nurses, registered dieticians, nutritionists, exercise specialists, pharmacists, dentists, podiatrists and mental health professionals."⁷

The Centers for Disease Control (CDC) offers guidance about oral care for persons with diabetes. Oral disease (periodontal disease, xerostomia, candidiasis) is one of the eight complications from diabetes,⁸ and is thereby inextricably linked to diabetes. The American Association of Clinical Endocrinologists takes the position that "the connection between uncontrolled diabetes and serious periodontal disease has been well documented. Further, untreated periodontal disease makes it more difficult to control diabetes, leading to the dreaded microvascular and macrovascular complications, including, but not limited to, cardiovascular events, neuropathy, and nephropathy."⁹

Similarly, the Renal Physicians Association and The National Forum of ESRD Networks state, "diabetes and hypertension are among the most prevalent precursor conditions to patients with End Stage Renal Disease (ESRD), and thus it is critically important for patients to maintain a proper diet and nutrition regimen. However, poor 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. These issues are particularly important in ESRD care as dialysis patients are highly vulnerable patients with morbidity and mortality rates that typically are much higher than those in other chronic illness populations."¹⁰

According to the American Diabetes Association, facilitating positive health behaviors and wellbeing to improve outcomes (sec. 5; p. 550) is an important standard of care.¹¹ Health professionals' communication with people with diabetes should acknowledge that multiple factors impact glycemic management. Collaboratively developed treatment plans and a healthy lifestyle can significantly improve disease outcomes and well-being.

Further, the American Diabetes Association focuses on lifestyle management and psychosocial care as cornerstones of diabetes management. People with diabetes should receive recommended preventive care services (e.g., immunizations, cancer screenings, smoking cessation counseling, ophthalmological, dental, nutrition counseling, and podiatric referrals). Clinicians should therefore ensure that people with diabetes are appropriately screened for complications and co-morbidities.

In the comprehensive medical evaluation and history, the last dental visit should be included in the initial and annual visit assessments. In the assessment of diabetic co-morbidities, periodontal disease is addressed. Moreover, referral to a dentist is recommended in the standard of care for comprehensive dental and periodontal examination (ElSayed et al., 2023, p.S51, Recommendation 4.4). Periodontal disease is more severe and may be more prevalent in people with diabetes than in persons without the disease, and it has been associated with higher A1c levels. In the longitudinal TILDA study, people with periodontal disease had higher rates of incident diabetes.¹²

The following comprises the recommended comprehensive, coordinated care for patients with diabetes that include covered medical services for which such patients are eligible: (American Diabetes Association Guidelines – El Sayed et al., 2023)

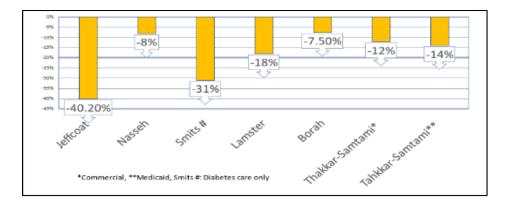
Comprehensive Initial Visit H&P

- Motivational Interviewing for promoting lifestyle changes
 - o Diet
 - Weight loss
 - o Exercise
- Medication Management for Promoting Glycemic Control
- Diabetes Self-Management Training
- Diabetic Health Literacy
- Management of Diabetic co-morbidities
 - o Xerostomia
 - Burning mouth/tongue
 - Inflamed, bleeding gums, loose teeth
 - Candida infections
- Referrals
 - o Dentist
 - Podiatrist
 - Ophthalmologist
 - Certified Diabetic Educator
 - Endocrinologist

The Role of Treatment in Improving Patient Outcomes

Clarifying payment policy for dental services that are inextricably linked and substantially related and integral to the clinical success of covered medical services used for the treatment of Medicare beneficiaries with diabetes will reduce the utilization of healthcare resources. As documented by a series of important analyses of insurance databases, these studies include but are not limited to hospitalizations, medications, and health care costs. The important takeaway: *reduction of healthcare utilization and costs can be achieved by medically necessary dental treatment. These data demonstrate the absolute clinical necessity of such dental care.* (See expanded summary of these insurance studies in the Additional Considerations section of this nomination),

By way of example, studies of total health care costs (illustrated below) document that provision of medically necessary dental treatment services achieves lower resource utilization.^{13,14,15,16,17,18}

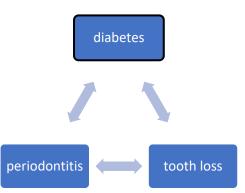


The Inextricable Link Between Diabetes, Diet, and Tooth Loss

Diet is a critical component of diabetes treatment. The American Diabetes Association regularly stresses the importance of "diet" in the treatment of diabetes. The five diets included are the Mediterranean, DASH, Flexitarian, Mayo Clinic, and Vegan diets.¹⁹ All of the recommended diets are intended to be permanent, and encourage eating more plant foods, e.g., vegetables, fruits, whole grains, beans, and legumes. Mastication and digestion are impaired by tooth loss – which is commonly associated with diabetes – and impairs the ability to chew fibrous foods.

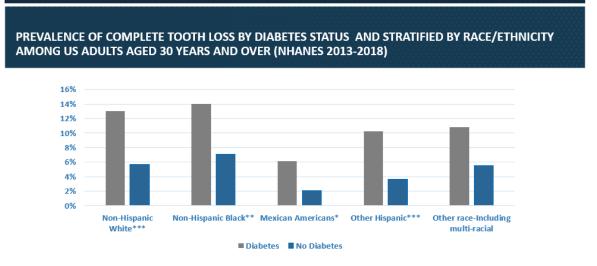
The link between tooth loss and diabetes is bidirectional. Luo et al. (2015), used NHANES data from 1971-2012, and found that adults with diabetes lost more teeth than adults without the disease. In The Irish Longitudinal Study on Ageing (TILDA), total tooth loss (complete edentulism) was associated with prevalent diabetes at baseline compared to participants with teeth

(PR 2.12, 95% CI 1.27-3.52).²⁰ Importantly, people with fewer teeth (<20) at baseline were almost twice as likely (OR: 1.94; 1-3.75) to develop diabetes over a four-year period than people with \geq 20 teeth. Participants with poorly controlled diabetes lost approximately twice the number of teeth compared to their non-diabetic peers. The effect is an inextricable link between diabetes, tooth loss and



periodontitis.²¹ Further, Nowjack-Raymer and Sheiham used U.S. NHANES data to show that tooth loss impairs dietary quality, as measured by lower intake of vegetables and vitamins.²²

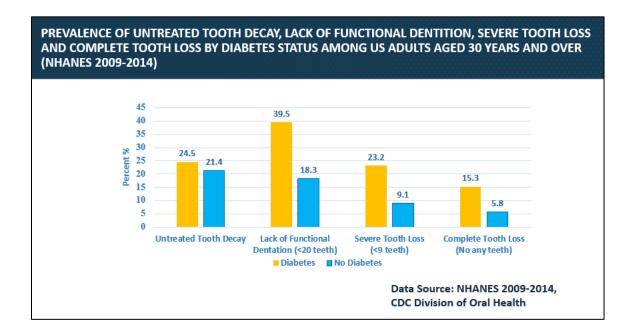
The figure below shows that Non-Hispanic Blacks with diabetes are most likely to be edentulous (CDC Division of Oral Health). Thus, the issue becomes one of healthy equity.



Data Source: NHANES 2013-2018

The importance of necessary dental care and tooth retention needs to be promoted among patients with diabetes and their clinical providers. Patel et al. (2013), showed that Americans with diabetes were more than twice as likely to be edentulous, and experienced more tooth loss than persons without diabetes.²³ Helal et al. (2019) conducted meta-analyses of tooth loss among persons with periodontitis; they found that diabetes increased likelihood of tooth loss by 80%.²⁴

NHANES Data from 2009-2014 (below) show that the prevalences of lack of functional dentition, severe tooth loss, and complete tooth loss are 39.5%, 23.2% and 15.3% respectively, among adults with diabetes; and are 18.3%, 9.1%, and 5.8% respectively among adults without diabetes (CDC, Division of Oral Health). Note that the prevalences in the three levels of tooth loss among adults with diabetes are more than double compared to adults without diabetes (P-values <0.0001, Chi-square tests). By contrast, the prevalence of untreated decay is 24.5% among those adults with diabetes, and 21.4% among those adults without diabetes (P-value >0.05).



The data above demonstrate that inclusion of dental care that preserves a functional dentition is inextricably linked to diabetes. To prevent diabetes complications, an interprofessional approach, including dentists and hygienists, is needed to ensure better care and disease management.

Additional Considerations: Inequities in the Incidence, Severity, and Treatment of Diabetes

The U.S. Department of Health and Human Services (HHS) has prioritized action to improve healthcare equity in America. For example, HHS' Strategic Objective 1.3 calls for the expansion of "equitable access to comprehensive, community-based, innovative, and culturally competent healthcare services while addressing social determinants of health." The Centers for Medicare and Medicaid Services (CMS) has also placed a priority on health equity with a Priority to "Assess Causes of Disparities Within CMS Programs, and Address Inequities in Policies and Operations to Close Gaps."

We respectfully submit that clarifying Medicare payment for dental services that are inextricably linked to covered medical services for beneficiaries with diabetes will take a highly meaningful step towards realization of these laudable and urgent goals. The reason is that considerable racial and ethnic inequities continue to persist in America with respect to the disproportionate incidence, severity, and treatment of diabetes and its associated oral and dental conditions. To illustrate:

- According to the Centers for Disease Control and Prevention (CDC), 32.5% of Hispanic, 28.5% of Black, 25.1% of Asian, and 16.6% of White Medicare beneficiaries aged 65-74 years old have been diagnosed with diabetes.
- As beneficiaries age, these disparities become even more pronounced. Among persons 75 and older, for example, CDC reports that 36.3% of Black, 27.7% of Hispanic, 25.6% of Asian, and 15% of White Medicare beneficiaries have diabetes.
- CDC reports that adults with diabetes face higher cost barriers to dental care. Increasing
 access to medical and dental insurance among adults with diabetes could reduce delaying
 needed dental care due to cost.²⁵
- Importantly, the National Institute of Dental and Craniofacial Research (NICDR) has also determined that inequities in the incidence and severity of diabetes are echoed in the inequities experienced by Medicare beneficiaries in functional dentition, periodontal disease, and severe periodontal disease.

For these reasons, we submit that *clarifying Medicare payment for inextricably linked dental care services needed by beneficiaries with diabetes can do much to address racial and ethnic health inequities in the Medicare program.* Americans who rely on the Medicare program for their health should be able to access or afford treatment services that are vital for preservation of health. As a result, increasing access to and the affordability of inextricably linked dental and oral health services holds the promise of significantly improved health equity and outcomes for all aging Americans.

Additional Considerations: Stakeholder Support for the Nomination

Leading organizations are clear about the importance of the action being contemplated by the Agency. For example:

"People with diabetes are more likely to have periodontal disease and its complications. Additionally, untreated periodontal disease makes it more difficult to control blood glucose and is associated with increased risk of diabetes complications, including kidney failure and cardiovascular disease. People with diabetes are more likely to need medical procedures such as cardiac surgery or kidney transplantation. These needed procedures may have to be delayed due dental problems."

American Diabetes Association

"[T]he connection between uncontrolled diabetes and serious periodontal disease has been well documented. Further, untreated periodontal disease makes it more difficult to control diabetes, leading to the dreaded diabetic microvascular and macrovascular complications. Chronic periodontitis has been associated with increased incidence of cardiovascular events, the leading cause of morbidity and mortality in the United States."

American Association of Clinical Endocrinology

"Poor 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. These issues are particularly important in ESRD care as dialysis patients are highly vulnerable patients with morbidity and mortality rates that typically are much higher than those in other chronic illness populations."

American Society of Nephrology

In addition, this nomination has been endorsed by the more than 240 organizations that make up the Consortium for Medically Necessary Oral Health Coverage (Consortium). A leading voice for Medicare payment clarification for medically necessary oral and dental services that are inextricably linked, essential, and of profound clinical, fiscal, and human value to Medicare beneficiaries, the Consortium recognizes that overall health is inextricably linked to oral health. Regrettably, dental care has long been inaccessible to millions of Medicare beneficiaries, leading to an alarming situation in which two-thirds of older Americans have periodontal disease and one-fifth have lost all of their teeth. Untreated oral conditions also significantly increase Medicare beneficiaries' risk of suffering chronic conditions, resulting in impaired well-being, increased hospitalizations, and higher program costs.

In support of transformative change, the Consortium has urged Congress and the Administration to explore options for extending access to evidence-based treatment to all Medicare beneficiaries. Consortium members include the leading organizations listed at <u>www.HealthCareConsortium.org</u>.

Additional Considerations: In-Depth Examination of Studies Reporting the Effect on Health Outcomes for Medicare Beneficiaries with Diabetes

This nomination has focused on the biological and clinical processes and disease outcomes which we understand to be the Agency's areas of primary interest. As a result, the preceding discussion has addressed: biological mechanisms of action, especially the combined impact of inflammation derived both from infected oral tissues and systemic inflammation that characterizes diabetes; clinical studies showing an inextricable link between diabetes treatments and oral disease treatments; established diabetes treatment guidelines from respected institutions; the professional opinion of medical thought leaders; and strong stakeholder support from prestigious organizations underscoring the linkage between diabetes care and treatment of oral disease.

In contrast, we have not emphasized data on the positive economic impact of dental treatments for patients with diabetes because we understand and agree such data are not primary drivers of decision making in such reviews. Nevertheless, a series of compelling insurance studies completed in the past decade may be helpful, in that they focus on both clinical outcomes and costs when patients with certain medical conditions access dental care. We present a summary of these studies below, which document reduced utilization of healthcare resources as a surrogate marker for improved clinical outcomes, such as but not limited to fewer emergency room visits, lower hospital admissions, and reduced drug utilization. Although these studies are retrospective, use disparate populations, are conducted by different investigators, and employ different methodologies, their outcomes are strikingly similar. Moreover, they are derived from the real-world care experience of more than 1.6 million individuals. As such, we view them as complementary to the other data presented above and list them below as an additional resource for the Agency:

- Jeffcoat MK, et al. Am J Prev Med 2014, Aug;47(2): 166-74. Examined records of 338,891
 enrollees in an insurance plan that provided both medical and dental benefits. Enrollees
 with type 2 diabetes (DM), cardiovascular disease (CAD), cerebrovascular disease (CVD),
 rheumatoid arthritis (RA) and women who were pregnant were considered. Reporting both
 total medical costs and hospitalizations, they found that health outcomes were significantly
 better for enrollees with DM, CVD, CAD, and pregnancy (40.2%, 40.9%, 10.7% and
 73.7%, respectively), but not RA with preventive dental treatment. Although this study has
 been criticized due to certain methodological issues, it is the first in the following series of
 papers which identified key relationships between dental treatment and diabetes outcomes.
- 2. Nasseh K, et al. Health Econ 2017 Apr; 26(4):519-527. Examined records of 15,002 persons in the Truven Health MarketScan database. Examining individuals with newly diagnosed DM who were in the database for one year and four years after the diagnosis, periodontal treatment was associated with reduced total health care costs (-\$1799) and lower total healthcare costs related to diabetes (-\$408) suggesting better health outcomes.

- 3. Smits KP, et al. BMJ Open Diabetes Res Care 2020 Oct;8(1): e001666. Examined records of 41,598 persons with DM in the Netherlands whose records were in a Dutch insurance database. Records were collected from 2012 to 2018. Analyzing health care costs related to DM revealed a median amount of E38.45 (95% confidence interval E11.52 263.14) per quarter. When periodontal care was provided, the median health care costs were reduced by E12.03 per quarter (95% confidence interval -E15.77 to -E8.29). This is a 31% reduction in DM related healthcare costs suggesting improved health outcomes.
- 4. Blaschke K, et al. Diabetes Res Clin Pract. 2021 Feb: 172:109641. Examined 23,771 records from a German health insurance company. Individuals who were continuously enrolled between 2011 and 2016 who were recently diagnosed with DM were studied. Persons receiving periodontal care were compared with persons not receiving this care. For persons receiving periodontal treatment there was a 4% reduction in total health care costs, 13% reduction in hospital costs, and a 7% reduction in the cost of drugs for diabetes suggesting improved total health outcomes.
- 5. Lamster IB, et al. J Dent Res 2021 Aug:100(9):928-934 and Lamster IB, et al. Front Dent Med 2022 3:952182. Examined records from the New York State Department of Health Medicaid database. All 551,689 enrollees between the ages of 42 and 64 who were continuously enrolled between 2012 to 2015 were analyzed (1st study). Enrollees who did and did not access dental care were compared. For the entire cohort, in a fully adjusted model, preventive dental services were associated with a 3% reduction in visits to the emergency department, and a 13% reduction in in-patient admissions. In terms of healthcare costs, there were no differences in terms of cost per enrollee for emergency department usage but there was a reduction for in-patient cost (-\$380 per year). When analyzing the enrollees in this cohort with a diagnosis of DM (2nd study), a more pronounced reduction in health care utilization and costs were associated with a 7% reduction in visits to the emergency department admissions. Similarly, the cost of in-patient admissions was dramatically lower (-\$823 per year) for enrollees with diabetes who received preventive dental care versus those with

diabetes who did not access dental services. <u>These studies are the first to report health</u> <u>outcomes associated with preventive dental care in a publicly insured population, A</u> <u>disproportionate beneficial effect is realized by enrollees with diabetes.</u>

- 6. Borah et al. Compend Contin Educ Dent. 2022 Mar; 43 (3): 130-139. Examined records from an insurance plan in Arkansas that had an affiliated dental plan. Data for 11,374 enrollees who were in the plan were included in the evaluation. All were enrolled in the plan for one to five years. Comparison was between enrollees with diabetes, coronary artery disease, or both diabetes and coronary artery disease who received conservative periodontal care as compared to those that did not receive such care. The outcome was the total yearly health care costs. With provision of periodontal treatment, they observed a reduction in total health care costs for enrollees with DM (\$515-\$574), CVD (\$548-\$675) and both DM and CVD (\$866-\$1718). This report provides further evidence of the association between preventive dental care and diabetes outcomes, with even greater improvement for enrollees with both diabetes and coronary artery disease.
- 7. Thakkar-Samtani M, et al. J Am Dent Assoc. 2023 Apr;154(4):283-292. Using the IBM MarketScan commercial insurance database and Medicaid databases, examined a total of 671,483 enrollees. For enrollees with DM, the relationship of periodontal treatment in years 1 and 2 to the cost of medical services in year 3. Compared to no periodontal treatment, use of periodontal treatment was associated with a 12% reduction in total health care costs (\$13,915 vs. \$15,739) for those with commercial insurance, and a 14% reduction for those with Medicaid (\$14,796 vs. \$17,181). A study with findings similar to what was reported in "5" above.
- 8. Michalowicz BS, et al. PLoS One. 2023 18(8): e0290028. Examined data from 9,503 enrollees in the HealthPartners database. A total of 9,503 enrollees having both periodontitis and DM, CAD or CVD were analyzed for the relationship of treatment for periodontitis to clinical outcomes and the cost of medical care. (There were 4,879 individuals in the DM cohort.) For all groups, those enrollees receiving periodontal treatment had a significantly reduced chance of being hospitalized [CAD odds ratio (OR)

= 0.71, CVD = 0.73, DM = 0.80). In this relatively small study, there was no difference in total treatment costs among enrollees who received periodontal care, but lower inpatient costs and higher drug costs were seen.

In sum, these studies of more than 1.6 million individuals enrolled in both private and public insurance programs examined persons with chronic diseases and reported findings in persons with diabetes mellitus. Reductions in both total health care costs (reported in all studies) and utilization of health care (reported in 3 studies) were observed. Indeed, there is a close association of health care costs and utilization (Lehnert T, et al. Med Care Res Rev 2011 Aug:68 (4):387-420).

Closing

The Santa Fe Group is grateful for the opportunity to submit this nomination to the Agency for its consideration and believe its adoption would be of substantial benefit to Medicare beneficiaries with diabetes who today lack access to the medically necessary dental treatment services that are inextricably linked and substantially related and integral to the clinical success of their diabetes treatment.

As detailed above, the delivery of appropriate dental services in accordance with clinical guidelines and standard of care is substantially related and integral to the optimal outcome of covered medical services. Clinical studies, including the Cochrane Collaborative's extensive review, document that treatment of oral infections, such as periodontitis and related inflammation, meaningfully improves the treatment and management of diabetes. By contrast, the absence of treatment of chronic dental infections complicates covered medical treatment for the management of diabetes and exacerbates insulin resistance, worsens glycemic control, and other diabetes related complications. The nexus between such care and covered medical services is also detailed above, as are the bidirectional relationship between oral disease and diabetes, its clinical guidelines and pathophysiology, as well as its implications for tooth loss and resolution of longstanding inequities. It is for these reasons, access to such care has garnered strong support from key stakeholders and is widely recognized as improving outcomes while reducing health care resource utilization.

In summation, improving oral health improves overall health, health equity, and quality of life. On behalf of the Santa Fe Group, I therefore want to commend and thank you for all you are doing for the older adults and people with disabilities who depend on the Medicare program.

Sincerely,

Ralph Fucillo

Ralph Fuccillo President, The Santa Fe Group <u>https://santafegroup.org/</u>

For additional information, please do not hesitate to contact the collaborators on this nomination:

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APPENDIX

University of Colorado Medical Campus

Department of Medicine Division of Endocrinology, Metabolism & Diabetes Robert H. Eckel, MD Professor of Medicine, Emeritus Aurora, CO 80045 Phone: 720-273-1475

January7, 2024

The Honorable Chiquita Brooks-LaSure Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244-8016

Re: Support for Diabetes-focused Nominations for Medicare Coverage

Dear Administrator Brooks-LaSure:

I am pleased to submit this letter in support of nominations I understand you are receiving for clarification of payment policy for dental services that are inextricably linked and substantially related and integral to the clinical success of covered medical services used for the treatment of Medicare beneficiaries with diabetes mellitus (diabetes).

I am Robert H. Eckel MD. a distinguished alumnus of the University of Cincinnati College of Medicine and the former Charles A Boettcher II Endowed Chair in Atherosclerosis, Professor of Medicine, Emeritus with previous appointments in the Division of Endocrinology, Metabolism and Diabetes, the Division of Cardiology, and Physiology and Biophysics at the University of Colorado School of Medicine, and Director of the Lipid Clinic at the University of Colorado Hospital. Until August 2014, I directed the Clinical Translational Research Center Network, a component of the Colorado Clinical Translational Sciences Institute, and previously served as Program Director of the Adult General Clinical Research Center for 15 years. In January 2018, I assumed the position of interim Vice Chancellor of Research at UC Denver. I previously served as President of the American Heart Association, Obesity Society and of Medicine and Science of the American Diabetes Association. For four decades, my NIH-funded translational research focused on the pathophysiology and treatment of lipoprotein metabolism, insulin action, nutrition, obesity, and type 1 and type 2 diabetes and how these metabolic disorders relate to cardiovascular disease. As a clinician for over 40 years, I cared for numerous patients with diabetes, many with cardiovascular disease or at high risk of cardiovascular disease. There is no question that dental services are often integral to the successful care and management of individuals with diabetes. That is because oral disease and diabetes are closely connected. For example, patients living with diabetes are documented to be at an increased risk and severity of oral diseases, such as periodontitis, tooth loss, dry mouth, and oral infections. Similarly, oral diseases are documented as affecting insulin sensitivity and blood glucose control which contribute to the development of diabetes complications, such as cardiovascular disease and kidney disease. As a result, ensuring that chronic dental infections are diagnosed and treated will protect beneficiaries with diabetes from suffering insulin resistance, worsened glycemic control, and other complications.

Thank you for considering diabetes as you clarify Medicare payment policy for medically necessary oral and dental care. Your efforts hold the promise of making a direct and meaningful impact in the lives of millions of Medicare beneficiaries.

Sincerely,

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Robert H. Eckel, M.D. Professor of Medicine, Emeritus Division of Endocrinology, Metabolism and Diabetes Division of Cardiology S/P Professor of Physiology and Biophysics S/P Charles A. Boettcher II Chair in Atherosclerosis University of Colorado Anschutz Medical Campus robert.eckel@cuanschutz.edu



Ira J. Goldberg, MD. Clarissa and Edgar Bronfman, Jr. Professor Director, Division of Endocrinology, Diabetes and Metabolism

December 6, 2023

The Honorable Chiquita Brooks-LaSure Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244-8016

MedicarePhysicianFeeSchedule@cms.hhs.gov

Re: Support for Diabetes-focused Nominations for Medicare Coverage

Dear Administrator Brooks-LaSure:

I am pleased to submit this letter in support of nominations I understand you are receiving for clarification of payment policy for dental services that are inextricably linked and substantially related and integral to the clinical success of covered medical services used for the treatment of Medicare beneficiaries with diabetes mellitus (diabetes).

I am the Director of Endocrinology at NYU Langone Medical Center and a Professor of Medicine at NYU Grossman School of Medicine. Our Center cares for numbers of patients with diabetes. Dental services are often integral to the successful care and management of individuals with diabetes. That is because oral disease and diabetes are closely connected. For example, diabetes is documented as increasing the risk and severity of oral diseases, such as periodontitis, tooth loss, dry mouth, and oral infections. Similarly, oral diseases are documented as affecting blood glucose control and contributing to the development of diabetes complications, such as cardiovascular disease and kidney disease. As a result, Indeed, ensuring that chronic dental infections are treated will protect beneficiaries with diabetes from suffering insulin resistance, worsened glycemic control, and other complications. Also, as a researcher studying vascular disease in diabetes, both the laboratory and clinical literature have clearly list periodontal disease and the development of atherosclerosis.

Thank you for considering diabetes as you clarify Medicare payment policy for medically necessary oral and dental care. Your efforts hold the promise of making a direct and meaningful impact in the lives of millions of Medicare beneficiaries.

Sincerely,

S. J. Males

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UNIVERSITY OF MIAMI MIAMI HERBERT BUSINESS SCHOOL DEPARTMENT of HEALTH MANAGEMENT & POLICY

5250 University Drive, Coral Gables, FL 33146

The Honorable Chiquita Brooks-LaSure Centers for Medicare and Medicaid Services 7500 Security Boulevard, Baltimore, MD 21244-8016

Re: Payment Clarification of Dental Treatment for Medicare Beneficiaries with Diabetes

Dear Administrator Brooks-LaSure:

We are pleased to submit this letter in support of nominations we understand you are receiving for clarification of payment policy for dental services that are inextricably linked and substantially related and integral to the clinical success of covered medical services used for the treatment of Medicare beneficiaries with diabetes mellitus (diabetes). As former Secretary of Health and Human Services, and as an active researcher and Director of the Center for Health Management and Policy at the University of Miami, we are well versed on this issue.

As demonstrated by the clinical evidence, dental services are often integral to the successful care and management of individuals with diabetes due to the close connection between oral disease and diabetes. Specifically, individuals living with diabetes are documented to be at increased risk and severity of oral diseases, such as periodontitis, tooth loss, dry mouth, and oral infections. The role played by oral diseases in fostering inflammation puts persons with diabetes at risk for an array of micro and macrovascular complications, including retinopathy, nephropathy, neuropathy, cardiovascular diseases, and stroke. Similarly, oral diseases are documented as affecting insulin sensitivity and blood glucose control which contribute to serious diabetes complications, such as cardiovascular disease and kidney disease.

Fortunately, the diagnosis and treatment of dental infections is proven effective in protecting beneficiaries with diabetes, resulting in reduced hospitalizations. For this reason, such treatment is recommended by American Diabetes Association clinical guidelines and is supported by the American Association of Clinical Endocrinologists, among other notable stakeholders.

Thank you for considering diabetes as you work to clarify Medicare payment policy for medically necessary oral and dental care. With a substantial portion of the Medicare population currently lacking access to medically necessary dental treatment, your efforts hold the promise of making a direct and meaningful impact in the lives of millions of Medicare beneficiaries.

Sincerely,

L M

Steven G. Ullmann, PhD Professor Department of Health Management and Policy Director, Center for Health Management and Policy and Special Assistant to the Provost

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Donna E. Shalala, PhD Trustee Professor Former Secretary of Health and Human Services

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