SANTA FE GROUP

Improving Lives Through Oral Health

September 9, 2024

Submitted electronically via:
Regulations.gov

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS-1807-P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2025 Physician Fee Schedule Proposed Rule

Dear Administrator Brooks-LaSure:

The Santa Fe Group appreciates the opportunity to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the proposals and request for information on Medicare Parts A and B Payment for Dental Services in the CY 2025 Physician Fee Schedule Proposed Rule.

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 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 proud to be a member of the Consortium for Medically Necessary Oral Health Coverage, a leading consensus-building alliance of more than 240 dental, medical, patient, and consumer organizations (please see the Consortium's Community Statement at www.OralHealthConsortium.org).

Along with hundreds of medical, nursing, dental, patient, and consumer advocacy organizations, we deeply appreciate the Administration's work to create a more equitable healthcare delivery system through expanded clarification of Medicare payment for medically necessary oral and dental treatment. The importance of this undertaking cannot be overemphasized, as it will have a direct and meaningful impact on the lives of millions of Medicare beneficiaries.

As a result, we wish to express our gratitude to the Center for Medicare and Medicaid Services (CMS) for its work to improve patient access to medically necessary oral and dental services. We applaud CMS for including oral health in its cross-cutting initiatives to advance health equity, expand coverage, and improve health outcomes and for taking historic steps to clarify that Medicare payment is available for such services when they are inextricably linked and substantially related and integral to the clinical success of certain Medicare-covered medical services. Among the medical services for which coverage of medically necessary oral care has been approved are organ and stem cell transplant surgery, cardiac valve replacement, valvuloplasty procedures, head and neck cancer treatment, as well as chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and high-dose bone-modifying agents used in the treatment of cancer.

In the proposed Physician Fee Schedule for 2025, CMS expands the scope of this payment policy to include clarification of payment for dental services that are inextricably linked to dialysis services received by beneficiaries with End Stage Renal Disease (ESRD). In addition, CMS provides a series of targeted information requests relating to autoimmune disease and diabetes, among other conditions, for potential inclusion in forthcoming Physician Fee Schedules.

By further clarifying Medicare payment of medically necessary dental treatment services, CMS is continuing to chart an important course to improved outcomes and lower costs. Though incremental, CMS' proposal for 2025 will help ensure that more older adults and patients with disabilities have access to the medically necessary oral care they need, enabling additional progress to be made towards equitable health care for all who rely on Medicare. In addition, it is clear CMS has heard stakeholders' request for more transparency on how to seek additional payment clarification, and its detail on its decision making process and the information on which it relies will be very helpful as future nominations are offered.

Key Points Overview

- Oral health is essential to control systemic inflammation, and dental care helps improves health outcomes for patients with ESRD, diabetes, and autoimmune conditions, prevents costly services and hospitalizations, and reduces the financial burden on Medicare and taxpayers.

- We are therefore pleased to support CMS' proposal to extend Medicare coverage of medically necessary dental care to beneficiaries with End-Stage Renal Disease (ESRD) receiving dialysis because addressing dental infections is crucial to preventing severe medical complications.

- We urge CMS to ensure this policy encompasses Chronic Kidney Disease (CKD) Stage 5 patients not yet on dialysis, ensuring they too receive the dental care needed to prevent infections that exacerbate diabetes and kidney disease.

- We also urge CMS not to make tooth extractions the default dental treatment, since restorative dental services, such as crowns, are essential to preventing serious complications like root canal failure and infection, which could worsen both diabetes and ESRD outcomes.

- Further, we urge the Agency to recognize that dental services, particularly periodontal treatments, are critical to the success of diabetes management, as poor oral health significantly increases inflammation and worsens glycemic control in diabetics.

- Periodontal care is proven to reduce HbA1c levels in patients with poorly controlled diabetes, directly lowering the risks of morbidity and mortality. This makes dental care a standard component of effective diabetes management for Medicare beneficiaries.

- We likewise urge the Agency to recognize that the risk of immunosuppression is real, as is the associated risk for infection-related complications. As a result, best practice requires appropriate treatment of any infection, including those originating or occurring in the mouth.

- Medicare Advantage plans are required to pay for essential dental services when inextricably linked to the success of medical procedures for chronic conditions like diabetes. We urge CMS to provide clear guidance to ensure enrollees have unimpeded access to the dental care they need.

- Aligning Medicare and Medicare Advantage dental provider enrollment policies will streamline access to inextricably linked dental services, ensuring beneficiaries with diabetes and ESRD can receive seamless, continuous care from their existing dental providers.

Medicare Payment Clarification Related to ESRD and Dialysis

In light of the above, we wish to express our strong support for the proposed payment clarification for medically necessary oral and dental care for the more than half a million Medicare beneficiaries with ESRD who are or will be receiving dialysis treatment. As noted by the American Society Nephrology (ASN) and the National Kidney Foundation (NKF), dental treatment can be integral and substantially related to the clinical success of Medicare-covered nephrology related services. Further, ASN and NKF demonstrated that identifying and resolving dental infections is integral and essential to the clinical success of covered medical services for co-morbidities frequently associated with ESRD. By proposing to make medically necessary oral and dental care available in such circumstances, CMS will significantly reduce the risk of medical complications currently faced by beneficiaries and avoid the costly interventions now borne by Medicare, beneficiaries, and taxpayers.

Indeed, research highlights the critical role of oral health in the overall prognosis of individuals with ESRD. It is well documented that effective management of dental health is vital for preventing complications including bloodstream infections, poor glycemic control, and other issues that can impact the success of ESRD treatment. For example, periodontitis can worsen blood glucose control in diabetics by increasing the levels of inflammatory mediators, such as cytokines and C-reactive protein, and such systemic inflammation can interfere with insulin and increase insulin resistance. Severe oral diseases, such as caries and periodontitis, are also more prevalent in such patients and are linked to increased mortality. Additionally, oral pathologies can lead to inflammation and malnutrition, potentially accelerating cardiovascular events in patients with ESRD.

As a result, addressing oral health is essential for improving outcomes and quality of life for those undergoing treatment for kidney failure. With oral health, patients with ESRD have greater transplant access, less risk of negative cardiovascular events, and protection against systemic infections and peritonitis. Further, maintaining good oral hygiene is essential to effectively managing overall health and mitigating health risks for patients with kidney failure, which is why we are pleased to commend the Agency on its work and urge it to finalize the proposed extension of payment clarification for medically

necessary oral health to beneficiaries with ESRD who receive dialysis treatment.

Should this worthy policy be finalized, we request that CMS furnish guidance to its contractors to ensure reimbursement would be applicable not only to patients diagnosed with ESRD (ICD-10 code N18.6), but also to patients documented to have CKD stage 5 who have not yet started dialysis (ICD-10 code N18.5). The policy should also apply to claims for patients with a diagnosis encompassing one of those conditions, such as Hypertensive Chronic Kidney Disease with stage 5 CKD or ESRD (ICD-10 code I12.0).

Just as important, we urge CMS to take care not to suggest a preference for tooth extraction as "the necessary treatment" for eradicating infections, despite the listing of other restorative (and tooth-sparing) services that may be paid for. Doing so could lead contractors to improperly impose an extra burden on providers to justify choosing a procedure other than an extraction in a particular instance. Similarly, the definition of "additional" services, such as a crown, that may not be paid should be approached with ample clinical basis since the standard of care in certain root canal procedures, among other situations, requires application of a crown to prevent root canal failure, fracture, infection, and other complications in the immediate and longer term.

Guidance on the Inextricable Linkage Standard

In addition to the above comments relating to ESRD, we are carefully examining the guidance provided in the proposed rule on the inextricable linkage future nominations need to present. In the CY 2023 and CY 2024 Physician Fee Schedule rules, CMS informed stakeholders it would review clinical evidence to assess whether dental services are a clinical prerequisite to proceeding with a primary medical procedure and/or treatment, or whether the standard of care warns against proceeding with the covered medical service absent the provision of the dental services. CMS also asserted that "section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to other covered services, such that the standard of care for the medical service would be compromised or require the dental services to be performed in conjunction with the covered services (87 FR 69666)." 88 FR 79015

In the submissions made on or before February 10, 2024, stakeholders worked hard to comply with CMS' directives regarding the evidence needed to support an inextricable linkage between dental services and covered diabetes treatment. Specifically, they presented "clinically meaningful" medical evidence that unresolved dental and oral disease compromises the trajectories and outcomes of diabetes treatment. With respect to diabetes, for example, stakeholders referenced studies demonstrating that appropriate dental services (and periodontal therapies in particular) "result in a material difference in terms of the clinical outcomes and success" of diabetes treatment. Indeed, the materials provided evidence that certain dental services significantly improve HbA1c levels and reduce the risk and rate of morbidity and mortality in diabetes patients.

In the rule proposed for 2025, we note the detailed guidance that the Agency,

> *"…would find that there is an inextricable link where the standard of care for a service is such that the practitioner would not proceed with the procedure or service without performing the dental service(s), for example, because the covered services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment. As such, documentation accompanying recommendations should include medical evidence to support that certain dental services are inextricably linked to certain covered services.*

We also acknowledge the methods identified in the proposed rule as likely to be most conducive to a finding of medical necessity. Specifically, we note that nominations need to:

(1) Provide support that the provision of certain dental services leads to improved healing, improved quality of surgery outcomes, and the reduced likelihood of readmission and/or surgical revisions because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure;

(2) Be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the procedure such that the dental services are inextricably linked to other covered services; and,

(3) Be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient) (87 FR 69686).

This evidence should include at least one of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686).

We appreciate of the Agency's solicitation of "comments on whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services such that they are not subject to the statutory preclusion on Medicare payment for dental services under section 1862(a)(12) of the Act (88 FR 79033)." Towards that end, we wish to provide the following perspectives and are doing so for two reasons:

- As the Physician Fee Schedule rule for 2025 is finalized, we seek consideration of the nominations submitted for autoimmune disease and diabetes which, with respect, we believe provided clinical evidence consistent with the standard defined above; and,

- As stakeholders embark on nominations for the February 10, 2026 deadline, we request feedback that will be of significant assistance.

Medicare Payment Clarification Related to Diabetes

With respect to diabetes, for example, a review of medical literature on dental care and diabetes compiled by the New York University Health Sciences Library and demonstrates the standard of care that exists in the U.S. and internationally. We also appreciate and applaud CMS' consideration of the evidence

presented by key stakeholders and wish to convey information from the American Diabetes Association (ADA) that we include for the Agency's consideration. Specifically, in Diabetes and Periodontal Disease: An Update for Health Care Providers, the ADA offers this guidance:

> *Patents with poorly controlled type 2 diabetes are at greater risk for periodontal disease progression than patients with well-controlled type 2 diabetes.*
>
> *Physicians should refer patients with type 2 diabetes to dentists for treatment of gingival or periodontal inflammation. This is especially important because the pathophysiology of periodontal inflammation is not limited to the oral cavity and can have important effects on glycemic control. Indeed, periodontitis has been identified as the sixth complication of diabetes.*
>
> *In patients with A1C levels > 9.0%, periodontal therapy may reduce A1C by 0.6% in the absence of changes in medication and by 1.4% if changes in diabetes medications are introduced.*
>
> *Referral of patients with uncontrolled diabetes for dental evaluation and periodontal treatment may result in better control of blood glucose levels*.
>
> - *There is substantial evidence of the impact of periodontitis on systemic inflammatory markers.*
> - *Periodontal treatment of patients with diabetes may have limited effects on slightly elevated A1C levels, but in patients with more severe diabetes, such treatment may reduce A1C levels significantly if coordinated with blood glucose control.*

In addition, the following are informative quotes from the American Diabetes Association Comprehensive Medical Evaluation and Assessment of Comorbidities: Standards of Care in Diabetes—2024:

> *The American Diabetes Association (ADA) "Standards of Care in Diabetes" includes the ADA's current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care.*
>
> *People with diabetes can benefit from a coordinated interprofessional team that may include and is not limited to diabetes care and education specialists, primary care and subspecialty clinicians, nurses, registered dietitian nutritionists, exercise specialists, pharmacists, dentists, podiatrists, and behavioral health professionals.*
>
> *Components of comprehensive diabetes medical evaluation at initial, follow-up, and annual visits:*

		INITIAL VISIT	EVERY FOLLOW-UP VISIT	ANNUAL VISIT
PAST MEDICAL AND FAMILY HISTORY	**Diabetes history**			
	• Characteristics at onset (e.g., age, symptoms)	✓		
	• Review of previous treatment plans and response	✓		
	• Assess frequency/cause/severity of past hospitalizations	✓		
	Family history			
	• Family history of diabetes in a first-degree relative	✓		
	• Family history of autoimmune disorder	✓		
	Personal history of complications and common comorbidities			
	• Common comorbidities (e.g., obesity, OSA, NAFLD)	✓		
	• High blood pressure or abnormal lipids	✓		✓
	• Macrovascular and microvascular complications	✓		✓
	• Hypoglycemia: awareness/frequency/causes/timing of episodes	✓	✓	✓
	• Presence of hemoglobinopathies or anemias	✓		✓
	• Last dental visit	✓		✓
	• Last dilated eye exam			✓
	• Visits to specialists			✓
	• Disability assessment and use of assistive devices (e.g., physical, cognitive, vision and auditory, history of fractures, podiatry)	✓	✓	✓
	• Personal history of autoimmune disease	✓		
	Interval history			
	• Changes in medical/family history since last visit		✓	✓
BEHAVIORAL FACTORS	• Eating patterns and weight history	✓	✓	✓
	• Assess familiarity with carbohydrate counting (e.g., type 1 diabetes, type 2 diabetes treated with MDI)	✓		✓
	• Physical activity and sleep behaviors; screen for obstructive sleep apnea	✓	✓	✓
	• Tobacco, alcohol, and substance use	✓		✓
MEDICATIONS AND VACCINATIONS	• Current medication plan	✓	✓	✓
	• Medication-taking behavior, including rationing of medications and/or medical equipment	✓	✓	✓
	• Medication intolerance or side effects	✓	✓	✓
	• Complementary and alternative medicine use	✓	✓	✓
	• Vaccination history and needs	✓		✓
TECHNOLOGY USE	• Assess use of health apps, online education, patient portals, etc.	✓		✓
	• Glucose monitoring (meter/CGM): results and data use	✓	✓	✓
	• Review insulin pump settings and use, connected pen and glucose data	✓	✓	✓
SOCIAL LIFE ASSESSMENT	**Social network**			
	• Identify existing social supports	✓		✓
	• Identify surrogate decision maker, advanced care plan	✓		✓
	• Identify social determinants of health (e.g., food security, housing stability & homelessness, transportation access, financial security, community safety)	✓		✓
	• Assess daily routine and environment, including school/work schedules and ability to engage in diabetes self-management	✓	✓	✓

The ADA also lists the variety of diabetes-related bases that exist today for referral of patients with diabetes for needed treatment and care management (emphasis added):

• Eye care professional for annual dilated eye exam
• Family planning for individuals of childbearing potential
• Registered dietitian nutritionist for medical nutrition therapy
• Diabetes self-management education and support
• ***Dentist for comprehensive dental and periodontal examination***
• Behavioral health professional, if indicated
• Audiology, if indicated
• Social worker/community resources, if indicated
• Rehabilitation medicine or another relevant health care professional for physical and cognitive disability evaluation, if indicated
• Other appropriate health care professionals

With specific respect to periodontal disease, the American Diabetes Association states the following:

> *Periodontal disease is more severe, and may be more prevalent, in people with diabetes than in those without and has been associated with higher A1C levels. Longitudinal studies suggest that people with periodontal disease have higher rates of incident diabetes. Current evidence suggests that periodontal disease adversely affects diabetes outcomes, although evidence for treatment benefits remains controversial. In an RCT, intensive periodontal treatment was associated with better glycemic outcomes (A1C 8.3% vs. 7.8% in control subjects and the intensive-treatment group, respectively) and reduction in inflammatory markers after 12 months of follow-up.*

Nor is the ADA alone in its recognition of the close link between diabetes and dental infections; quite the contrary. For example, the Endocrine Society states in its comment to CMS, "The data overwhelmingly shows that diabetes and periodontitis negatively affect each other. Routine dental cleanings can lead to improved glycemic control in individuals with periodontitis and type 2 diabetes…Maintaining oral health is a key component of an individual's diabetes management overseen by an endocrinologist…Better dental care, including treating periodontal infections, will result in improved diabetes management and reduce diabetes' burden on public health and the Medicare system." As a result, it is the policy of the Endocrine Society to "urge CMS to work within its authority and with stakeholders to support policies for individuals with diabetes to receive appropriate dental care."

In addition, notable payers recognize this linkage and make it a policy so their enrollees with diabetes are screened for conditions, like periodontal disease, that have a causal link to and may be a complication of diabetes. For example, the table below is featured by Blue Cross Blue Shield of Alabama in its Documentation and Coding Guide for Type 2 Diabetes Mellitus (emphasis added). The plan's approach makes eminent clinical sense, of course, because of the bidirectional relationship of periodontal disease with poorly managed glycemic control and, in turn, poor glycemic control's relationship to complications. As a result, addressing periodontal disease is "automatically considered" for patients with diabetes because of the potential to improve medical outcomes and reduce costs by addressing it.

Diabetes Causal Link Condition List

When diabetes mellitus is supported in the record, any diagnosis listed below is automatically considered to have a causal link to the diabetes and considered a complication, unless documented otherwise in the medical record.

- Amyotrophy
- Arthropathy
- Autonomic (poly) neuropathy
- Cataract
- Charcot's joints
- Chronic kidney disease
- Circulatory complication
- Dermatitis
- Foot ulcer
- Gangrene
- Gastroparesis
- Glomerulonephrosis
- Kimmelstiel-Wilson disease
- Loss of protective sensation (LOPS)
- Mononeuropathy
- Myasthenia
- Necrobiosis lipoidica
- Nephropathy
- Neuralgia
- Neurologic complication NEC
- Neuropathic arthropathy
- Neuropathy
- Ophthalmic complication NEC
- Oral complication NEC
- Osteomyelitis
- Periodontal disease
- Peripheral angiopathy
- Polyneuropathy
- Renal complication NEC
- Renal tubular degeneration
- Retinopathy
- Skin complication NEC
- Skin ulcer NEC

Finally, we would like to offer the following thoughts on the questions posed by the Agency:

Are dental services a standard of care in the management of diabetes? Semi-annual examinations and prophylaxis are the minimum standard of care for the management of diabetes. For reference, we wish to refer the Agency to the United Kingdon's National Health Service (UK NHS) standard (contained in the NYU literature search) which evidences that oral health/dental/periodontal services are inextricably linked to covered diabetes medical services. (See also*: Diabetes and Periodontal Diseases: Consensus Report to the Joint EFP/AAP Workshop on Periodontitis and Systemic Diseases, Journal of Clinical Periodontology*, vol. 40, issue s14, p. s106-112, 2013.) Periodontal treatment is also listed as a mandatory service of the UK NHS Commissioning Standard, with key components of periodontal treatment in primary dental care set out in *Delivering Better Oral Health: An Evidence-Based Toolkit for Prevention* (4th edition, 2021).

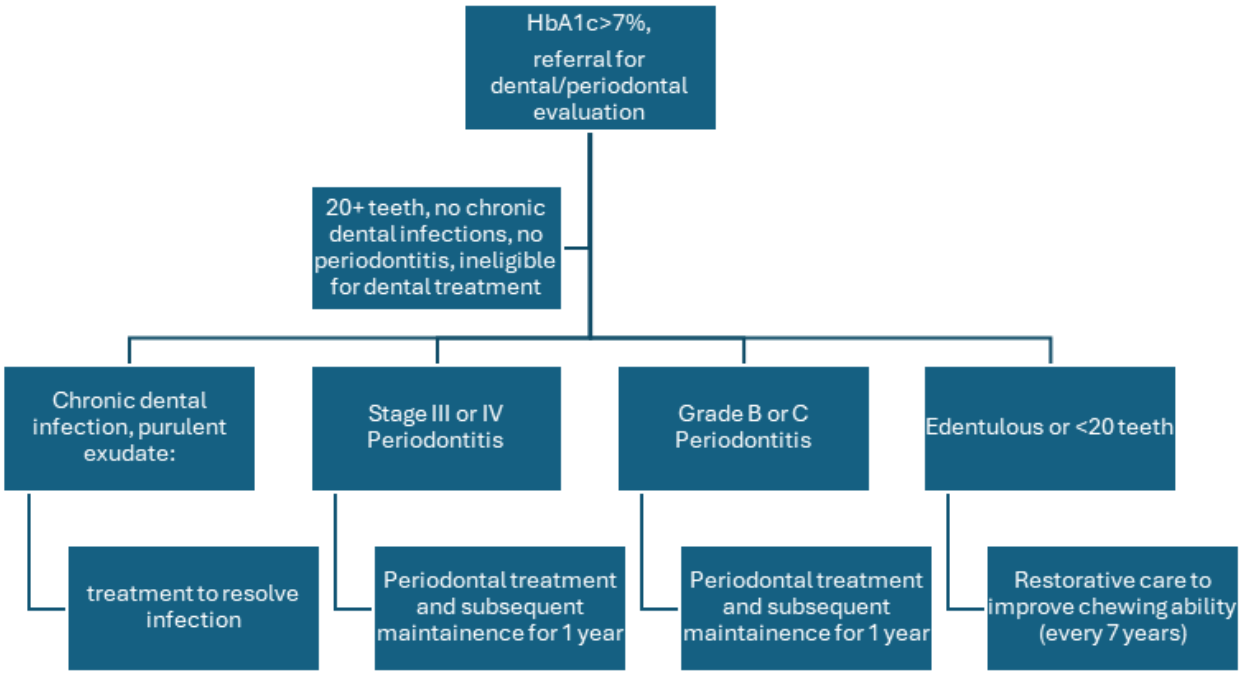
Additionally, high-quality evidence (Sanz et al. 2017) underscores that type 2 diabetes is a risk factor for periodontitis, causing people with diabetes to be more likely to suffer severe gum disease. This evidence also exists that people with type 2 diabetes benefit from intensive periodontal therapy involving scaling and subgingival professional plaque removal (PMPR), reducing HbA1c at 3-4 months by between 0.27% and 1.03% (Sanz et al., 2017), by 0.6% at 12 months following intensive periodontal treatment (D'Aiuto et al., 2028), and by 0.4% at 3 months (EFP/AAP Workshop on Periodontitis and Systemic Diseases, 2013), which offers a clinical impact equivalent to adding a second drug to a pharmacological regimen for diabetes and may mean the patient does not need a second diabetes medication.

Indeed, the greatest impact has been achieved by ensuring that all patients with diabetes are sign-posted to a general dentist for periodontal screening. Patients who are diagnosed with periodontitis will then be assessed for care complexity levels and managed accordingly. Similarly, economic analyses show that periodontal treatment is cost effective for people with type 2 diabetes, assuming that improvements in HbA1c are maintained (NICE, 2022).

At what stages and grading would periodontitis be considered advanced and/or requiring dental and oral treatment intervention? Periodontitis is currently staged and graded based on the systems proposed by Tonetti, Greenwell, Kornman. J Periodontol 2018;89 (Suppl 1): S159-S172. Specifically, the staging refers to the severity, complexity and extent of the disease and ranges from Stage I-Stage IV, based on clinical loss of attachment of the teeth to the underlying bone and

soft tissue, as measured by a dental professional with a periodontal probe and x-rays.

Grading indicates the rate of progression, as measured in bone loss over time, and is modified by smoking and glycemic control. An approach to identifying persons whose dental services are considered "so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services", is to use cutoff levels in the periodontal grading and staging where it would be most beneficial to the beneficiary with diabetes to receive periodontal care. Thus, if HbA1c>7, after referral to a dentist for dental / periodontal evaluation, anyone meeting a certain threshold, would be eligible for care as shown in this flow chart:



What types of practitioners are able to make determinations regarding the staging of periodontitis? Dentists, periodontists, dental hygienists, and dental therapists are able to perform periodontal classifications on their patients.

What determines patient eligibility for treatment for advanced periodontitis? The Grading and Staging described above plus an HbA1c level of 8 or above.

Are there other criteria for consideration? The presence of active infection in the mouth should be addressed regardless of the source.

What should be the duration of periodontal treatment? Patients with diabetes are more vulnerable to periodontal pathogens, so they should be on a maintenance program of 3 to 6 months.

If a patient's clinical status improves with respect to the periodontal disease, what factors determine when periodontal treatment comes to an end? Improvement of glycemic control and lack of periodontal disease progression. After initial treatment, additional root planing and scaling may be required. This will depend on both metabolic control and periodontal status.

What does maintenance treatment entail? What services are provided in treatment of advanced periodontal disease? The essential components of a dental assessment, which includes a clinical examination and necessary radiographs, as well as scaling, root planing, and extraction of hopeless teeth. Other adjunctive treatment may be necessary (i.e. local and systemic antibiotics) but are included in the above.

Are services bundled? If yes, what is included in the bundle? As described above, adjunctive therapies may be provided based on the judgment of the clinician.

When are the services provided and over what period? Is it provided over a calendar month period? A single day? Multiple days? Are services timed? Who provides the services? Services may be performed by a dentist, dental hygienist, or dental therapist. Depending on the complexity and patient comorbidities, the period of treatment may vary from 1 to 4 visits to complete examination, root planing and scaling, and any extractions (if needed). Maintenance therapy will be on a 3-6 month schedule.

What specific terminology is involved? Are these services ever provided under supervision? Or "incident to" by other clinical staff? Standard medical and dental terminology is involved. The supervision required is state specific pending the language of the Dental Practice Acts.

Where and how are services for treatment of advanced periodontal disease provided? Are there any special rules, such as obtaining advance consent or performance of an initiating visit? Services may be provided in a dental office as well as in other settings, such as Skilled Nursing Facilities, when served by mobile clinics. An examination including dental radiographs initially assess periodontal status; periodic examinations (with or without radiographs as warranted) are also used.

What coding is utilized for the treatment services for advanced periodontal disease? What claims format is employed for the submission of claims with related oral and dental services (for example, 837D and/or 837P)? The most frequent codes for management of advanced periodontal disease, as differentiated from mild to moderate disease, include CDT D4210 – D4278 and D4322 – D4323. The most common claims format is 837D.

We also wish to offer for CMS' consideration that applying its framework to medically necessary coverage for beneficiaries with diabetes would result in an applicable population that are most in need of enhanced access to care. For example, we note that the Veterans Health Administration (VHA) has long recognized that certain patients with diabetes have a medically compelling need for dental care, in that their oral condition is "negatively impacting a systemic illness." The VHA has indicated, for example, that veterans who have "poorly controlled diabetes with a HbA1c greater than 9 percent" may receive treatment for the "elimination or prevention of the foci of infection." Under current VHA policy, eligibility for medically necessary dental care is "predicated on referral (consult), followed by a new dental evaluation."

Since "[t]he goal of care is to provide a specific improvement of the oral conditions that directly impact the medical condition," coverage is "limited to the treatment of dental conditions that are professionally determined by a dentist to be aggravating or compromising" the medical condition. As this has typically meant treatment of "dental caries, active periodontal disease, or acute and chronic dentoalveolar abscess," covered procedures have been "generally limited to supportive periodontal therapy, non-cast restorative dentistry, oral surgical procedures, and endodontics." However, "if dental care results in edentulism or significant compromise to speech or aesthetics, prosthetic rehabilitation may be authorized."

We urge CMS to consider whether the nexus that the VHA has identified between aggravating dental conditions and diabetes treatment is akin to the "inextricable link" that would qualify dental services for payment under Medicare. Although the VHA has in the past delineated a HbA1c of greater than 9.0% as a concerning range requiring intervention, we believe that the threshold for uncontrolled hyperglycemia should be HbA1c above 8.0%, as defined in the current literature and guidelines by the American Diabetes Association, American College of Physicians, Association of Clinical Endocrinologists, and American College of Endocrinology. In the illustration below, for example, we project a total population of fewer than 300,000 adult Medicare enrollees with poorly controlled diabetes (HbA1c of 8% or higher) and severe/advanced periodontitis. This analysis is based on the following data:

Number of people 65 years of age and older in the Medicare program: 57.9 million

Percent of the population 65 years of age and older with diabetes: 29.2%

Percentage of older adults with diabetes and HbA1c of 8% and higher: 17.4%

Percentage of older adults with severe/advanced periodontitis: 10%

57,900,000 x 29.2% = 16,907,000 x 17.4% = 2,941,800x 10% = 294,180 enrollees

Medicare Advantage Coverage

More than half (54 percent) of eligible Medicare beneficiaries are now enrolled in a Medicare Advantage (MA) plan. The number of dually eligible beneficiaries enrolled in Dual Eligible Special Needs Plans (D-SNPs) is also growing. We therefore believe it is vital that MA organizations understand their plans must pay for "inextricably linked" dental services on top of any supplemental dental benefits those plans offer. As recommended by the Center for Medicare Advocacy (CMA), this information should be included in the annual Evidence of Coverage (EOC) sent to enrollees. Moreover, plans should make sure that their customer service representatives have scripts and protocols to furnish accurate information to enrollees and providers about the requirements for payment of inextricably-linked dental services. If an enrollee qualifies for payment of inextricably-linked dental services, their plan should assist them in locating a provider who can furnish and bill for that care.

We understand some MA organizations have yet to implement the dental payment clarification, in violation of their obligation to plan enrollees. We hope CMS will take measures to ensure that all plans understand and promptly comply with this obligation. We also understand that while enrollees may be able to access plan-delineated dental benefits from in-network dentists, those same dentists cannot submit claims for "inextricably linked" dental care they may need. This is because of CMS' policy that permits dental providers to contract with MA plans without enrolling in Medicare. Even dentists who have formally opted out of Medicare are allowed to participate in MA plan networks and furnish the dental benefits outlined in those plans. However, MA plans say they can only accept and reimburse claims for "inextricably linked" dental services from providers who are actually enrolled in Medicare.

As a result, we recommend the Agency's consideration of policy changes to align enrollment in Medicare Advantage and Medicare alike, wherein those dental professionals who are contracted by the former to provide services are also enrolled to serve patients covered by the latter. This could be readily accomplished by reverting to the policy in effect prior to January 1, 2022, when CMS required dental service providers desiring to furnish supplemental dental benefits through MA plans to enroll in Medicare, just as other providers are required to. Additionally, CMS could allow dentists who have already opted

out of Medicare to immediately terminate their opt-out status and not have to wait two years, when their opt-out status is automatically renewed if they take no action.

Implementation and Operational Issues

Finally, we wish to offer the following perspectives on issues that are of significant importance as CMS proceeds with implementing and operationalizing its payment policy for oral and dental services that are inextricably linked and substantially related and integral to the clinical success of Medicare-covered medical services.

Fair Health Data

The Consortium believes that the best data available on payment information on the pricing of dental services is national benchmark prices, with Fair Health being one of the best sources, as it takes cost estimates from a wide variety of private insurance companies. While we deeply believe that private insurance rates, which have largely not been improved upon since the 1970s, leave much room for improvement, the data provides the best snapshot of current dental rates, and can be used to help accurately set standard dental rates within CMS.

We believe that it is important for CMS to provide guidance to MACs on provider reimbursement rates. Currently, there is variation on rates even within the same region, with little transparency into how reimbursement rates are being set. While there may be slight regional differences in cost, it is important that there is consistency in the payment to allow providers and their teams to understand the reimbursement rates and system.

It is for these reason that the Consortium respectfully suggests the MACs should be required to reimburse for covered dental services in calendar year 2025 using national benchmark prices such as those in the FAIR Health database, and the dental service reimbursement should be at or near the 80th percentile of average billed charges. Going forward, CMS should require the MACs to update those payment rates annually by using the Medicare Economic Index methodology.

KX Modifier

The Consortium supports CMS' proposal that the KX modifier would be required for claims submission for dental services inextricably linked to covered medical services on both the dental claim format 837D and the professional claim format 837P effective on the January 1, 2025. The Consortium believes that using the KX modifier will streamline the claims process, making it easier for both providers and the MACs to process claims quickly, as supporting medical information is only asked upon request. When the KX modifier is used for services that are inextricably linked, it creates a marker on the claim that dental care was provided and that both dentist and medical doctor believed the dental services were linked to the medical condition and should, therefore, be paid.

GY Modifier

The Consortium appreciates the recommendation of the GY modifier requirement on the 837D or 837P dental claim format in instances where a Medicare claim denial is sought for purposes of submission to third party payers or when the service does not fit within a Medicare benefit category and is statutorily excluded from coverage.

However, the Consortium is concerned about overuse of this modifier, as using the same modifier may create confusion procedurally for providers and their teams because it may be unclear on how to proceed on reimbursements. We recommend consideration of the use of two or more unique modifiers – one for coordination of benefits issues or third-party responsibility, another when the service is statutory excluded from coverage (the dental procedure), and one in which the service may not be statutorily excluded but does not meet the linked requirements. Using the same modifier may create confusion on what to do next for the dentist or patient seeking coverage/ payment from a secondary payor besides Medicare. A unique modifier for each situation would provide better direction to the dentist for reimbursement, or other processes such as appeals or reprocessing or submission to a third party. It would also allow CMS to better track experience with the dental procedures and services and their connection with clinical conditions and treatments.

Conclusion

Thank you for this opportunity to provide comments about the Administration's proposal to expand the scope of medically necessary oral and dental services that are eligible for the Medicare program's payment clarification. Improving oral health will improve health, health equity, and quality of life for many of this nation's most underserved seniors. As a result, we stand ready to serve as a continuing resource to CMS as continuing progress is made for a healthier and more equitable America. We also wish to assist in any way needed as the Agency undertakes educational outreach to expand awareness across the dental care community of this vital progress it is making a reality.

If you have additional questions regarding these matters and the comments offered herein, please contact Ralph Fuccillo, rfuccillo@cambridgeconcord.com, 617-877-0620.

Sincerely,

Ralph Fuccillo, President
Santa Fe Group