February 5, 2025

John Brooks

Deputy Administrator & Chief Policy and Regulatory Officer

Centers for Medicare & Medicaid Services

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# Re: Oral Health Recommendations for CY 2026 Review

Dear Deputy Administrator Brooks:

On behalf of the more than 37,000,000 Americans living with kidney disease and the 22,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to nominate this clarification of payment policy for oral health services that are inextricably linked, substantially related, and integral to the clinical success of covered medical services used for the treatment of individuals covered by Medicare with diabetes mellitus.

Diabetic kidney disease (DKD) is the most frequent cause of kidney failure, accounting for half of all cases worldwide. DKD has enormous personal and societal consequences in terms of worsened quality of life, mortality, and health care costs. Access to care and implementation of breakthrough therapies for DKD can save millions of lives by preventing kidney failure, cardiovascular events, and premature death (Tuttle, 2022).

ASN greatly appreciates the actions the Centers for Medicare & Medicaid Services (CMS) took last year in clarifying that Medicare coverage for oral health care for patients with end-stage kidney disease is medically necessary. This letter is intended to submit for nomination dental services that are inextricably linked to covered medical services on which beneficiaries with diabetes mellitus depend. The delivery of appropriate dental services in accordance with clinical guidelines and standards of care is substantially related and integral to the optimal outcome of covered medical services related to diabetes complicated by retinopathy and kidney disease. Numerous clinical studies document that the treatment of oral infections such as periodontitis and related inflammation improve the medical treatment and management of diabetes mellitus. The absence of treatment for chronic dental infections complicated covered medical treatment for the management of diabetes and exacerbates insulin resistance, worsens glycemic control, and other complications related to diabetes.

# Key Background Issues

A Cochrane collaboration systematic review found that preventive dental care and conservative periodontal treatment are associated with a reduction in glycosylated hemoglobin (hgbA1c) of 0.43-0.50% over 3-12 months as a result of removal of biofilm and the related inflammatory response. The resulting decrease in systemic inflammatory burden combined with improved glycemic control leads to the reduction of diabetes-related complications. The authors found that this clinical outcome is statistically and clinically significant. They noted that the

improved glycemic control is comparable to that seen with addition of a second hypoglycemic agent added to metformin (Simpson, 2022). The authors’ confidence in this result is highlighted by their conclusion “further trials evaluating treatment vs usual care are unlikely to change this conclusion”.

Additionally, this nomination relies on numerous basic and clinical studies that document the connection between oral diseases and inflammation in patients with diabetes mellitus, especially among those with increased risk for microvascular complications including retinopathy and kidney disease. There is a bi-directional relationship between diabetes complications and dental infections which is mediated by inflammation related to periodontal disease and diabetes. Diabetes mellitus is a chronic condition in which circulating levels of glucose enhance systemic inflammation through mechanisms which include formation of advanced glycation end products. As type 2 diabetes progresses, cells become less responsive to insulin; insulin resistance increases blood glucose levels and the systemic inflammatory burden. Clearly, inflammation plays a central role in the pathophysiology of type 2 diabetes, its associated metabolic abnormalities and complications and a variety of related chronic illnesses.

Reciprocal management of glycemic control and periodontal disease decreases the risk for development of type 2 diabetes and its related complications. Glycemic control may require less medication if inflammation related to periodontal disease is reduced. Clinical analyses show that medically necessary dental and oral health treatment lowers the risk of medical complications, improves clinical outcomes, and reduces hospitalization and utilization of other healthcare resources decreasing total healthcare costs (Simpson).

The bidirectionally of the relationship between oral diseases and diabetes mellitus is documented but he increased risk and severity of oral diseases among patients with diabetes: periodontitis (gum inflammation and bone loss), tooth loss, caries, dry mouth and oral fungal infections. Oral diseases raise circulating blood glucose levels and contribute to the development of related complications like retinopathy and nephropathy.

Coverage of dental benefits in the Medicare program for “medically necessary dental care” has been provided since 2023 when changes to the Physician’s Fee Schedule (PFS) allowed consideration of dental care nominations. The approved services are defined in the context of inextricable linkage to specific medical conditions and treatments covered by Medicare. The need for dental care must be based on evidence that the dental services positively impact the desired outcome for medical treatment. In this case, diabetes and related complications.

Recent rule making authorized the coverage of dental benefits for patients with end- stage renal disease receiving dialysis. Basic dental services are authorized to decrease the risk of local or disseminated infection of oral origin or local chronic inflammation contributing to the systemic inflammatory burden in a debilitated individual.

# Relationship and Pathophysiology of the Link between Oral Disease, Diabetes Mellitus and Diabetic Kidney Disease (DKD)

The magnitude of the problem posed by CKD is immense. Among Medicare beneficiaries, diabetes is the leading cause of kidney failure in the US according to the Centers for Disease Control and Prevention (CDC). In 2019, treatment of Medicare beneficiaries with CKD cost $87.2 billion; treating people with ESKD cost an additional $50 billion. Further evidence of the problem is data showing that 33% of patients with type 2 diabetes among beneficiaries covered by Medicare Fee-for-Service received treatment for DKD in 2017 at an average annual cost of $9,576 per person (Wang, 2022). Reduction of the risk for DKD requires keeping hgbA1c levels in the target range.

Periodontitis is a risk factor for complications of diabetes. Conservative periodontal treatment produces a clinically significant reduction in HbA1c. There is a clear association between periodontitis and nephropathy in patients with diabetes mellitus. Yang et al (2024) identified the AGE-RAGE pathway, the complement system and immune inflammatory pathways as common features in both diabetes and periodontitis. Park et. al. (2022) conducted a prospective cohort study of more than 11,000 patients with diabetes. A multivariable Cox regression analysis found that periodontitis was an independent risk factor for diabetes-related microvascular complications (adjusted hazard ratio 1.13; 95% confidence interval (CI)

1.04-1.23; p = 0.004).

In a systematic review of periodontitis and diabetes complications, Nguyen et.al. (2020) showed that those with periodontitis had higher risk for kidney disease (1.9-8.5X), cardiovascular complications (1.28-17.7X) and mortality (2.3-8.5X) than those without periodontitis. Zhang et.al. (2021) conducted a meta-analysis of 13 cross-sectional studies including more than 10,000 participants. They found that periodontitis was associated with increased risk of microangiopathy (odds ratio (OR): 2.43; 95% CI 1.65-3.56), diabetic retinopathy (OR 4.33, 95% CI 2.19-8.55) and DKD (OR 1.75, 95% CI 1.07-2.85).

Sharma et.al. (2016) studied the impact of periodontitis and diabetes on mortality among patients with CKD using NHANES IIII data. They linked mortality data and adjusted for confounders and found the 10-year-all-case mortality rate increased from 32% (95% CI 29-35%) to 41% (36-47%) in those with periodontitis. Similarly, for diabetes, the 10-year all-cause mortality increased to 43% (38049%). They concluded “there is a strong association between periodontitis and increased mortality in individuals with CKD. Sources of chronic systemic inflammation (including periodontitis and other dental infections) may be important contributors to mortality in patients with CKD.”

Zheng et.al. (2012) found an association between infections of the head and neck caused by dental infections and diabetes. Not only are patients with diabetes more likely to develop complications, but the complications are also more likely to be severe and result in death than in those without diabetes. Further, these dental space infections exacerbate hyperglycemia and contribute to CKD.

Multiple research studies have documented that improved glycemic control reduces the risk of DKD. The 2017 Endocrine Society Scientific Statement by Barrett et.al. “The DCCT and subsequent EDIC trial demonstrated that intensive glucose control in T1DM delayed the development and progression of microalbuminuria (DCCT, 1995; EDIC, 2003). The UKPDS reached similar conclusions in patients with T2DM: improved glycemic control produced prolonged delays or reductions in microvascular complications which are potentially linked to epigenetic factors (UKPDS, 1998; Holman, 2008). The more recent ADVANCE, ACCORD, and Veterans Affairs Diabetes trials extended this finding, demonstrating significant reductions in microalbuminuria and overt proteinuria with intensive glycemic control” (Ismail-Beigi, 2010; Duckworth, 2009; Patel, 2008).

Stratton et.al. (2000) demonstrated decreases in mortality and complications with improved glycemic control. They concluded “the lower the glycaemia the lower the risk of complications, and that the rate of increase of risk for microvascular disease with hyperglycemia is greater than that for microvascular disease.”

To summarize the evidence in support of this application:

* Poor glycemic control exacerbates the risk of diabetic kidney disease.
* Poorly controlled diabetes and advanced periodontitis negatively impact the treatment, outcomes and mortality associated with DKD.
* The treatment of dental infections, including periodontitis improves glycemic control and kidney outcomes.
* Lack of treatment of oral infections compromises treatment of DKD.

The standard of care for the treatment of in individuals with DKD is that the practitioner should refer the patient for treatment of oral infections. Services covered by Medicare for the treatment of DKD are significantly and materially compromised without inextricably linked dental services. Dental services are a clear clinical companion to proceeding with the primary medical procedure and/or treatment.

# Covered Medical Services Related to Recommended Payment Clarification

This nomination focuses on the need for coverage of medically necessary dental and oral health services for people with diabetes mellitus. The following covered medical services are examples of ICD diagnostic codes that require coverage:

E1021 Type 1 diabetes mellitus with diabetic nephropathy

E1022 Type 1 diabetes mellitus with diabetic chronic kidney disease E1029 Type 1 diabetes with other diabetic kidney complication E1121 Type 2 diabetes mellitus with diabetic nephropathy

E1122 Type 2 diabetes mellitus with diabetic chronic kidney disease E1129 Type 2 diabetes mellitus with other diabetic kidney complication E1321 Other specified diabetes mellitus with diabetic nephropathy

E1322 Other specified diabetes mellitus with diabetic chronic kidney disease E1329 Other specified diabetes mellitus with other diabetic kidney complication

The following codes are examples of services that warrant coverage but this is not an exhaustive list:

82043 quantitative measurement of proteinuria 36901-36906 dialysis circuit procedures

90935,90937,90940 hemodialysis procedures

90961-90964 physician or other qualified healthcare professional visits for ESRD

90989-90999 other dialysis procedures

99212-99215 evaluation and management (E/M) services

Examples of dental treatment codes to resolve/manage infections inextricably linked to improved outcomes of referenced covered medical services include:

Endodontic Therapy (including treatment plan, clinical procedures and follow-up care) D3330 endodontic therapy, molar tooth (excluding final restoration)

D3421 apicoectomy - premolar (first root)

Periodontal Therapies (including usual postoperative care)

D4241 Gingival flap procedure including root planing - one to three contiguous teeth D4260 Osseous surgery (including elevation of a full thickness flap and closure) D4265 Biologic materials to aid in soft and osseous tissue regeneration, per site D4341 Periodontal scaling and root planing - four or more teeth per quadrant D4342 Periodontal scaling and root planing - one to three teeth per quadrant

D4346 Scaling in presence generalized gingival inflammation, full mouth

Oral and Maxillofacial Surgery Procedures (incl. suturing and usual postoperative care) D7140 Extraction, erupted tooth or exposed root (elevation and/or forceps removal) D7310 Alveoplasty in conjunction with extractions, four or more teeth per quadrant D7510 Incision and drainage of abscess

D7511 incision and drainage of abscess, intramural soft tissues, complicated (includes drainage of multiple facial spaces)

# Healthcare Savings through the Recommended Payment Clarification

Research consistently demonstrates that poor dental health exacerbates diabetes complications, contributing to higher hospitalization rates, increased medical costs, and worsening health outcomes. Despite this, many Medicare beneficiaries with diabetes struggle to access necessary dental care, particularly individuals of color and those from underserved communities. Data compiled by CMS paints a stark picture of the racial and ethnic disparities in diabetes prevalence among Medicare beneficiaries.

As the CDC reports, the prevalence of diabetes is greater among American Indians and Alaska Natives (13.6%), Blacks (12.1%), Hispanics (11.7%) and Asians (9.1%). In 2024, the prevalence rate of diabetes among White adults was 6.9%. This disparity is not just a statistical anomaly, it translates into higher rates of diabetes-related complications including retinopathy and nephropathy leading to preventable suffering and higher Medicare costs.

The CDC reports that adults with diabetes face higher cost barriers to dental care than the general population. Many delay or forego needed dental treatment due to cost concerns which worsens outcomes over time. Clarifying Medicare coverage for oral health services that are inextricably linked to diabetes-associated medical treatment would remove a critical barrier to care and help prevent complications that drive up healthcare costs.

The clarifications suggested by this nomination are not just a matter of expanding coverage, they are a fiscally responsible and patient-centered reform that aligns with the Trump Administration’s principles of reducing long-term healthcare costs while improving outcomes.

President Trump has called for clinically- and cost-effective healthcare reforms that reduce wasteful spending while ensuring that Americans receive the care they need. Expanding access to oral healthcare for patients with diabetes complicated by retinopathy or kidney disease would achieve both of these goals by:

* Reducing unnecessary complications and hospitalizations reducing Medicare costs;
* Improving diabetes management for better outcomes and quality of life; and,
* Ensuring all beneficiaries have access to needed care.

ASN appreciates CMS nomination of this integral care for people with diabetes mellitus. To discuss this further, please contact David L. White, ASN Senior Regulatory and Quality Officer, at dwhite@asn-online.org.

Sincerely,



Prabir Roy-Chaudhury, MD, PhD, FASN

President

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