Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

Submitted electronically via:
Regulations.gov

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1832-P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Oral Health Recommendations for CY 2027 Consideration

Dear Administrator Oz:

The Oral Health Nursing Education and Practice (OHNEP) program is pleased to nominate for payment under 42 C.F.R. § 411.15(i) the following clinical situations in which dental services are inextricably linked, substantially related, and integral to the success of covered medical services. Respectfully, we ask the Agency to recognize payment to address dental infections in Medicare patients who are scheduled to undergo certain covered in-hospital procedures or treatments and are at high risk of developing hospital-acquired pneumonia (see pages 4-10). Additionally, we ask the Agency to recognize payment for dental services that are medically integral to the treatment of diabetes-associated retinopathy (pages 13-16) and diabetes-associated nephropathy (pages 16-19).

The OHNEP program is a national nursing initiative that, for the past 12 years, has focused on advancing oral health equity for populations across the lifespan. Our objective is to integrate oral health with overall health in undergraduate and graduate nursing programs and as a standard of care in clinical settings. As the largest component of the healthcare workforce, the nursing profession is making a significant contribution to advancing medical-dental integration in academic and clinical settings, especially for populations bearing a disproportionate burden of chronic health problems and poor oral health.

As a result, we commend the Centers for Medicare and Medicaid Services (CMS) for its efforts in this critical area. By clarifying Medicare payment policy for medically necessary oral and

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dental care, the Agency is making better health possible for millions of Medicare beneficiaries. Also appreciated is the annual nominations process CMS created, which enables stakeholders to provide input on oral health services that are inextricably linked, substantially related, and integral to the clinical success of covered medical services.

The OHNEP program is grateful for the Administration's leadership in strengthening the connection between oral health and overall health across the Medicare program. The foundation for today's medically necessary oral health coverage was established in 2020 during the President's first term, when CMS clarified (correctly and decisively) that the statutory exclusion of dental services under Medicare does not apply when those services are inextricably linked to the clinical success of covered medical procedures. That clarification created the long-sought pathway under Parts A and B for Medicare to make essential dental treatment available when it is integral to the clinical effectiveness of surgeries, therapies, and other medical services. This principle has been repeatedly reaffirmed and serves as a meaningful driver in the nation's integration of medical and dental care.

Since the establishment of the medically necessary framework, CMS has taken thoughtful action to extend Medicare coverage to medically necessary oral health services for patients undergoing some of the most complex and high-risk treatments in modern medicine. These include organ transplant surgery, cardiac valve replacement, valvuloplasty procedures, head and neck cancer therapies, chemotherapy, CAR T-cell therapy, high-dose bone-modifying agents, and dialysis for End Stage Renal Disease. Each of these coverage decisions reflects careful clinical review and a shared recognition that timely and targeted oral health interventions can prevent life-threatening complications, reduce avoidable hospitalizations, improve clinical outcomes, and generate substantial savings for the Medicare program.

As evidenced by CMS' emphasis in the CY 2026 Medicare Physician Fee Schedule (MPFS) Final Rule, Medical-Dental Integration (MDI) is vital to further improvement of public health. For example, the Agency's decision to expand the Merit-Based Incentive Payment System (MIPS) to include oral health risk assessments, intraoral screenings, patient education and counseling, and dental referrals for patients without a dental home is a significant step forward. As the Final Rule noted, these activities are simple, practical, and highly effective tools for identifying risk early and ensuring patients receive care when it can still prevent downstream harm.

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Integrating oral health into routine medical encounters materially helps Make America Healthy Again by advancing whole-person care. Underscoring the urgency of its efforts, CMS spelled out a highly compelling case for action in the CY 2026 MPFS:

Oral health is closely related to overall health. According to the Centers for Disease Control and Prevention (CDC), approximately 35 percent of American adults did not see a dentist in the past year. The Kaiser Family Foundation (KFF) identified nearly half of all people on Medicare have no dental coverage, and the CDC identified one out of six adults 65 or older are completely edentulous (have lost all their teeth), which can greatly impact nutrition. Moreover, a significant portion of the Medicare population has or is at risk for chronic health conditions, which can be further complicated by poor oral health. Dental issues can be early indicators of systematic diseases, such as Alzheimer's, and may also lead to severe health complications such as diabetes and cardiovascular disease, all of which have a significant impact on the Medicare population. For example, researchers have concluded that periodontal disease "might be a modifiable risk factor" for Alzheimer's disease. Moreover, Medicare spends $520 million annually on dental related emergency department care. If these issues were caught and managed early, many of those expenditures could be avoided.

The WHO has suggested that integrating age-appropriate oral health concerns into general medicine may lead to improvements in older adults' oral health conditions and improve quality of life. WHO's suggestion combined with the fact that nearly two-thirds of the older adult population in the United States are experiencing periodontitis, creates an oral health care imperative among U.S. Seniors on Medicare.

As patients visit their primary care office for medical treatment, there is an opportunity for primary care providers to address oral health by assessing oral health risk and reinforcing at-home care messaging, creating an access point for patients who might not otherwise seek dental care. By including quick oral evaluations during routine medical exams (ref HEENOT, Haber et al.), medical providers can ensure comprehensive patient care and early interventions for potential oral health issues. There is growing evidence that health outcomes improve when dental assessments by medical professionals are integrated into care. This medical-dental integration (MDI) activity can positively address the oral health needs of a high-risk and medically complex population by increasing access, and promoting comprehensive, continuous patient care.

The above realities form a strong factual foundation for the nominations we submit today, which reflects the evidence-based understanding that oral health is neither optional nor

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ancillary but an essential medical service, particularly for patients with complex or high-risk conditions. Our proposals also follow CMS' established framework for inextricably linked oral health coverage and seek to extend that logic to additional clinical scenarios where the evidence demonstrates a clear, direct, and medically necessary connection between timely dental treatment and the success of Medicare-covered medical care.

Before proceeding with our nomination, we wish to thank the Agency for providing assurances in the CY 2026 MPFS that it will "take the information and recommendations submitted into consideration for the future." This commitment is consistent with the clinically grounded process the Agency has used since this coverage pathway was first established in 2020. We are therefore pleased to submit these nominations, which build directly upon the above progress and aligns squarely with CMS' leadership in advancing a modern, evidence-based Medicare program.

HOSPITAL-ACQUIRED PNEUMONIA

Pneumonias, broadly classified as community and nosocomial (hospital acquired) and encompassing non-ventilator hospital acquired pneumonia (NVHAP) and ventilator acquired pneumonia (VAP), are some of the most prevalent and lethal infections in the United States.

Non-Ventilator Hospital Acquired Pneumonia (NVHAP)

Non-ventilator hospital acquired pneumonia (NVHAP) represents 60 percent of the cases and is associated with the onset of symptoms reported within 48 hours of admission (Munro et al. 2021, Feet et al. 2024). NVHAP occurs in ~1 in 100 hospitalized patients and has an associated crude mortality of 15-30 percent. It has also been calculated that a case of NVHAP costs $20-40,000 (Zimlichman et al. 2013, Giuliano et al. 2023), driving an estimated cost to the U.S. healthcare system of approximately $3 billion per year.

Research shows that people with poor oral health and medically fragile patients are at high risk for NVHAP, including persons 65 and older, with multiple chronic conditions, patients with dysphagia, impaired cough reflex, xerostomia, inadequate nutrition, and poor oral hygiene. (Scannapieco et al. 2022) NVHAP is also associated with increased intensive care unit utilization rates, readmission rates, and sepsis.

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Proven NVHAP-preventive measures include: 1) elevation of the head of bed to 30°–45°, 2) reduced exposure to sedation, 3) limited use of stress ulcer prophylaxis, 4) frequent patient mobility, and 5) provision of effective oral hygiene care (mechanical and topical antiseptic biofilm control). With respect to the latter, evidence accumulated over recent decades links poor oral health (in the form of poor oral hygiene, tooth decay, and/or periodontal disease) with increased risk of pneumonia. Given the anatomical connection between the oral cavity and lungs, conditions in the oral cavity have a direct influence on the lungs.

Poor oral health and oral hygiene permits growth of microbial oral biofilms (dental plaque) that increase the number of free microorganisms in saliva that can be micro-aspirated into the lungs. Numerous studies have tested the hypothesis that improved oral care helps prevent NVHAP, finding that toothbrushing is effective in reducing pneumonia in the hospital. Evidence also suggests that dental services prior to hospitalization and surgery reduces post-operative pneumonia (Baker, 2022).

Ventilator Acquired Pneumonia (VAP)

VAP is a case of pneumonia that develops at least 48 hours following endotracheal intubation and mechanical ventilation. It is the most important nosocomial infection in intensive care units (ICUs) today, causing considerable morbidity, mortality, and health care costs. (Ashraf and Ostrosky-Zeichner 2012). Evidence suggests that provision of oral hygiene to patients who are ventilated enhances the efficacy of the VAP prevention bundle (Pileggi, Mascato et al, 2018).

Pneumonia is the result of aspiration of infectious agents colonizing the oral cavity and/or upper respiratory tract. (Scannapieco 1999, Mehta and Niederman 2002). Several mechanisms have been proposed to explain how microorganisms can enter the lung to cause infection. Four classical mechanisms have been described for the development of VAP (Ulsamer et al. 2025):

1) Via microaspiration of secretions containing bacteria, either from the oral cavity and then into the lungs, or by reflux from the stomach into the oral cavity and then into the lungs, in a process called transcolonization.
2) By continuity, due to the formation of microbial biofilm in/on the endotracheal tube. The source of the microbes that colonize the tube to form the biofilms derive from the oropharyngeal microflora.

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3) Directly through the artificial airway, without previous colonization, due to the use of an incorrect aseptic technique during the intubation procedure or aspiration of secretions, and/or aerosolization by contamination of ventilation devices (gas blenders, flow regulators, humidifiers, etc.).
4) Via hematogenous route through dissemination of bacteria to the lower respiratory.

Thus, microbes first colonize the upper airway and are then aspirated, almost always as a mixed-infection by multiple microbial species that express microbial virulence factors, which then results in the host inflammatory response that will cause the resulting organ damage.

Among the most common types of pneumonia among hospitalized elderly Americans is aspiration pneumonia, which occurs when large-volume aspiration of oropharyngeal or upper gastrointestinal contents that contain microorganisms inadvertently enter the lungs. Patients admitted to the hospital who are intubated are also particularly vulnerable to pneumonia. In many cases, patients succumb to pneumonia due to the aspiration of oral bacteria resulting from poor oral health practices. This condition is estimated to occur in up to 40% of individuals on mechanical ventilation. (Suljevic et al. 2020; Li, Cai, Ding, Chen, Wang, Hongyan, 2024), with risk increasing at a rate of 1-3 percent per day of intubation.

Patients with VAP have a longer stay in the ICU and a total hospital length of stay (LOS) averaging an additional 7-9 days. A single case of VAP costs a minimum of $40,000 in additional hospital costs and 36-60 percent of all health associated infection-related deaths are attributable to VAP (Gupta, Gupta, Singh. Saxsena, 2016).

Colonization

Many respiratory pathogens are commensal organisms; that is, they are part of the normal flora. Other pathogens originate from the environment (nosocomial pathogens such as Pseudomonas aeruginosa, Staphylococuus aureus and enteric organisms such as Klebsiella pneumonia) transiently colonize the oral cavity and nasopharynx. In some cases, pathogens that are members of the gastrointestinal flora are passed onto the oro-pharynx by regurgitation due to reflux. All pathogens originate in the oro-pharynx, from where they are aspirated into the lung.

Oral conditions play a key role in the etiology of hospital acquired pneumonia. In critically ill hospitalized patients, the normal flora of the oropharynx changes to include increased numbers of well-known pathogens such as Pseudomonas aeruginosa, Staphylococcus aureus, Acinetobacter spp. and Enterobacterales (Ulsamer et al. 2025). The oral biofilm of hospitalized and ICU patients is rapidly colonized by these respiratory pathogens (Heo et al. 2008).

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Respiratory pathogens from the lungs often match strains from the oral cavity of mechanically ventilated patients, suggesting that the oral cavity is an important reservoir for these microbes (Heo et al. 2008).

Many organisms can induce the inflammatory cascade leading to infection (Scannapieco 2023, Almirall et al. 2024, Ulsamer et al. 2025). Gram-negative pathogens release toxic substances such as lipopolysaccharides that are well known to incite inflammatory pathways. Anaerobic species common to the oral cavity release potent enzymes that can contribute to the destruction of host defense molecules and lung parenchyma.

Conditions that compromise upper airway defenses or allow secretions to bypass containment increase pneumonia risk. Allowing aspirated microbes to enter the lower airway and attach to the respiratory epithelium triggers the cascade of events that result in overt infection. For example, dysfunctional swallowing, or dysphagia, will allow more frequent and larger bolus of the oral contents, containing numerous microorganisms, to be aspirated into the lower airway to set up infection of the lung (Scannapieco 1999, Almirall, Boixeda et al. 2024). The impact of dysphagia is exacerbated when oral hygiene is poor, which would allow for the growth of many more bacteria in the mouth to be aspirated.

Prevention Methods

While oral care provided by nursing staff in the hospital can help reduce the risk of pneumonia, a substantial share of hospitalized older patients do not have good oral health and hygiene upon admission. Instead, most have excess oral biofilms on their teeth which can become calcified in the form of dental calculus, which is a rough surface prone to colonization by pathogenic bacteria.

Compelling evidence documents that poor oral health – primarily tooth decay, periodontal disease, and poor oral hygiene – significantly influence respiratory health and serves as a major contributor to NVHAP and VAP. (Scannapieco 1999, Gomes-Filho et al. 2020, Kelly et al. 2021, Ploenes et al. 2022, Scannapieco et al. 2022) Microbes capable of causing pneumonia colonize the oral cavity. (Scannapieco et al. 1992, Scannapieco 1999) When these organisms proliferate, they can easily be aspirated into the lower airway to cause infection. This is especially true when patients are intubated, as is often the case during surgery or following traumatic injury. (Raghavendran et al. 2007) Intubation can bypass normal mechanisms that minimize aspiration of oral microbes into the lung. The tubing used for intubation can also serve as a substrate for microbial biofilms derived from these aspirated organisms. (Ulsamer et al. 2025)

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In critically ill hospitalized patients, the normal flora of the oropharynx changes to include increased numbers of well-known pathogens such as Pseudomonas aeruginosa, Staphylococcus aureus, Acinetobacter spp. and Enterobacterales. The oral biofilm of hospitalized and ICU patients is rapidly colonized by these respiratory pathogens. There is good evidence that the respiratory pathogens from the lungs often match strains from the oral cavity of mechanically ventilated patients, suggesting that the oral cavity is an important reservoir for these microbes and that poor oral health is an important risk factor. (Scannapieco, Giuliano et al. 2022)

Fortunately, receipt of dental services prior to hospitalization has been found to decrease the risk of pneumonia. For example, a recent study examined hospital records of Medicaid beneficiaries who were afflicted with NVHAP, and its results demonstrate that preventive dental treatment in the 12 months prior to hospitalization, or periodontal therapy (which includes extensive tooth-cleaning) in the 6 months prior to hospitalization, was associated with a reduced risk of NVHAP.

In addition, systematic review with meta-analysis suggests that oral care interventions given to hospital patients by dental personnel reduced mortality from hospital-acquired pneumonia. This evidence supports the concept that provision of preventive dental services (tooth cleaning and basic dental procedures) prior to hospitalization will prevent pneumonia and therefore reduce the cost of medical care. Additionally, maintaining oral cleanliness while in the hospital, particularly prior to intubation, can reduce infection risk by minimizing the numbers of organisms present in the secretions that could be aspirated.

Taken together, the evidence demonstrates that provision of preventive dental services before and during hospitalization or peri-operatively can reduce the risk of pneumonia in the hospital and the cost of treatment. Studies document that provision of preventive dental services prior to hospital admission and peri-operatively reduce the risk for pneumonia (Baker, 2022 #7495; Pains, 2025 #780; Ohi, 2025 #7801).

A study by Soutome and colleagues (2017) investigated the effect of perioperative oral care on prevention of postoperative pneumonia associated with esophageal cancer surgery. Participants in the experimental group received care by a dentist and dental hygienist from the time the decision for hospitalization was made. The care included oral health instruction, removal of calculus, professional tooth cleaning, removal of tongue coating, denture cleaning, extraction of teeth for severe periodontitis. Patients were instructed to clean their teeth using a toothbrush, interdental brush, and dental floss, followed by gargling 3 times per day. All patients received a final oral cleaning by a dentist or dental hygienist the day before surgery.

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After surgery, patients were asked to perform gargling every 3-6 hours with water during the daytime. The control group received the standard pre-operative care protocol.

The findings reveal that lack of dental services and/or oral care intervention was significantly associated with development of postoperative pneumonia ($p<.003$). These data are supported by findings in a study by Sato and colleagues (2016). Further, Iwata and colleagues (2019) evaluated the clinical effect of perioperative dental/oral management on 721 patients who received lung resection for lung cancer and report that the incidence of postoperative pneumonia was significantly higher in the non-perioperative oral care (9.3% vs. 4.6%). Pre-hospital oral care services were most effective when provided by a dentist or dental hygienist (Aoyama and Tamagawa, 2019). Moreover, findings reported by Nobuhara and colleagues (2018) suggest that the number of oral/dental care sessions is important for ensuring a positive outcome; receiving perioperative dental/oral care over two or more sessions was more effective preventing periodontal inflammation and enhancing self-care capacity.

Further, Baker and colleagues (2022) examined the association between accessing dental services and non-ventilator hospital-acquired pneumonia among 2019 Medicaid recipients. Data from their model reveal that the probability of a diagnosis of NVHAP decreased with each additional preventive dental visit one year prior to hospitalization. Beneficiaries who had at least one preventive dental visit within a year of hospitalization were 10% less likely to get NVHAP ($p<.001$) compared to beneficiaries with no preventive dental visit or visits >one year prior to hospitalization. Moreover, use of periodontal services less than six months prior to hospitalization decreased the odds of an NVHAP diagnosis by 30% ($p<.003$). These findings align with the data reported by Nobuhara and colleagues. (Nobuhara et al. 2018)

A Cochrane review of 40 randomized trials, including 5,675 ICU patients, likewise showed that provision of oral hygiene interventions (toothbrushing and use of antiseptic rinses) significantly reduced incidence of pneumonia in critically ill adults. (Zhao, Wu et al. 2020) A network meta-analysis included 11 randomized trials of 2,395 patients and demonstrated that toothbrushing combined with 0.12% chlorhexidine was an effective intervention in preventing pneumonia. (Yamakita, Unoki et al. 2024)

It should also be noted that oral care has been introduced into “bundles” of preventive procedures that all aim to reduce the numbers of oro-pharyngeal microbes that can be aspirated by vulnerable patients. Such bundles include subglottic suction endotracheal tubes, probiotics, and the Institute for Healthcare Improvement VAP Prevention Bundle, where oral care serves as an important component. (Branch-Elliman et al. 2015, Martinez-Reviejo et al. 2023) Indeed, a meta-analysis of the implementation of VAP bundles found that the provision

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of several simple interventions not only reduces the incidence of ventilator-associated pneumonia but may improve survival.

Importantly, the U.S. Centers for Disease Control and Prevention (CDC) has also organized a NVHAP Prevention Toolkit (https://www.cdc.gov), and the nursing community within the Veterans Administration has implemented the HAPPEN Initiative (Hospital Acquired Pneumonia Prevention by Engaging Nurses – (https://marketplace.va.gov). These initiatives recognize that hospitalized patients typically have extensive dental biofilm buildup that fosters aerosolized pathogens that can be aspirated to cause pneumonia, especially when the patient is intubated as occurs during many surgical procedures. The VA's HAPPEN program implemented standardized oral care and achieved substantial reductions in non-ventilator hospital-acquired pneumonia, with substantial cost savings per case avoided.

Finally, strong evidence indicates that providing needed oral care to vulnerable patients improves medical outcomes and can lead to significant cost savings. Dental services provided before and during hospitalization or peri-operatively are associated with lower pneumonia rates (Sekiya, Kurasawa et al. 2021, Baker, Giuliano et al. 2022, Ohi, Hattori et al. 2025, Pains, de Melo et al. 2025) that result in considerable cost savings. Cost-benefit calculations argue that provision of oral care to prevent pneumonia in hospitals and nursing homes would result in the saving of millions of dollars annually from substantial overall healthcare cost savings, including reductions in antibiotic use and time on ventilators (Munro and Baker 2018, Munro, Baker et al. 2021, Sekiya, Kurasawa et al. 2021, Okubo, Hoshi et al. 2022, Rodrigues, de Souza et al. 2023).

Recommendation

It is well established that pre-hospital dental and dental hygiene services for planned medical and surgical hospitalization decrease the incidence and prevalence of NVHAP and VAP for at risk groups. As a result, preventive dental services to examine, diagnose and eradicate such as cleaning and treatment of oral and dental infections conditions prior to hospital admission for high-risk patients scheduled for surgery is inextricably linked, substantially related to, and integral to decreasing the incidence and prevalence of NVHAP and VAP for at risk groups that could jeopardize their medical outcomes. For this reason, we recommend that payment be clarified for dental preventive services, including assessment, treatment, and resolution of dental infection problems prior to hospitalization for medical or surgical conditions.

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DIABETES-ASSOCIATED RETINOPATHY AND NEPHROPATHY

The Cochrane Collaboration's recent, extensive, systematic review found that preventive dental care and conservative periodontal treatment are associated with a reduction in glycated hemoglobin (HbA1c) of 0.43 – 0.50% over 3 to 12 months. This reduction is due to the removal of the biofilm, with a resulting reduction in the local inflammatory response, and systemic inflammatory burden. Because there is an inextricable link between HbA1c and clinical complications, reflective of long-term effective management of blood glucose levels, reducing oral and dental disease is inextricably linked to the effective treatment of diabetes-related conditions.

The Cochrane authors described the above clinical outcome related to preventive dental care, conservative periodontal treatment, and reduction in HbA1c, as clinically important and statistically significant. Importantly, it is 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 Cochrane authors stated that "further trials evaluating no treatment *vs* usual care are unlikely to change this conclusion."

The present nomination relies on both basic and clinical studies that document the connection between oral diseases and inflammation in persons with diabetes, *especially among persons facing heightened risk for microvascular complications, including retinopathy and nephropathy*.

Central to this connection is the bi-directional relationship between diabetes and dental infections, as well as the pathophysiology of inflammation related to periodontal disease and diabetes. Diabetes is a chronic condition in which circulating levels of glucose lead to enhanced systemic inflammation through several mechanisms, including the formation of advanced glycation end products (Lalla et al., 2000). As type 2 diabetes (T2D) develops, cells become less responsive to insulin, and the resulting insulin resistance increases blood glucose and the systemic inflammatory burden. This is crucially important because inflammation plays a central role in the pathophysiology of T2D, its associated metabolic abnormalities, and subsequently the devasting clinical complications of diabetes.

Reciprocal management of glycemic control and periodontal disease decreases risk for the development and severity of diabetes and periodontal disease. For example, medical management of glycemic control in diabetes may also involve less medication if inflammation related to periodontal risk and disease is minimized. As determined by clinical analyses discussed below, medically necessary dental/oral treatment would lower level of glycated hemoglobin, and consequently the risk of clinical complications, improve clinical outcomes, and

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reduce hospitalization and the use of other health care resources, thereby decreasing total healthcare costs.

As stated above, 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, dental caries, dry mouth, and oral fungal infections. Additionally, oral diseases are documented to adversely affect the concentration of glycated hemoglobin in blood. As a result, poor metabolic control in T2D contributes to the development of diabetes complications, including retinopathy and nephropathy. These are traditionally considered the earliest clinical complications of diabetes.

Provision of Medicare dental benefits for what has been termed “medically necessary dental care” has been provided since 2023 following changes to the Physician’s Fee Schedule (PFS) to consider dental care nominations. The approved dental services are defined in the context of inextricable linkage to specific medical conditions and treatments covered by the Medicare program. The need for dental care must be based on evidence that the dental services positively impact the desired outcome for the medical treatment, here diabetes, and /or decreases the risk for, or mitigates the related complications, here diabetes-associated retinopathy, or nephropathy.

As we make the case for inclusion of persons with T2D, retinopathy/nephropathy, and moderate and advanced periodontitis as eligible for medically necessary dental care, parallel examples are provided by previously authorized medically necessary dental services for specific medical conditions.

- For example, a patient diagnosed with large B-cell lymphoma (the disease) who is receiving chimeric antigen receptor therapy (CART; the treatment) is eligible to receive basic dental services. These services are authorized because they decrease the risk of dissemination of oral bacteria and/or limit the contribution of the local inflammatory response associated with infection to the systemic inflammatory burden in an immunocompromised individual. In these patients, resulting complications such as sepsis or fungal infections can interrupt successful treatment of lymphoma, increase hospital admissions, and prolong length of hospital stays.
- A patient diagnosed with end-stage renal disease (the disease) who is receiving dialysis (the treatment) is eligible to receive medically necessary dental services. 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.

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In this application we provide evidence that oral infection/inflammation adversely affect the outcomes of treatment for people with diabetes associated retinopathy who are receiving various treatments for macular edema and/or microvascular retinal hemorrhages, receiving treatment with Medicare-approved medical services that are standard of care for treatment of diabetes associated retinopathy, including intravitreal pharmacotherapy and laser photocoagulation. Similarly, research shows that the complications and mortality related to the treatment of nephropathy are reduced when patients with diabetes improve their glycemic control.

The control of oral and periodontal infections and resultant inflammation, preventing local and/or disseminated infection, coupled with reduction of the systemic inflammatory burden represent a logical approach to achieving the desired outcome of the medical therapies for diabetes-associated retinopathy and nephropathy. Evidence for these statements is presented below.

Relationship and Pathophysiologic Link between Oral Disease, Diabetes, and Diabetes-associated Retinopathy

Diabetes mellitus (DM) remains an enormous health care challenge in the United States, taking a personal and economic toll of enormous proportions. According to the Centers for Disease Control and Prevention (CDC), the direct and indirect cost of DM in the U.S. was $412.9 Billion (2022 data). The percentage of people with DM is 15.8%, but for adults 65 years of age and older the prevalence is 29.2%.

Effective metabolic management is difficult to achieve. Less than half of adults with diabetes have an HbA1c of 7%, which is the clinical target for disease management. Further, 24.5% of adults have an HbA1c equal to or greater than 8%, placing them at increased risk for clinical complications of DM (CDC 1).

The clinical complications of DM are associated with significant morbidity and mortality. One of the earliest complications of diabetes is retinopathy. Vision becomes impaired, and retinopathy associated with DM is the major cause of blindness in the U.S. (CDC 2). More than 10% of persons with diabetes report severe vision impairment or blindness (CDC 2).

Diabetic retinopathy is the most common cause of severe vision loss in working-age adults in the western world and can lead to vision-threatening damage to the retina and eventual blindness. The number of people with diabetic retinopathy in America is estimated to reach 16 million by 2050, with vision-threatening complications affecting ~3.4 million. Poor glycemic control is linked with worsening retinopathy.

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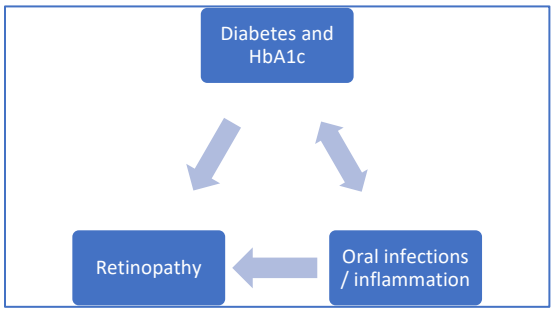
Chronic inflammation is an essential component of the pathophysiology of diabetes and diabetes-associated retinopathy. Microvascular changes in the retina occur relatively early in the natural course of diabetes. Leukocyte activation is a characteristic feature of diabetes-associated retinopathy, with adherent macrophages playing a key role in development of capillary occlusion in the retina (Forrester et al. 2020). These authors note that the treatment of diabetes-associated retinopathy now often involves injection of anti-Vascular Endothelial Growth Factor (VEGF). However, many affected individuals do not respond to Anti-VEGF therapy. This reinforces the need to control other chronic sources of inflammation, including periodontitis.



An association between periodontitis and retinopathy in patients with DM has been identified.

A recent Cochrane systematic review of prognostic factors in persons with diabetes-associated retinopathy identified *elevated glycated hemoglobin as the most important prognostic factor for retinopathy in persons with type 2 diabetes*. Several other markers, including duration of diabetes and body mass index (BMI), were not found to be predictive of this complication (Perais et al., 2023). The authors of this review emphasized the importance of metabolic control of diabetes, stating that "maintaining adequate glucose control throughout life, irrespective of the stage of (diabetes retinopathy) severity, may help to prevent progression to (diabetes-associated retinopathy) and risk of its sight-threatening complications."

Periodontitis is a risk factor for complications of DM, and conservative periodontal treatment has been associated with a clinically significant reduction in HbA1c (Simpson et. al., 2022). A recent review examined the underlying pathology that links periodontitis and retinopathy in persons with DM (Zhao & Shen, 2024). The authors concluded that the systemic inflammatory response, and specifically oxidative stress and formation of advanced glycation end-products resulting in vascular/endothelial cell dysfunction, were responsible for the pathology in both DM-associated periodontitis and DM-associated retinopathy. The over-production of VEGF drives the excess development of microvasculature. While the retinal environment is sterile, the periodontal environment is chronically infected by the periodontal biofilm, driving the development and progression of the periodontal lesion. This local periodontal inflammatory response contributes to the systemic inflammatory response (Martinez-Garcia & Hernandez-Lemus 2021), thereby contributing to hyper-vasculature/microangiopathy that characterizes DM retinopathy.

OHNEP
Oral Health Nursing Education and Practice

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

Clinical studies identify periodontitis as a risk factor for diabetic retinopathy. An early cross-sectional study (Amiri et.al., 2014) demonstrated the relationship between these two disorders. A fully adjusted analysis of the relationship of periodontitis to diabetic retinopathy confirmed this relationship for adults with diabetes who were not obese (Song et al., 2017). The diabetes-periodontitis-retinopathy relationship was confirmed in a more detailed study that observed increased retinopathy when periodontitis was present (Veena et.al, 2018). A review paper published a few years later (Nguyen 2020) reported increased risk of retinopathy for people with DM and periodontitis versus those with DM without periodontitis (odds ratio of 2.8-8.7).

Subsequent studies provided additional information about this relationship. A meta-analysis of studies examining the relationship of periodontitis to microangiopathy also concluded that periodontitis is associated with microangiography in persons with diabetes. Of the microangiography-associated complications of DM, the highest odds ratio (OR = 4.33) was seen for retinopathy (Zhang et.al., 2021). Another meta-analysis confirmed these findings (Wu et al., 2021). Further, the periodontitis-diabetic retinopathy linkage has been reported in other developed countries. A population study from Denmark included more than 15,000 participants After a comprehensive consideration of potential confounders (inverse probability of treatment weighting), retinopathy in persons with diabetes was “significantly associated with moderate/severe periodontitis.” (Bitencourt et al., 2024).

Of note is a report from South Korea that analyzed data from a national health survey. This included more than 11,000 participants with diabetes who were followed for mean of 7 years. The study’s finding is worth consideration: “Multivariable Cox regression analyses showed that periodontitis was an independent risk factor for diabetes-related microvascular complications and that periodontitis was an independent risk factor for retinopathy.” (Park et al., 2022)

A recent detailed assessment examined a detailed clinical evaluation of periodontal inflammation (tissue surface area with inflammation) in relationship to serum levels of interleukin 6 and lipoprotein(a) and diabetic retinopathy (Poyil et.al., 2024). Periodontitis was more severe in persons with DM plus retinopathy versus persons with DM only. The tissue inflammatory index was correlated to serum levels of IL-6, suggesting the contribution of locally persistent periodontal inflammation to systemic inflammation. Further, the measure of the severity of periodontal disease was higher in persons with DM retinopathy versus those with DM but not retinopathy.

An editorial in the World Journal of Diabetes followed the publication of the Poyil article; the authors stated that the observed “…correlation highlights the importance of addressing periodontal health in diabetes management to potentially reduce the severity of (diabetic

OHNEP Oral Health Nursing Education and Practice

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

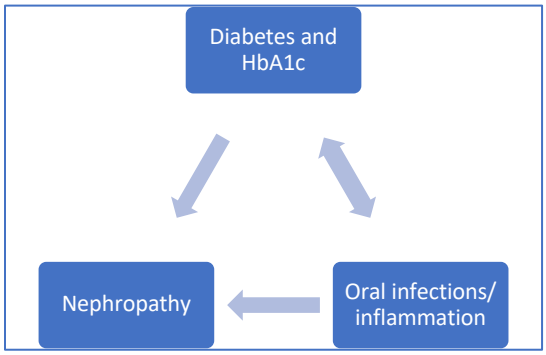
Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

retinopathy), a complication of diabetes." The authors continued: "This article highlights the importance of collaboration amongst diabetes specialists, ophthalmologists, periodontists, and public health professionals to advance the prevention, early detection and treatment of (periodontal disease) and (diabetic retinopathy)" (Martinez et. al., 2024).

In summary, the available literature supports the concept that periodontitis is a preventable risk factor for diabetic retinopathy, and that conservative periodontal treatment as a part of basic dental services meets the description of medically necessary dental care. Above we provided evidence that oral infection/inflammation adversely affects the outcomes of treatment for persons with diabetes-associated retinopathy. The findings of the studies reported indicate that:

- Poor glycemic control increases the risk of retinopathy.
- Poorly controlled diabetes and advanced periodontitis negatively impact risk for, and treatment and outcomes of retinopathy.
- Periodontitis and diabetic retinopathy share many pathologic characteristics, including a dense infiltrate of chronic inflammatory cells, capillary dysfunction, and increased levels of inflammatory interleukins and matrix metalloproteinases.
- The treatment of dental infections like periodontitis and other oral infections improves glycemic control and, by extension, retinopathy outcomes.
- Lack of treatment of oral infections will exacerbate symptoms of retinopathy (macular edema, retinal hemorrhage) and increase the need for treatment for retinopathy
- The standard of care for medical services by a retinal specialist for treatment of retinopathy in persons with diabetes includes assessment questions about glycemic control. As evidenced by Simpson (2022), glycemic control is adversely affected by periodontitis.

Relationship and Pathophysiologic Link between Oral Disease, Diabetes, and Diabetes-associated Nephropathy



An important complication of diabetes is chronic kidney disease (CKD). Among Medicare Beneficiaries, diabetes is the leading cause of kidney failure in the U.S. (CDC, 2025). In 2019, treating Medicare beneficiaries with CKD cost $87.2 Billion, and treating people with end-stage kidney disease

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

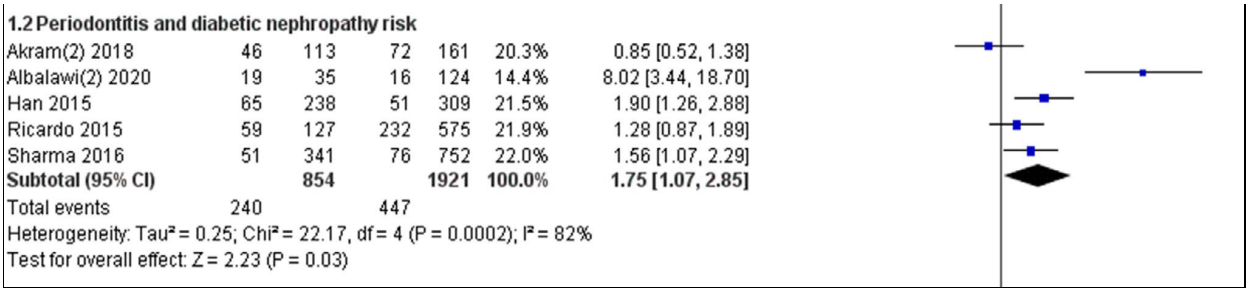
cost an additional $37.3 Billion (CDC 2025). One in three, 33%, of persons with type 2 diabetes among Medicare Fee for Service Population received treatment for nephropathy in 2017, at an average annual cost of $9,576/person (Wang, 2022). Risk reduction for CKD in diabetes includes keeping blood sugar (HbA1c) in the target range (CDC, 2025).

Periodontitis is a risk factor for complications of Diabetes. Conservative periodontal treatment is associated with a clinically significant reduction in HbA1c (Simpson 2022). The association between periodontitis and nephropathy in patients with DM has been identified, with pathways illustrated by the Figure above and described below.

Yang et al. (2024) studied the pathophysiological relationship between diabetic nephropathy and periodontitis; they found that AGE-RAGE pathway signaling, the complement system, and immune inflammatory pathways appear as common features of both diseases. They proposed CSF1R, CXCL6, VCAM1, JUN and IL1β as potential crosstalk aging genes linking periodontal disease and diabetic nephropathy.

Park and colleagues (2022) conducted a prospective cohort study (N=11,353) among persons with diabetes. Multivariable Cox regression analyses showed that periodontitis was an independent risk factor for diabetes-related microvascular complications (adjusted hazard ratio (HR):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 persons with periodontitis had higher risks for nephropathy (1.9-8.5), cardiovascular complications (1.28-17.7), and mortality (2.3-8.5) than people without periodontitis. Further, Zhang and coworkers (2021) conducted a meta-analysis of cross-sectional studies including 10,570 participants, which showed that periodontitis was associated with increased risk of Type 2 diabetic microangiopathy (OR: 2.43, 95% CI: 1.65-3.56), diabetic retinopathy (OR: 4.33, 95% CI: 2.19-8.55), and diabetic nephropathy (OR: 1.75, 95% CI: 1.07-2.85). (see Figure below)



Further amplifying the link between diabetes, periodontitis, CKD and its outcomes, Sharma et al. (2016) studied the impact of periodontitis and diabetes on mortality among persons with chronic kidney disease (CKD). Using data from NHANES III and linked mortality data, and

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

adjusting for confounders, the 10-year all-cause mortality rate for persons with CKD increased from 32% (95% CI: 29–35%) to 41% (36–47%) in persons with periodontitis. Similarly, for diabetes, the 10-year all-cause mortality rate increased to 43% (38–49%). The authors concluded, "there is a strong association between periodontitis and increased mortality in individuals with CKD. Sources of chronic systemic inflammation (including periodontitis, other dental infections) may be important contributors to mortality in patients with CKD."

As early as 2012, Zheng and coworkers found an association between multiple space infections of the head and neck caused by dental infections in persons with diabetes. They found that not only are patients with diabetes more likely to develop complications; space infections are also more likely to be severe, and result in death, than in persons without diabetes. Similar to other infections, head and neck space infections exacerbate hyperglycemia, and can thereby contribute to CKD.

The above studies demonstrate that the need for treatment of nephropathy is reduced when patients with diabetes improve their glycemic control. Specifically, Barrett et al. described in the 2017 Endocrine Society Scientific Statement: that "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, reporting that 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).

In their seminal work, Stratton et al (2000) showed that increases in mortality and complications in diabetes are associated with poor glycemic control. They concluded that "the lower the glycaemia, the lower the risk of complications, and that the rate of increase risk for microvascular disease with hyperglycaemia is greater than that for macrovascular disease."

In the recent Nature Reviews Nephrology, Chapple and coworkers (2025) conclude that "periodontitis is associated with all-cause and cardiovascular mortality, as well as poor diabetes control and complications; this relationship is regarded as robust and independent of common risk factors. Periodontitis is also positively associated with CKD independently of shared risk factors, and longitudinal studies demonstrate a more rapid decline in kidney function in people with periodontitis, as well as a 2-fold increase in incident CKD over a 5-year follow-up."

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Oral Health Nursing Education and Practice

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

The above research and reviews demonstrate the link between periodontitis and diabetic nephropathy. Equally important, for people with poorly controlled diabetes (A1c of 8 or higher) and severe periodontitis or other forms of dental infection, there is improvement in the management and treatment of nephropathy achieved through dental treatment. As previously noted, Simpson et al stated "we now have evidence that periodontal treatment improves glycemic control in people with both periodontitis and diabetes by a clinically significant amount when compared to no treatment or usual care." Thus, the provision of periodontal therapy will improve both periodontitis and glycemic control.

In summary, oral infection and inflammation adversely affect the outcomes of treatment for persons with diabetes associated nephropathy. The findings of the studies reported indicate that:

- Poor glycemic control exacerbates the risk of nephropathy.
- Poorly controlled diabetes and advanced periodontitis negatively impact treatment, outcomes, and mortality of nephropathy.
- The treatment of dental infections (periodontitis, others) will improve glycemic control and, by extension, nephropathy outcomes.
- Lack of treatment or oral infections will compromise treatment for nephropathy.

In closing, the covered services for managing diabetes-associated nephropathy could be materially compromised absent the provision of the inextricably linked dental services. Dental services are a clear clinical companion to proceeding with the primary medical procedure and/or treatment. The above studies provide compelling evidence accompanying recommendations to support that certain dental services are inextricably linked to covered services for nephropathy.

COVERED MEDICAL SERVICES

Quoting from the 2025 final rule, "Are there codes that describe specific services that align to patients with these conditions or needs (for example, an uncontrolled diabetic that has periodontitis)? Are there physicians' services that dental services would be inextricably linked to for beneficiaries with these needs?" 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:

Exemplary ICD diagnostic codes for individuals with diabetic nephropathy or diabetic retinopathy; i.e., the specific groups for which coverage is requested:

OHNEP Oral Health Nursing Education and Practice

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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

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E11.331 DM with moderate non proliferative diabetic retinopathy w/macular edema

E11.319 DM with unspecified diabetic retinopathy without macular edema

H35.82 Retinal Ischemia

H35.81 Retinal Edema

H47.01 Optic Neuropathy

Exemplary related CPT treatment codes relevant to the proposed diabetic complications:
<u>Diabetic Retinopathy</u>

67028 Intravitreal Injection of a pharmacologic agent (Separate Procedure)

67028 LT left eye injection

67028 RT right eye museum

67028 Bilateral eye injections

J0177 Injection, Aflibercept HD, 2 U

J0178 Injection, Aflibercept, 1 MG

09035 Injection, Avastin – 1u only MCR

02778 Injection, /LU-RO/AMD-5 DME-3

17312 Dexameth-OZ Impl-7u

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

67288	Laser treatment for diabetic retinopathy (one or more sessions)
67105	Laser treatment
92002	Eye exam – new
92014	Eye exam – established
92202	Opscpy Extnd Ocular Nerve/Macular Drawing I&R Uni/B
	(to establish location and extent of retinopathy)
92134	Opscpy Retina (screening for diabetic macular edema)

Diabetic Nephropathy

82043	Quantitative measurement of proteinuria
36901-36906	Dialysis circuit procedures
90935, 90937, 90940	Hemodialysis procedures
90961	Physician or other qualified healthcare professional visits for ESRD
90989-90999	Other dialysis procedures
99212-99215	Evaluation and Management (E/M) Services
DRG code 872	Hospitalization for septicemia or severe sepsis

Diabetes-covered medical procedures to control/improve hyperglycemia integrally and inextricably linked to prevention/slowing progression of diabetic retinopathy and nephropathy:

Hypoglycemic drugs (Insulin, Metformin, SGLT2 inhibitors, GLP-1 agonists, Sulfonylureas)

ICD-10-CM code Z79.4	diagnostic code for long-term (current) use of insulin
ICD-10-CM code Z79.84	long-term use of oral hypoglycemic drugs
ICD-10-CM code Z79.85	long-term use of injectable non-insulin anti-diabetic drug
HCPCS code J1815	Insulin, injection, per 5 units
HCPCS code J1817	Insulin for administration through DME (insulin pump)
HCPCS code J3490	Unclassified injectable drugs (used for GLP-1 agonists)

Insulin Infusion Pump

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

HCPCS code E0784	External ambulatory infusion pump, insulin
HCPCS code S9145	Insulin pump initiation, instructions in initial use
HCPCS code K0554	Receiver (monitor) for use w/ therapeutic CGMS
HCPCS code A4224	Supplies for maintenance of insulin infusion catheter, per week
HCPCS code A4225	Supplies for external insulin infusion pump
Continuous Glucose Monitoring Systems (CGMS)	
95249, 95250, 95251	Continuous glucose monitoring (CGM) data
0446T, 0447T, 0448T	Insertion & removal of Implantable Interstitial Glucose Sensor
HCPCS codes A4238, 4239	CGM Supply Allowance
HCPCS code E0607	Home blood glucose monitor
HCPCS code E2103	Durable Medical Equipment, Non-implanted CGM
Remote Patient Monitoring (RPM)	
99091	Collection and interpretation of remote physiologic data.
99453	Onboarding patient for RPM services
99454	Monthly data transmission for patients receiving RPM services

Exemplary codes for procedures that are likely to be prevented by pre-admission and during-admission oral health care include but are not limited to the following in concert with Y95, designating condition was acquired during hospitalization:

ICD-10 code J95.851	diagnosis of NVHAP and VAP
ICD-10 code J18.0-J18.9	pneumonia, unspecified organism
ICD-10 code J15.0-J15.9	bacterial pneumonia
ICD-10 code J13	pneumonia due to *Streptococcus pneumoniae*
ICD-10 code J12-J15-J17	Viral or other specified pneumonias

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

Exemplary dental treatment codes to resolve/manage infections inextricably linked to improved outcomes of referenced covered medical services.

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 of 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 Alveoloplasty in conjunction with extractions, four or more teeth per quadrant

D7510 Incision and drainage of abscess

D7511 Incision and drainage of abscess, intraoral soft tissues, complicated (includes drainage of multiple facial spaces)

COST SAVINGS

A series of compelling academic and market analyses completed in the past decade demonstrate that improved outcomes and savings are achieved when patients with certain medical conditions access dental care. We present a summary of these studies below, which document reduced utilization of healthcare resources, such as but not limited to fewer emergency room visits, lower hospital admissions, and reduced drug utilization.

OHNEP Oral Health Nursing Education and Practice

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

With the caveats that 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:

1. Impact of Periodontal Therapy on General Health: Evidence from Insurance Data for Five Systemic Conditions **Jeffcoat et al. (Am J Prev Med)**	• 338,891 health insurance enrollees • Health outcomes were improved for cardiovascular disease (40.9%), type 2 diabetes (40.2%), and cerebrovascular disease (10.7%)
2. The Relationship between Periodontal Interventions and Healthcare Costs and Utilization **Nasseh et al. (Health Econ.)**	• 15,002 newly diagnosed diabetes patients • Lower total health care costs (-$1799) and lower total healthcare costs related to diabetes (-$408)
3. Effect of Periodontal Treatment on Diabetes-related Healthcare Costs: a Retrospective Study **Smits et al. (BMJ Open Diabetes Res Care)**	• 41,598 diabetes patients • 31% reduction in diabetes-related healthcare costs
4. The Impact of Periodontal Treatment on Healthcare Costs in Newly Diagnosed Diabetes Patients **Blaschke et al. (Diabetes Res Clin Pract.)**	• 23,771 health insurance enrollees • 4% reduction in total healthcare costs, 13% reduction in hospital costs, 7% reduction in diabetes drug cost
5. Dental Services and Health Outcomes in the New York State Medicaid Program **Lamster et al. (J Dent Res)**	• 551,689 Medicaid enrollees • 7% reduction in emergency department visits, 20% reduction in inpatient admits, and $823 reduction inpatient costs
6. Association Between Preventive Dental Care and Healthcare Cost for Enrollees With Diabetes or Coronary Artery Disease: 5-Year Experience	• 11,374 health insurance enrollees • Lower total costs for enrollees with diabetes ($515-$574), cardiovascular

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

Borah et al. (Compend Contin Educ Dent)	disease ($548-$675) and both diabetes and cardiovascular disease ($866-$1718)
7. Periodontal Treatment Associated with Decreased Diabetes Mellitus-related Treatment Costs **Thakkar-Samtani, et al. (J Am Dent Assoc)**	• 671,483 health insurance and Medicaid enrollees • 12% reduction in health insurance costs and 14% reduction in Medicaid costs
8. Periodontal Treatment and Subsequent Clinical Outcomes and Medical Care Costs **Michalowicz et al. (PLoS One)**	• 9,503 patients with periodontitis and diabetes, coronary heart disease, or cardiovascular disease • Lower risk of hospitalization, lower inpatient costs, and higher drug costs

1. 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 methodological issues, it is the first in a 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

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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. Participants continuously enrolled between 2011 and 2016 and 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 seen for enrollees who accessed preventive dental services. Preventive dental services were associated with a 7% reduction in visits to the emergency department and a 20% reduction in in-patient 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. These studies are the first to report health outcomes associated with preventive dental care in a publicly insured population, A disproportionate beneficial effect is realized by enrollees with diabetes.
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

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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.

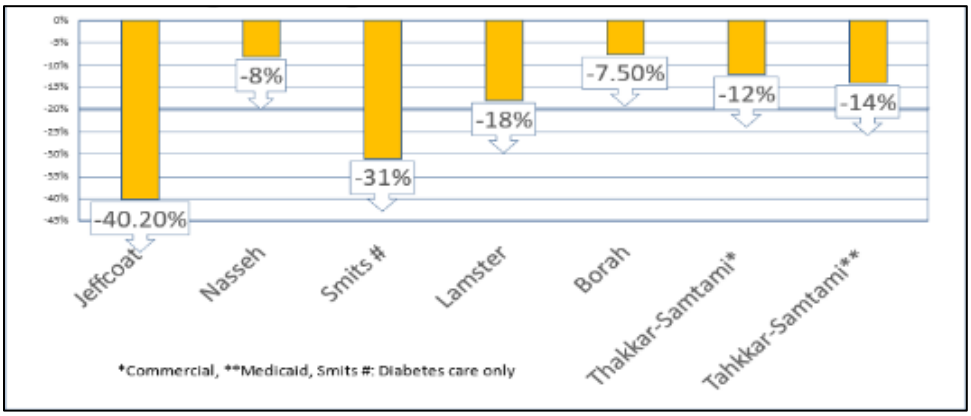
7. Thakkar-Samtani M, et al. J Am Dent Assoc. 2023 Apr;154(4):283-292. Using the IBM MarketScan commercial insurance database and Medicaid databases, examined a total of 671,483 enrollees. For enrollees with DM, the relationship of periodontal treatment in years 1 and 2 to the cost of medical services 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). This study had 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, 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).

This thesis is further supported by a series of important analyses of insurance databases, which indicate that reduction of healthcare utilization and costs can be achieved by medically necessary dental treatment. 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.

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu



Based on the above, we submit that clarifying payment policy for dental services that are inextricably linked and substantially related and integral to the clinical success of diabetes-associated covered medical services will meaningfully reduce healthcare resource utilization.

CLOSING

The OHNEP program is grateful for the opportunity to submit these nominations to the Agency for its consideration and believe their adoption would be of substantial benefit to Medicare beneficiaries. As detailed above, substantial research has shown that timely dental care in advance of planned in-hospital medical and surgical treatment prevents potentially severe and costly complications from hospital-acquired pneumonia and improves clinical outcomes. Accordingly, services to examine, diagnose, and eliminate dental infection in patients at high risk of hospital-acquired pneumonia, prior to certain scheduled and covered hospital procedures, should be recognized as integral to the success of those procedures and payable under the standard established at 42 C.F.R. § 411.15(i).

In addition, 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 for diabetes-associated retinopathy and nephropathy. Clinical studies, including the Cochrane Collaborative's extensive review, document that treatment of oral infections meaningfully improves the treatment and management of diabetes-associated conditions. Similarly, healthcare utilization and costs are substantially reduced when medically necessary oral and dental treatment is provided, as evidenced by extensive academic and industry analyses.

By contrast, the absence of timely, targeted dental care both prevents potentially severe and costly complications from hospital-acquired pneumonia and improves the outcome of covered medical services for diabetes-associated retinopathy and nephropathy. It is for these reasons

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

that access to such care has garnered strong support from key stakeholders due to its power to improve outcomes while reducing health care costs.

On behalf of the OHNEP program, thank you for all you are doing for the older adults and people with disabilities who depend on the Medicare program.

Sincerely,

Judith Haber, PhD, APRN, FAAN

Professor Emerita, NYU Rory Meyers College of Nursing

Executive Director, Oral Health Nursing Education and Practice (OHNEP) Program

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

APPENDIX

OHNEP
Oral Health Nursing Education and Practice

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

STAKEHOLDER SUPPORT

"Dental and respiratory health are interrelated. Bacterial biofilms between teeth harbor pathogens that, when aspirated, can increase susceptibility or complicate the management of pulmonary diseases such as pneumonia, bronchitis, and chronic obstructive pulmonary disease (COPD). The risk is greater in immune-compromised individuals."

American Thoracic Society

"Older adults with poor oral health are at increased risk for aspiration pneumonia, poorly controlled diabetes, endocarditis, and inadequate nutrition, among other systemic health problems."

The Gerontological Society of America

"This bidirectional relationship underscores the need for comprehensive management strategies in diabetic patients, targeting both glycemic control and periodontal health, to mitigate the progression of DR [diabetic retinopathy] and improve overall vascular health."

World J. Diabetes

Link Between Periodontitis and Diabetic Retinopathy:
Inflammatory Pathways And Clinical Implications

"Chronic dental infections can exacerbate management of diabetes, which is the most common cause of kidney failure."

"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. Periodontitis can worsen blood glucose control in diabetics by increasing the levels of inflammatory mediators, such as cytokines and C-reactive protein. This enhanced systemic inflammation can interfere with insulin, increase insulin resistance, resulting in clinical complications of diabetes, including CKD."

"The consequences of poor oral health are worse for kidney failure patients due to advanced age, diabetes, polypharmacy, and impaired immune function."

"The consequences of poor oral health are worse for kidney failure patients due to advanced age, diabetes, polypharmacy, and impaired immune function."

American Society of Nephrology

National Kidney Foundation

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Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

"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 diabetic microvascular and macrovascular complications."

American Association of Clinical Endocrinology

"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."

American Diabetes Association

"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."

Renal Physicians Association

"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

Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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

"Improving oral health through Medicare authorized dental services for periodontitis and related dental care, we can help patients better manage their diabetes and reduce their risk of severe complications like retinopathy and vision impairment … Studies indicate that treating gum disease can improve glycemic control, thereby slowing the progression of diabetes associated complications. This is crucial in preventing diabetic retinopathy."

Jay Fleischman, M.D.

Clinical Associate Professor of Ophthalmology

Albert Einstein College of Medicine, Montefiore Medical Center

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Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

Song SJ, Lee SS, Han K, Park JB. Periodontitis is associated with diabetic retinopathy in non-obese adults. Endocrine. 2017 Apr;56(1):82–9.

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Judith Haber, PhD, APRN, FAAN
Professor Emerita
Executive Director

Oral Health Nursing Education and Practice (OHNEP)
NYU Rory Meyers College of Nursing
433 First Avenue, New York, NY 10010
jh33@nyu.edu

Wu HQ, Wei X, Yao JY, Qi JY, Xie HM, Sang AM, et al. Association between retinopathy, nephropathy, and periodontitis in type 2 diabetic patients: a Meta-analysis. Int J Ophthalmol. 2021;14(1):141–7.

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