- Are there barriers to digital CBT reaching underserved populations, and would a supervision requirement impact access to digital CBT for underserved populations?
- What strategies, if any, within the digital therapeutics for behavioral health support disadvantaged/hard to reach populations in advancing equity in health care services?
- What are some potential considerations for protecting the privacy and confidentiality of the patient population in digital therapeutics, including compliance with State behavioral health privacy requirements?

K. Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

1. Medicare Payment for Dental Services

a. Overview

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to "the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth" as "dental services.") In the CY 2023 PFS final rule (87 FR 69663 through 69688), we identified certain clinical scenarios where payment is permitted under both Medicare Parts A and B for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act.

The regulation at § 411.15(i)(3)(i) includes examples of services for which payment can be made under Medicare Parts A and B for dental services, furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related to the clinical success of, certain other covered services (hereafter in this section, "inextricably linked to other covered services").

Recognizing that there may be other instances where covered services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services, we are proposing to expressly identify other instances

where dental services are inextricably linked to other covered services such that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act. At the same time, we recognize that there are dental services that are not inextricably linked to other covered services. In these instances, we continue to believe that Medicare payment is precluded by section 1862(a)(12) of the Act, except when, due to the patient's underlying medical condition and clinical status or the severity of the dental procedure, hospitalization is required; and that in those instances, the Medicare Part A exception provided under section 1862(a)(12) of the Act would apply.

In the CY 2023 PFS final rule (87 FR 69682, 69685, 69687), we also established a process for the public to submit additional dental services that may be inextricably linked to other covered services for our consideration and review, and finalized a policy to permit payment for certain dental services, such as dental examinations and necessary treatment, prior to or contemporaneously with the treatment of head and neck cancers, beginning in CY 2024.

We are proposing to codify in section § 411.15(i)(3)(i)(A) additional policies to permit payment for certain dental services that are inextricably linked to, and substantially related and integral to, the clinical success of, other covered services. We are also proposing to make non-substantive technical changes to improve clarity of the regulation text.

b. Other Medical Services for which Dental Services may be Inextricably Linked

In the CY 2023 PFS final rule, we discussed whether we should specify that payment can be made under Medicare Parts A and B for certain dental services prior to the initiation of immunosuppressant therapy, joint replacement procedures, or other surgical procedures. We stated that we remain committed to exploring the inextricable link between dental and covered services associated with immunosuppressant therapy, joint replacement surgeries, and other surgical procedures, and that we welcomed continued engagement with the public to review the clinical evidence to determine whether certain dental services were inextricably linked to covered services (87 FR 69668 and 69680 through 69686).

We partnered with researchers at the Agency for Healthcare Research and Quality (AHRQ) to consider the relationship between dental services and specific covered services, and review available clinical evidence regarding the relationship between dental services and medical services in the treatment of cancer using chemotherapeutic agents, which may lead to more clinically severe infections and often involve immunosuppression in patients.[45] [46] The AHRQ report[47] regarding dental services and the link between medical services is available at *https://effectivehealthcare.ahrq.gov/products/receiving-chemotherapy-cancer/rapid-review*. For example, it is generally understood that many chemotherapeutic agents used in the treatment of cancer target rapidly proliferating cells (which include those cells found in healthy tissue, like the oral mucosa). This targeting of rapidly reproducing cells in the oral mucosa can lead to the development of oral mucositis, which can negatively affect individuals with periodontitis and other dental conditions more severely, especially when they are exposed to higher doses/duration of chemotherapy.[48] Another example of a dental-related issue resulting from covered services that are immunosuppressive in nature is medication-related osteonecrosis of the jaw (MRONJ). MRONJ may occur as an adverse effect when patients with cancer receive specific covered services, such as high-dose antiresorptive and/or antiangiogenic drug therapy (for example, high doses of bisphosphonates or drugs like denosumab used to treat osteoporosis) or bone-modifying therapy in conjunction with their chemotherapy regimen. Patients with existing dental disease are most at risk for developing MRONJ secondary to bone-modifying therapy. MRONJ complicates the cancer treatment and can lead to reduced survival rates up to 3 years post-

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[45] Immunosuppression describes an impairment of the cells of a patient's immune system and a reduction in their ability to fight infections and other diseases.

[46] National Cancer Institute. NCI Dictionary of Cancer Terms. 2019. Available at *https://www.cancer.gov/publications/dictionaries/cancer-terms*.

[47] Hickam DH, Gordon CJ, Armstrong CE, Coen MJ, Paynter R, Helfand M. The Efficacy of Dental Services for Reducing Adverse Events in Those Receiving Chemotherapy for Cancer. Rapid Response. (Prepared by the Scientific Resource Center under Contract No. 75Q80122C00002.) AHRQ Publication No. 23-EHC021. Rockville, MD: Agency for Healthcare Research and Quality; June 2023. DOI: https://doi.org/AHRQEPCRAPIDDENTALCANCER.

[48] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35-49. *http://dx.doi.org/10.20517/2573-0002.2017.03.*

treatment.[49] Dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer.[50] Further, AHRQ noted that there is abundant worldwide experience and related standards of care in the management of patients whose medical conditions require chemotherapy regimens that induce immunosuppression, and that this experience has led to an understanding of how improved dental care potentially can reduce the incidence of serious infections and improve overall patient outcomes.

The AHRQ examined the effects of dental care prior to treatment on the success of medical services for patients receiving chemotherapy regimens (primary medical service) in the treatment of cancer (primary medical illness). As part of this analysis, AHRQ identified 26 primary research studies, 7 systematic reviews, and 5 practice guidelines that outline benefits and harms of pre-treatment dental services and their effects on cancer chemotherapy regimens. The studies were selected using specific inclusion criteria: a sample of patients beginning cancer treatment within two months; targeted dental services occurring prior to cancer treatment; outcomes data, such as rates of serious adverse events, quality of life, cancer relapse rates, mortality, or adherence to cancer treatment; and a minimum sample size of 10 patients.

The 26 primary research studies identified by AHRQ included prospective cohort studies, retrospective cohort studies, randomized controlled trials, and registry-based studies. From this group of studies, AHRQ found evidence to support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications (such as, oral mucositis and osteonecrosis) with the covered services, as well as

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[49] Corraini, P., Heide-Jørgensen, U., Schiødt, M., Nørholt, S. E., Acquavella, J., Sørensen, H. T., & Ehrenstein, V. (2017). Osteonecrosis of the jaw and survival of patients with cancer: a nationwide cohort study in Denmark. Cancer medicine, 6(10), 2271–2277. *https://doi.org/10.1002/cam4.1173.*

[50] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35-49. *http://dx.doi.org/10.20517/2573-0002.2017.03.*

requiring fewer emergency treatments.[51] [52] There was further evidence found in systematic reviews that showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2-3 weeks prior to initiation of cancer treatment, further complicating the totality of services a patient received to treat their cancer.[53] They note that treatment of a broad range of malignancies often requires the use of chemotherapeutic agents that suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (often life-threatening) bacterial and fungal infections, and that the route of entry of these offending bacteria can be the mouth. AHRQ also analyzed several clinical practice guidelines that supported a dental evaluation/treatment before initiating chemotherapy so that any oral complications could be mitigated prior to initiating care to treat the cancer.[54] [55] [56]

c. Submissions Received Through Public Submission Process

In the CY 2023 PFS final rule, we stated that we believed there may be additional clinical scenarios we have not yet identified under which Medicare payment could be made for certain dental services on the basis that dental services are inextricably linked to other covered services (87 FR 69686). In order to ensure we are appropriately considering other potential clinical scenarios that may involve such dental services, we finalized an annual public process, including notice and comment rulemaking, whereby interested parties can submit recommendations for

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[51] Watson EE, Metcalfe JE, Kreher MR, et al. Screening for Dental Infections Achieves 6-Fold Reduction in Dental Emergencies During Induction Chemotherapy for Acute Myeloid Leukemia. JCO Oncol Pract. 2020 11;16(11):e1397-e405. doi: *https://dx.doi.org/10.1200/OP.20.00107. PMID: 32609586.*

[52] Owosho AA, Liang STY, Sax AZ, et al. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018 May;125(5):440-5. doi: *https://dx.doi.org/10.1016/j.oooo.2018.02.003. PMID: 29580668*.

[53] Mazzetti T, Sergio da Silva Santos P, Spindola Antunes H, et al. Required time for pre-oncological dental management - A rapid review of the literature. Oral Oncol. 2022 11;134:106116. doi: *https://dx.doi.org/10.1016/j.oraloncology.2022.106116. PMID: 36115328*.

[54] Elad S, Cheng KKF, Lalla RV, et al. MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. Cancer. 2020 Oct 1;126(19):4423-31. doi: *https://dx.doi.org/10.1002/cncr.33100. PMID: 32786044*.

[55] Yarom N, Shapiro CL, Peterson DE, et al. Medication-Related Osteonecrosis of the Jaw: MASCC/ISOO/ASCO Clinical Practice Guideline. J Clin Oncol. 2019 Sep 1;37(25):2270-90. doi: *https://dx.doi.org/10.1200/JCO.19.01186. PMID: 31329513*.

[56] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41-S4. PMID: 27841112.

other clinical scenarios for potential inclusion on the list of dental services for which payment can be made under § 411.15(i)(3)(i).

Through this process, we stated that we would review clinical evidence to assess whether there is an inextricable link between certain dental and covered services because the standard of care for that medical service is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment (87 FR 69685). We also stated that, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services. (87 FR 69666) As such, we requested that documentation accompanying recommendations should include medical evidence to support that certain dental services are inextricably linked to certain other covered services. Specifically, we requested that the medical evidence should:

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

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

(3) Be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer

readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient). (87 FR 69686)

We stated that interested parties should submit medical evidence to support, for the recommended clinical scenario, the inextricable link between certain dental services and other covered services by providing any of the following:

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

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

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

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686, 69687).

We stated that we intended to use the PFS annual rulemaking process to discuss public submissions when considering whether the recommended dental services associated with certain clinical scenarios should be considered outside the scope of the general preclusion on payment for dental services under section 1862(a)(12) of the Act because they are inextricably linked to other covered services. We continue to believe that public feedback is important, especially when considering Medicare payment for dental services that may benefit the clinical outcomes for certain covered services. We believe that using our annual notice and comment rulemaking process to discuss submitted recommendations will allow the public to comment and submit further medical evidence to assist us in evaluating whether certain dental services furnished in certain clinical scenarios would meet the standard to permit Medicare payment for the dental services. Under the public process established in the CY 2023 PFS final rule, recommendations received by February 10th of a calendar year would be reviewed for consideration and potential inclusion within the PFS proposed rule for the subsequent calendar year. The deadline for submissions for potential consideration for CY 2024 rulemaking was February 10, 2023. We

received eight submissions from various organizations on or before February 10, 2023. We received one submission after the deadline that presented nominations for covered services that have already been addressed by this payment policy.

Submissions included recommendations for payment under Medicare Parts A and B of dental services prior to covered services associated with the treatment of cancer (chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, bone-modifying agents or antiresorptive therapy), total joint arthroplasty, all cardiovascular procedures, diabetes treatment, treatment for sickle-cell anemia and hemophilia, and systemic autoimmune diseases. Additionally, many submissions recommended that CMS refine certain terminology surrounding previously finalized policies, specifically around whether payment can be made for dental services furnished during and after the performance of certain covered services.

Several submissions recommended that Medicare make payment under Parts A and B for dental services prior to covered services associated with the treatment of patients with leukemia and lymphoma, as well as other cancers. Most submitting organizations stated that, by examining and addressing the oral health of the patient prior to the initiation of chemotherapy in the treatment of cancer, with or without radiation, oral complications could be appropriately addressed or prevented that would improve the clinical success of the overall cancer treatment. Submissions also recommended Medicare payment under Parts A and B for dental services before, during, and after CAR T-cell therapy and other lymphodepleting covered services (lymphodepleting therapy involves a short course of chemotherapy that targets T-cells, preconditioning the body prior to enhance treatments like CAR T-cell therapy). These submissions stressed the need to detect early and monitor dental issues and to avoid the increased risk of related infections and complications.

Most submissions stated that medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of antiresorptive and/or antiangiogenic drug therapy used to help manage the treatment of cancer. Several recommended that Medicare make payment under Parts A and B

for dental services for patients where high-dose bisphosphonate therapy for cancers is indicated, such as blood and solid tumor cancers and metastatic cancers associated with risk of osteonecrosis of the jaw. These submissions recommended payment of dental services prior to and during antiresorptive therapy or prior to, during, and after the use of bone-modifying drugs. One provided references that support the provision of dental services to prevent, or as part of treatment for MRONJ. Another submission stated that the risk of MRONJ is significantly greater in patients receiving antiresorptive therapy in connection with cancer treatment compared to patients receiving antiresorptive therapy for osteoporosis. However, the submitter stated that the combination of poly-pharmaceutical management of cancer patients and related immunosuppression are risk factors for MRONJ without exposure to antiresorptive agents, and that it would be difficult to identify a single medication as the etiologic agent for MRONJ in case reports or mini-case series. The submitter stated that prevention of MRONJ would be the clinical gold standard.

One submission also recommend that Medicare make payment under Parts A and B for dental services prior to all cardiovascular procedures. In their view, the provision of dental services to reduce risk of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures. They cited a literature review in support of the need for screening and treatment for oral/dental infections prior to cardiac surgery. This submission did not recommend dental services prior to a specific cardiovascular procedure; rather, it recommended dental services prior to all cardiovascular procedures. The literature review they cited, (which we discuss below at section II.K.3. of this proposed rule) noted that there was a mixture of medical literature to support the performance of dental services prior to all cardiac procedures in part because such cardiovascular procedures are more urgent or emergent than elective.

One submission recommended that Medicare make payment under Medicare Parts A and B for dental services prior to joint replacement surgeries, specifically total knee and hip

arthroplasty. The submitting organization stated that the provision of dental services prior to or contemporaneously with joint replacement surgeries may result in more rapid healing and quicker rehabilitation, especially if a known dental infection could be addressed and potentially prevent surgical and rehabilitation complications for the patient. However, the submission acknowledged that there is no consensus on whether performing dental services prior to joint replacement surgeries improves the clinical outcomes of the medical service, or whether it is typical in practice to furnish dental services before joint replacement procedures.

Other submissions recommended Medicare make payment for dental services for patients diagnosed with a specific condition(s), such as patients with poorly controlled diabetes mellitus, or individuals living with sickle cell disease (SCD) or hemophilia.

Submissions also recommended Medicare payment for dental services for persons affected by systemic autoimmune disease. They argued that dental services are an essential component of medical treatment for these individuals who are at much higher risk of advanced dental decay, dental loss, and/or gum disease. They stated that reducing oral infection of the mucosa, teeth, and gums; oral inflammation; and tooth loss through consistent oral management reduces the systemic impact that these dental conditions have on a patient's systemic autoimmune disease. One submission stated that oral health disparities disproportionately affect members of racial or ethnic minority groups, which they offered is most pronounced in populations aged 65 and older. Another presented their proposal to bridge the gap in health equity and to improve the health outcomes for those ages 65 and older living with autoimmune diseases.

We thank all those who submitted recommendations for clinical scenarios for which they believe Medicare payment for dental services would be consistent with the policies we codified and clarified in the CY 2023 PFS final rule under which Medicare payment could be made for dental services when inextricably linked to other covered services. We continue to encourage interested parties to engage with us regularly and to submit recommendations for our

consideration of additional clinical scenarios where dental services may be inextricably linked to specific covered services. As stated earlier, interested parties should provide evidence to support or refute that at least one of the three criteria listed above for submissions is met. Furthermore, submissions should focus on the inextricably linked relationship between dental and medical services, not a specific medical condition, and whether it is not clinically advisable to move forward with the medical service without having first completed the dental service(s). We remind readers that, to be considered for purposes of CY 2025 PFS rulemaking, submissions through our public process for recommendations on payment for dental services should be received by February 10, 2024, via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov*. Interested parties should include the words "dental recommendations for CY 2025 review" in the subject line of their email submission to facilitate processing. We stress to submitters that recommendations must include at least one of the types of evidence listed earlier when submitting documentation to support the inextricable link between specified dental services and other covered services. We note that we may also consider recommendations that are submitted as public comments during the comment period following the publication of the PFS proposed rule.

2. Proposed Additions to Current Policies Permitting Payment for Dental Services Inextricably Linked to Other Covered Services

Under our current policy, we have identified several clinical scenarios where dental services are inextricably linked to a primary medical service that is covered by Medicare, such that Medicare payment for the dental services is not precluded by section 1862(a)(12) of the Act. After further review of current medical practice, and through internal and external consultations and consideration of the submissions received through the public process established in the CY 2023 PFS final rule (87 FR 69669), we believe there are additional circumstances that are clinically similar to the scenarios we codified in our regulation at § 411.15(i)(3)(i) as examples

of clinical scenarios under which Medicare payment may be made for certain dental services because they are inextricably linked to other covered medical service(s).

In the case of the proposed primary, covered services, we believe that dental services are inextricably linked to, and substantially related and integral to the clinical success of, the proposed covered services because such dental services serve to mitigate the substantial risk to the success of the medical services, due to the occurrence and severity of complications caused by the primary medical services, including infection. Additionally, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services or if the dental services are considered to be a critical clinical precondition to proceeding with the primary medical procedure and/or treatment. As such, we believe the dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, the following medical services, and the statutory dental exclusion would not apply:

(1) Chemotherapy when used in the treatment of cancer;

(2) CAR T-Cell therapy, when used in the treatment of cancer; and

(3) Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

As such, we propose to amend our regulation at § 411.15(i)(3)(i)(A) to permit payment under Medicare Parts A and Part B for:

(1) Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered: chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment

of cancer, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of; and

(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with: chemotherapy when used in the treatment of cancer, CAR T-cell therapy when used in the treatment of cancer , and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Furthermore, we propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as currently described in our regulation at § 411.15(i)(3)(ii).

a. Dental services inextricably linked to chemotherapy services when used in the treatment of cancer

In the CY 2023 PFS final rule (87 FR 69663 through 69688), and as described in section II.K.1 of this proposed rule, we stated that we would continue to study the relationship between dental care and medical services that cause immunosuppression in patients, and the risk of dental infection and complications that arise because of the treatment-induced immunosuppression. As discussed in section II.K.1 of this proposed rule, we received submissions through the public process and comments on the CY 2023 PFS proposed rule requesting that Medicare payment should be permitted under Parts A and B for dental services when medical services that cause immunosuppression are being provided to treat a variety of medical conditions.

Commenters asserted that immunocompromised patients are at an increased risk of serious infection that can lead to severe conditions (87 FR 69683). We stated that we agreed with commenters that individuals who are immunocompromised may be prone to serious infection, and that we would continue to consider feedback and the clinical literature provided by interested parties to determine whether there are other clinical scenarios, such as the initiation of immunosuppressive therapies, where Medicare payment should not be excluded for dental

services under section 1862(a)(12) of the Act, because the services are inextricably linked to certain other covered services.

In the CY 2023 PFS final rule (87 FR 69681) and as discussed in section II.K.2 of this rule, we stated that we were finalizing a policy for CY 2024 that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to or contemporaneously with Medicare-covered treatments for head and neck cancer. We stated that removing infections in the oral cavity is necessary to prepare patients for treatment and is inextricably linked to the clinical success of treatment for cancers of the head and neck. Additionally, as described in the comments received on the CY 2023 PFS proposed rule and summarized in the CY 2023 PFS final rule (87 FR 69683), commenters suggested that the patient population with any cancer receiving chemotherapy treatments required dental services that were linked to the clinical success of the completion of the chemotherapy treatment. They indicated that immunocompromised patients, such as individuals with blood cancers (leukemia and lymphoma) or other types of cancers, are at increased risk of serious infection that can lead to severe complications and adverse outcomes. Commenters provided information showing that chemotherapy drugs used for treatment of head and neck cancers can have many side effects, including sores and lesions in the mouth and throat tissues, difficulty swallowing, bleeding in the mouth, and tooth decay. Additionally, commenters stated that, because chemotherapy reduces the body's ability to fight opportunistic infections, patients who begin chemotherapy with untreated infections (including infections in the oral cavity) are at risk of developing a number of complications, ranging from fungal or viral infections of the mouth and throat to systemic infections or fatal sepsis. Commenters observed that complications arising from untreated infections could cause treatment interruptions which could compromise the success of the treatment and the patient’s outcomes. One commenter observed that the need for removing oral

infection prior to starting chemotherapy is analogous to the rationale for providing oral care prior to renal transplant, and thus (like a dental exam prior to renal transplant) should be considered substantially related and inextricably linked to the clinical success of the treatment. Commenters recommended that patients receiving chemotherapy for head or neck cancer receive a dental exam and stabilization, if applicable. Several commenters noted that providing an oral exam prior to starting chemotherapy is the standard of care in many cancer centers (87 FR 69681 through 69683).

Additionally, in the CY 2023 PFS final rule (87 FR 69682), we stated that many commenters recommended that we permit payment under Medicare Parts A and B for dental services prior to treatment for all types of cancer patients instead of just those with head and neck cancers; commenters suggested that the linkage between the medical services (chemotherapy, with or without radiation) and dental services was the same whether the medical services are used to specifically treat head and neck cancers or other cancers. Commenters stated that the increased risk of infections and sepsis among cancer patients could constitute major health setbacks that are costly to treat and can compromise the success of the cancer treatment. We reiterated that we would continue to review and evaluate information that supports the relationship between dental care and covered treatments for cancer (including treatments related to conditions not localized in the head, neck, or oral cavity), and have continued to study this issue.

We believe immunosuppression is commonly understood to be a suppression or reduction of the body's immune response, which can be caused by various factors that increase susceptibility to infections and an increased risk of developing certain types of conditions.[57] There is significant and abundant worldwide experience and research regarding the care of patients whose medical conditions require chemotherapy regimens that induce acute

[57] Abbas AK, Lichtman AH, Pillai S. Basic Immunology: Functions and Disorders of the Immune System. 5th edition. Philadelphia: Elsevier; 2016. Chapter 8, Immune Suppression.

immunosuppression.[58,59] The treatment of a broad range of malignancies often requires the use of chemotherapeutic agents that in turn suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (potentially life-threatening) infections. The route of entry of the offending pathogens can be the mouth.[60,61,62] Therefore, individuals receiving chemotherapy treatment for cancer who become immunosuppressed may be more susceptible to infection and other adverse events with serious consequences for the patient. We understand that medical services used in the treatment of cancer, such as chemotherapy, induce immunosuppression. As such, we believe that cancer patients being treated with chemotherapy represent an acutely-impacted, immunocompromised patient population due to the nature of the effects of such chemotherapy treatment. If dental or oral infections are left undetected or untreated in these patients, serious complications may occur, negatively impacting the clinical success of the medical services and outcomes for the patients. Moreover, the immunosuppression induced by the chemotherapy medical services in the treatment of cancer increases the likelihood and intensity of complications for the patient that could potentially jeopardize or impact the ability to complete the totality of the treatment across a normal course of treatment. [63,64] If an oral or dental infection is not properly diagnosed and treated prior to and/or during the chemotherapy in the treatment of cancer, which suppresses the immune system, there may be an increased risk for local and systemic infections from odontogenic

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[58] Spijkervet FKL, Schuurhuis JM, Stokman MA, et al. Should oral foci of infection be removed before the onset of radiotherapy or chemotherapy? Oral Dis. 2021 Jan;27(1):7-13. doi: *https://dx.doi.org/10.1111/odi.13329. PMID: 32166855*.

[59] Hanna N, Einhorn LH. Testicular cancer: a reflection on 50 years of discovery. J Clin Oncol. 2014 Oct 1;32(28):3085-92. doi: *https://dx.doi.org/10.1200/JCO.2014.56.0896*. PMID: 25024068.

[60] Mirowski GW, Bettencourt JD, Hood AF. Oral infections in the immunocompromised host. Semin Cutan Med Surg. 1997 Dec;16(4):249-56. doi: *https://dx.doi.org/10.1016/s1085-5629(97)80013-2*. PMID: 9421215.

[61] Greenberg MS, Cohen SG, McKitrick JC, et al. The oral flor as a source of septicemia in patients with acute leukemia. Oral Surg Oral Med Oral Pathol. 1982 Jan;53(1):32-6. PMID: 6948251.

[62] King A, Irvine S, McFadyen A, et al. Do we overtreat patients with presumed neutropenic sepsis? Postgrad Med J. 2022 Nov;98(1165):825-9. doi: *https://dx.doi.org/10.1136/postgradmedj-2021-140675*. PMID: 34611037.

[63] Spijkervet FKL, Schuurhuis JM, Stokman MA, et al. Should oral foci of infection be removed before the onset of radiotherapy or chemotherapy? Oral Dis. 2021 Jan;27(1):7-13. doi: *https://dx.doi.org/10.1111/odi.13329. PMID: 32166855*.

[64] Hanna N, Einhorn LH. Testicular cancer: a reflection on 50 years of discovery. J Clin Oncol. 2014 Oct 1;32(28):3085-92. doi: *https://dx.doi.org/10.1200/JCO.2014.56.0896*. PMID: 25024068.

sources; and furthermore, the successful completion of that treatment could be compromised. Additionally, if such an infection is not treated, then there is an increased likelihood of morbidity and mortality resulting from the spreading of the local infection to sepsis[65] [66]

Individuals undergoing chemotherapy services used in the treatment of cancer who become immunosuppressed by the treatment may also experience oral mucositis, which often facilitates entry of oral bacteria into the body, potentially increasing the risk of infection for the patient and compromising the chemotherapy regimen. The risk of mucositis and potential complications to the clinical success of medical services for cancer treatment is similar to the risk for patients receiving Hematopoietic Stem Cell Transplants (HSCT) and bone marrow transplants[67] [68], for which we finalized payment for certain dental services prior to these medical services (87 FR 69677). These potential complications, resulting from the combined immunosuppression and mucositis caused by the chemotherapy services, present a risk to the patient and the success of the medical chemotherapy regimen, unless mitigated by the provision of dental services. Additionally, as described above, evidence found in systematic reviews showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2-3 weeks prior to initiation of cancer treatment, further complicating the totality of services a patient received to treat their cancer.[69]

Moreover, as described above in section II.K.1. of this proposed rule, dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout

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[65] Ruescher TJ, Sodeifi A, Scrivani SJ, Kaban LB, Sonis ST. The impact of mucositis on alpha-hemolytic streptococcal infection in patients undergoing autologous bone marrow transplantation for hematologic malignancies. Cancer 1998;82(11):2275–2281. [PubMed: 9610710].

[66] Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of allogeneic hematopoietic stem-cell transplantation in patients with hematologic malignancies. Support Care Cancer May;2007 15(5):491–496. [PubMed: 17139495].

[67] Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of allogeneic hematopoietic stem-cell transplantation in patients with hematologic malignancies. Support Care Cancer May,2007 15(5):491–496. [PubMed: 17139495].

[68] Ruescher TJ, Sodeifi A, Scrivani SJ, Kaban LB, Sonis ST. The impact of mucositis on alpha-hemolytic streptococcal infection in patients undergoing autologous bone marrow transplantation for hematologic malignancies. Cancer 1998;82(11):2275–2281. [PubMed: 9610710].

[69] Mazzetti T, Sergio da Silva Santos P, Spindola Antunes H, et al. Required time for pre-oncological dental management - A rapid review of the literature. Oral Oncol. 2022 11;134:106116. doi: *https://dx.doi.org/10.1016/j.oraloncology.2022.106116. PMID: 36115328*.

chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer.[70] Additionally, as discussed in section II.K.1. of this proposed rule, research studies support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications (such as, oral mucositis and osteonecrosis) with the medical services, as well as requiring fewer emergency treatments.[71] [72]

Consequently, we believe that the evidence supports that the standard of care is such that one would not proceed with the chemotherapy when used in the treatment of cancer without performing the dental services, because the covered services would or could be significantly and materially compromised, such that clinical outcomes of the chemotherapy treatment could be compromised absent the provision of the inextricably-linked dental services.

As described in the CY 2023 PFS final rule (87 FR 69685), we noted that evidence to support the linkage between the dental and covered services could include information demonstrating that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to clear the patient of an oral or dental infection; or, in instances where a known oral or dental infection is present, the standard is such that the medical professional would not proceed with the medical service until the patient received the necessary treatment to eradicate the infection. Our review of relevant clinical practice guidelines demonstrated that multiple professional societies recommend the performance of dental services prior to the initiation of or during chemotherapy.[73] [74] For

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[70] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35-49. *http://dx.doi.org/10.20517/2573-0002.2017.03.*

[71] Watson EE, Metcalfe JE, Kreher MR, et al. Screening for Dental Infections Achieves 6-Fold Reduction in Dental Emergencies During Induction Chemotherapy for Acute Myeloid Leukemia. JCO Oncol Pract. 2020 11;16(11):e1397-e405. doi: *https://dx.doi.org/10.1200/OP.20.00107. PMID: 32609586.*

[72] Owosho AA, Liang STY, Sax AZ, et al. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018 May;125(5):440-5. doi: *https://dx.doi.org/10.1016/j.oooo.2018.02.003. PMID: 29580668*.

[73] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41-S4. PMID: 27841112.

[74] American Academy of Pediatric Dentistry. Dental management of pediatric patients receiving immunosuppressive therapy and/or head and neck radiation. The Reference Manual of Pediatric Dentistry. Chicago, Ill.; 2022:507-16.

instance, the United Kingdom published a guideline for dental evaluation and treatment before and after treatments for head and neck cancer (5th edition of the UK Multi-Disciplinary Guidelines for Head and Neck Cancer), based on guidance from the National Institute for Health and Care Excellence (NICE) and expert recommendations: "Preventive oral care must be delivered to patients whose cancer treatment will affect the oral cavity, jaws, salivary glands and oral accessibility." [75] Additionally, as described in the CY 2023 PFS final rule (87 FR 69680), several commenters provided data regarding the treatment of head and neck cancer that illustrated that conditions such as oral mucositis or osteonecrosis of the jaw that occur during the treatment may compromise the clinical success of the primary medical service (chemotherapy for the treatment of head and neck cancer), potentially leading to multiple hospitalizations, including systemic infections or fatal sepsis, if dental infections remained untreated.

We believe chemotherapy used in the treatment of cancer causes acute immunosuppression, causing significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn may lead to serious and imminent risks to the success of the primary medical procedures and treatments. These treatment-induced complications, including possible infection, prevent the ability to proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy) and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of the Medicare covered chemotherapy when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently the dental services facilitate the successful completion of the prescribed course of treatment and

[75] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41-S4. PMID: 27841112.

therefore the dental services are integral and inextricably linked to these medical services, and the statutory dental exclusion would not apply.

We believe that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to chemotherapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. We also believe that an oral or dental infection could present substantial risk to the success of chemotherapy when used in the treatment of cancer, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered services.

We also seek comment on whether we should consider radiation therapy in the treatment of cancer more broadly (not in conjunction with chemotherapy, and not in relation to head and neck cancer treatment) as medical services that may be inextricably linked to dental services. We do not believe that radiation therapy alone necessarily leads to the same level of treatment-induced immunosuppression as for cancer patients receiving chemotherapy since radiation specifically targets malignant cells and has more targeted and localized effects on the body as compared to system-wide immunosuppression effects of chemotherapy for cancer treatment. However, we seek comment on whether dental services prior to radiation therapy in the treatment of cancer, when furnished without chemotherapy, such as second line therapy for metastasized cancer in the head and neck, would be inextricably linked to the radiation therapy services, and therefore payable under Medicare Parts A and B.

In summary, after consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of chemotherapy services, we believe that there is an inextricable link between certain dental and chemotherapy services when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the chemotherapy services when used in the treatment of cancer. Chemotherapy services when used in the treatment of cancer cause immunosuppression which may lead to significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn lead to serious and imminent risks to the success of the primary medical procedures and treatments. The complications, including possible infection, may prevent the ability to both initiate and proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy) such that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of chemotherapy services when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently the dental services facilitate the successful completion of the prescribed course of treatment. Therefore, we believe the dental services are integral and inextricably linked to the chemotherapy when used in the treatment of cancer, and the statutory dental exclusion under section 1862(a)(12) of the Act would not apply.

We are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A).

Specifically, we propose to amend the regulation to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered chemotherapy when used in the treatment of cancer; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer. We seek comments on all aspects of this proposal. Additionally, we note that we are proposing to make payment for dental services that are inextricably linked to chemotherapy used in the treatment of cancer with or without the use of other therapy types, including radiation therapy in the treatment of cancer. That is, this proposal is not meant to be limited to cases where chemotherapy in the treatment of cancer is provided without the use of other therapies. We seek comment on this aspect of the proposal.

b. Dental services inextricably linked to CAR T-Cell therapy, when used in the treatment of cancer

In the CY 2023 PFS final rule (87 FR 69677), commenters stated that individuals receiving CAR T-cell treatment for cancer may also require dental services, suggesting that these dental services are inextricably linked to covered CAR T-cell medical services, asserting that dental and oral services improve clinical outcomes for these types of medical services. We also received submissions through the public process providing evidence to show that dental services are inextricably linked to the clinical success of CAR T-cell medical services and other lymphodepleting therapy when used in the treatment of cancer. The submissions stated that, because CAR T-cell medical services cause a patient to be immunosuppressed, an untreated oral or dental infection could complicate or compromise the clinical outcome of the CAR T-cell medical service. Two submissions cited research indicating that patients undergoing CAR T-cell therapy and other lymphodepleting therapy, which is a short course of chemotherapy for the purpose of killing off a portion (or all) of the patient's own lymphocytes and/or other white blood cells prior to an immunotherapy or a bone marrow transplant, experience a higher

infection risk in the first 100 days post-treatment.[76] Submitters also stressed the need to detect early and monitor for dental issues during CAR T-cell therapy in order to avoid the increased risk of related infections and complications. These submissions also highlighted that clinical practice guidelines recommend dental services prior to initiating the CAR T-cell therapy and other lymphodepleting therapy in order to eliminate any sources of infection before and during treatment. [77,78,79,80,81]

After consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of CAR T-cell therapy, we are persuaded that dental services to diagnose and treat infection prior to CAR T-cell therapy are inextricably linked to the clinical success of CAR T-cell therapy, and that these services also represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the inpatient or outpatient setting, such as prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures. We believe there is an inextricable link between dental and CAR T-cell therapy when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or

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[76] Wudhikarn K, Palomba ML, Pennisi M, Garcia-Recio M, Flynn JR, Devlin SM, Afuye A, Silverberg ML, Maloy MA, Shah GL, Scordo M, Dahi PB, Sauter CS, Batlevi CL, Santomasso BD, Mead E, Seo SK, Perales MA. Infection during the first year in patients treated with CD19 CAR T cells for diffuse large B cell lymphoma. Blood Cancer J. 2020 Aug 5;10(8):79. *doi: 10.1038/s41408-020-00346-7*. PMID: 32759935; PMCID: PMC7405315.

[77] Elad S, Raber-Durlacher JE, Brennan MT, Saunders DP, Mank AP, Zadik Y, Quinn B, Epstein JB, Blijlevens NM, Waltimo T, Passweg JR, Correa ME, Dahllöf G, Garming-Legert KU, Logan RM, Potting CM, Shapira MY, Soga Y, Stringer J, Stokman MA, Vokurka S, Wallhult E, Yarom N, Jensen SB. Basic oral care for hematology-oncology patients and hematopoietic stem cell transplantation recipients: a position paper from the joint task force of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) and the European Society for Blood and Marrow Transplantation (EBMT). Support Care Cancer. 2015 Jan;23(1):223-36. Epub 2014 Sep 5. PMID: 25189149; PMCID: PMC4328129. *doi: 10.1007/s00520-014-2378-x*.

[78] University of Michigan, CAR-T Cell Patient Dental Clearance Instructions, no date. CellularTherapyDentalForm.pdf (*umich.edu*).

[79] Guideline on dental management of pediatric patients receiving chemotherapy, hematopoietic cell transplantation, and/or radiation. Pediatr Dent, 2008; 30(7 Suppl):219–225.

[80] McGuire DB, CorreaME, Johnson J, Wienandts P. The role of basic oral care and good clinical practice principles in the management of oral mucositis. Support Care Cancer, 2006; 14(6):541– 547. *doi:10.1007/s00520-006-0051-8 8*.

[81] Vendrell Rankin K, Jones DL, Redding SW (Eds.), Oral Health in Cancer Therapy: A Guide for Health Care Professionals [3rd edition], Baylor Oral Health Foundation and the Cancer Prevention and Research Institute of Texas, 2008. *https://doi.org/10.1002/9781118416426.ch101*.

service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the CAR T-cell therapy when used in the treatment of cancer.

We believe that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to (CAR) T-cell therapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. We also believe that an oral or dental infection could present substantial risk to the success of the (CAR) T-cell therapy when used in the treatment of cancer, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with (CAR) T-cell therapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services. As such, we are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). Specifically, we propose to amend the regulation to include a dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered CAR T-cell therapy when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, CAR T-cell therapy when used in the treatment of . We seek comments on all aspects of this proposal.

We also seek comment on whether we should add as an example of dental services for which payment may be made under Medicare Parts A and B other types of lymphodepleting medical services used for cancer treatment, in addition to those used in conjunction with CAR T-

cell therapy for cancer treatment. Commenters specifically stated that CAR T-Cell therapies constituted lymphodepleting therapies, and we believe there may be other immunotherapies that may have a similar lymphodepletion component, but we received no specific information regarding such therapies. Evidence submitted by the public through the finalized public submission process indicates that treatment-induced immunosuppression may also occur with lymphodepleting medical services, and that complications caused by the treatment-induced immunosuppression, including possible infection, may prevent the ability to proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing the effectiveness of the therapy) and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. However, we request comment on what specific medical services also involve lymphodepletion and should therefore be considered in addition to CAR T-cell therapy. We also request additional information regarding how those specific services might be impacted by dental infections/conditions. We note that if we receive compelling clinical evidence, we may finalize in the CY 2024 PFS final rule additional clinical scenarios, such as dental services prior to other types of specific lymphodepleting medical services where the treatment may induce immunosuppression for patients with cancer and the standard of care would be to not proceed with the medical services without having first complete the dental services, where payment could be made under Medicare Part A or Part B. We are seeking comment on whether there is a significant quality of care detriment if certain dental services are not provided prior to these other types of lymphodepleting medical services, and if so, we request a description of that systematic evidence. Specifically, similar to the evidence we requested in the CY 2023 PFS proposed rule, we are looking for medical evidence that the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has

interfered with the integration of the implant and interfered with the implant to the skeletal structure. If commenters are able to provide us with compelling evidence to support that a dental exam and necessary treatment prior to specific other lymphodepleting medical services where the treatment may induce immunosuppression for patients with cancer, would result in clinically significant improvements in quality and safety outcomes, for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, quicker rehabilitation for the patient, then we would consider whether such dental services may be inextricably linked to, and substantially related and integral to the clinical success of, the specific lymphodepleting medical services for patients with cancer.

c. Dental services inextricably linked to administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer

As discussed above, submissions received through the public process we established in the CY 2023 PFS final rule stated that medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of the administration of bone-modifying agents (such as bisphosphonates and denosumab, and other biosimilar agents) used when managing certain cancers. [82] MRONJ is a rare occurrence, multifactorial in nature, and can have the same clinical presentation in patients who have not been exposed to an antiresorptive medication[83]. that Medicare make payment under Parts A and B for dental services for patients where high-dose bisphosphonate therapy for cancers is indicated and recommended payment for dental services prior to and during antiresorptive therapy or prior to, during, and after the use of bone-modifying drugs. Additionally, in our internal review of clinical practice guidelines, we noted that one professional society provided recommendations regarding dental services prior to the initiation of, or during, the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the

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[82] American Association of Oral and Maxillofacial Surgeons. (2022). Medication-related osteonecrosis of the Jawn-2022 update (position paper). Available at: *https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/mronj_position_paper.pdf.*

[83] American Association of Oral and Maxillofacial Surgeons. (2022). Medication-related osteonecrosis of the Jawn-2022 update (position paper). Available at: *https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/mronj_position_paper.pdf.*

treatment of cancer. Specifically, the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) and American Society of Clinical Oncology (ASCO) Clinical Practice Guideline[84] states that cancer patients should receive an oral care assessment (including a comprehensive dental, periodontal, and oral radiographic exam, when feasible) prior to initiating the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer in order to reduce complications and manage modifiable risk factors. We believe that this practice guideline demonstrate that the standard of care would be to address dental infections prior to proceeding with the covered medical procedure, including oral care assessments and the completion of medically necessary dental procedures prior to the start of the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, especially as these dental concerns and/or procedures may relate to the cancer treatment and avoidance of MRONJ.

In summary, after consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, we are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). We believe that there is an inextricable link between dental and administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that

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[84] Yarom N, Shapiro CL, Peterson DE, et al. Medication-Related Osteonecrosis of the Jaw: MASCC/ISOO/ASCO Clinical Practice Guideline. J Clin Oncol. 2019 Sep 1;37(25):2270-90. doi: *https://dx.doi.org/10.1200/JCO.19.01186*. PMID: 31329513.

dental services are a clinical prerequisite to proceeding with the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Specifically, we propose to amend the regulation to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered the administration of Medicare-covered high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, administration of high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer. We seek comments on all aspects of this proposal.

We note that in the CY 2023 PFS final rule (87 FR 70225) and now codified in our regulation at § 411.15(i)(3)(i), we finalized that for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service, payment may be made under Medicare Parts A and B for services when furnished in either the inpatient or outpatient setting; therefore, we proposed that these provisions would apply to the proposed amendments to regulation at § 411.15(i)(3)(i) to allow for payment under Medicare Parts A and Part B in either the inpatient or outpatient setting. We further propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as described in our regulation at § 411.15(i)(3)(ii).

If the proposed policies are finalized, we anticipate making conforming changes to the Medicare Benefit Policy Manual (IOM Pub. 100-02) to reflect the final changes or clarifications. Additionally, if finalized, we intend to issue educational and outreach materials to inform billing and payment for any policies finalized in the final rule We seek comments on these proposals.

d. Proposed amendments to regulations regarding dental services inextricably linked to treatment for head and neck cancer

In the CY 2023 PFS final rule, we finalized for CY 2024 that payment under Medicare Parts A and B can be made for an oral or dental examination as part of a comprehensive workup in either the inpatient or outpatient setting, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to and contemporaneously with treatments (radiation, chemotherapy, and surgery) for head and neck cancer (87 FR 69671, 69677, and 69681-69682). We note that we stated the policy in some instances without explicitly including both "prior to" and "contemporaneously with." (87 FR 69669, 69681, 69682, and 69687.)

We also indicated that we wanted to continue to consider various aspects of our finalized policy and that we anticipated additional clarifying rulemaking on this final policy for CY 2024. In the CY 2023 PFS final rule we stated that we wanted to examine the clinical data and consider whether greater specificity may be needed to describe the medical services involved in this type of treatment. We stated that we were cognizant of concerns that, absent clear guidelines and definitions, beneficiaries, practitioners, and MACs may need additional information prior to providing payment under Medicare Parts A and B, and without it could lead to inconsistent application of the policy. In particular, we stated that it is important to determine whether any additional guidance is necessary to identify conditions considered "head and neck cancer" and qualifying covered medical services considered within the treatments for these cancers beyond just radiation (with or without chemotherapy).

Upon further study, as pointed out by one submitter, we understand that the term "head and neck cancer" encompasses a multitude of pathologies that often require multi-modality therapies including radiation, chemotherapy and surgery. This submitter noted that approximately 80 percent of head and neck cancer patients will receive radiation therapy at least once during the course of their disease. While the majority of head and neck cancers are squamous cell carcinomas that originate from the mucosa of the oral cavity, pharynx or larynx, they may also arise from the salivary glands, the nasal cavities and the paranasal sinuses. They can be locally advanced, regionally metastatic to the cervical nodes and can spread to distant

sites such as the lungs and liver. According to the submitter, regardless of origin, the clinical diagnostic and therapeutic approaches for head and neck cancers are fundamentally similar, and treatment modalities often result in both acute and chronic oral toxicities.

If unaddressed, existing oral or dental infection may compromise the delivery of the appropriate modalities of care (radiation, chemotherapy, surgery). The standard of care is to address and eliminate oral and dental infections prior to the treatment of some (or many) head and neck cancers. Additionally, as discussed in section II.K.2.a of this proposed rule, the complications caused by treatment-induced vulnerabilities, which may include infection and osteoradionecrosis, can prevent the ability to proceed with the primary, covered medical service (that is, can lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy); and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

As discussed in the CY 2023 final rule, we believe that addressing any oral or dental infection prior to the initiation of treatment serves to minimize the potential development of the treatment-induced complications. Moreover, we believe that these treatment-induced complications can occur as a result of and during multiple rounds of treatment.

Therefore, we are proposing to clarify that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as for the medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to the initiation of, or during, treatments for head and neck cancer, whether primary or metastatic, regardless of site of origin, and regardless of initial modality of treatment.

In summary, we are proposing to amend our regulation at § 411.15(i)(3)(i)(A) to allow for payment under Medicare Parts A and Part B for:

(1) Dental or oral examination in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer; and

(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer.

We note that in the CY 2023 PFS final rule (87 FR 70225) and now codified in our regulation at § 411.15(i)(3)(i), we finalized that for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service, payment may be made under Medicare Parts A and B for services when furnished in either the inpatient or outpatient setting; therefore, we proposed that these provisions would apply to the proposed amendments to regulation at § 411.15(i)(3)(i) to allow for payment under Medicare Parts A and Part B in either the inpatient or outpatient setting. We further propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as described in our regulation at § 411.15(i)(3)(ii). If finalized, we anticipate making conforming changes to the Medicare Benefit Policy Manual (IOM Pub. 100-02) to reflect the final changes or clarifications. We seek comments on all aspects of these proposals.

3. Request for Information on Dental Services Integral to Covered Cardiac Interventions

In the CY 2023 PFS final rule, we finalized a policy to permit payment for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered cardiac valve replacement or valvuloplasty procedures; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the cardiac valve replacement or valvuloplasty procedure (87 FR 69675).

We recognized that, without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to a cardiac valve replacement or valvuloplasty

procedure, an undetected, non-eradicated oral or dental infection could lead to bacteria seeding the valves and the surrounding cardiac muscle tissues involved with the surgical site and conceivably leading to systemic infection or sepsis, all of which increase the likelihood of unnecessary and preventable acute and chronic complications for the patient (87 FR 69667).[85] Specifically, we noted that the replaced valve is also at risk of being a seeding source for future endocarditis. Endocarditis can carry a high risk of mortality for these patients, and eliminating an infection prior to or contemporaneously with the procedure would be important for preventing future endocarditis related to the new valve (87 FR 69678).

We also concluded that an oral or dental infection could present a substantial risk to the success of organ transplants, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We stated that we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services (89 FR 69667).

We encouraged the public to use the public submission process finalized in the CY 2023 PFS final rule to identify additional clinical scenarios and related medical evidence to support an inextricable link between specified dental services and other covered medical services.

Through the submission process, an interested party has encouraged CMS to consider extending Medicare payment to include dental services to eliminate infection prior to all cardiovascular procedures, as the mitigation of risks of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures. This submission noted that the current standard of care does not conclusively require dental evaluation, diagnosis, or treatment services

[85] Knox, K.W., & Hunter, N. (1991). The role of oral bacteria in the pathogenesis of infective endocarditis. Australian dental journal, 36(4), 286–292. *https://doi.org/10.1111/j.1834-7819.1991.tb00724.x*.

prior to certain cardiac procedures, perhaps in part because such cardiac procedures are often performed on a more urgent or emergent basis where there is not an opportunity to consider the possible presence of dental infection. Moreover, the submission noted that much of the scientific literature is inconclusive as to whether pre-operative dental treatments impact postoperative surgical outcomes in cardiovascular surgery, including cardiac valve procedures.[86] A systematic literature review by Cotti *et al.* found that, based upon expert opinion, there is general agreement on the need for screening and treatment of oral/dental infections in patients who are to undergo cardiac surgery (although no standardized clinical guidelines or protocols exist to outline the screening process, in terms of either dental treatment options and/or timing of such procedures in relation to the planned cardiac intervention).[87] The authors convened an expert panel from six Italian scientific societies (including cardiologists, cardiac surgeons, and dental specialists) to establish a consensus on early screening and resolution of dental or periodontal infections prior to cardiac surgery, that they intended would result in a standardized protocol for evaluating oral infections and dental treatments for cardiac patients to be used in the interventional preparation phase by both dental and cardiac teams.[88] The authors noted, however, the lack of scientific evidence on the risk-to-benefit ratio for perioperative dental treatment in patients undergoing cardiovascular surgery.

We believe, after further review of current medical practice, through consultations with interested parties (including commenters on last year's final rule and those commenting on current topics) and our medical officers, and through evidence submitted through the public submission process we established in the CY 2023 PFS final rule, that there may be additional

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[86] Lockhart, P.B., DeLong, H.R., Lipman, R.D., Estrich, C.G., Araujo, M.W.B. and Carrasco-Labra, A. (2019). Effect of dental treatment before cardiac valve surgery: Systematic review and meta-analysis. Journal of the American Dental Association,150(9). 739-747. *https://doi.org/10.1016/j.adaj.2019.04.024*.

[87] Cotti, E., Cairo, F., Bassareo, P.P., Fonzar, F., Venturi, M., Landi, L., Parolari, A., Franco, V., Fabiani, C., Barili, F., Di Lenarda, A., Gulizia, M., Borzi, M., Campus, G., Musumeci, F., and Mercuro, G. (2019). Perioperative dental screening and treatment in patients undergoing cardiothoracic surgery and interventional cardiovascular procedures. A consensus report based on RAND/UCLA methodology. International Endodontic Journal,53. 186-199. *https://doi.org/10.1111/iej.13166*.

[88] *Ibid.*

circumstances that are clinically similar to examples we codified in our regulation at § 411.15(i)(3)(i) where Medicare payment for dental services could be made under other clinical circumstances where the dental services are inextricably linked to a covered cardiac medical service(s).

To gain further understanding of any potential relationship between dental services and specific covered cardiac medical services, we again partnered with researchers at the AHRQ to review available clinical evidence regarding the relationship between dental services and covered cardiac medical services, including implantation of ventricular assist devices, artificial pacemakers, implantable defibrillators, synthetic vascular grafts and patches, and coronary and vascular stents. This AHRQ report[89] is available at *https://effectivehealthcare.ahrq.gov/products/implantable-cardiovascular-devices/rapid-review.*

As stated in their report, the available evidence does not permit conclusions regarding the effect of pre-treatment dental care for preventing downstream infections related to any of these devices. They noted that professional society guidelines endorse the provision of patient education on routine oral hygiene practices but have not recommended other pre-treatment dental care prior to insertion of these devices. They also noted that professional society guidelines recommend ongoing routine dental examinations for some patients treated with cardiovascular devices.

Nonetheless we seek comment to identify additional cardiac interventions (that is, specific medical services) where the risk of infection posed to beneficiaries is similar to that associated with cardiac valve replacement or valvuloplasty. We note that, in order to consider whether certain dental services are inextricably linked to the clinical success of other covered medical services, we need to identify specific medical services for which there is clinical

[89] Hickam DH, Gordon CJ, Armstrong CE, Paynter R. The Efficacy of Dental Services for Reducing Adverse Events in Those Undergoing Insertion of Implantable Cardiovascular Devices. Rapid Response. (Prepared by the Scientific Resource Center under Contract No. 75Q80122C00002.) AHRQ Publication No. 23-EHC020. Rockville, MD: Agency for Healthcare Research and Quality; June 2023. DOI: *https://doi.org/AHRQEPCRAPIDDENTALCARDIO.*

evidence that certain dental services are so integral to the clinical success that they are inextricably linked to other covered service(s). We encourage interested parties to use the public submission process to submit recommendations and relevant clinical evidence for establishing this connection. Above, in section II.K.1.c. of this proposed rule, we have described the various types of documentation to support recommendations through this process. We are considering, and seek comment on, whether the following cardiac interventions are examples of specific medical services for which dental services are inextricably linked to clinical success: implantation of electronic devices in the heart, such as pacemakers, cardioverter defibrillators, and monitors. We are also considering, and seek comment on, whether the following procedures would be considered examples of specific medical services for which dental services are inextricably linked to their clinical success: the placement of intracardiac or intravascular foreign material, such as a stent or for hemodialysis, or for a vascular access graft, whereas you would not proceed with the medical service without having first completed a dental evaluation and/or treatment as determined necessary. We seek comment on whether preoperative and perioperative dental services are inextricably linked to any other covered cardiac interventions as supported by clinical evidence.

4. Request for Comment on Dental Services Integral to Specific Covered Services to Treat Sickle Cell Disease (SCD) and Hemophilia

Interested parties using the public submission process we finalized in the CY 2023 PFS final rule urged us to propose to provide that payment can be made for dental services for individuals living with SCD and hemophilia.

These submissions provided information and references supporting prevention of dental infection among individuals with SCD to reduce need for more extensive procedures that may result in bleeding complications and require hospitalization. They also provided information

detailing increased dental caries and periodontal disease in people with SCD,[90] many of whom lose a number of teeth, which greatly limits nutrition, general well-being, and overall quality of life.

We seek comment on whether certain dental services are inextricably linked to other covered services used in the treatment of SCD, such as, but not limited to, hydroxyurea therapy. We seek comment identifying such covered services for SCD and whether an inextricable link is supported by clinical evidence as described in section II.K.1.c. of this proposed rule.

Interested parties also urged us to propose a policy to permit payment for dental services for individuals living with hemophilia. They noted that periodic dental care reduces the risks of dental complications requiring haemostatic therapy (such as tooth extractions that may require clotting factor treatment) or oral surgeries requiring clotting factor replacement therapy.[91] [92] [93]

We note that many submitters stated that good dental and oral health benefits a patient's overall health generally. Several commenters on the CY 2023 PFS proposed rule also expressed that good oral hygiene, along with routine dental services, contributes to better outcomes for patients. We recognized in the CY 2023 PFS final rule in response to those comments that there is a great deal of evidence suggesting that dental health is generally an important component of overall health; however, we are interested in comments on whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary

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[90] Kakkar M, Holderle K, ShethM, Arany S, Schiff L, Planerova A. Orofacial Manifestation and Dental Management of Sickle Cell Disease: A Scoping Review. Anemia. 2021 Oct22; 2021:5556708. Doi: 10.1155/2021/5556708. PMID: 34721900; PMCID: PMC8556080.

[91] Raso S, Napolitano M, Sirocchi D, Siragusa S, Hermans C. The important impact of dental care on haemostatic treatment burden in patients with mild haemophilia. Haemophilia. 2022 Nov;28(6):996-999. doi: 10.1111/hae.14626. Epub 2022 Jul 25. PMID: 35879819.

[92] Srivastava A, Santagostino E, Dougall A, Kitchen S, Sutherland M, Pipe SW, Carcao M, Mahlangu J, Ragni MV, Windyga J, Llinás A, Goddard NJ, Mohan R, Poonnoose PM, Feldman BM, Lewis SZ, van den Berg HM, Pierce GF; WFH Guidelines for the Management of Hemophilia panelists and co-authors. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug;26 Suppl 6:1-158. doi: 10.1111/hae.14046. Epub 2020 Aug 3. Erratum in: Haemophilia. 2021 Jul;27(4):699. PMID: 32744769.

[93] Peisker A, Raschke GF, Schultze-Mosgau S. Management of dental extraction in patients with Haemophilia A and B: a report of 58 extractions. Med Oral Patol Oral Cir Bucal. 2014 Jan 1;19(1):e55-60. doi: 10.4317/medoral.19191. PMID: 24121912; PMCID: PMC3909433.

covered services such that they are not subject to the statutory preclusion on Medicare payment for dental services under section 1862(a)(12) of the Act.

We seek comment on whether certain dental services are inextricably linked to certain other covered services for hemophilia, supported by clinical evidence as described in section II.K.1.c., above. We seek comment identifying such covered services for the treatment of hemophilia. We also seek comment specifically on whether dental services such as prophylaxis are a standard of care in the management of hemophilia.

5. Request for Comment Regarding Dental Services Possibly Inextricably Linked to Other Medicare-Covered Services,

Commenters, submitters, and other interested parties have urged us to consider the importance of access to oral health care for people with chronic auto-immune conditions, and other chronic disease conditions, such as, but not limited to, diabetes. We understand and appreciate the interest in such requests. Because the Medicare statute generally prohibits payment for dental services payment may only be made when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services. We urge interested parties to consider the circumstances under which dental services are inextricably linked to specific covered services (not diagnoses) used to treat patients with auto-immune conditions or other chronic conditions, supported by clinical evidence as described in section II.K.1.c. of this proposed rule.

We have encouraged interested parties who believe certain dental services are inextricably linked to certain covered services to use our public submission process to provide information on these clinical scenarios, supported by clinical evidence or other documentation, as discussed in section II.K.1.c. of this proposed rule, such as that it would be the standard of care to not proceed with the medical service without having completed the dental service. Commenters are welcome to submit additional information regarding clinical scenarios presented in the CY 2023 PFS rulemaking discussions, which we are not proposing for the CY 2024, such

as dental services involved with the treatment of chronic conditions such as, but not limited to, diabetes (87 FR 69686). As summarized above in section II.K.1.c. of this proposed rule, through the public submission process we finalized in the CY 2023 PFS final rule, interested parties should submit medical evidence to support an inextricable link between certain dental services and covered services by providing any of the following:

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

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

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

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

As discussed above in section II.K.1.c. of this proposed rule, in order to consider whether certain dental services are inextricably linked to the clinical success of other covered services, we need to identify specific medical services for which there is medical evidence that certain dental services are so integral to the clinical success that they are inextricably linked to the covered service. The medical evidence should support that in the case of surgery, the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure. Medical evidence should be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the primary medical procedure such that the dental services are inextricably linked to, and substantially related and integral to, the clinical success of the covered services. Medical evidence should support that the dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions,

more rapid healing, quicker discharge, and quicker rehabilitation for the patient), or, medical evidence should demonstrate that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection

6. Request for Information on Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services

We continue to consider improvements to our payment policies for dental services as finalized in the CY 2023 PFS final rule (87 FR 69663 through 69688). As such, we are interested in receiving comments from interested parties on ways to best continue to implement these policies. Additionally, given comments and questions we have received from interested parties through rulemaking and the public submission process, we want to provide further clarity on the policies we finalized in the CY 2023 PFS final rule. Therefore, we are requesting comments on several policies related to implementation of policies for dental services for which Medicare payment can be made.

In the CY 2023 PFS final rule, we clarified and codified our policy on payment for dental services and added in § 411.15(i)(3)(i) of our regulation examples of circumstances where payment can be made for certain dental services, including a dental exam and services to diagnose and eliminate an oral or dental infection prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures (87 FR 69664 through 69667).

We provided as examples of dental services that could be furnished to eradicate infection services such as, but not limited to, diagnostic services, evaluations and exams (for example, CDT codes payable with D0120, D0140 or D0150), extractions (for example, CDT codes payable with D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as filling procedures - for example, CDT codes payable with D2000-2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planing - for example, CDT codes payable with D4000-4999, more specifically D4341, D4342, D4335

and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal - for example, CDT codes payable with D3000-3999). However, we continue to believe that additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source. Therefore, we reiterate that such additional services would not be inextricably linked to the specific covered services. As such, no Medicare payment would be made for the additional services that are not immediately necessary to eliminate or eradicate the infection. We further clarify that we did not in CY 2023 nor are we proposing in CY 2024 to adjust any payment policy for services involving the preparation for, or placement of dentures, and maintain that these services are not payable under Medicare Parts A and B. We also reiterate our policy, as finalized in the CY 2023 PFS final rule, that Medicare could make payment for dental services occurring over multiple visits, as clinically appropriate. We refer readers to 87 FR 69678 for a more full description of this policy.

We continue to recognize that many Medicare beneficiaries have separate or supplemental dental coverage, such as through a Medigap plan, another private insurance plan offering commercial dental coverage, or for those individuals dually eligible for Medicare and Medicaid, through a state Medicaid program. As a result, we seek comment on the coordination of multiple dental benefits that Medicare beneficiaries may have, if and how other plans currently cover and pay for dental services, and what type of guidance CMS should provide about the dental payment policies we have established and their relationship to other separate or supplemental dental coverages. We also seek comment on approaches utilized by other plans to mitigate issues with third party payment, including when Medicare is secondary payer and when coordinating with state Medicaid programs. In addition, we note there is an informal practice where dental professionals may submit a dental claim to Medicare for the purposes of producing a denial so that Medicaid or another third-party payer can make primary payment. Given the complexity of dental professionals submitting claims for purposes of denial, we seek comment

on the impact of third-party payers, including state Medicaid programs, requiring a Medicare denial for adjudication of primary payment for dental services that are not inextricably linked to another specific covered service. In these cases where the dental services are not inextricably linked to another specific covered service, dental professionals must include the appropriate HCPCS modifier on the respective dental claim form, which serves as a certification that the professionals believe that Medicare should not pay the claim. We also seek comment regarding an informal process on claims denials for the purposes of supporting payment by other payers is currently achieved in practice when using the dental claim form 837d. We note that the submission of a claim without one or more of the HCPCS modifier(s) meant to produce a denial shows belief by the enrolled billing practitioner that Medicare, not another payer, should be the primary payer in accordance with all applicable payment policies. As such, submission of a claim for dental services without such a modifier would mean that the billing practitioner believes the dental service is inextricably linked to another Medicare-covered service, or that payment for the service is otherwise permitted under our regulation at § 411.15(i). We seek comment on the practices of other payers related to submission of claims in order to generate a denial and how these practices impact claim submission and claim adjudication with third party payers, including state Medicaid programs. Additionally, we are seeking comment on types of guidance, such as best practices or criteria, that are needed for purposes of coordinating payment for dental services under the policies specified in the rule.

As described in the CY 2023 PFS final rule (87 FR 69663 through 69688), Medicare payment under Parts A and B may be made for dental services that are inextricably linked to the covered primary service. We believe the dental and covered services would most often be furnished by different professionals, and that in order for the dental services to be inextricably linked to the covered services such that Medicare payment can be made, there must be coordination between these professionals. This coordination should occur between the practitioners furnishing the dental and covered services regardless of whether both individuals

are affiliated with or employed by the same entity. This coordination can occur in various forms such as, but not limited to, a referral or exchange of information between the practitioners furnishing the dental and covered services. Additionally, any evidence of coordination between the professionals furnishing the primary medical service and dental services should be documented. If there is no evidence to support exchange of information, or integration, between the professionals furnishing the primary medical service and the dental services, then there would not be an inextricable link between the dental and other covered services within the meaning of our regulation at § 411.15(i)(3). As such, Medicare payment for the dental services would be excluded under section 1862(a)(12) of the statute (though payment for the dental services might be available through supplemental health or dental coverage). Additionally, we are seeking information regarding the potential impact of these payment policies in settings other than inpatient and outpatient facilities, such as federally qualified health centers, rural health clinics, etc. We understand that some Medicare beneficiaries may access dental services in these settings and seek to understand what, if any, impact may potentially occur within the context of this payment policy.

As stated in the CY 2023 PFS final rule, we note that, to be eligible to bill and receive direct payment for professional services under Medicare Part B, a dentist must be enrolled in Medicare and meet all other requirements for billing under the PFS. Alternatively, a dentist not enrolled in Medicare could perform services incident to the professional services of a Medicare enrolled physician or other practitioner. In that case, the services would need to meet the requirements for incident to services under § 410.26, including the appropriate level of supervision, and payment would be made to the enrolled physician or practitioner who would bill for the services (87 FR 69673). In the CY 2023 PFS final rule (87 FR 69687), we finalized that we would continue to contractor price the dental services for which payment is made under § 411.15(i)(3). We will maintain this policy and continue to contractor price the dental services for which payment is made under § 411.15(i)(3) for CY 2024. Additionally, in the CY 2023 PFS

final rule, we agreed with the suggestions made by commenters that there may be publicly available data sources that could aid MACs in determining these payment rates in order to account for geographic variation. Recognizing that dental offices may range in the services that they provide, from simple office visits to complex surgical procedures, dental services will continue to be contractor priced. We are seeking comment on what specific information could help inform appropriate payment for these dental services (87 FR 69679).

In the CY 2023 PFS final rule (87 FR 69682), we stated that we would update our payment files, so that these dental services could be billed appropriately under the applicable payment system for services furnished in either the inpatient or outpatient setting. We have revised the HCPCS and PFS payment and coding files to include payment indicators for Current Dental Terminology (CDT) codes, such as bilateralism, multiple procedures, and other indicators that are included in the PFS Relative Value (RVU) files (posted at our website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files*) for CDT codes. We seek comment on whether payment indicators as outlined in the PFS RVU files appropriately align with existing dental billing and coding conventions, or whether edits are necessary. Medical and dental providers should bill using CDT or Current Procedure Terminology (CPT) codes where applicable, and for claims submissions during CY 2023, should submit claims using the professional or institutional claim forms, as appropriate. Although we propose to continue contractor pricing services billed using CDT codes, we are soliciting comment on whether the current payment indicators included for these CDT codes follow existing dental billing conventions, for example, for payment adjustment for multiple procedures, and whether there is a need for additional guidance regarding the submission of claims for services for which payment is permitted under the regulation at § 411.15(i)(3). In the CY 2023 PFS final rule (87 FR 69679), we acknowledged the need to address and clarify certain operational issues, and we are continuing to work to address these operational issues, including efforts to adopt the dental claim form. These efforts include continuing to work with our MACs

and encouraging continued feedback from interested parties to help identify concerns or questions regarding the submission and processing of dental claims.

Finally, in order to promote the correct coding and processing of Medicare claims, dentists who practice general or specialized dentistry currently self-designate their specialty under two specialty codes, specialty 19 (oral surgery—dentists only) or specialty 85 (maxillofacial surgery). We seek comment on whether additional specialty codes should be considered for use in Medicare, and if so, what are the other specific specialties that should be included. We also seek comment on whether these specialty codes may impact the coordination of benefits with a third-party payer. Finally, we recognize that issues could occur related to coordination of benefits for dual eligible beneficiaries, for example beneficiaries with hemophilia, and we seek comment on how to best coordinate a potential payment policy in this area with respect to state Medicaid plans or private insurance. We also seek comment on other coordination of benefits issues, or implementation topics that would be helpful for CMS to address in relation to continuing to implement these PFS payment policies.

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B (§§ 410.152, 414.902, 414.904, 489.30)

Drugs and biologicals (for the purposes of the discussion in this section III.A., "drugs") payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as "incident to") (section 1861(s)(2) of the Act), those administered via a covered item of durable medical equipment (DME) (section 1861(n) of the Act), and others as specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment amounts for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent