



Oncology Nursing Society

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September 11, 2023

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via www.regulations.gov

RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure,

Oncology nurses are privileged to support people with cancer through their entire cancer experience, from diagnosis and treatment into survivorship or as they face their end-of-life journey. Today, the Oncology Nursing Society (ONS) writes in response to proposals in the aforementioned proposed rule.

Principal Illness Navigation (PIN) Services

ONS appreciates CMS' recognition of the benefits of navigation services and that the Agency has proposed coding and payment for their delivery to Medicare beneficiaries. However, we have specific concerns about several aspects of the Principal Illness Navigation (PIN) Services proposal.

Personnel Training. ONS understands that CMS' proposal would require all auxiliary personnel who provide PIN services to be certified or trained to provide all included PIN service elements, and be authorized to perform them under applicable State law and regulations. Where States do not have applicable licensure, certification, or other laws or regulations, CMS proposes to require auxiliary personnel providing PIN services to be trained to provide them. ONS contends that nurses or social workers, by virtue of their training and licensure, would meet the requirements. ***CMS should specify that licensure, as well as certification or training, as meeting the personnel requirements.***

In addition, we have concerns about the delivery of PIN services by auxiliary personnel that receive training or certification, but are not licensed professionals. ONS wants to ensure auxiliary personnel are not misled that training or certification allows them to provide services that must be delivered by a licensed professional, such as a nurse or social worker. ***CMS must clarify that training and certification is not equivalent to licensure.***

Further, before auxiliary personnel can be trained to deliver PIN services, ONS also believes they should meet a minimum level of requirements and qualifications, that would include:

- Holding an associate’s or higher degree in a healthcare-related field;
- Having at least five years of experience in a healthcare setting; and,
- Possessing knowledge of
 - healthcare systems,
 - medical insurance and pharmacy benefit plans, including knowledge of utilization management, step-therapy and prior authorization protocols,
 - Medicare coverage and benefits, and
 - privacy and other relevant health laws.

Without an appropriate foundation, we are concerned that cancer patients seeking PIN services will be connected with individuals who are unable to meaningfully assist them with navigating an increasing complex healthcare system. ***CMS should establish minimum qualifications for auxiliary personnel to be trained to provide PIN services.***

With regards to whom may provide the training and certification, this is best left to accredited higher education institutions.

Telehealth. To improve access to PIN services, ***CMS should allow them to be delivered as telehealth and other modalities, including audio-only telephone.*** This is particularly important for those in rural and underserved communities, as well as for patients with limited access to technology due to socioeconomic conditions, technology literacy, or both.

Patient Consent. Research is confirming that navigation services are beneficial in the delivery of high quality cancer care and treatment. However, under this proposal, there will be a cost-sharing obligation when PIN services are provided. This is disappointing considering the high-cost burden cancer patients already face, not to mention it could inadvertently limit access to a service meant to improve health equity and reduce disparities. We believe a cost-sharing obligation for this service is inconsistent with the goal of the Cancer Moonshot to “improve the experience of people who are touched by cancer.” We believe patients need to be informed if they receive services that require cost-sharing, but we are concerned they will decline non-clinical services if it increases their out-of-pocket spend. To remove this barrier, ***CMS should include waiving PIN service cost-sharing as a legislative proposal in its FY 2025 budget request.***

External Contracting. We are deeply concerned about PIN services being outsourced to entities external to the billing practice. This will create a significant burden on practices to ensure the navigation services are being delivered by the appropriate personnel and in accordance with CMS’ requirements, including associated documentation requirements. More importantly, external contracting could lead to more care transitions and “handoffs,” in contrast to the goal of navigation services that are meant to decrease such fragmentation. Without proper oversight by the billing practice, cancer patients may receive PIN services that fail to meet their needs or create additional challenges. ***CMS should withdraw this proposal.***

Other Concerns. We view PIN services as being a covered benefit under Medicare Part B, therefore, beneficiaries that have opted to enroll in a Medicare Advantage, or Part C plan, must also have access to these services. Nevertheless, it is unclear how PIN services would be submitted to Medicare Advantage

plans on claims if these plans do not recognize the new HCPCS codes. ***CMS should clarify in the final rule that PIN services are a covered benefit that must be available to beneficiaries in Medicare Advantage. In addition, CMS should require Medicare Advantage plans to adopt the CMS-established G codes for coding and payment of PIN services, as well as the associated policies.***

ONS also understands that CMS has limited authority to compel private and certain other plans to cover and pay for CMS-established services in their insured populations. Without broad access to PIN services for all cancer patients, the goal of the policy and of the Cancer Moonshot, will be diminished, and increase – rather than reduce – disparities in cancer care and treatment.

CMS has some regulatory authority when it comes to the benefits that must be available in Medicaid and Children’s Health Insurance Program (CHIP), and those plans that operate on the Health Insurance Exchange. As noted above, without broad access to PIN services, disparities will be intensified. ***CMS must use its authority and work across its Centers to ensure PIN services are deemed a covered or essential health benefit, and are appropriately reimbursed.***

Dental Services

ONS appreciates CMS’ ongoing effort to ensure dental services that are inextricably linked to specific covered medical services are accessible and reimbursed. In our CY 2023 PFS comments, we highlighted clinical scenarios where dental services may be inextricably linked to specific covered services and recommended CMS include them. We appreciate that CMS is now proposing to amend its regulation at § 411.15(i)(3)(i)(A) to permit payment under Medicare Part A and Part B for certain dental services, including exams and other dental care that is inextricably linked.

We also appreciate CMS’ proposal that payment under the applicable payment system could 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 regulation at § 411.15(i)(3)(ii).

In addition, we applaud CMS for highlighting the importance of coordination between various healthcare providers, and emphasizing that coordination should be documented. Without it, significant harm could come to cancer patients who receive ill-timed dental care during high-risk oncology treatments.

Radiation Therapy. Given radiation has become more precise and targeted, ONS believes that dental coverage is necessary in the following clinical scenarios:

- When radiation therapy is delivered in conjunction with chemotherapy, related to head and neck cancer of any type, ***and as part of total body irradiation for the treatment of any condition, including cancer,*** and
- ***When radiation is delivered to bone-marrow dense areas such as the sternum or pelvis for the treatment or palliation of disease, where there is a higher likelihood of immunosuppression related to the treatment.***

CMS should consider the above as it continues to refine its proposals to cover certain dental services.

Anti-resorptive Therapy. We appreciate CMS’ proposals related to antiresorptive therapy. We note that anti-resorptive therapy is also used in survivors of cancer who are on antineoplastic treatments in order to reduce their risk of bone loss (for example, denosumab (Xgeva)). Another anti-resorptive therapy

used in cancer care is aromatase inhibitors, which is given to individuals to prevent breast cancer recurrence. ***CMS should expand its proposal to cover dental services in these patients, as well.***

Other Medicare-Covered Services. Dental services are inextricably linked when patients are on immunosuppressive therapy, given they are at increased risk of infections and oral complications. This would include patients who have undergone bone marrow, hematopoietic stem cell, and organ transplants. Studies in support of this include the following:

- Kwak, E. J., Kim, D. J., Choi, Y., Joo, D. J., & Park, W. (2020). Importance of oral health and dental treatment in organ transplant recipients. *International dental journal*, 70(6), 477–481. <https://doi.org/10.1111/idj.12585>
- National Institute of Dental and Craniofacial Research. (2016, July). Dental management of the organ or stem cell transplant patient. <https://www.nidcr.nih.gov/sites/default/files/2017-09/dental-management-organ-stem-cell-transplant.pdf>
- Gurenlian, J. R., & Brenchley, L. (2019, March 1). *Oral effects of hematopoietic stem cell transplant therapy*. *Decisions in Dentistry*. <https://decisionsindentistry.com/article/oral-effects-hematopoietic-stem-cell-transplant-therapy/>

CMS should consider the above resources and finalize expanded coverage of dental services in patients on immunosuppressive therapy.

We appreciate your consideration of these important issues as the agency drafts proposals to implement the legislation. If CMS has any questions or would like to discuss these comments in more detail, please contact us at healthpolicy@ons.org.

Sincerely,

The Oncology Nursing Society

About ONS

The Oncology Nursing Society (ONS) is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.