



September 08, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS Proposed FY 2024 Physician Fee Schedule (CMS-1784-P)

Dear Administrator Brooks-LaSure:

The National Comprehensive Cancer Network® (NCCN®) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) CMS Proposed FY 2024 Physician Fee Schedule as it relates to NCCN's mission of improving and facilitating, quality, effective, equitable, and accessible cancer care. NCCN will focus our comments on the SDOH risk assessment, patient navigation, and community health integration proposals, the Appropriate Use Criteria program, payment for caregiver training, and the Quality Payment Program (QPP) portions of the rule.

NCCN Background

As an alliance of 33 leading academic cancer centers in the United States that treat hundreds of thousands of patients with cancer annually, NCCN® is a developer of authoritative information regarding cancer prevention, screening, diagnosis, treatment, and supportive care that is widely used by clinical professionals and payers alike. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States.

NCCN Guidelines® and Library of Compendia products help ensure access to appropriate care, clinical decision-making, and assessment of quality improvement initiatives. The NCCN Drugs & Biologics Compendium (NCCN Compendium®) has been recognized by CMS and clinical professionals in the commercial payer setting since 2008 as an evidence-based reference for establishment of coverage policy and coverage decisions regarding off-label use of anticancer and cancer-related medications. NCCN was recognized by CMS in 2016 and renewed in 2021 as a qualified Provider Led Entity (PLE) for the Medicare Appropriate Use Criteria (AUC) Program for the development of AUC and the establishment of policy and decision-making for diagnostic imaging in patients with cancer.

NCCN is an alliance of leading cancer centers dedicated to improving and facilitating quality, effective, equitable, and accessible cancer care so all patients can live better lives.

For Clinicians: [NCCN.org](https://www.nccn.org) | For Patients: [NCCN.org/patients](https://www.nccn.org/patients) | Member Institutions: [NCCN.org/cancercenters](https://www.nccn.org/cancercenters)

NCCN imposes strict policies to shield the guidelines development processes from external influences. The “firewall” surrounding the NCCN Guidelines processes includes financial support policies; panel participation and communication policies; guidelines disclosure policies; and policies regarding relationships to NCCN’s other business development activities. The guidelines development is supported exclusively by the Member Institutions’ dues and does not accept any form of industry or other external financial support for the guidelines development program. The NCCN Guidelines are updated at least annually in an evidence-based process integrated with the expert judgment of multidisciplinary panels of expert physicians from NCCN Member Institutions. The NCCN Guidelines are transparent, continuously updated, available free of charge online for non-commercial use and are available through a multitude of health information technology (HIT) vendors.

Social Determinants of Health Risk Assessment, Community Health Integration Services, and Principal Illness Navigation Services

Within the draft Physician Fee Schedule CMS proposes to create codes and reimbursement for Social Determinant of Health (SDOH) risk assessment, community health integration (CHI) services, and principal illness navigation services. NCCN applauds CMS for its efforts to advance health equity by bridging gaps between health and health-related social systems. NCCN agrees with CMS that these proposals hold great potential to improve health outcomes particularly for historically disenfranchised patient communities. NCCN is pleased to provide comments on these three inter-related proposals.

SDOH Risk Assessment

Within the rule, CMS notes that SDOH risk assessment elements would include the administration of a standardized, evidence-based SDOH risk assessment tool that has been tested and validated through research. CMS also notes the tool must include at least the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties. CMS proposes the service would be billed at the time of an evaluation and management visit so that the results could be used to inform care delivery and would not be reimbursable more than once every 6 months. NCCN agrees with CMS that factors such as housing, transportation, utility, and food access have significant impacts on health access, treatment adherence, and health outcomes. However, NCCN is concerned that the current allowable reimbursement is not more often than once every six months. NCCN recently convened a working group to discuss the need for health-related social needs screening in cancer care and the working group concluded that screening should be done at any critical care junctures. This may include during a change in treatment plan or shifting to a different level of care. For some patients with cancer, these critical care junctures may occur more frequently than every six months. NCCN encourages CMS to finalize the reimbursement of this service but to allow flexibility for reimbursement more frequently than every six months for certain complex illnesses such as cancer. NCCN again thanks CMS for its commitment to addressing SDOH and is pleased to provide information on several resources to aid in this effort including the NCCN Distress Thermometer

and Problem List, the Elevating Cancer Equity Health Equity Report Card, and the recommendations of the aforementioned Health-Related Social Needs working group.

The NCCN Distress Thermometer and Problem List is a well-known and widely used screening tool among global oncology providers. The Distress Thermometer measures distress on a 0 to 10 scale and the Problem List includes five areas of life: practical, family, emotional, spiritual/religious, and physical problems. Within the Problem List, patients are questioned about Housing, Transportation, and Food Security among other variables offering providers flexibility in how they implement the tool. The distress thermometer and problems list has been extensively studied and utilized and has been incorporated into Health Information Technology.^{1,2,3,4} CMMI's Enhancing Oncology Model recently referenced the Distress Thermometer and Problem List as a tool for providers to address health-related social needs. NCCN encourages CMS to include the Distress Thermometer as a useful tool for providers seeking free resources to meet these measures.

In 2020, NCCN, the National Minority Quality Forum (NMQF), and the American Cancer Society Cancer Action Network (ACS CAN) launched the Elevating Cancer Equity (ECE) initiative. The ECE initiative sought to better understand patient experiences of racial disparities in access to guideline adherent cancer care in the United States through surveys of patients, caregivers, and oncologists, and then to address these disparities through a framework of actionable policy and practice change recommendations developed by a working group of national experts. The ECE Working Group (ECEWG), comprised of 17 national experts on racial disparities in cancer care including patients, caregivers, physicians, researchers, and industry, arose from the initiative. Convened in January 2021, the ECEWG developed two products: 1.) the Health Equity Report Card (HERC) as a means to put forth both best practice recommendations and ensure appropriate and necessary accountability for health systems and 2.) a Policy Framework to advance more equitable systems of care. The Health Equity Report Card includes measures that score providers on their collection of social determinants of health (SDOH) data and on their referral processes to resources.⁵ In early 2022, NCCN launched a feasibility pilot of the HERC across five academic cancer centers and is in the process of launching an additional pilot in community settings. NCCN

¹ Cuttillo A, O'Hea E, Person S, Lessard D, Harralson T, Boudreaux E. The Distress Thermometer: Cutoff Points and Clinical Use. *Oncol Nurs Forum*. 2017 May 1;44(3):329-336. doi: 10.1188/17.ONF.329-336. PMID: 29493167; PMCID: PMC5839660.

² Ma X, Zhang J, Zhong W, Shu C, Wang F, Wen J, Zhou M, Sang Y, Jiang Y, Liu L. The diagnostic role of a short screening tool--the distress thermometer: a meta-analysis. *Support Care Cancer*. 2014 Jul;22(7):1741-55. doi: 10.1007/s00520-014-2143-1. Epub 2014 Feb 8. PMID: 24510195.

³ Cormio C, Caporale F, Spatuzzi R, Lagattolla F, Lisi A, Graziano G. Psychosocial distress in oncology: using the distress thermometer for assessing risk classes. *Support Care Cancer*. 2019 Nov;27(11):4115-4121. doi: 10.1007/s00520-019-04694-4. Epub 2019 Feb 20. PMID: 30788626.

⁴ Snowden A, White CA, Christie Z, Murray E, McGowan C, Scott R. The clinical utility of the distress thermometer: a review. *Br J Nurs*. 2011 Feb 24-Mar 9;20(4):220-7. doi: 10.12968/bjon.2011.20.4.220. PMID: 21471860.

⁵ Schatz AA, Chambers S, Wartman GC, et al. Advancing More Equitable Care Through the Development of a Health Equity Report Card. *J Natl Compr Canc Netw*. 2023;21(2):117-124.e3. doi:10.6004/jnccn.2023.7003

believes the HERC can be a useful tool for providers, health systems, payers, developers of value-based models of care, and accreditation entities seeking to advance more equitable care delivery among their constituencies. NCCN will be pleased to keep CMS informed of these efforts as CMS works to advance better measurement and incentivization of equitable care delivery practices.

In April 2023, NCCN convened a multi-stakeholder working group to evaluate Health-Related Social Needs in oncology. The group, chaired by Dr. Loretta Erhunmwunsee of City of Hope and Yelak Biru of the International Myeloma Foundation, was tasked with identifying high-impact measures for screening and referral as well as policy and practice recommendations to bring these efforts to scale. The results of this working group will be presented at the September 12th NCCN Policy Summit at the National Press Club. NCCN will also release a publication detailing the working group efforts and recommendations. NCCN would be happy to engage in further conversation and information sharing around these initiatives and how they may complement CMS' efforts. NCCN again thanks CMS for this proposal which will address existing gaps in reimbursement to enhance access to SDOH risk assessment and follow-up.

Community Health Integration Services

CMS proposes to cover a broad range of services anticipated to impact health outcomes under the umbrella of the CHI services codes for individuals that have been identified as having health related social needs through the above SDOH risk assessment. These services include person-centered assessment, practitioner, home, and community-based care coordination, health education and self-advocacy skills training, and a variety of services related to social and emotional support. These services are proposed to be performed by certified or trained auxiliary personnel under the supervision of an ordering practitioner and limited to 60 minutes per month. NCCN supports the proposal to cover these services as a promising effort to reduce inequities in care outcomes. However, NCCN is concerned that the supervising practitioner requirement may pose challenges for some community-based organizations to be reimbursed for these services. NCCN encourages CMS to engage with community-based organizations highly skilled in these services to understand their available infrastructure, unique contributions, and needs to provide these services. NCCN further encourages CMS to explore with these organizations whether 60 minutes per month is an appropriate limit, especially for patients with complex health-related social needs and health conditions such as cancer. NCCN also encourages CMS to consider the impact of a twenty percent co-pay for these services on patients with complex needs and to consider payment mechanisms that may reduce this burden so patients are able to access these services.

Principal Illness Navigation Services

Within the draft Physician Fee Schedule, CMS proposes to “*better recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient’s health care navigation as part of the treatment plan for a serious, high-risk disease*

expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death. Examples of serious, high-risk diseases for which patient navigation services could be reasonable and necessary could include cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder. We are proposing new coding for Principal Illness Navigation (PIN) services.” NCCN applauds CMS for this important proposal. Patient navigators are emerging as a promising practice to reduce disparities in cancer care outcomes.⁶ Among the ECE Working Group noted above, there was significant consensus that connection to culturally and linguistically appropriate patient navigators and community health workers is a key strategy for advancing equitable cancer care. As such, NCCN applauds and supports this proposal.

In line with our comments above, NCCN encourages CMS to consider the impact of a twenty-percent co-pay on patients’ ability to access this service and to consider alternative payment mechanisms that may reduce this burden for patients. NCCN further encourages CMS to work with healthcare providers and community-based organizations to understand an appropriate frequency and length of service as 60 minutes monthly may not be sufficient for complex conditions such as cancer. NCCN again thanks CMS for these important proposals which, if finalized, are anticipated to have significantly positive impacts on equity in optimal cancer care outcomes.

Caregiver Training Reimbursement

Within the proposed rule CMS states that “*caregivers can play a key role in developing and carrying out the treatment plan.....In this context, we believe Caregiver Training Services (CTS) could be reasonable and necessary to treat the patient’s illness or injury.... In this context, caregivers would be trained by the treating practitioner in strategies and specific activities that improve symptoms, functioning, and adherence to treatment related to the patient’s primary clinical diagnoses. Caregiver understanding and competence in assisting and implementing these interventions and activities from the treating practitioner is critical for patients with functional limitations resulting from various conditions.*” NCCN agrees that caregivers are an integral component of the care team, particularly in complex diseases including cancer care. Caregivers for patients with cancer have a significant impact on care outcomes and also face significant burden related to caregiving.⁷ Caregiver self-reports of poor health have been found to have a negative impact on care access and outcomes for patients.⁷ However, one study found that enhanced caregiver training programs effectively increased caregiver self-efficacy for symptom management

⁶ Roland KB, Milliken EL, Rohan EA, DeGroff A, White S, Melillo S, Rorie WE, Signes CC, Young PA. Use of Community Health Workers and Patient Navigators to Improve Cancer Outcomes Among Patients Served by Federally Qualified Health Centers: A Systematic Literature Review. *Health Equity*. 2017 May 1;1(1):61-76. doi: 10.1089/heq.2017.0001. PMID: 28905047; PMCID: PMC5586005.

⁷ Litzelman K. Caregiver Well-being and the Quality of Cancer Care. *Semin Oncol Nurs*. 2019 Aug;35(4):348-353. doi: 10.1016/j.soncn.2019.06.006. Epub 2019 Jun 20. PMID: 31229346; PMCID: PMC6728914.

as well as caregiver stress management.⁸ Caregiver training and education is one important tool needed within a larger strategy to provide support to caregivers of patients with cancer as crucial members of the care team. As such, NCCN applauds and supports this proposal.

Appropriate Use Criteria

Within the proposed rule, CMS states “*we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we propose to pause implementation of the AUC program for reevaluation, and rescind the current AUC program regulations from § 414.94. We expect this to be a hard pause to facilitate thorough program reevaluation and, as such, we are not proposing a time frame within which implementation efforts may recommence.*” NCCN is supportive of the Appropriate Use Criteria program as an important effort to advance high-quality, high-value imaging services in cancer care and other specialties. NCCN is concerned that the proposed program pause will impede progress in advancing high-value imaging. NCCN would like to note that in the oncology care field there is ample opportunity to expand the AUC priority clinical areas which currently only includes lung cancer. NCCN’s Imaging AUC Compendium includes recommendations across a wide variety of cancers and along the full care continuum. NCCN understands that CMS faces challenges in implementing the program as outlined in statute, but we are concerned that a full pause of the program will delay progress in advancing high value imaging services. NCCN would welcome the opportunity to meet with CMS to discuss possible resources for implementation of the program.

Quality Payment Program

NCCN thanks CMS for its commitment to advancing high-quality cancer care, a commitment that NCCN shares. CMS proposes a number of changes to the Quality Payment Program, and NCCN is pleased to provide feedback on quality provisions of relevance to optimal cancer care.

Breast Cancer Screening and Colorectal Cancer Screening in Preventative Care and Wellness

CMS proposes to remove Breast Cancer Screening (Q112) and Colorectal Cancer Screening (Q113) as a quality measure from traditional MIPS and instead include them as components of the proposed Preventative Care and Wellness (composite) measure. The composite measure will combine *seven current preventive care measures with age and sex appropriate preventive*

⁸ Hendrix CC, Bailey DE Jr, Steinhauser KE, Olsen MK, Stechuchak KM, Lowman SG, Schwartz AJ, Riedel RF, Keefe FJ, Porter LS, Tulskey JA. Effects of enhanced caregiver training program on cancer caregiver's self-efficacy, preparedness, and psychological well-being. *Support Care Cancer*. 2016 Jan;24(1):327-336. doi: 10.1007/s00520-015-2797-3. Epub 2015 Jun 12. PMID: 26062925; PMCID: PMC4670577.

screenings and wellness services to create a robust, broadly encompassing preventive care assessment. NCCN agrees that requiring a comprehensive set of preventative screenings will support patient centered, high quality care for prevention or early detection of disease. NCCN also supports these measures being retained for use in the relevant MVPs.

Breast Cancer Screening Age

CMS proposes to update the eligible age criteria for the Breast Cancer Screening measure to 40-74 (from 50-74) to align with the May 2023 draft recommendation statement issued by the USPSTF. NCCN is supportive of this change, as it aligns with our guidelines that individuals with average risk of breast cancer should have annual mammographic screening starting at age 40.

Tobacco Use: Screening and Cessation Intervention

CMS proposes to combine the adolescent and adult patient populations, previously separate measures, into a single component under the proposed Preventative Care and Wellness (composite) measure. NCCN agrees that all patients aged 12 years and older should be screened for tobacco use and offered cessation support. As stated in the NCCN Guidelines for Smoking Cessation, NCCN agrees that tobacco use screening and cessation intervention is an important component of preventative care for all patients given the sufficient evidence⁹ that supports a causal relationship between adverse health outcomes, increased all-cause mortality and cancer-specific mortality, and increased risk for secondary primary cancers. The NCCN Guidelines for Smoking Cessation provide recommendations for the treatment of smoking for patients with cancer and cancer survivors, which providers can utilize to assess tobacco use and support cessation efforts.

Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer

CMS proposes to revise the denominator definition to better classify risk category for patients receiving treatment for prostate cancer in accordance with revised NCCN guidelines. NCCN thanks CMS for these appropriate changes. However, NCCN notes further suggested edits to fully align with NCCN Guidelines including the following:

- Add “At least one of the following:” to the beginning of Intermediate Risk section.
- Update the NCCN reference year to 2023.

⁹ The Health Consequences of Smoking-50 Years of Progress: A Report of the Surgeon General. Atlanta (GA); 2014. Available at: <https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf>. Accessed March 3, 2020.

Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level — Outpatient) Electronic Clinical Quality Measure (eCQM)

CMS proposes to include a new measure related to radiation dose and image quality for diagnostic computed tomography (CT). CMS states that this measure will provide “a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses while preserving image quality. The measure calculates the percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam.”. NCCN agrees that both radiation dose and image quality are critical quality and patient safety measures worthy of quality improvement and standardization efforts. However, NCCN remains concerned that current infrastructure is insufficient to appropriately track these metrics. Additionally, NCCN notes that, as radiation exposure is cumulative over a lifespan, age and prior or anticipated radiation exposure history, including therapeutic irradiation for malignancies, are also crucial considerations not currently considered within the measure. As such, while NCCN does support the overall goals of the measure, NCCN opposes the finalization of the measure as stated until further testing in oncology settings can be conducted.

MIPS Value Pathways (MVPs)

NCCN acknowledges the efforts by CMS to move away from siloed reporting of measures and activities toward focused sets of measures and activities that are more meaningful to a clinician’s specialty. NCCN appreciates the opportunity to provide comments on the newly proposed *Focusing on Women’s Health MVP* and proposed changes to *Advancing Cancer Care MVP*.

Focusing on Women’s Health

CMS proposes a new MVP, *Focusing on Women’s Health*, which includes a comprehensive set of measures to assess women’s health, including measures for breast cancer screening, cervical cancer screening, tobacco use screening, and social drivers of health. NCCN applauds and supports the addition of this MVP and inclusion of these measures and the proposed improvement activities relevant to food insecurity and addressing social drivers of health.

Advancing Cancer Care MVP

CMS proposes to add several measures and improvement activities to the *Advancing Cancer Care MVP*. NCCN appreciates CMS’s focus on biomarker testing and would like to highlight the importance of biomarker testing for non-small cell lung cancer prior to the start of *any* systemic therapy. NCCN recommends that CMS encourage the expansion of this measure to encompass all patients treated for stage IV lung cancer, regardless of planned therapy type, and in the interim to issue appropriate evidence-based guidance to practices. NCCN shares a commitment to evidence-based treatment decisions, and as such offers the NCCN Biomarkers Compendium as a resource.

The NCCN Biomarkers Compendium is updated in conjunction with the NCCN Guidelines on a continual basis, and contains relevant information designed to support decision-making around the use of biomarker testing in patients with cancer.

Value in Primary Care MVP

CMS proposes to include a new improvement activity in the previously finalized ***Value in Primary Care MVP***, *Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines* (IA_PM_XX). CMS proposes to modify one existing activity's description, titled "*Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs,*" and its validation criteria to explicitly promote the use of clinical decision support (CDS), particularly open-source, freely available, interoperable CDS. NCCN supports this proposal which is anticipated to improve access to appropriate and recommended cervical cancer screening.

NCCN appreciates the opportunity to comment on the CMS Proposed FY 2024 Physician Fee Schedule. NCCN is happy to serve as a resource and looks forward to working together to advance access to equitable, high-quality cancer care.

Sincerely,



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