National Comprehensive Cancer Network®

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NCCN Member Institutions

Abramson Cancer Center
at the University of Pennsylvania

Fred & Pamela Buffett
Cancer Center

Case Comprehensive Cancer
Center/University Hospitals
Seidman Cancer Center and
Cleveland Clinic Taussig
Cancer Institute

City of Hope National Medical Center

Dana-Farber/Brigham and
Women's Cancer Center
Massachusetts General Hospital
Cancer Center

Duke Cancer Institute

Fox Chase Cancer Center

Huntsman Cancer Institute
at the University of Utah

Fred Hutchinson Cancer
Research Center/
Seattle Cancer Care Alliance

The Sidney Kimmel
Comprehensive Cancer
Center at Johns Hopkins

Robert H. Lurie Comprehensive
Cancer Center of Northwestern
University

Mayo Clinic Cancer Center

Memorial Sloan Kettering
Cancer Center

Moffitt Cancer Center

The Ohio State University
Comprehensive Cancer Center -
James Cancer Hospital and
Solove Research Institute

O'Neal Comprehensive
Cancer Center at UAB

Roswell Park Comprehensive
Cancer Center

Siteman Cancer Center
at Barnes-Jewish Hospital
and Washington University
School of Medicine

St. Jude Children's
Research Hospital/
The University of Tennessee
Health Science Center

Stanford Cancer Institute

UC San Diego
Moores Cancer Center

UCSF Helen Diller Family
Comprehensive Cancer Center

University of Colorado
Cancer Center

University of Michigan
Rogel Cancer Center

The University of Texas
MD Anderson Cancer Center

University of Wisconsin
Carbone Cancer Center

Vanderbilt-Ingram
Cancer Center

Yale Cancer Center/
Smilow Cancer Hospital

March 31, 2020

The Honorable Seema Verma
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-4190-P CY 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program and Medicare Prescription Drug Benefit Program

Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) is pleased to comment on the Centers for Medicare and Medicaid Services Contract Year (CY) 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program and Medicare Prescription Drug Benefit Program as it relates to NCCN's mission to improve and facilitate quality, effective, efficient, and accessible cancer care. NCCN appreciates the opportunity to respond and will focus our comments on how NCCN content may be used as a resource within beneficiary real time benefit tools to ensure patient access to clinically appropriate information, on methods to ensure appropriate opioid access for Americans with cancer, and on the proposed quality provisions of the rule.

NCCN Background

As an alliance of 30 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 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 imposes strict policies to shield the guidelines development processes from inappropriate 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. 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 available through a multitude of HIT vendors.

Beneficiary Real Time Benefit Tool

In the proposed rule, CMS proposes to "require that Part D plan sponsors implement, no later than January 1, 2022, a beneficiary real-time benefit tool (RTBT)." CMS proposes that the tool would allow enrollees to view "accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information". Specifically, CMS notes that the beneficiary RTBT would provide the information before a treatment plan is chosen, so that beneficiaries and prescribers can have meaningful conversations before selecting the most appropriate medication. NCCN has long recognized the importance of patient-provider communication and education in cancer care and applauds CMS for advancing timely patient access to health information through the use of a RTBT.

In implementing a RTBT, CMS should ensure patient-provider treatment decisions are based on the most current available evidence. Over the past twenty-five years, NCCN has developed a collection of resources and programs to support and educate stakeholders across the oncology spectrum, including physicians, researchers, nurses, policymakers, industry, payers, patients, and patient advocates. NCCN publishes a library of NCCN Guidelines for Patients® based directly on the information found in the NCCN Guidelines to provide patients with the same information their doctors use in easy-to-understand language. Additionally, the NCCN Evidence Blocks™ are a visual representation of five key components of value that provide important information about specific recommendations contained within the NCCN Guidelines. These five components are: efficacy, safety, quality and quantity of evidence, consistency of evidence, and affordability. The NCCN Guidelines with NCCN Evidence Blocks™ and

NCCN Guidelines for Patients are free of charge and available online or through a mobile application for non-commercial use by physicians and patients.

Numerous independent studies prove that adherence to NCCN Guidelines improves care delivery and outcomes for patients. Improved health outcomes proven through concordance with NCCN Guidelines include: improved rates of survival for colon cancer, ovarian cancer, gastric cancer, nasopharyngeal cancer, and pancreatic cancer; decreased locoregional recurrence of melanoma; and improved pain control.[1,2,3,4,5,6] Additionally, NCCN Guidelines have been shown to lower healthcare costs caused by overutilization and inappropriate use of services and therapeutics. A recently published study "Guideline Discordance and Patient Cost Responsibility in Medicare Beneficiaries With Metastatic Breast Cancer" by Williams et al. found median cost for metastatic breast cancer patients receiving guideline-discordant treatment was $7,421 versus $5,171 for those receiving guideline-concordant care. This study found an additional $1,841 in out-of-pocket costs for patients receiving guideline concordant care versus patients who received guideline-concordant care.

The NCCN Guidelines for Patients and NCCN Evidence Blocks could be implemented within Part D sponsors' beneficiary RTBT to ensure patients are accessing appropriate clinical information. Evidence-based guidelines can serve as a tool to ensure patients have access to clinically appropriate and up-to-date information as they consider their treatment options. Additionally, as noted above, guideline adherence lowers out of pocket costs for patients and improves cancer care outcomes. NCCN applauds CMS for the proposal to advance beneficiary RTBTs in Medicare Part D and would welcome the opportunity to serve as a resource upon implementation.

Ensuring Appropriate Opioid Prescribing

NCCN appreciates CMS' efforts to address inappropriate prescribing of opioids and recommends the use of evidence-based and population-specific prescribing guidelines to ensure appropriate prescribing across patient populations. The proposed rule notes that most Part D plans are voluntarily implementing Drug Management Programs

1 Foster, et al., Annals of Surgical Oncology 2008 15:2395-2402; doi: 10.1245/s10434-008-0021-0 https://www.ncbi.nlm.nih.gov/pubmed/18600380
2 Visser, et al., Journal of International Hepato-Pancreato-Biliary Association 2012 14(8): 539-547; doi: 10.1111/j.1477-2574.2012.00496.x https://www.ncbi.nlm.nih.gov/pubmed/22762402
3 Bristow, et al., Journal of the National Cancer Institute 2013 105(11):823-832; doi: 10.1093/jnci/djt065 https://www.ncbi.nlm.nih.gov/pubmed/23539755
4 Bristow, et al., Gynecologic Oncology 2014 132(2):403-410; doi: 10.1016/j.ygyno.2013.12.017 https://www.ncbi.nlm.nih.gov/pubmed/24361578
5 Mearis, M, Shega, JW, and Knoebel, RW Journal of Pain and Symptom Management 2013 48(3) 451-458; doi: 10.1016/j.jpainsymman.2013.09.016 https://www.ncbi.nlm.nih.gov/pubmed/24439844
6 Schwam et al., Clinical Oncology 2016 28(6):402-409; doi: 10.1016/j.jpainsymman https://www.ncbi.nlm.nih.gov/pubmed/26868285

(DMPs) and CMS proposes to require the implementation of DMPs by all Part D plan sponsors beginning in 2021. CMS seeks public comment on specific populations or diagnoses that could be excluded from DMPs for purposes of this definition and welcomes evidence from clinical experts regarding evidence based guidelines for opioid prescribing across clinical specialties and care settings.

NCCN applauds CMS for acknowledging the important role that evidence-based guidelines play in determining appropriate patient access to opioids. However, NCCN is concerned that the only guideline specifically cited in the proposed rule is the CDC Guideline for Prescribing Opioids for Chronic Pain. Although the CDC Guideline clearly states that the guideline is not intended to apply to patients with cancer, many payers are still inaccurately applying the CDC guidelines to patients in active cancer treatment for coverage determinations relating to opioids. While this is not the CDC's intention for the guideline, the resulting actions by payers are likely to cause unnecessary pain and suffering to patients with cancer. Additionally, although the CDC Guideline does not exempt cancer survivors as it does patients in active cancer treatment, the CDC has acknowledged that this is a special population and for select groups of cancer survivors, the relationship of benefits to risk in the use of opioids is unique and distinct from the needs of other patients with chronic pain.

The CDC acknowledged these challenges in a February 2019 letter (Appendix A) that stated that clinical practice guidelines for special populations including active cancer treatment, palliative care, and end of life care should be used to guide treatment and reimbursement. Additionally, the letter states that "*for select groups of cancer survivors with persistent pain due to past cancer or past cancer treatment, the relationship of benefits to risks in use of opioids for chronic pain is unique. Clinical practice guidelines addressing pain control for cancer survivors, such as the 2016 American Society of Clinical Oncology Clinical Practice Guideline on Management of Chronic Pain in Survivors of Adult Cancers and the 2018 National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain, have been published subsequent to release of CDC's Guideline for Prescribing Opioids for Chronic Pain. Such guidelines provide useful guidance on unique considerations for use of opioids for pain control in cancer survivors."* In alignment with this communication from the CDC, NCCN encourages CMS to direct Part D plan sponsors to high-quality, nationally recognized clinical practice guidelines for specialized patient populations including patients in active cancer treatment, cancer survivors, and patients with sickle cell disease. NCCN notes that the NCCN Clinical Practice Guidelines for Adult Cancer Pain and NCCN Clinical Practice Guidelines for Survivorship offer useful guidance for adults with cancer and cancer survivors.

Advancing Quality Care

NCCN supports the advancement of quality and value models in oncology to ensure patients have access to the highest quality of care and health systems benefit from the most efficient use of resources possible. NCCN believes quality measurement must be informed by a variety of key stakeholder perspectives, and applauds CMS for putting patients first with proposed changes to the Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System. Increasing the weight of patient experience/complaints and access measures emphasizes the importance of the patient voice and helps to ensure patients are active participants in their care experience. NCCN thanks CMS for considering patient perceptions of care in this model, and supports the proposed change in weight.

Additionally, NCCN would like to highlight a recent publication by our multidisciplinary panel on quality measures specific to oncology. The NCCN Quality & Outcome Committee was charged with reviewing the existing quality landscape, and to identify contemporary, relevant cancer quality and outcomes measures by both evaluating current validated measures and proposing new measure concepts to fill crucial gaps. CMS may be particularly interested in the seven cross-cancer measures endorsed by the committee (Appendix B), which are applicable in measuring care for most cancer patients and feasible for implementation across most practices. This work is intended to serve as a resource for quality measurement in oncology, and should be considered for future CMS programming.[7]

NCCN appreciates the opportunity to comment on the impact of the CMS Proposed CY 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program and Medicare Prescription Drug Benefit Program on Americans with cancer. We welcome the opportunity to discuss our comments further and look forward to working together to ensure Medicare beneficiary access to high-quality cancer care.

Sincerely,

Robert W. Carlson, MD
Chief Executive Officer
National Comprehensive Cancer Network
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[7] D'Amico, T. A., et al. (2020). Quality Measurement in Cancer Care: A Review and Endorsement of High-Impact Measures and Concepts. *Journal of the National Comprehensive Cancer Network*, *18*(3), 250-259.

Appendix A: CDC Letter (February 2019)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

February 28, 2019

Robert W. Carlson, MD
National Comprehensive Cancer Network

Clifford A. Hudis, MD
American Society of Clinical Oncology

Martha Liggett, Esq.
American Society of Hematology

Dear Dr. Carlson, Dr. Hudis, and Ms. Liggett,

Thank you for your letter regarding CDC's *Guideline for Prescribing Opioids for Chronic Pain*. CDC greatly appreciates your feedback regarding the interpretation of the Guideline, particularly with regard to patients undergoing cancer treatment, cancer survivors who have chronic pain, and individuals with sickle cell disease.

The Guideline was developed to provide recommendations for primary care clinicians who prescribe opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. Because of the unique therapeutic goals, and balance of risks and benefits with opioid therapy in such care, clinical practice guidelines specific to cancer treatment, palliative care, and end of life care should be used to guide treatment and reimbursement decisions regarding use of opioids as part of pain control in these circumstances.

The Guideline may apply to cancer survivors in specific conditions, namely, when these patients experience chronic pain after completion of cancer treatment, are in clinical remission, and are under cancer surveillance only. As you note, for select groups of cancer survivors with persistent pain due to past cancer or past cancer treatment, the relationship of benefits to risks in use of opioids for chronic pain is unique. Clinical practice guidelines addressing pain control for cancer survivors, such as the 2016 *American Society of Clinical Oncology Clinical Practice Guideline on Management of Chronic Pain in Survivors of Adult Cancers* and the 2018 *National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain*, have been published subsequent to release of CDC's *Guideline for Prescribing Opioids for Chronic Pain.* Such guidelines provide useful guidance on unique considerations for use of opioids for pain control in cancer survivors.

As you additionally note, unique considerations in sickle cell disease can change the balance of benefits and risks for the use of opioids in pain management. Given the challenges of managing the painful complications of sickle cell disease, clinical practice guidelines addressing use of opioids as part of pain control in patients with sickle cell disease should be used to guide treatment and reimbursement decisions. The CDC Guideline refers readers to NIH's *National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for guidance for management of sickle cell disease*. This resource can be found at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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and Prevention (CDC)
Atlanta GA 30333

The Guideline is not intended to deny any patients who suffer with chronic pain from opioid therapy as an option for pain management. Rather, the Guideline is intended to ensure that clinicians and patients consider all safe and effective treatment options for patients. Clinical decision-making should be based on the relationship between the clinician and patient, with an understanding of the patient's clinical situation, functioning, and life context, as well as a careful consideration of the benefits and risk of all treatment options, including opioid therapy. CDC encourages physicians to continue to use their clinical judgment and base treatment on what they know about their patients, including the use of opioids if determined to be the best course of treatment. Providers should communicate frequently with their patients to discuss both the benefits and risks of opioid therapy and revisit treatment plans for pain regularly to achieve the most positive outcomes for patients.

CDC has developed translational materials and trainings for providers to continue to emphasize that the Guideline is intended for primary care physicians for the treatment of chronic pain. Some of these resources include:

- *Assessing Benefits and Harms of Opioid Therapy*: https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf.
- CDC Training Series *Applying CDC's Guideline for Prescribing Opioids*, a web-based training to help providers gain a deeper understanding of the Guideline. Trainings address a variety of topics, including provider-patient communication and decision-making on initiating opioids for chronic pain. https://www.cdc.gov/drugoverdose/training/online-training.html

Chronic pain is common and multidimensional, and patients deserve safe and effective pain management. Collaborative relationships between patients and providers are critical to provide optimal pain management. CDC will continue to emphasize what the Guideline and associated materials say about communication, patient engagement in decision-making, and maintenance of the patient-provider relationship.

CDC will revisit the Guideline as new evidence and recommendations become available to determine when gaps have been sufficiently closed to warrant an update. We value stakeholder input to assist with such an update.

Sincerely,

Deborah R Dowell

Deborah Dowell, MD, MPH
Chief Medical Officer
The National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Appendix B: Cross-cancer Measures Endorsed by NCCN Quality and Outcomes Committee

- Proportion admitted to the intensive care unit (ICU) in the last 30 days of life
- Performance status documented prior to initiating chemotherapy regimen
- Patients are offered smoking cessation counseling if current smoker
- Proportion receiving chemotherapy in the last 14 days of life
- Chemotherapy given within 30 days of end of life
- Cancer stage documented
- Proportion dying from cancer in an acute care setting