



National Comprehensive
Cancer Network®

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The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn HOB
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
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Washington, DC 20515

Dear Congresswoman DeGette and Congressman Upton,

The National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of 28 leading cancer centers, thanks Congresswoman DeGette and Congressman Upton for their recently released Request for Information (RFI) on pending Cures 2.0 legislation. NCCN's mission is to improve and facilitate quality, effective, efficient, and accessible cancer so patients can live better lives and NCCN appreciates the opportunity to comment on Cures 2.0 as aligns with our mission.

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) and Library of Compendia products ensure access to appropriate care and clinical decision-making across the continuum of care. NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that apply to 97 percent of cancers affecting patients. Commercial and government payers, representing more than 85% of covered lives in the United States, utilize our Guidelines and compendia products. NCCN Compendium® has also been recognized by the Centers for Medicare and Medicaid Services (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.

Clinical Decision Support Mechanisms

As cancer care becomes increasingly complex, access to real-time, electronic, clinical decision support mechanisms (CDSMs) is increasingly important for prescribing professionals and payers. As such, NCCN supports the advancement of real-time CDSMs across payer systems. Numerous independent studies have proven that adherence to NCCN Guideline concordant care changes care delivery and improves outcomes for patients. Significantly enhanced measures associated with NCCN guidelines concordant management include: improved rates of survival for colon cancer, ovarian cancer, gastric cancer, nasopharyngeal cancer, and pancreatic cancer;

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

decreased locoregional recurrence of melanoma; and improved pain control.^{1,2,3,4,5,6} These studies underscore the importance of guideline adherence as a baseline to ensure patient access to appropriate clinical care.

Adherence to Guidelines also reduces health care costs. A peer-reviewed, published study by UnitedHealthcare, eviCore and NCCN entitled “Transforming Prior Authorization to Decision Support” demonstrated mandatory adherence to NCCN Guidelines and NCCN Compendium significantly reduced total and episodic costs of care. In Florida, UnitedHealthcare adopted an integrated prior authorization tool using NCCN real-time decision support over a one-year period. Specifically, the study found that adding decision support to prior authorization reduced denials from 4 to 1 percent. When compared to UnitedHealthcare’s cancer drug costs nationwide, the study found that mere adherence to NCCN Guidelines and Compendium reduced chemotherapy drug cost trends by 20 percent; a savings of \$5.3 million for the State of Florida. Administrative burden was also reduced through the integration of the decision-making tool as the majority of prior authorization requests were approved immediately; the remaining requests were approved within 24 hours.⁷

Additionally, 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.⁸ In adjusted models, guideline-discordant treatment was significantly associated with \$1,841 higher patient out-of-pocket costs. Guideline adherence through the use of CDSMs shows potential to improve quality of care, efficiency of care and affordability of care.

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>

⁷ Lee N. Newcomer, Richard Weininger, and Robert W. Carlson, *Journal of Oncology Practice* 2017 13:1, e57-e61,
<http://ascopubs.org/doi/full/10.1200/JOP.2016.015198>

⁸ Williams et al., *Journal of the National Comprehensive Cancer Network* 2019 17(10) doi:
<https://doi.org/10.6004/jnccn.2019.7316>

Cures 2.0 legislation presents an opportunity to implement CDSMs as an evidence-based, cost-efficient alternative to traditional prior authorization. NCCN encourages Congresswoman DeGette and Congressman Upton to consider the incorporation of language directing HHS to consider areas within the Medicare and Medicaid systems that CDSMs may be used to ensure timely patient access to evidence-based care. Another vehicle to ensure timely patient access to evidence-based care is, HR 3107, the Improving Senior Timely Access to Care Act. The Improving Seniors' Timely Access to Care Act would ensure timeliness and appropriateness of care by requiring the use of real-time transmissions for PA-approved items and services informed by evidence-based medical guidelines. Additionally, the act provides transparency in PA by directing MA plans to maintain a publicly available, regularly updated, website of PA-approved services and items, which will prevent confusion among patients and providers. NCCN believes that Cures 2.0 has the potential to advance patient access to high-quality cancer care through the inclusion of HR 3107, as well as language directing HHS to consider the use of CDSMs within Medicare and Medicaid. NCCN believes these requested provisions are aligned with the intent of Cures 2.0

Biomarker Coverage

As cancer becomes increasingly personalized, and with the proliferation of predictive diagnostic tests, it is becoming more challenging to ensure patients have access to clinically appropriate testing informed by evidence. To meet this need, NCCN has developed The NCCN Biomarkers Compendium®, a tool that identifies the appropriate use of biomarkers to screen, diagnose, monitor, and provide predictive and prognostic information for the treatment of patients. Based directly on the NCCN Guidelines, the NCCN Biomarkers Compendium contains information designed to support decision-making around the use of biomarker testing in patients with cancer. The goal of the NCCN Biomarkers Compendium is to provide essential details for those tests which have been approved by NCCN Guidelines Panels and are recommended by the NCCN Guidelines. The NCCN Biomarkers Compendium aims to ensure that patients have coverage and access to appropriate biomarker testing based on the evaluations and recommendations of NCCN Guidelines Panel members.

Recognizing the need for an evidence-based approach to coverage for biomarker testing, CVS Health recently launched an initiative called Transform Oncology Care™ that uses results of broad-panel gene sequencing tests and the latest National Comprehensive Cancer Network (NCCN) treatment and supportive care guidelines to help oncologists identify and start their patients on the most precise, appropriate treatment regimen based on their clinical and genetic profiles. Therapeutic regimens that align to NCCN guidelines, including those matched with the results of the broad-

panel gene sequencing tests, will automatically receive prior authorization approval, speeding time to start of the therapy for patients. The strategy is enabled by an innovative collaboration with Tempus, a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare.

The advent of personalized medicine poses new challenges for healthcare professionals, payers, and patients. NCCN believes that the Cures 2.0 package is an appropriate vehicle to advance the use of innovative strategies like the Transform Oncology Care™ to ensure patients are accessing appropriate testing that is rooted in evidence and clinical utility. NCCN encourages the inclusion of language directing HHS to consider evidence-based, nationally recognized, and continuously updated biomarker compendia products for use in coverage determinations.

CLINICAL TREATMENT Act

NCCN believes that the best management for any patient with cancer is within a clinical trial and encourages participation in clinical trials. Unfortunately, many barriers to diverse participation in clinical trials remain. Medicaid insures nearly one-fifth of the US population and is the only major payer that is not required by federal law to cover routine costs associated with participation in clinical trials. Although twelve states require their Medicaid programs to cover these costs, there are still as many as 42.2 million Medicaid patients that are potentially without this needed coverage.

Clinical trials often provide patients with the best and perhaps only treatment option for their condition. Without the guarantee of coverage, however, many Medicaid beneficiaries do not have the latest technological and scientific advancements as a treatment option. Medicaid serves many demographics, including populations that are underrepresented in current clinical trial enrollment. Barriers to participation in clinical trials for Medicaid beneficiaries harms patient access to potentially life- saving trials as well as the quality and diversity of clinical research.

NCCN supports the CLINICAL TREATMENT Act, HR 913, legislation that would promote access to life-saving therapies for Medicaid enrollees by ensuring coverage of routine patient costs associated with participation in qualifying clinical trials. Routine costs include the non-experimental costs of treating a patient who is participating in a clinical trial, such as the cost of physician visits or laboratory tests. These costs are part of standard care and would be incurred regardless of whether a patient participates in a clinical trial. The cost of any investigative device or drug would continue to be covered by the trial sponsor. As such, this coverage would have little to no impact on the overall cost of care to Medicaid programs. NCCN believes the CLINICAL

TREATMENT Act aligns with Congresswoman DeGette and Congressman Upton's goals to "modernize coverage and access to life-savings cures in the United States and across the globe" and would be an excellent addition to the Cures 2.0 package.

MODERN Labeling Act

Currently, many generic drugs on the market have labels that are considerably out of date, despite the critical role they can play in informing treatment decisions. The MODERN Labeling Act addresses the large number of outdated drug labels by giving the FDA the authority to require updating of labels to reflect new information relevant to the drug and its use. This Act also determines a process through which the FDA can identify labels to be updated, notice label holders, and allows for a process for label holders to submit modifications to the notice. NCCN notes that nationally recognized guidelines are a readily available and free resource for the FDA to utilize in this work. NCCN guidelines are updated a minimum of once annually with many guidelines updated multiple times within a year as new evidence emerges. Partnerships between the FDA and nationally recognized guideline organizations would make this work affordable, efficient, and easily implementable in the immediate future.

Drug labels provide health care providers with an unbiased source of information that helps them to prescribe treatments safely and effectively. Patients and their caregivers, physicians and nurses, need high quality sources of information about the prescription drugs they use, and out-of-date drug labels may cause confusion. As such, NCCN believes this important legislation aligns with the goals outlined for the Cures 2.0 legislation and encourages the addition of this language to the bill.

We appreciate the commitment of you and your staff to ensuring American patients have access to the highest quality care. NCCN looks forward to working with your offices to ensure patients with cancer have access to high-quality, effective, efficient, and accessible cancer care.

Sincerely,



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