National Comprehensive Cancer Network®

Crystal S. Denlinger, MD, FACP
Chief Executive Officer
denlinger@nccn.org
3025 Chemical Road, Suite 100
Plymouth Meeting, PA 19462
215.690.0300

February 10, 2025

RE: Support for SB 476 & HB 830– Genetic Testing & Cancer Imaging Required Coverage and Prohibited Cost-Sharing

Dear Honorable Members of the Maryland Senate Finance Committee:

The National Comprehensive Cancer Network® (NCCN®) appreciates the opportunity to comment on companion bills SB 476 & HB 830, an act relating to coverage of genetic testing and cancer imaging. Genetic Testing is of paramount importance as it relates to NCCN's mission of improving and facilitating, quality, effective, equitable, and accessible cancer care and prevention so all people can live better lives. NCCN will focus our supportive comments on the importance of comprehensive genetic (germline) testing for residents of Maryland and the role of NCCN Guidelines® in determining clinically appropriate care.

NCCN Background
As an alliance of 33 leading academic cancer centers in the United States, including Johns Hopkins Kimmel Cancer Center, 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 and are used by payers representing more than 85% of covered lives in the United States including CMS. NCCN imposes strict policies to shield the guidelines development processes from external influences. The NCCN 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 process. The NCCN Guidelines® are updated at least annually in an evidence-based process integrated with the expert consensus of multidisciplinary panels of expert oncology health care professionals from NCCN Member Institutions. Most Guidelines panels also include a patient advocate, who has an equal role in the process to Member Institution representatives. 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.

Germline Testing vs. Biomarker Testing
Cancers can develop as a result of pathogenic or likely pathogenic (P/LP) variants in certain genes, such as those involved in the regulation of cell growth and/or DNA repair[1,2]. Family studies have long documented an increased risk for several forms of cancer among first-degree relatives (i.e., parents, siblings, children) and second-degree relatives (i.e., grandparents, aunts or uncles, grandchildren, nieces or nephews) of affected individuals. These individuals may have an increased susceptibility to cancer as the result of one or more P/LP variants present in parental germline cells. Hereditary cancers are often characterized by P/LP variants associated with increased risk for certain cancers and transmission to offspring through the mother and/or father[3,4].

An individual suspected of being at risk for hereditary cancer should be offered genetic counseling[5,6] and testing as appropriate, consistent with recommendations from the U.S. Preventive Services Task Force

(USPSTF) and the NCCN Clinical Practice Guidelines[7]. With respect to hereditary cancers, advances in molecular genetics have identified several genes associated with inherited susceptibility to several types of cancer (i.e., BRCA1/2, PALB2, ATM) and have provided a means of characterizing the specific P/LP variant present in certain individuals and families exhibiting an increased risk for cancer. The field of cancer genetics has implications for all aspects of cancer-related care of individuals with hereditary or familial cancers, including prevention, screening, and treatment[8].

Despite a wide body of literature supporting the need for guideline adherent genetic testing, coverage, and access to appropriate genetic testing is still widely variable leaving many patients unable to access appropriate care. A 2023 study evaluating genetic testing for cancer patients between 2013 and 2019 found that only 6.8% of patients went through germline genetic testing within two years of their cancer diagnosis[9]. This critical care gap must be addressed to ensure all people can access optimal cancer care. SB 476/HB 830 creates coverage for appropriate germline testing as recognized in our evidence-based clinical practice guidelines. As such, NCCN is pleased to support SB 476/HB 830.

To be sure, there are differences in germline testing and biomarker testing. NCCN applauds the work of your legislative body in successful passage of access to clinically appropriate biomarker testing in Chapter 322 of 2023 through cross-filed companion bills SB 0805/HB 1217. Your legislative success in advancing coverage access to patients becomes effective July 1, 2025.

However, whereby biomarker testing typically analyzes a sample of tumor tissue or other bodily fluids to guide treatment decisions based on specific mutations in an existing cancer, germline testing leads patients to important shared clinical decision-making conversations with their providers on customizing screening and prevention care plans and may have implications for cancer treatment recommendations in certain cancers. There are some cancers where germline mutations can impact cancer treatment recommendations, such as BRCA mutations in prostate, breast, ovarian, and pancreatic. Eliminating coverage barriers for both tests benefits both patients and providers when biomarker testing is appropriate in identifying potential inherited mutations within a tumor; however, germline testing leads to increased awareness not only within the patient community, but for the family members who may also share these mutations and can lead to personalized shared clinical decision-making on appropriate lifetime screening and prevention plans.

Access to both forms of precision medicine reduce cost barriers to patients and payers, can help prevent disease diagnosis and/or progression, reduces more costly and toxic treatment options, and can also reduce onerous administrative prior authorization burdens on already overly worked providers.

NCCN Biomarkers Compendium®

The NCCN Guidelines® include biomarkers used for the purposes of diagnosis, screening, monitoring, surveillance, prediction, therapeutic decision-making and prognostication. The NCCN Biomarkers Compendium® contains biomarker information derived directly from the NCCN Guidelines to support decision-making around the use of biomarker testing in patients with cancer and is intended to be a resource for payers, providers, and health care entities navigating the rapidly changing evidence base for medically necessary biomarker testing in oncology. Information is provided in a searchable database that is updated continuously in conjunction with the NCCN Guidelines® to remain evergreen. In addition to providing information regarding clinical indication(s) for specific biomarker testing, the NCCN Biomarkers Compendium provides essential details for testing methodologies recommended within the NCCN Guidelines.

NCCN Supports Clinically Appropriate Germline Genetic Testing
NCCN recommends covering genetic testing as delineated in evidence-based nationally recognized clinical practice guidelines such as ours. NCCN would like to note that the most recent versions of our Guidelines are always available on our website. As NCCN Guidelines® are continuously updated to stay current with the evidence, NCCN encourages your committee to refer to the current recommendations and Guideline versions on the NCCN website as a health policy tool to ensure those decisions are up to date with the standard of care.

NCCN appreciates the opportunity to comment on and support SB 476/ HB 830. We are proud to support this legislation in harmony with our coalition partners. As a nationally recognized clinical guidelines organization, NCCN is happy to serve as a resource during the legislative process. We look forward to working together to ensure access to high-quality cancer care.

Respectfully,

Crystal Denlinger, MD, FACP
Chief Executive Officer
National Comprehensive Cancer Network
denlinger@nccn.org 267.622.6654

References

1. Fearon ER, Vogelstein B. A genetic model for colorectal tumorigenesis. Cell 1990;61:759-767. Available at: http://www.ncbi.nlm.nih.gov/pubmed/2188735.

2 Vogelstein B, Kinzler KW. The multistep nature of cancer. Trends Genet 1993;9:138-141. Available at: http://www.ncbi.nlm.nih.gov/pubmed/8516849.

3 . Lynch HT, Watson P, Conway TA, Lynch JF. Clinical/genetic features in hereditary breast cancer. Breast Cancer Res Treat 1990;15:63-71. Available at: http://www.ncbi.nlm.nih.gov/pubmed/2322650.

4 Pharoah PD, Day NE, Duffy S, et al. Family history and the risk of breast cancer: a systematic review and meta-analysis. Int J Cancer 1997;71:800-809. Available at: http://www.ncbi.nlm.nih.gov/pubmed/9180149

5 Lancaster JM, Powell CB, Chen LM, Richardson DL. Society of Gynecologic Oncology statement on risk assessment for inherited gynecologic cancer predispositions. Gynecol Oncol 2015;136:3-7. Available at: http://www.ncbi.nlm.nih.gov/pubmed/25238946.

6. Shiovitz S, Korde LA. Genetics of breast cancer: a topic in evolution. Ann Oncol 2015;26:1291-1299. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25605744.

7. Moyer VA. Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2014;160:271-281. Available at: https://www.ncbi.nlm.nih.gov/pubmed/24366376.

8. Weitzel JN, Blazer KR, MacDonald DJ, et al. Genetics, genomics, and cancer risk assessment: state of the art and future directions in the era of personalized medicine. CA Cancer J Clin 2011;61:327-359. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21858794.

9. Kurian AW, Abrahamse P, Furgal A, et al. Germline Genetic Testing After Cancer Diagnosis. JAMA. 2023;330(1):43–51. doi:10.1001/jama.2023.9526.