FORCE

Facing Hereditary Cancer EMPOWERED

August 2, 2024

The Honorable Diana DeGette
House Energy and Commerce Committee
2313 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

The Honorable Larry Bucshon
House Energy and Commerce Committee
2111 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

*Submitted electronically to **cures.rfi@mail.house.gov***

Dear Representatives DeGette and Bucshon:

We appreciate the opportunity to provide input on the 21st Century Cures and CURES 2.0 initiatives. FORCE (Facing Our Risk of Cancer Empowered) is a national nonprofit organization representing the millions of Americans with or at increased risk of hereditary cancers due to an inherited genetic mutation such as BRCA1, BRCA2, ATM, CHEK2, PALB2, Lynch syndrome, etc. In addition to our organization, the following comments reflect feedback from members of the Hereditary Cancer Advocacy Coalition, a diverse group of over 70 stakeholders committed to healthcare policy and practice reform that leads to improved outcomes for individuals with or at risk of hereditary cancers.

The below touches on a small portion of the many CURES 2.0 components. While we support expanded access to telehealth services, better integration of patient experience and real-world data, increasing clinical trial diversity and coverage, improving health literacy, etc., these comments focus on issues specific to individuals and families affected by hereditary cancer.

Cancer is a disease that affects everyone, but it does not affect everyone equally. More than one in 350 Americans carries an inherited genetic mutation associated with increased cancer risk (as high as 80% lifetime risk); an estimated 10% of all cancers can be attributed to a heritable mutation. These individuals and their families face a heavy cancer burden, which is exacerbated by health systems and coverage policies that focus on treatment instead of screening and prevention.

Cures 2.0 aimed to build on the success of 21st Century Cures Act by focusing on ways we can modernize coverage and access to life-saving cures. Finding cures is an admirable goal, but improved access to cancer screening and prevention is a crucial step in this process. Expanding access to genetic testing and precision medicine, Medicare reimbursement, and coverage of innovative health technologies are key components of CURES 2.0. Strides have been made, but many gaps and unmet needs persist.

Gap: Medicare Coverage of Genetic Testing and Downstream Care
Genetic testing for a hereditary predisposition to cancer is the standard of care and widely recognized as medically necessary for individuals with certain personal or family histories of the disease. Knowledge of an inherited genetic mutation can be lifesaving for an individual and their family members. Unfortunately, *Medicare covers genetic testing only for Medicare beneficiaries already diagnosed with cancer*, regardless of family cancer history or a known genetic mutation in the family. This presents a barrier to evidence-based care as many beneficiaries live on fixed incomes and cannot afford the cost of genetic testing.

Conversely, many people learn about their hereditary cancer risk before Medicare eligibility. They assume that the guideline-recommended supplemental screenings and preventive measures will be covered by Medicare. Patients and providers are often shocked that the continuum of care is interrupted because Medicare doesn't cover many of the screenings and interventions recommended for individuals at increased risk of cancer. Congress has facilitated coverage of cancer screenings such as mammograms for the "average risk" Medicare population. However, most guideline-recommended measures for individuals at increased risk of cancer are not covered.

As such, those with a genetic mutation may have the knowledge that they face a high risk of certain cancers, but they aren't able to access the services needed to prevent or detect cancer earlier, when it is easier and less expensive to treat. Ultimately, these patients face a dilemma: forgo the guideline-recommended screenings and interventions or shoulder the cost of tests such as annual breast MRIs and pancreatic cancer screenings, or risk-reducing surgery such as hysterectomy.

Solution: Reducing Hereditary Cancer Act
The Reducing Hereditary Cancer Act (H.R.1526/S.765) aims to remedy this coverage gap, ensuring that Medicare beneficiaries have access to evidence-based, medically necessary screening and preventive services.

This legislation would modify the Medicare statutes to align with current medical guidelines, enabling coverage of:

- Genetic testing for inherited genetic mutations that increase cancer risk for those with a known hereditary cancer mutation in their family and those with a personal or family history suspicious of hereditary cancer.
- And for people identified with a mutation, it would enable coverage of increased cancer screening and risk-reducing surgeries as recommended by medical guidelines (e.g. removal of ovaries and fallopian tubes).

Research shows discrepancies in access to genetic counseling and testing among underserved racial and ethnic minorities, leading to disparities in cancer screening, prevention, and early detection. This bill will help alleviate disparities by reducing financial barriers to genetic testing and guided cancer prevention strategies. Medicare will realize savings by implementing this coverage because prevention and early detection are less costly than treatment.

Gap: Medicare Coverage of Genetic Counseling
The services of genetic counselors are increasingly important in the era of personalized medicine. Genetic counseling is particularly helpful for individuals considering genetic testing for certain conditions that have a genetic component, such as cancer or cardiovascular disease.

Currently, genetic counselors do not have provider status under Medicare, although the service they provide is a covered benefit. As a result, patients have poor access to these uniquely trained healthcare professionals. Certified Genetic Counselors (CGCs) bring expertise to patients and their healthcare teams, helping them understand how inherited diseases and conditions might affect patients and their families.

Solution: Access to Genetic Counselor Services Act
The Access to Genetic Counselor Services Act (H.R.3876/S.2323) takes a measured approach to modernizing Medicare to better utilize genetic and genomic medicine. The bill would:

- Improve the ability of other practitioners, such as physicians, to refer patients for genetic counseling under Medicare Part B.
- Provide reimbursement to genetic counselors at 85% of the physician fee schedule amount.

Passage of this Act would change the current Medicare policy that limits physician referrals to genetic counselor services. Lack of access to these trained genetics professionals can result in harm such as incorrect interpretation of genetic test results, failure to identify individuals with increased genetic risk of disease, and inaccurate risk assessments leading to inappropriate medical management, including unnecessary surgery or ineffective treatments.

Broader Medicare beneficiary access to genetic counselors will help expand the utilization of genetic testing by ensuring the appropriate test is ordered, helping beneficiaries understand test results, and further integrating genetic counselors into the healthcare team. We expect the legislation will enhance team-based care coordination for Medicare beneficiaries, and may also save healthcare dollars.

Gap: Coverage of Genetic Testing and Downstream Care for the Non-Medicare Population
(Note: We understand that the Braidwood decision may affect the preventive services provided under the Affordable Care Act (ACA) but view the landscape under the current implementation of the law.)

The ACA requires coverage of certain essential health benefits and preventive services with no out-of-pocket costs to the patient. These services are guided by U.S. Preventive Services Task Force (USPSTF) recommendations. The USPSTF, however, focuses only on health services for the general population, provided by primary care physicians. If a patient is identified as having an increased risk of a disease such as cancer, their care moves to a specialist; the USPSTF doesn't address or provide guidance on the needs of these patients.

Currently, the USPSTF recommends genetic counseling and *BRCA* genetic testing for *women* with specific personal and/or family cancer history.[1] As a result, BRCA genetic testing for men—and women who are currently being treated for cancer—is not covered under the ACA preventive services. Many health insurers will cover testing for those who meet specific personal and/or family cancer history criteria, but deductibles, coinsurance, and copays apply.

<u>Benefits of Multigene Panel Genetic Testing</u>
Multiple studies demonstrate that compared with multigene panels, testing for BRCA mutations alone misses potentially actionable findings in a substantial proportion of cases.[2,3,4,5,6,7] Testing for a mutation in the BRCA1 and BRCA2 genes gives a very limited picture of potential cancer risk. Patients and their families benefit from multigene panel testing. Knowledge about a mutation—whether classified as moderate- or high-risk—is useful in guiding cancer risk management and preventive measures, providing tremendous health benefits to patients and their families.

<u>Inclusion of Men</u>
Men carry gene mutations associated with increased risk of cancer at the same rate as women and benefit from increased screening for associated cancers. The USPSTF recognizes this stating, "*Clinical practice guidelines recommend that BRCA mutation testing begin with a relative with known BRCA-related cancer, including male relatives, to determine if a clinically significant mutation is detected in the family before testing individuals without cancer*" but it still excludes men from the recommendation.

Men with a BRCA2 mutation are seven times more likely than the average risk population to develop prostate cancer.[8] While BRCA2 is the most common gene mutation found in men with breast cancer, a significant proportion of patients have a mutation in another cancer susceptibility gene, particularly CHEK2, PALB2, and ATM.[9,10] These cancers occur earlier, have a more aggressive phenotype, and are associated with reduced survival times.[11] Men with Lynch syndrome have a 60% to 80% lifetime risk of developing colon cancer, higher than their female counterparts with the same mutation. These numbers are similar to the breast cancer risk in women with BRCA1 mutations.

Men carry cancer-related genetic mutations at the same rate as women and therefore, benefit from genetic testing. Those identified with a mutation can undergo earlier, increased screening for prostate, breast, colon, and other related cancers.[12] Lack of inclusion in USPSTF guidelines presents a barrier to genetic testing for men. This results in a lost opportunity to prevent or detect cancer early when it is most likely to respond to treatment. In addition, it is a lost opportunity to inform biological relatives of male mutation carriers of their increased cancer risk, especially in families with few females.

Coverage of Downstream Care

The USPSTF mentions risk-management interventions for individuals with BRCA genetic mutations but indicates, "*Management of BRCA mutations to reduce risk of future cancer is beyond the scope of this recommendation statement.*" The reasoning is faulty as the USPSTF provides recommendations for cancer screening interventions including mammography, colonoscopy, PSA testing, and more—but the focus is on the average-risk population.

Women and men with inherited cancer-causing mutations are managed with a variety of interventions, including intensive cancer screening at younger ages, chemoprevention, and risk-reducing surgeries. Note that these are not "treatments"—they are PREVENTION. The community needs clear guidelines and recommendations for appropriate screening and preventive modalities for individuals at increased risk of hereditary cancer.

Many health insurers look to Medicare, the USPSTF and ACA to determine which health services are medically necessary for disease prevention. Without coverage, guidelines and letter grades for specific preventive, screening, and risk-management options, many patients struggle to access services such as breast screening MRIs, mammograms before age 40, risk-reducing surgeries, earlier/more frequent colonoscopies, etc.

The current USPSTF recommendation acknowledges that genetic counseling and testing have clinical utility as preventive services. However, the value of genetic testing lies in an individual's ability to access interventions that will lower their risk or detect cancers at an earlier stage. Without a letter grade assigned to the interventions, these preventive services are not covered under the ACA, and may not be covered by health insurers. In many cases, they are "covered" but the cost is applied to the patient's deductible, which results in large out-of-pocket costs.

Interventions include, but are not limited to:

- Breast Screening, such as MRI and Mammography. Research shows that increased breast screening with mammography and breast MRI leads to earlier detection of breast cancer in this cohort.[13,14,15]
- Prostate Cancer Screening. NCCN Guidelines currently recommend that men with BRCA2 mutations start prostate cancer screening at age 45 and men with BRCA1 mutations consider the same.

- Colonoscopy. NCCN guidelines recommend starting colonoscopies at age 20-25 (or 2-5 years prior to the earliest colon cancer in the family) for those with Lynch syndrome.
- Prophylactic Mastectomy. Prospective data shows that bilateral risk-reducing mastectomy lowers the risk for breast cancer in high-risk women.[16]
- Prophylactic Bilateral Salpingo-Oophorectomy and Hysterectomy. Data demonstrates that risk-reducing bilateral salpingo-oophorectomy lowers cancer-specific and overall mortality in BRCA mutation carriers.[17] NCCN guidelines recommend hysterectomy and bilateral salpingo-oophorectomy be offered to women who have completed childbearing and carry MLH1, MSH2, or MSH6 mutations.[18]
- Oral Contraceptives. Research shows that use of oral contraceptives is associated with a lower risk of ovarian and endometrial cancer.[19,20,21]
- Chemoprevention. Evidence supporting the role of chemoprevention agents in reducing the risk of breast cancer in high-risk women has been previously described.[22,23,24]

It's important to note that we have engaged with the USPSTF and HHS in an effort to remedy these gaps, but our efforts have been unsuccessful. The Task Force interprets its mandate very narrowly. In addition, it lacks the expertise and resources to develop guidelines for more complex health risks and conditions. In its current form, the Task Force is ill-equipped to embrace the promise of precision medicine/prevention.

Solution: Develop a Pathway to ensure access to guideline-recommended genetic counseling, testing, and downstream care for people with private/commercial health insurance.
Whether it involves expanding the USPSTF's authority and capacity or another approach, this coverage should be comprehensive—not gender specific—and must include the high-risk/supplemental cancer screenings for individuals at increased risk of cancer. Ensuring access to these services with minimal or no cost-sharing is crucial to facilitate patient uptake. The fact that cancer screenings for patients at "average risk" are covered with no cost, but patients at increased risk often fight for coverage and incur large out-of-pocket expenses is senseless.

Other Gaps and Considerations:

<u>Coverage Parity for Diagnostic Imaging and Tests</u>
Follow-up imaging and diagnostic tests are recommended for patients with an irregularity in their cancer screening and/or signs and symptoms of the disease. Many individuals delay these important tests because they cannot afford the associated costs. These interventions are an extension of preventive care and should be treated as such. If a polyp is found and removed during a colonoscopy or a mammogram shows something suspicious and an MRI is indicated, this should be covered with no cost-sharing (like a screening).

<u>Reimbursement for Prevention-Focused Patient Navigation</u>
With the growing utilization of genetics and genomics in disease prevention and treatment, healthcare is becoming more complex. The services of specialists such as genetic counselors and nurse navigators are needed more than ever before. For instance, patients with an inherited PTEN mutation have an increased risk of several cancers including breast, colorectal, endometrial, kidney, thyroid, and melanoma. Ultimately, these patients must undergo numerous cancer screenings and seek out a variety of specialists including a breast surgeon or breast oncologist, gynecologic oncologist, urologist, dermatologist, and endocrinologist. It's a lot to coordinate—and many primary care physicians lack the time, knowledge, and expertise to guide patients with disease-related genetic mutations.

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As such, there is an increasing need for patient navigation focused on cancer/disease prevention for patients at increased risk. Coverage of navigation for patients diagnosed with cancer is on the rise but reimbursement for navigators who provide care coordination, guidance on the recommended screenings and risk management, financial navigation, etc. will be beneficial to patients and providers alike.

Eliminate/Limit Potential Genetic Discrimination

The Genetic Information Nondiscrimination Act (GINA) prohibits genetic discrimination by health insurance plans and employers. However, this federal law does not apply to life, long-term care, or disability insurance. These insurers can use knowledge of a genetic mutation to make coverage and premium decisions. We have numerous stories of individuals being denied policies or charged significantly higher rates for these types of insurance based on their genetic risk of a disease—not a diagnosis of the disease. Recently, we've learned of individuals whose policies were canceled after the insurer learned about their inherited genetic mutation.

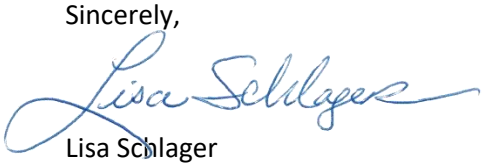
This situation deters many Americans from undergoing medically appropriate genetic testing. Some states have laws stipulating that life, long-term care, and disability insurers cannot require an individual to undergo genetic testing. If an individual wishes to purchase anything beyond a small policy, however, insurers request access to the applicant's medical records. Information about a genetic mutation or hereditary risk of a disease such as cancer is typically in a person's medical chart to justify coverage of the associated care. This is all the insurer needs to unfavorably adjust its policy decision or rate. To truly realize the promise of genetics and genomics in healthcare, this practice needs to be banned

In summary, CURES 2.0 has made a positive impact in numerous areas but there's more work to be done. We must ensure that current genetic and genomic technologies are accessible to patients. Genetic testing for hereditary cancer risk is not new, but antiquated policies are hindering access and limiting potential benefits. Individuals and families with hereditary cancer risk are poster children for prevention and early detection.

Genetic counseling and testing, followed by appropriate screening and risk-reducing interventions will reduce the unequal burden of cancer these families face. Access to guideline-recommended care can also improve survival by finding cancer at an early stage when treatment is more effective and less costly. We have the ability to provide hope to families impacted by hereditary cancers. Affordable access to appropriate care will help these patients more effectively prevent, detect, treat, and survive cancer. And ultimately, it will save lives and healthcare dollars.

Thank you for your time and consideration of these comments. We look forward to working with you.

Sincerely,



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