FORCE’s Mission is: To improve the lives of individuals and families affected by hereditary breast, ovarian, and related cancers.
The hereditary cancer community shoulders a disproportionate cancer burden. It is crucial that our community has a voice in policies which impact us, our families, and our access to care.
Challenges

Over 2 million Americans are at increased risk of HBOC due to a hereditary predisposition. We face:

- Significantly elevated lifetime risk of cancer
- Diagnoses at younger ages
- More aggressive disease
- Increased risk of 2\textsuperscript{nd} and 3\textsuperscript{rd} diagnoses
- Multiple family members affected
- Lack of understanding, clear guidelines or policies on management of high risk patients, leading to health insurance coverage/reimbursement challenges
Challenges

- Higher out-of-pocket health care costs due to:
  - Earlier, more intensive cancer screening
  - Surgery and/or treatment
  - Associated loss of income, childcare costs, etc. due to earlier start of screening and preventive services and younger ages at diagnosis
Challenges

- Long-term quality of life issues due to young-onset cancer diagnosis, treatment, and/or early menopause, including:
  - Infertility
  - Osteoporosis
  - Cardiac disease
  - Quality of life issues
- Concerns about genetic privacy and discrimination
- Psycho-social distress due to the familial and health implications
Patient Protection and Affordable Care Act (ACA)

- Access to health insurance for all Americans
- Elimination of pre-existing conditions as barrier to coverage
- Coverage for screening and preventative services without copay or deductible
- Coverage of young adults up to the age of 26 on parent’s plan
- Abolishment of annual and lifetime caps
- Capping out-of-pocket healthcare expenditures
- Coverage for those enrolled in clinical trials
### ACA, USPSTF & Prevention for High-Risk Women

#### Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer in Women

**Clinical Summary of U.S. Preventive Services Task Force Recommendation**

<table>
<thead>
<tr>
<th>Population</th>
<th>Asymptomatic women who have not been diagnosed with BRCA-related cancer</th>
<th>Do not routinely recommend genetic counseling or BRCA testing to women whose family history is not associated with an increased risk for potentially harmful BRCA mutations.</th>
<th>Grade: B</th>
<th>Grade: D</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendation</strong></td>
<td>Screen women whose family history may be associated with an increased risk for potentially harmful BRCA mutations. Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing.</td>
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<tr>
<td><strong>Treatment</strong></td>
<td>Interventions in women who are BRCA mutation carriers include earlier, more frequent, or intensive cancer screening, risk-reducing medications (e.g., tamoxifen or raloxifene); and risk-reducing surgery (e.g., mastectomy or salpingo-oophorectomy).</td>
<td></td>
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</tr>
</tbody>
</table>
ACA, USPSTF & Prevention for High-Risk Women

Reliance on USPSTF to guide insurance coverage of preventive services has pros and cons

Example

- USPSTF failed to assign letter grades to most of the expert-recommended interventions for high-risk women
  - Mammograms (before age 40)
  - Breast screening MRI
  - Prophylactic salpingo-oophorectomy
  - Risk-reducing mastectomy
Current Gaps in Coverage

USPSTF Guidelines Do Not Address

- Increased screening and preventive options for high-risk women (other than chemoprevention for certain women)
- Cancer survivors in treatment
- Genetic counseling and testing for Lynch and other hereditary cancer syndromes - single gene or multigene panel
- Second genetic test for women who previously tested negative
- Genetic testing for men

*Some health plans use lack of USPSTF letter grade A/B as justification to exclude or deny ANY coverage for these services*
Consequences of these Gaps

Some people at high-risk of inherited cancer are...

- Deprived of the opportunity to receive genetic counseling with a certified genetic counselor
- Unable to access genetic testing and important risk information
- Denied coverage of evidence-based preventive services, i.e. screening mammograms, breast MRIs, chemoprevention, and surgery
- Faced with substantial out-of-pocket expenses year after year
Consequences of these Gaps

This puts them at risk for...

- Financial toxicity
- Foregoing standard-of-care prevention and detection due to financial constraints
- Need for more treatment due to more advanced cancer at diagnosis
- Impact on relatives who may also be at similar risk
Hereditary Cancer Landscape

Annual Screening Mammograms

- USPSTF Breast Cancer Screening Guidelines
  - Stop the Guidelines Campaign
  - PALS Act
- Women ages 40-49 continue to have access to annual mammogram screenings with no cost-sharing
- Waiting until age 50 to start screening mammograms could lead to more aggressive cancers being missed, more treatment, and premature death
Hereditary Cancer Landscape

Breast Density

- 50% of women have increased density
- Notification laws
  - Inform women who have undergone mammography about the risks posed by breast density
  - Only 4 states have laws requiring insurance coverage for additional imaging for women with dense breasts
Hereditary Cancer Landscape

3D Mammograms (Tomosynthesis)

- Expands legal definition of breast cancer screening mammogram to include tomosynthesis
- Guarantees health insurance coverage
Hereditary Cancer Landscape

Medicare covers

- BRCA testing for people who have had breast or ovarian cancer
- BRCA testing for people who have pancreatic cancer (some regions)
- BRCA testing for men with breast cancer (some regions)
- Multigene panel testing (some regions)
Hereditary Cancer Landscape

Medicare Expansion

- Medicare recipients in 19 States have expanded access to genetic testing
  - Expanded coverage of BRCA testing to include those affected by prostate and pancreatic cancer
  - Coverage of multigene test panel if indicated
  - Clarification of BRCA testing policy for use of Lynparza (Olaparib)
Hereditary Cancer Landscape

Medicare doesn’t cover

- BRCA counseling and testing for people who haven’t had cancer (unaffected carriers)
- Prophylactic surgery for unaffected carriers (however some have been able to get coverage)
- Genetic counseling with a certified genetic counselor
Hereditary Cancer Landscape

Medicaid

- Coverage of BRCA genetic counseling, testing, screening and risk management services varies by state
  - Current information indicates about 75% of states cover BRCA counseling and testing
  - Data on coverage of related services such as breast MRI or preventive surgeries is difficult to find
Oral Chemotherapy Parity

- Working to ensure that patients have equality of access (and equality of insurance coverage) to all approved anticancer regimens

“A patient’s out of pocket costs related to coverage for orally administered chemotherapy shall be on a basis no less favorable than current coverage provided for intravenously administered or injected chemotherapy under the policy.”

Hereditary Cancer Landscape
Hereditary Cancer Landscape

PSA Testing

- USPSTF guidelines give a grade “C” to the use of prostate-specific antigen (PSA) testing to screen for prostate cancer
- High-risk men benefited when the USPSTF modified its recommendation to clarify that BRCA+ Men should not be precluded from PSA testing

“This recommendation also does not include ... SA-based testing in men with known BRCA gene mutations who may be at increased risk for prostate cancer.”
Recent Accomplishments

- Successfully advocated for a 2-year extension of the medical expense deduction at 7.5% of one's adjusted gross income (2017 and 2018 tax years)
- Worked to preserve mammograms with no out-of-pocket costs for women ages 40-49 for another year—until January 1, 2020
- Supported passage of oral parity laws in 43 states
Recent Accomplishments

- Collaborated in successful challenge of EEOC regulations allowing employers to impose penalties on employees who do not participate in wellness programs
- Facilitated health insurance appeals and coverage of screening and preventive services for numerous members of the high-risk community
- Increased or sustained medical research funding (NIH and DoD CDMRP)
- Expanded of genetic testing in 4 Medicare regions, covering 19 states
Public Policy Efforts… looking ahead

- Supporting legislation to continue mammograms with no out-of-pocket costs for women ages 40-49 indefinitely
- Working to make 7.5% medical expense deduction threshold permanent
- Engaging in efforts to pass state and federal legislation ensuring equal access to anticancer treatments, regardless of how they are administered
Public Policy Efforts... looking ahead

- Spearheading legislation to facilitate Medicare coverage of screening and preventive services for previvors
- Driving establishment of fertility preservation assistance fund for previvors
- Collaborating in efforts to require insurance coverage of fertility treatments for previvors and survivors
Fertility Preservation & Treatments

Coverage Varies by State

- 16 states have infertility insurance coverage laws
- 4 states have laws for medically-induced infertility

Exemptions may include:

- Religious employers
- Employers with fewer than 50 employees
- Employers who self-insure
- Storage of sperm or oocytes
- Experimental infertility procedures
- Surrogacy
Public Policy Efforts... looking ahead

- National guidelines around cancer screening (PSA testing, genetic testing, mammograms, etc.)
- Medicare & Medicaid coverage of broader cancer genetic services for high-risk individuals
- Coverage of screening and preventive interventions for those with private/group health insurance
- Equity in insurance coverage of cancer treatments (IV vs. oral, injections, etc.)
- Preservation of pre-existing condition protections
Public Policy Efforts... looking ahead

- Maintenance of key ACA components
- Federal regulation of genetic and genomic testing
- Direct-to-Consumer genetic testing
- Breast density notifications laws
- 3D mammography/tomosynthesis coverage

- Essential health benefits and pre-existing conditions
- International data sharing initiatives
- Genetic protections and privacy
Patient Advocate Leaders (PALs)

- San Francisco, CA: Previvor
- Phoenix, AZ: Colon & Kidney Cancer
- Boulder, CO: Ovarian Cancer
- Houston, TX: Previvor
- Minneapolis, MN: Breast Cancer
- Chicago, IL: Previvor
- Pittsburgh, PA: Previvor
- NJ (central): Previvor
- DC area: Previvor
- DC area: Previvor
- DC area: Previvor
- Tampa, FL: Previvor
- Orlando, FL: Breast & Ovarian Cancer
Patient Advocate Leaders

- Grow and expand our advocacy efforts
  - Harness the power of patient advocates
  - Mobilize members of the hereditary cancer community
    - Stronger, more strategic role in driving state and national policies
    - Represent the distinct needs of those affected by hereditary cancer—women, men, survivors, previvors, young and old
  - More comprehensive program & capacity
Website

FORCE advocates for families facing hereditary breast and ovarian cancer in areas such as access to care, research funding, insurance, and privacy.

Advocacy

FORCE is the leader in hereditary cancer advocacy. FORCE ensures that the unique needs of the cancer community—women, men, survivors, providers, family members and more—are represented in national and state legislative and regulatory arenas. This section highlights some of the many ways we address on behalf of our constituents.

Advocacy

- What is Advocacy
- Advocacy Accomplishments
- Advocacy Issues
- Advocacy Resources

- Check out current and past advocacy issues FORCE has addressed in areas including cancer screening & prevention, insurance coverage & barriers, genetic privacy and more.

Current Issues

Two Legal Challenges Take Forefront in Health Care Debate

Congress was on recess during the month of August, but the legal jockeying around health care reform has continued. On August 2, a coalition of cities filed a federal lawsuit against the President and high-ranking officials at the Department of Health and Human Services (HHS), alleging that the Administration has “intentionally and unconstitutionally” sabotaged the Affordable Care Act (ACA).

Read More
**Website**

**Newsflash**

9/26/2018
FORCE joined nearly 100 patient advocacy orgs in expressing concern about allowing Medicare Advantage plans to use step therapy. Read letter...

9/13/2018
We joined in a letter encouraging the House Ways and Means Committee to make the 7.5% medical expense deduction permanent.

9/7/2018
We sent a letter to Senator Collins (R-ME) seeking her leadership on national oral parity legislation.

9/5/2018
FORCE signed on to a coalition letter urging the Senate to maintain the allowed medical expense deduction at 7.5% of one’s adjusted gross income.

7/25/2018
This week, the House of Representatives passed the Palliative Care and Hospice Education and Training Act to improve health professional training in palliative care. Read Bill...

**Federal “Right to Try” Legislation Passes, Signed by President**

May 30, 2018 - Federal right-to-try legislation aimed at loosening oversight of access to unapproved drugs for “compassionate use” was signed by President Trump today. The law allows patients with cancer or other serious illnesses to circumvent the Food and Drug Administration (FDA) when requesting access to experimental therapies not yet approved for public use. Congress passed the final right-to-try bill on May 22 after months of negotiation and changes to the legislation.

Read More

**FORCE Leads the Charge for Medicaid Coverage of Genetic Testing**

Genetic testing for increased risk of breast, ovarian, and other cancers has become standard-of-care for prevention and risk management. Medicaid coverage of health services, however, is managed independently by each state. Only 4 Medicaid programs do not cover genetic counseling and/or testing for inherited BRCA genetic mutations. FORCE wrote comments and secured the support of over 30 partner organizations to encourage NC Medicaid to offer this service to its enrollees.

Read More

**Medicare Establishes National Policy for Coverage of Tumor Testing**

The Centers for Medicare and Medicaid Services (CMS) recently finalized a National Coverage Determination (NCD) to provide Medicare beneficiaries with coverage of FDA-approved or -cleared tests that help identify the best treatment options for an individual’s disease. These tests, also known as companion diagnostics, examine a person’s tumor or blood to determine which targeted medications may be most effective for treating their cancer. The new policy applies only to patients with advanced cancer.

Read More

**FDA Approves New Direct-to-Consumer Genetic Test for 3 BRCA Mutations**

On March 6, 2018, the Food and Drug Administration (FDA) announced approval of a new direct-to-consumer genetic test for three BRCA mutations most commonly found in people with Ashkenazi Jewish (Eastern European) ancestry, often referred to as founder mutations. With thousands of known BRCA1 and BRCA2 mutations, 23andMe’s “Personal Genome Service Genetic Health Risk (GHR) Report for BRCA1/BRCA2 (Selected Variants)” provides consumers with an extremely limited snapshot of potential hereditary cancer risk.

Read More
Blogs

FORCE Blog
This blog will cover topics of interest that affect our community. Unless otherwise stated, the blog articles will be written by Sue Friedman, Executive Director of FORCE.

Hereditary Cancer Info > Hereditary Cancer > FORCE Blog

Insurance Coverage for Clinical Trial Participation: Significant Barriers Remain

September 28, 2018
by Lisa Schlager
Note: Adapted from an article in the October 2018 issue of The Oncology Nurse. In 2010, FORCE spearheaded passage of a Congressional resolution declaring the first-ever National Hereditary Breast and Ovarian Cancer Week and National Previvor Day. This year, Previvor Day is October 3rd. Over the past 8 years, the number of people ...

Patients Weigh In On Review of PARP Inhibitors for Treatment of Ovarian Cancer

October 12, 2017
by Jill Holdren
Last month on the FORCE Blog, Lisa Schlager wrote about the importance of understanding the clinical effectiveness and value of PARP inhibitors. She wrote...

Addressing Previvors' Needs for Affordable Access to Care

September 28, 2018
by Lisa Schlager
(Note: Adapted from an article in the September 2018 issue of The Oncology Nurse. In 2010, FORCE spearheaded passage of a Congressional resolution declaring the first-ever National Hereditary Breast and Ovarian Cancer Week and National Previvor Day. This year, Previvor Day is October 3rd. Over the past 8 years, the number of people...

+ read more
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