Genetic Testing for Hereditary Cancer Mutations

Coverage and Reimbursement Policy

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Hereditary Cancer Genetic Testing

Limited Gene Testing

BRCA

BRCA1

BRCA2

Lynch Syndrome

EPCAM

MLH1

MSH2

MSH6

PMS2

Multigene Panel Testing

ATM

BARD1

BRCA1

BRCA2

BRIP1

CDH1

CHEK2

EPCAM

MLH1

MSH2

MSH6

NBN

PALB2

PMS2

PTEN

RAD50

RAD51C

RAD51D

STK11

TP53

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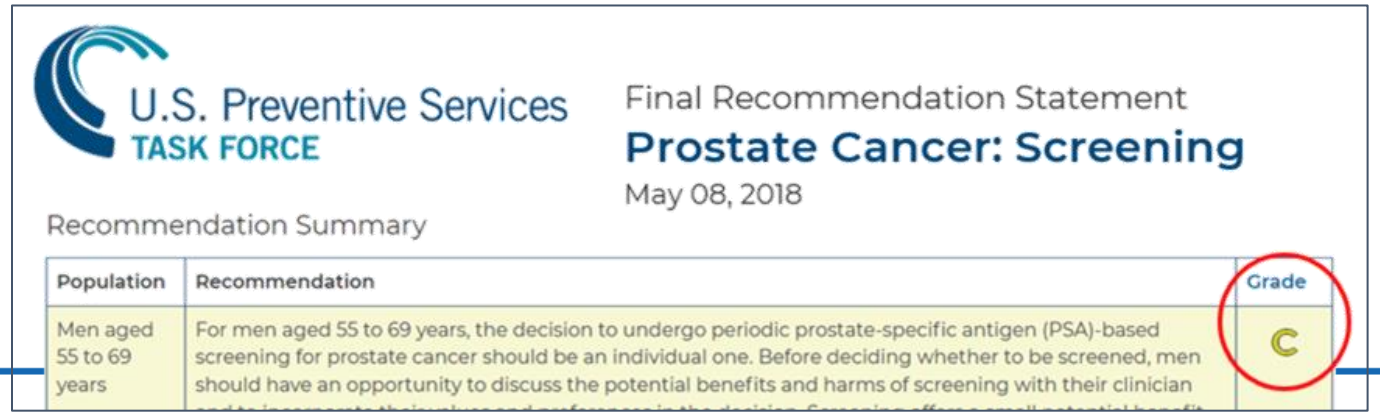
Cancers Linked to Inherited Mutations

Cancer	Genes
Breast cancer in women	ATM, BARD1, BRCA1, BRCA2, BRIP1, CHEK2, CDH1, NF1, NBN, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53
Breast cancer in men	BRCA1, BRCA2, CHEK2, PALB2
Colorectal cancer	EPCAM, MLH1, MSH2, MSH6, PMS2, CHEK2, PTEN, STK11, TP53, MUTYH
Endometrial cancer	EPCAM, MLH1, MSH2, MSH6, PMS2, PTEN, STK11
Fallopian tube, ovarian, primary peritoneal cancer	ATM, BRCA1, BRCA2, BRIP1, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, RAD51C, RAD51D, STK11
Gastric cancer	CDH1, STK11, EPCAM, MLH1, MSH2, MSH6, PMS2
Melanoma	BAP1, BRCA2, CDK4, CDKN2A, PTEN, TP53
Pancreatic cancer	ATM, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, STK11, TP53
Prostate cancer	ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13,MLH1, MSH2, MSH6, PALB2, PMS2

Affordable Care Act

Preventive services receiving a Grade “A” or “B” from the U.S. Preventive Services Task Force are covered at 100%, with no out-of-pocket costs.

Coverage of preventive services with USPSTF Grade “C” or below, or services without a letter grade is variable. If covered, these screening and preventive services are subject to copays, deductibles and coinsurance.



U.S. Preventive Services TASK FORCE

Final Recommendation Statement

Prostate Cancer: Screening

May 08, 2018

Recommendation Summary

Population	Recommendation	Grade
Men aged 55 to 69 years	For men aged 55 to 69 years, the decision to undergo periodic prostate-specific antigen (PSA)-based screening for prostate cancer should be an individual one. Before deciding whether to be screened, men should have an opportunity to discuss the potential benefits and harms of screening with their clinician	C

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Affordable Care Act

Coverage of *specific* screening and preventative services without copay or deductible:

- Genetic counseling and BRCA testing for **women** with specific personal and/or family cancer history

Currently being developed:

Recommendations for identification of those with a Lynch syndrome mutation

Coverage at 100% applies to in-network healthcare providers only.
Services provided by out-of-network providers could result in out-of-pocket costs.

Gaps Created by USPSTF

USPSTF guidelines do not address genetic counseling and/or testing for:

- Cancer survivors in treatment
- Men (previvors and survivors)
- Lynch syndrome and other hereditary cancer genes - single gene or multigene panel
- Second test for individuals who previously tested negative

Some health plans use lack of USPSTF letter grade A/B as justification to exclude or deny coverage for these services. Others apply the cost to an individual's deductible.

Private/Commercial/Group Health Plans

Majority Cover Genetic Testing for:

- BRCA testing for women (required under ACA)
- Lynch, multigene testing or testing for other mutations is optional but coverage has grown in recent years
- Willingness to test men has increased with links to prostate, pancreatic, colon and other cancers

Note: Some insurers require genetic counseling prior to testing

Coverage at 100% applies to BRCA testing for women not currently in treatment.
Testing for other mutations and testing for men may result in out-of-pocket costs.

Medicaid

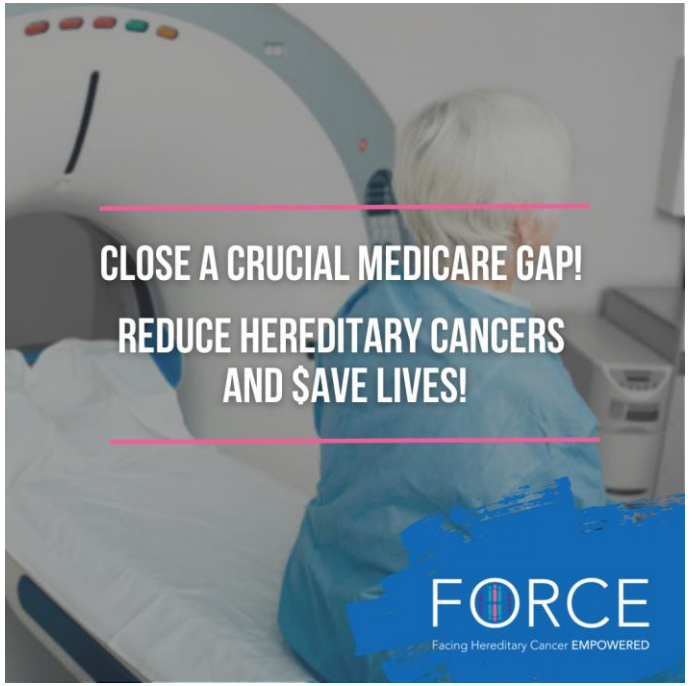
- All state Medicaid programs except Alabama cover BRCA genetic testing (some don't cover counseling)
- About 40 states cover Lynch syndrome testing
  - Related downstream services (i.e. increased screening and risk management interventions) varies by state
    - Data on coverage of services such as breast MRI or preventive surgeries is difficult to find

Medicare

Limited coverage of genetic testing for inherited mutations associated with increased cancer risk

- Medicare covers germline genetic testing only for beneficiaries *already diagnosed with cancer*, regardless of family cancer history or a known genetic mutation in the family.
- If an individual carries a mutation associated with increased cancer risk, coverage of the medically necessary high-risk cancer screenings or risk-reducing interventions is statutorily prohibited.

Reducing Hereditary Cancer Act H.R. 1526 / S. 765



Aims to modify the Medicare statutes to enable coverage of:

- Genetic testing for inherited mutations associated with increased cancer risk for beneficiaries with a:
  - Known hereditary cancer gene mutation in their family, or a
  - Personal or family history suspicious for hereditary cancer

For beneficiaries who carry a hereditary cancer mutation, the law would enable coverage of guideline-recommended:

- Increased cancer screening (e.g. breast MRI, pancreatic screenings)
- Risk-reducing surgery (e.g. removal of ovaries and fallopian tubes)

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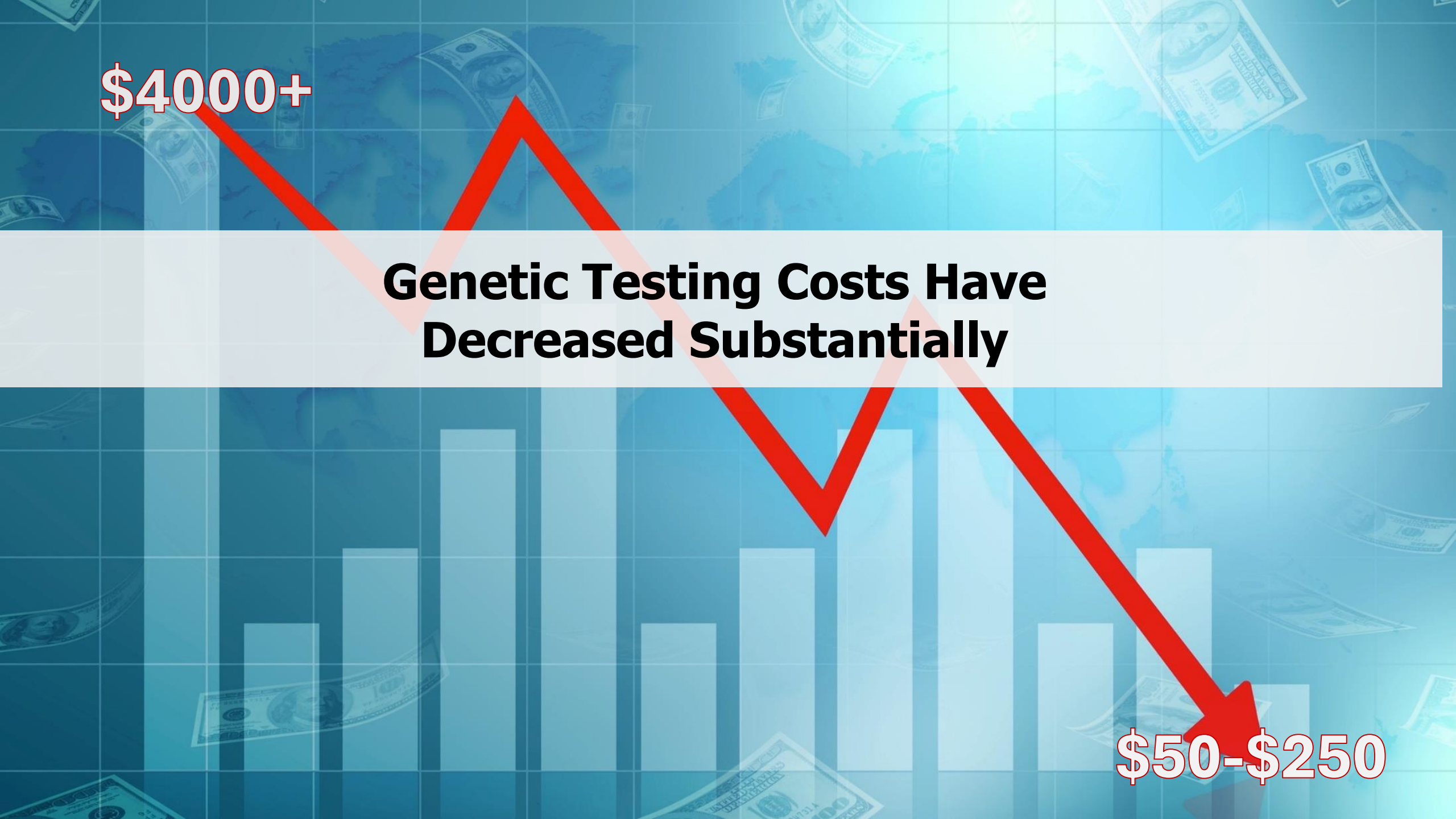

$4000+
Genetic Testing Costs Have Decreased Substantially
$50-$250

Current Federal Legislative Efforts

- **Access to Genetic Counselor Services Act** - would make genetic counselors approved Medicare providers, enabling them to be directly reimbursed for their services
- **PSA Screening for HIM Act** - would eliminate prostate cancer screening cost-sharing for those at higher risk starting at age 40, including African American men and those with a family history or genetic predisposition
- **Find it Early Act** - would require that most health plans, including Medicaid, Medicare, Tricare and the VA cover ACR- or NCCN-recommended screening and diagnostic mammograms as well as screening and diagnostic breast MRIs and ultrasounds at no cost to the patient
- **Access to Breast Cancer Diagnosis Act** (ABCD) - would require that private health plans cover diagnostic and NCCN-recommended high-risk breast imaging (MRIs and ultrasounds) with no patient cost-sharing

2023 State Legislative Successes

Delaware, Maryland & Nebraska

- Passed legislation to eliminate cost-sharing for high-risk “supplemental” breast screenings and diagnostic examinations. Laws take effect January 1, 2024.

Pennsylvania

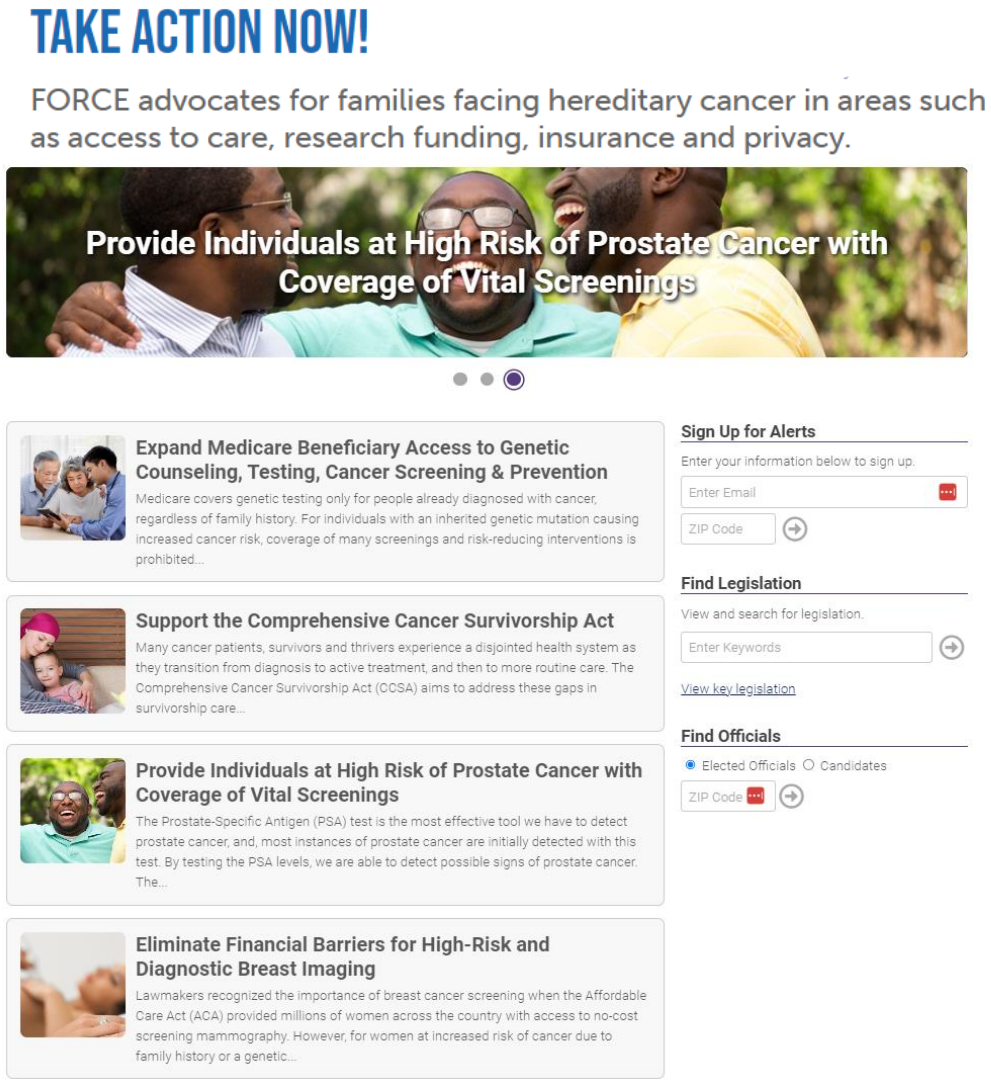
- Passed legislation providing enhanced insurance coverage of genetic counseling and BRCA testing, and one high-risk breast cancer screening per year with no cost-sharing. Law takes effect July 1, 2023.

Texas

- Passed legislation that enhances coverage of certain fertility preservation services. Goes into effect September 1, 2023. An amendment raised questions about coverage for previvors; we will be watching to see how the law is implemented.

FORCE Advocacy Action Center

www.facingourrisk.org/privacy-policy-legal/advocacy-take-action



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Genetic Privacy & Protections

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Affordable Care Act

- Access to health insurance for all Americans
- Elimination of pre-existing conditions as a 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

HIPAA provides additional protections

GINA

Genetic Information Nondiscrimination Act

- Prohibits health insurers and employers from discrimination based on an individual's genetic information or status

  "Genetic information" is defined as:
  - Patient's genetic test results
  - Patient's relatives' genetic test results (up to and including fourth-degree relatives), and/or
  - Information about family history of any disease or disorder

  Information about participation in research that includes genetic testing, counseling, or education is also protected.

Some states have implemented stronger laws (e.g. Florida)

**Does not apply to Life, Disability or Long-Term Care Insurance*

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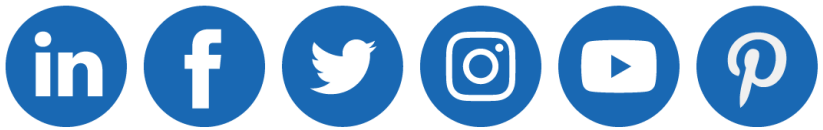

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