

CARE Program

COMPREHENSIVE ASSESSMENT, RISK & EDUCATION

Frequently Asked Questions

1. Why is an imaging center/radiologist offering breast cancer risk assessment and genetic testing?

Per recommendations from the American Cancer Society (ACS), American College of Obstetrics and Gynecology (ACOG), National Comprehensive Cancer Network (NCCN), and others, patients who are at increased risk for breast cancer may be candidates for earlier, more frequent, or additional types of breast cancer screening or may need to consider preventive surgical options. As breast health experts in the community, radiologists at our imaging centers are well positioned to assess patients' risk in order to make personalized imaging recommendations.

2. How are "high risk" patients identified?

Your patients will be asked to complete a questionnaire about their personal and family history. This information will be used to run various breast cancer risk models (such as Tyrer-Cuzick), which will calculate your patient's lifetime risk for breast cancer.

3. If my patient is deemed "high risk", how will this impact their care?

Identifying patients at increased risk for certain cancers based on clinical or family history risk factors can enable healthcare providers to make personalized medical management recommendations regarding earlier, more frequent or different types of cancer screening, as well as available preventive surgical options. For example, per the American College of Radiology, women with >20% lifetime risk for breast cancer should be referred for breast MRI.

4. Are there any professional society recommendations or other guidelines available related to genetic testing for hereditary cancer?

There are numerous professional society guidelines indicating that genetic testing for hereditary cancer is an important part of medical care. Here are a few:

ACOG Position Statement Recommendations: A hereditary cancer risk assessment is the key to identifying patients and families who may be at increased risk of developing certain types of cancer. This assessment should be performed by an ObGYN or other ObGYN providers, and should be updated regularly.

American Society of Breast Surgeons (ASBrS): Breast surgeons, genetic counselors, and other medical professionals knowledgeable in genetic testing can provide patient education and counseling and make recommendations to their patients regarding genetic testing and arrange testing. When the patient's history and/or test results are complex, referral to a certified genetic counselor or genetics professional may be useful. (Adapted from ASBrS Consensus Guideline, February 2019)

5. How will genetic testing results impact my patient's care?

For patients who receive a positive genetic test result, recommendations for personalized medical management, including increased cancer screening and sometimes prevention options, may be available. These recommendations vary greatly because there are distinct differences in cancer risks associated with each gene. The vast majority of genes tested have associated medical management guidelines that will guide recommendations for screening and/or preventive surgery. Additionally, closely related family members can be offered testing to learn more about their lifetime risks for certain cancers, so that they can also benefit from personalized medical management.

6. Which patients will receive genetic testing?

Your patient's personal and family history of cancer will be evaluated to determine if they are eligible for hereditary cancer genetic testing. Our program uses National Comprehensive Cancer Network (NCCN) genetic testing criteria, which outline various factors that may indicate a need for genetic testing, such as type of cancer, age of diagnosis, and number of family members with cancer. Any patient who meets these criteria will be offered genetic testing.

7. Who will manage my patient if they are identified to have a genetic risk?

Genetic test results and clear next steps regarding medical management recommendations will be sent to the referring physician, so that he/she is well-equipped to manage the patient's care moving forward. Additionally, genetic counseling will be made available as part of the CARE program.

8. Will genetic counseling be provided?

As part of the CARE program, participating patients will watch a pre-test genetics education video to learn about the basics of hereditary cancer and genetic testing, before deciding to proceed. Following the receipt of genetic testing results, post-test genetic counseling will be made available via a 3rd party organization for patients with a positive or variant of unknown significance (VUS) result. There is no cost to these patients for post-test genetic counseling.

9. What will be the cost to my patient for genetic testing?

Through the CARE program, eligible patients will receive genetic testing through Ambry Genetics. Due to Ambry's extensive contracts with commercial payers (covering 95% of insured lives), testing is affordable and accessible for the majority of patients. Four out of five patients pay \$0 and for those who do pay, they pay on average less than \$100. For additional questions on billing, please contact Ambry at 949.900.5500 or billing@ambrygen.com.

10. What if my patient is concerned about insurance discrimination?

In the U.S., the Genetic Information Nondiscrimination Act (2008) prohibits discrimination by health insurance companies and employers, based on genetic information. Visit ginahelp.org to learn more.

11. What is the difference between clinical genetic testing and at-home direct-to-consumer (DTC) testing?

DTC Testing	Clinical Testing
Basic Technology: SNP array	Advanced Technology: Full gene sequencing and deletion/duplication analysis
Not a comprehensive risk assessment: may not include all genes associated with a disease and may not test for all possible mutations within a gene	Comprehensive assessment for one or more diseases: likely to include all known genes associated with the target disease and includes a comprehensive analysis for all possible mutations
Results not intended for medical use	Results are intended for medical use with guidance of a healthcare professional