Myriad Genetics Financial Assistance Program (MFAP) for Uninsured Patients

Medical Criteria

The Myriad Financial Assistance Program offers aid to patients who meet specific financial and medical requirements. In addition to the medical criteria outlined in this document, patients must meet the financial requirements and complete an application located at https://myriad.com/about-myriad/myriad-cares/financial-assistance-program.

Hereditary cancer products

MyRisk™ Hereditary Cancer

MyRisk™ Hereditary Cancer (a multi-gene diagnostic test to assess hereditary cancer risk), is covered for patients who meet financial criteria for the MFAP program and any of the following society guidelines testing criteria:

National Comprehensive Cancer Network

- Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic https://www.nccn.org/guidelines/category_2
- Genetic/Familial High-Risk Assessment: Colorectal https://www.nccn.org/guidelines/category_2

U.S. Preventive Services Task Force (USPSTF) BRCA-Related Cancer Recommendation Statement

- https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing

American Society of Breast Surgeons Consensus Guideline on Genetic Testing for Hereditary Breast Cancer

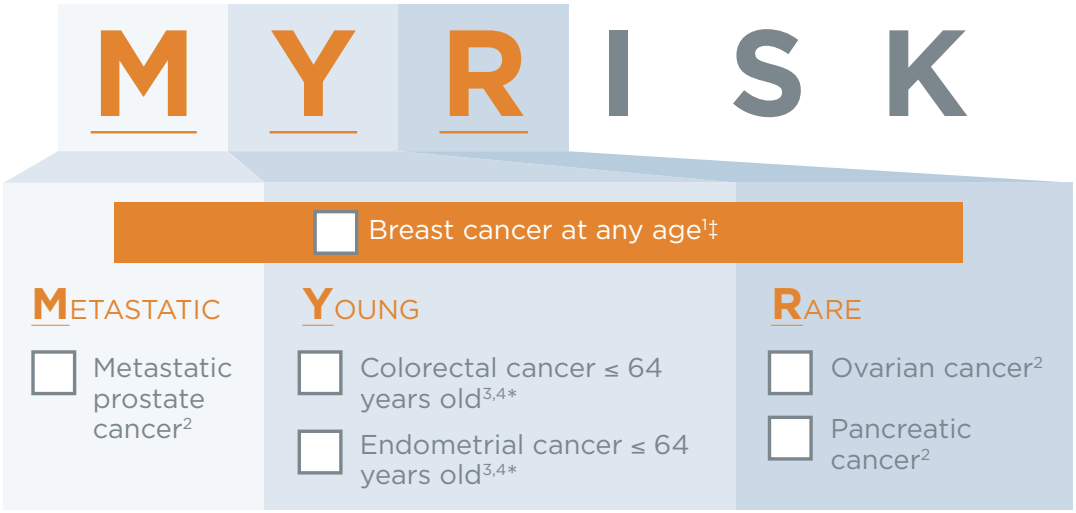
- https://www.breastsurgeons.org/docs/statements/Consensus-Guideline-on-Genetic-Testing-for-Hereditary-Breast-Cancer.pdf

Note: Our automated criteria review process will identify most patients who meet the above criteria. If you have questions about a specific patient's eligibility, please contact Medical Services at 800-469-7423 ext. 3850 for an individualized review.

Note: If single-syndrome testing is preferred, Integrated BRAC*Analysis*®, COLARIS®PLUS, or COLARIS *AP*®PLUS may be ordered and the patient must meet either the NCCN Genetic/Familial High-Risk Assessment criteria for Colorectal, Breast, Ovarian, or Pancreatic.

For patients with a personal history of cancer, eligibility would include (but is not limited to) the following. For additional qualifying histories, please refer to the guidelines referenced above.

These cancers meet genetic testing criteria



‡Some exceptions apply (e.g. government payers). For patients with Medicare who are currently or may become eligible for treatment with a PARP inhibitor, BRACAnalysis CDx with myRisk is available.

*Newly diagnosed men with colorectal cancer ≤64 and women with colorectal cancer ≤52 or endometrial ≤64 years old, meet genetic testing criteria based on $PREMM_5$

MyRisk™
Hereditary Cancer Test

For unaffected patients or those not meeting the above affected criteria, eligibility would include (but is not limited to) a family history of the following. For additional qualifying histories, please refer to the guidelines referenced above.

First or second degree relative(s) with any of the following:

- Breast cancer at 49 or younger
- Two primary breast cancers diagnosed at any age
- Ovarian cancer at any age
- A male relative with breast cancer at any age
- A relative of Ashkenazi Jewish ancestry with breast cancer at any age
- Three 1st or 2nd degree relatives on the same side of the family with a Lynch syndrome related cancer
- Any combination of family history that leads to a ≥ 2.5% risk of Lynch syndrome using the PREMM5 mutation prediction model**
- Any relative with a known mutation in any gene tested for by the MyRisk hereditary cancer panel

First degree relative with any of the following:

- Pancreatic cancer at any age
- Metastatic prostate cancer
- Colorectal cancer at 49 or younger
- Endometrial cancer at 49 or younger

For the purposes of these criteria, the following apply:

- Breast cancer includes DCIS and invasive carcinoma
- Ovarian cancer includes peritoneal and fallopian tube cancers
- Pancreatic cancer refers to exocrine cancers of the pancreas
- Relatives must be "blood relatives" and when more than one relative is required, all must be on the same side of the family
- Prostate cancer should be metastatic or have a Gleason score >7

****The risk model calculation should be completed by the healthcare provider and included on the test request form at the time of sample submission. The PREMM5 model can be accessed at https://premm.dfci.harvard.edu/.**

Lynch syndrome cancers/tumors include the following:

- colorectal
- endometrial/uterus
- ovarian
- small intestine/bowel
- gastric/stomach
- urinary tract
- sebaceous adenoma/sebaceous carcinomas
- brain tumor
- pancreas (adenocarcinoma)
- biliary tract
- Relatives must be "blood relatives" and when more than one relative is required, all must be on the same side of the family.

Prognostic products

Prolaris® testing covered when:

Patient has a personal diagnosis of:

- prostate cancer

EndoPredict® testing covered when:

Patient has a personal diagnosis of:

- ER+/HER2–, early-stage breast cancer

Companion diagnostic products

BRACAnalysis CDx® testing is covered when:

Patient has a personal diagnosis of:

- Ovarian cancer and is being considered for Lynparza® (olaparib) or Zejula® (niraparib) therapy
- Breast cancer and is or may become eligible for treatment with Lynparza® (olaparib)
- Pancreatic cancer who is or may become eligible for treatment with Lynparza® (olaparib)
- Prostate cancer who is or may become eligible for treatment with Lynparza® (olaparib)

Myriad MyChoice® CDx testing is covered when:

Patient has a personal diagnosis of:

- Ovarian, fallopian tube, or primary peritoneal cancer