Myriad Assistance Program (MFAP) for Uninsured Patients

MEDICAL CRITERIA

Hereditary Cancer Products

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 www.MyriadPromise.com.

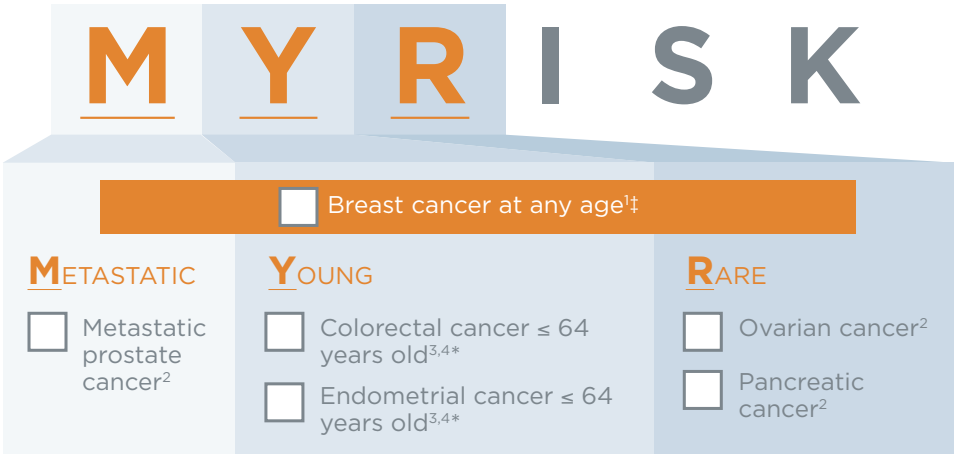
Myriad myRisk® Hereditary Cancer (A 35-gene diagnostic test to assess hereditary cancer risk), is covered when any of the testing criteria for Integrated BRAC*Analysis*®, COLARIS®PLUS, or COLARIS *AP*®PLUS are met. In addition, patients who previously tested negative with one of Myriad's comprehensive hereditary cancer or companion diagnostic products are eligible for Myriad myRisk® Hereditary Cancer if they meet the medical and financial criteria for the MFAP program.

Additionally, if your patient meets current NCCN® clinical diagnostic criteria for one of the following syndromes, please contact Medical Services at 800-469-7423 x3850 to review eligibility.

- Li-Fraumeni Syndrome
- PTEN Hamartoma Tumor Syndrome/Cowden Syndrome
- Peutz-Jeghers Syndrome
- Hereditary Diffuse Gastric Cancer syndrome*
- Juvenile Polyposis Syndrome

**International Gastric Cancer Linkage Consortium criteria are also acceptable*

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$_5$

MYRIAD myRisk® Hereditary Cancer

Myriad myRisk® Hereditary Cancer Single Site testing will be covered when:

PATIENT HAS A FAMILY HISTORY OF:

- A relative with a known mutation in *BRCA1, BRCA2, MLH1, MSH2, MSH6, PMS2, EPCAM (large rearrangement only), APC, MUTYH, CDK4, CDKN2A (p14ARF), TP53, PTEN, STK11, CDH1, BMPR1A, SMAD4, PALB2, ATM, CHEK2, NBN, BARD1, BRIP1, RAD51C, RAD51D, POLD1, POLE, GREM1, AXIN2, GALNT12, MSH3, NTHL1, RPS20, RNF43, HOXB13*
- Guidelines recommend that Ashkenazi Jewish and Central/Eastern European patients have Multisite 3 testing rather than a single-site for one of the 3 founder mutations
- A relative with a known *MLH1*, *MSH2*, *MSH6*, *PMS2*, *MUTYH** or *EPCAM* mutation (single-site only)

*Individuals who are positive for a single *MUTYH* mutation on Single Site analysis will automatically receive reflex to full *MUTYH* Analysis.

Integrated BRAC*Analysis*® (*BRCA1* and *BRCA2* sequencing and large rearrangement testing (BART)), covered when:

PATIENT HAS A PERSONAL HISTORY OF:

- Breast cancer diagnosed at any age
- Ovarian cancer diagnosed at any age
- Pancreatic cancer diagnosed at any age
- Metastatic prostate cancer diagnosed at any age
- High or Very High risk prostate cancer, as defined by NCCN
- Prostate cancer diagnosed at any age, with a 1st, 2nd or 3rd degree relative with breast, ovarian, pancreatic, or prostate cancer

PATIENT HAS A FAMILY HISTORY OF:

- 1st or 2nd degree relative diagnosed with:
  - Breast cancer under the age of 50
  - Two or more primary breast cancers
  - Triple negative breast cancer under the age of 60
- Three or more 1st, 2nd, or 3rd degree relatives diagnosed with breast cancer on the same side of the family
- 1st or 2nd degree relative who has been diagnosed with ovarian, metastatic prostate, pancreatic, or male breast cancer at any age

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

NOTE: Uninsured patients who had negative *BRCA1* and *BRCA2* sequencing prior to May 3, 2012 and who currently meet the financial criteria for MFAP and the Integrated BRAC*Analysis* medical criteria are eligible to receive large rearrangement testing (BART) at no charge. A new sample, test request form and MFAP application are required.

COLARIS®PLUS (*MLH1, MSH2, MSH6, PMS2, MUTYH* and *EPCAM*) testing covered when:

PATIENT HAS A PERSONAL HISTORY OF:

- Colon, rectal or uterine/endometrial cancer diagnosed under the age of 65
- Colon, rectal or uterine/endometrial cancer diagnosed at any age with MSI-High or IHC Positive tumor
- Two or more Lynch syndrome associated cancers (see list below) diagnosed at any age
- A Lynch syndrome associated cancer diagnosed at any age, with a 1st or 2nd degree relative with a Lynch syndrome associated cancer at any age
- Any combination of personal or family history that leads to a ≥2.5% risk of Lynch syndrome on one of the following mutation prediction models: PREMM5, MMR Pro, or MMR Predict.**

PATIENT HAS A FAMILY HISTORY OF:

- 1st or 2nd degree relative with colon, rectal, or uterine/endometrial cancer diagnosed under the age of 50
- Two or more 1st or 2nd degree relatives with a Lynch syndrome cancer and one diagnosed under 50
- Three or more 1st or 2nd degree relatives with Lynch syndrome cancers at any age
- Any combination of personal or family history that leads to a ≥2.5% risk of Lynch syndrome on one of the following mutation prediction models: PREMM5, MMR Pro, or MMR Predict.**

**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 http://premm.dfci.harvard.edu/.

Lynch syndrome cancers/tumors include the following:

- colorectal
- endometrium/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.

COLARIS *AP*®PLUS (*APC* and *MUTYH* analysis) covered when:

PATIENT HAS A PERSONAL HISTORY OF:

- >10 colorectal ademonas diagnosed at any age
- Colorectal cancer diagnosed at any age with a 1st or 2nd degree relative with > 10 adenomas at any age (cumulative) or an FAP/MAP-related tumor/clinical feature (see list below) at any age
- Colorectal cancer diagnosed at any age with > 6 colorectal adenomas
- Colorectal cancer diagnosed at any age with an additional FAP/MAP-related tumor/clinical feature

PATIENT HAS A FAMILY HISTORY OF:

- A relative with known *APC* or *MUTYH** mutation(s) (single-site only)
- Two or more 1st or 2nd degree relatives with > 10 colorectal adenomas at any age (cumulative)

* Individuals who are positive for a single *MUTYH* mutation on Single Site analysis will automatically receive reflex to full *MUTYH* Analysis.

FAP/MAP-related tumors include:

- desmoid
- fibroma
- epidermoid cyst
- osteoma
- CHRPE
- hepatoblastoma
- duodenal polyps
- ampula/periampulary/ampula of Vater

* Relatives must be "blood relatives" and when more than one relative is required, all must be on the same side of the family

MUTYH Analysis* (*MUTYH* sequencing and large rearrangement analysis) covered as a separate analysis or as a part of COLARIS®PLUS or COLARIS *AP*®PLUS testing when:

PATIENT HAS A PERSONAL HISTORY OF:

- >10 colorectal ademonas diagnosed at any age
- Colorectal cancer diagnosed < 65 years of age, regardless of adenomas
- Colorectal cancer diagnosed at any age with > 6 colorectal adenomas

PATIENT HAS A FAMILY HISTORY OF:

- Relative with known *MUTYH** mutation (single-site only)

**MUTYH* Analysis may be done alone or as part of COLARISPLUS or COLARIS *AP*PLUS testing.

Prognostic Products

Prolaris® testing covered when:

PATIENT HAS A PERSONAL HISTORY OF:

- Prostate cancer

EndoPredict® testing covered when:

PATIENT HAS A PERSONAL HISTORY OF:

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

Diagnostic Products

Myriad myPath® Melanoma testing covered when:

PATIENT HAS A PERSONAL HISTORY OF:

- Melanocytic lesion for which the diagnosis is equivocal/uncertain

Companion Diagnostic Products

BRACAnalysis CDx® testing covered when:

PATIENT HAS A PERSONAL HISTORY OF:

- Ovarian cancer and is being considered for Lynparza® (olaparib) or Zejula® (niraparib) therapy
- Metastatic breast cancer and is being considered for Lynparza® (olaparib)

Myriad myChoice® CDx testing covered when:

PATIENT HAS A PERSONAL HISTORY OF:

- Ovarian, fallopian tube, or primary peritoneal cancer

1. Referenced with permission from the NCCN: Genetic/Familial High-Risk Assessment: Breast and Ovarian. Version 2.2019. ©National Comprehensive Cancer Network, Inc. 2018. **2.** Referenced with permission from the NCCN: NCCN® Invasive Breast Cancer Version 1.2018 BINV-17. © National Comprehensive Cancer Network, Inc. 2018. **3.** American Society of Breast Surgeons 2016 Consensus Guideline on Hereditary Genetic Testing for Patients With and Without Breast Cancer **4.** Referenced with permission from the NCCN: Genetic/Familial High-Risk Assessment: Colorectal. Version 1.2018. ©National Comprehensive Cancer Network, Inc. 2018.