Myriad Financial 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.myriadpro.com/mfap.

Myriad myRisk® Hereditary Cancer (A 29-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. 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*

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

Personal or NO Personal History of CANCER	Family History
N/A	• relative with a known mutation in *ATM, BARD1, BMPR1A, BRIP1, CDH1, CDK4, CDKN2A (p14ARF), CHEK2, GREM1, HOXB13, NBN, PALB2, POLD1, POLE, PTEN, RAD51C, RAD51D, SMAD4, STK11, TP53* (patient would be appropriate for Single-Site testing only) • Single Site testing of all other Myriad myRisk genes are included under other test offerings

myriad®
WHEN DECISIONS MATTER

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

Personal History of BREAST CANCER	Family History (must meet at least 1)
Diagnosed ≤50 years of age	• no further family history needed
Diagnosed with two or more primary breast cancers	• no further family history needed
Diagnosed with triple negative breast cancer (ER-/PR-/Her2-)	• no further family history needed
Diagnosed any age	• Ashkenazi Jewish ancestry (Multisite 3 testing only unless patient also meets criteria for Comprehensive BRAC*Analysis*) • relative of a known BRCA mutation carrier (single-site only unless patient also meets criteria for Comprehensive BRAC*Analysis*) • 1st, 2nd or 3rd degree relative with breast cancer diagnosed ≤50 years of age, ovarian cancer, or bilateral breast cancer • two or more 1st, 2nd or 3rd degree relatives with any combination of breast, ovarian, pancreatic or prostate cancer at any age
Personal History of OVARIAN CANCER	**Family History**
Diagnosed at any age	• no further family history needed
Personal History of METASTATIC BREAST CANCER	**Family History**
Diagnosed at any age	• no further family history needed
Personal History of MALE BREAST CANCER	**Family History**
Diagnosed at any age	• no further family history needed
Personal History of PANCREATIC CANCER	**Family History**
Diagnosed at any age	• no further family history needed
Personal History of PROSTATE CANCER	**Family History**
Diagnosed at any age	• 1st, 2nd or 3rd degree relative with breast, ovarian, pancreatic or prostate cancer
Personal History of METASTATIC PROSTATE CANCER	**Family History**
Diagnosed at any age	• no further family history needed
NO Personal History of BREAST OR OVARIAN CANCER	**Family History**
Unaffected (no personal history of breast, ovarian or pancreatic cancer)	• relative of a known BRCA mutation carrier (single site only unless Ashkenazi Jewish, in which case Multisite 3) • 1st or 2nd degree relative who has had breast, ovarian, pancreatic or prostate cancer and who meets any of the criteria above • three or more 1st, 2nd or 3rd degree relatives with any combination of breast, ovarian, pancreatic or prostate cancers at any age • Ashkenazi Jewish ancestry and 1st or 2nd degree relative with breast, ovarian, pancreatic or prostate cancer at any age (Multisite 3 testing only unless patient also meets criteria for Comprehensive BRAC*Analysis*)

For the purposes of these criteria, the following apply:

- Breast cancer includes DCIS and invasive carcinoma
- Ovarian cancer includes peritoneal and fallopian tube cancers
- Ashkenazi Jewish and Central/Eastern European patients always have Multisite 3 testing rather than a single-site for one of the 3 founder mutations
- 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*, *MYH* and *EPCAM*) testing covered when:

Personal History of COLORECTAL OR ENDOMETRIAL CANCER	Family History
Diagnosed < 65 years of age	• no further family history needed
Diagnosed at any age, with MSI or IHC positive tumor	• no further family history needed
Personal History of ANY LYNCH SYNDROME CANCER	**Family History**
Diagnosed with a second Lynch syndrome cancer	• no further family history needed
Diagnosed at any age	• 1st or 2nd degree relative with a Lynch syndrome cancer diagnosed at any age • relative with a known *MLH1*, *MSH2*, *MSH6*, *PMS2*, *MYH** or *EPCAM* mutation (single-site only)
NO Personal History of ANY LYNCH SYNDROME CANCER	**Family History**
Diagnosed with ≥1 colorectal adenomas ≤40 years of age	• 1st or 2nd degree relatives with a Lynch syndrome cancer diagnosed at any age
Unaffected (no personal history of any Lynch syndrome cancer)	• two or more 1st or 2nd degree relatives with a Lynch syndrome cancer and one diagnosed under 50 • one or more 1st or 2nd degree relatives with colorectal cancer or endometrial cancer diagnosed <50 years of age • three or more 1st or 2nd degree relatives with Lynch syndrome cancers at any age • relative with a known *MLH1*, *MSH2*, *MSH6*, *PMS2*, *MYH** or *EPCAM* mutation (single-site only)
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.**	

**Individuals who are positive for a single MYH mutation on Single Site analysis will automatically receive reflex to full MYH Analysis.*
***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 $PREMM_5$ Model can be accessed at http://premm.dfci.harvard.edu/.*

Lynch syndrome cancers/tumors include the following:

- colorectal
- colon
- rectum
- endometrium/uterus
- ovarian
- small intestine/bowel
- duodenum
- jejunum
- gastric/stomach
- urinary tract
- sebaceous adenoma/sebaceous carcinomas
- glioblastoma
- medulloblastoma
- 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 *MYH* analysis) covered when:

Personal History of >10 COLORECTAL ADENOMAS	Family History
Diagnosed at any age	• no further family history needed
Personal History of COLON CANCER	**Family History**
Diagnosed at any age	• 1st or 2nd degree relative with >10 adenomas at any age (cumulative) • 1st or 2nd degree relative with an FAP/MAP-related tumor/clinical feature at any age • relative with known *APC* or *MYH** mutation(s) (single-site only)
Diagnosed at any age with ≥ 6 colorectal adenomas	• no further family history needed
Diagnosed with an additional FAP/MAP-related tumor/clinical feature	• no further family history needed
NO Personal History of COLORECTAL ADENOMAS OR COLORECTAL CANCER	**Family History**
Unaffected (no personal history)	• relative with known *APC* or *MYH** mutation(s) (single-site only) • two or more 1st or 2nd degree relatives with >10 colorectal adenomas at any age (cumulative)
Diagnosed with a desmoid or fibroma	• no further family history needed

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

FAP/MAP-related tumors include:

- desmoid
- fibroma
- epidermoid cyst
- osteoma
- CHRPE
- hepatoblastoma
- duodenal
- 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*

MYH Analysis* (*MYH* sequencing and large rearrangement analysis) covered only after Comprehensive COLARIS *AP*® or Comprehensive COLARIS® at Myriad or elsewhere when:

Personal History of >10 COLORECTAL ADENOMAS (CUMULATIVE)	Family History
Diagnosed at any age	• no further family history needed
Personal History of COLON CANCER	**Family History**
Diagnosed <65 years of age, regardless of adenomas	• no further family history needed
Diagnosed at any age with ≥ 6 colorectal adenomas (cumulative)	• no further family history needed
NO Personal History of COLORECTAL ADENOMAS OR COLORECTAL CANCER	**Family History**
Unaffected (no personal history)	• 1st or 2nd degree relative with known *MYH* mutation(s)

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

Prognostic Products

Prolaris® testing covered when:

Personal History of PROSTATE CANCER	Family History
Patient diagnosed with prostate cancer	• no further family history needed

EndoPredict® testing covered when:

Personal History of BREAST CANCER	Family History
Patient diagnosed with ER+ / HER2-, early-stage breast cancer	• no further family history needed

Diagnostic Products

Myriad myPath Melanoma® testing covered when:

Personal History of MELANOMA	Family History
Patient has a melanocytic lesion for which the diagnosis is equivocal/ uncertain	• no further family history needed

Companion Diagnostic Products

BRACAnalysis CDx® testing covered when:

Personal History of OVARIAN CANCER	Family History
Being considered for Lynparza® (olaparib) or Zejula® (niraparib) therapy	• no further family history needed
Personal History of METASTATIC BREAST CANCER	**Family History**
Being considered for Lynparza® (olaparib)	• no further family history needed

Myriad myChoice® HRD testing covered when:

Personal History of OVARIAN CANCER	Family History
Patient diagnosed with ovarian, fallopian tube, or primary peritoneal cancer	• no further family history needed

Notice and Statement Concerning Nondiscrimination and Accessibility

Discrimination is Against the Law

Myriad Genetic Laboratories, Inc. (Myriad) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Myriad does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Aids and Services

Myriad provides free aids and services to people with disabilities to communicate effectively with us, such as TTY/TDD calls or written information in suitable formats. Myriad will also provide free language services to people whose primary language is not English through qualified interpreters.

If you need these services, contact Ms. Sara Greene:
Sara Greene
Compliance Specialist
320 Wakara Way
Salt Lake City, UT 84108
Telephone: (801) 584-3600
Fax: (801) 883-3472
Email: compliance@myriad.com

Grievances

If you believe that Myriad has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex. You can file s grievance by mail, telephone, fax, or email. If you need help filing a grievance, Ms. Greene is available to help you (see contact information above).

Grievance Procedure

1. Any person who believes someone has been subjected to discrimination by Myriad on the basis of race, color, national origin, sex, age, or disability may file a grievance with Myriad. It is against the law for Myriad to retaliate against anyone who opposes discrimination, files a grievance, or participates in the investigation of a grievance.
2. Grievances must be submitted within 60 days of the date the person filing the grievance becomes aware of the alleged discriminatory action.
3. The complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
4. Myriad will conduct an investigation of the complaint, This investigation may be informal, but it will be thorough, affording all interested persons an opportunity to submit evidence relevant tot he complaint. Myriad will maintain the files and records relating to such grievances. To the extent possible, and in accordance with applicable law, Myriad will take appropriate steps to preserve the confidentiality of files and records relating to grievances and will share them only with those who have a need to know.
5. Myriad will issue a written decision on the grievance, based on a preponderance of the evidence, no later than 30 days after its filing, including a notice to the complainant of their right to pursue further administrative or legal remedies.
6. The person filing the grievance may appeal Myriad's decision in writing to the President of Myriad Genetic Laboratories, Inc. within 15 days of receiving Myriad's initial decision. The President will issue a written decision in response to the appeal no later than 30 days after its filing.
7. Individuals seeking access to Section 1557 and its implementing regulations may be facilitated by contacting Ms. Greene (see contact information above).
8. The availability and use of this grievance procedure does not prevent a person from pursuing other legal or administrative remedies, including filing a complaint of discrimination on the basis or race, color, national origin, sex, age, or disability in court in with the U.S. Department of Health and Human Services, Office for Civil Rights. A person can file a complaint of discrimination electronically through the Office for Civil Rights Complaint Portal, which is available at: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
   U.S. Department of Health and Human Services
   200 Independence Avenue, SW
   Room 509F, HHH Building
   Washington, DC 20201
9. Complaint forms are available at: http:www.hhs.gov/ocr/office/file/index.html. Such complaints must be filed within 180 days of the date of the alleged discrimination. Myriad will make appropriate arrangements to ensure that individuals with disabilities and individuals with limited English proficiency are provided auxiliary aids and services or language assistance services, respectively, if needed to participate in this grievance process. Ms. Greene will be responsible for such arrangements.

Español (Spanish)
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Tiếng Việt (Vietnamese)
Myriad Genetic Laboratories, Inc. tuân thủ luật dân quyền hiện hành của Liên bang và không phân biệt đối xử dựa trên chủng tộc, màu da, nguồn gốc quốc gia, độ tuổi, khuyết tật, hoặc giới tính. CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-801-584-3600.

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Tagalog (Tagalog – Filipino)
Sumusunod ang Myriad Genetic Laboratories, Inc. sa mga naaangkop na Pederal na batas sa karapatang sibil at hindi nandidiskrimina batay sa lahi, kulay, bansang pinagmulan, edad, kapansanan o kasarian. PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1-801-584-3600.

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Français (French)
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Deutsch (German)
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یسراف (Farsi)
توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 1-801-584-3600. تماس بگیرید.

Myriad Genetic Laboratories, Inc.

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