

Myriad Genetic Laboratories, Inc.

1-800-469-7423 Medical Services Department: prompt "2", Customer Service Department: prompt "0"

Instructions and Documentation Requirements for Medicare Patients

I. Determine if the patient meets Medicare requirements for genetic testing:

Medicare's current testing criteria are available on the Internet through the following link:

<http://www.myriadtests.com/medicarecriteria>

Testing criteria currently do not exist for MYH, MSH6, p16, BART and TheraGuide 5-FU™ testing—follow item III below. If you need assistance, please contact Myriad's Medical Services Department.

II. For patients who meet Medicare criteria for genetic testing, the following is required:

- 1) A completed Myriad Test Request Form (TRF) (including the healthcare provider's UPIN/NPI and signature), with special attention to:
 - Ancestry and Clinical History Section. This section must clearly document that the patient meets Medicare's testing criteria. The ICD-9 code for the patient diagnosis must identify the specific location of the cancer. For example, a current diagnosis of malignant neoplasm of female breast, lower-inner quadrant, would be represented as ICD-9 code 174.3. A past personal history of malignant neoplasm of female breast would be V10.3. A complete list of covered codes is available on the Medicare website (link appears above) or by contacting Myriad's Customer Service Department.
 - Test Requested Section. If this is a single site/known mutation test, list the known mutation and the relationship of the known mutation carrier to the patient (e.g., sister).

(TRFs are available in the Specimen Collection and Transport Kit or by calling Customer Service.)

- 2) A signed copy of "Informed Consent for Hereditary Cancer Genetic Testing" (eff. 01/06 or newer)
- 3) In the Insurance Billing section of the TRF, Medicare patients should check option 1 and should sign and date where indicated on the Patient Signature line.
- 4) A legible (enlarged if possible) photocopy of the front and back of the patient's Medicare card.

Note: Letters of medical necessity are n/a if the TRF documents that the patient meets Medicare criteria.

III. For patients who do not meet Medicare criteria for genetic testing (including tests for which no Medicare criteria exist or when test CPT codes are not covered) the following is required:

- a) A completed, signed TRF, copy of signed informed consent form, and photocopy of card as described in (1) through (4) above.
- b) A completed Advance Beneficiary Notice (ABN) for each test ordered for which the patient does not meet Medicare criteria. ABNs are available by contacting Customer Service or on the internet (http://www.myriadtests.com/doc/Myriad_ABN.pdf). Without an ABN, testing will not begin on patients who do not meet Medicare criteria. A duplicate or faxed copy of the ABN is considered to be the same as the original. All of the following must be completed on the ABN:
 - patient name and Medicare number (Health Insurance Claim Number (HICN));
 - the specific test must be selected in column three of the table;
 - estimated costs that will likely not be covered must be filled in (call Myriad Customer Service for assistance on test costs);
 - one of the two testing option boxes must be checked; and
 - the patient must sign and date the ABN.
- c) If the patient wants Medicare to review their claim for medical necessity, submit with items listed in (a) and (b) above, a letter of medical necessity indicating (1) why testing is necessary even though the criteria are not met and (2) how test results will change patient management.
- d) If the patient wishes secondary insurance to be billed after a Medicare denial has been received, legible photocopies both front and back of the patient's secondary insurance card should also be submitted with the TRF together with an indication to Myriad regarding this billing arrangement.

IV. For Medicare patients who are "in-patient" (hospitalized, under hospice care, or in a skilled nursing facility), Medicare Part B does not apply. Please contact Myriad Customer Service for billing options.

Patient's Name: _____

Medicare # (HICN): _____

ADVANCE BENEFICIARY NOTICE (ABN)

NOTE: You need to make a choice about receiving these laboratory tests.

We expect that Medicare will not pay for the laboratory test(s) that are described below. Medicare does not pay for all of your health care costs. Medicare only pays for covered items and services when Medicare rules are met. The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason your doctor recommended it. Right now, in your case, **Medicare probably will not pay for the laboratory test(s) indicated below for the following reasons:**

| Medicare does not pay for these tests for your condition | Medicare does not pay for these tests as often as this (denied as too frequent) | Medicare does not pay for non-covered CPT codes, for tests that are not medically necessary, or for tests that do not meet Medicare criteria (Refer to "Instructions for Completing the ABN for Patients that Do Not Meet Medicare Criteria") |
|--|---|--|
| | | <p>Patient does not meet Medicare criteria for:</p> <ul style="list-style-type: none"> <input type="checkbox"/> BRACAnalysis® BRCA1/BRCA2 genetic testing <input type="checkbox"/> COLARIS® MSH2/MLH1 genetic testing <input type="checkbox"/> COLARIS APSM APC genetic testing <p>Non-covered CPT codes for:</p> <ul style="list-style-type: none"> <input type="checkbox"/> COLARIS® MSH2/MLH1 genetic testing-(Southern Blot) <input type="checkbox"/> COLARIS APSM APC genetic testing-(Southern Blot) <p>No Medicare criteria for:</p> <ul style="list-style-type: none"> <input type="checkbox"/> MYH genetic testing <input type="checkbox"/> MSH6 genetic testing <input type="checkbox"/> MELARIS® p16 genetic testing <input type="checkbox"/> BART-BRACAnalysis® Rearrangement genetic testing <input type="checkbox"/> TheraGuide 5-FU™ genetic testing |

The purpose of this form is to help you make an informed choice about whether or not you want to receive these laboratory tests, knowing that you might have to pay for them yourself. Before you make a decision about your options, you should **read this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare probably won't pay.
- Ask us how much these laboratory tests will cost you (**Estimated Cost: \$ _____**), in case you have to pay for them yourself or through other insurance.

PLEASE CHOOSE ONE OPTION. CHECK ONE BOX. SIGN & DATE YOUR CHOICE.

Option 1. YES. I want to receive these laboratory tests.
 I understand that Medicare will not decide whether to pay unless I receive these laboratory tests. Please submit my claim to Medicare. I understand that you may bill me for laboratory tests and that I may have to pay the bill while Medicare is making its decision. If Medicare does pay, you will refund to me any payments I made to you that are due to me. If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have. I understand I can appeal Medicare's decision.

Option 2. NO. I have decided not to receive these laboratory tests.
 I will not receive these laboratory tests. I understand that you will not be able to submit a claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay. I will notify my doctor who ordered these laboratory tests that I did not receive them.

Date

Signature of patient or person acting on patient's behalf

NOTE: Your health information will be kept confidential. Any information that we collect about you on this form will be kept confidential in our offices. If a claim is submitted to Medicare, your health information on this form may be shared with Medicare. Your health information which Medicare sees will be kept confidential by Medicare.