MAYO CLINIC LABORATORIES

Hereditary Breast and Colorectal Cancer Panel (BRCRC) Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Hereditary Breast and Colorectal Cancer Panel, Next-Generation Sequencing, Varies (BRCRC). To utilize our prior authorization services on this test, you must follow the process as outlined below.

Ordering and Prior Authorization Process

Mayo Clinic Laboratories utilizes an extract and hold process for prior authorization. To order BRCRC with prior authorization services, complete this document as instructed below by insurance type. **You must order test code BRCRC and send the completed paperwork in with the sample**. The receipt of the paperwork and sample at Mayo Clinic Laboratories will trigger the extract and hold process and generate a request to the MCL Business Office to verify your patient's insurance coverage for the testing and begin any additional prior authorization services.

If the expected patient out-of-pocket expense is $200 or less after prior authorization services, Mayo Clinic Laboratories will automatically proceed with BRCRC testing. If the expected patient out-of-pocket expense is greater than $200, Mayo Clinic Laboratories will seek approval from the client contact listed on the Patient Demographics and Third Party Billing Information form **before proceeding** with BRCRC testing. The MCL Business Office offers interest-free payment plans on balances over $200.

Commercial Insurance

For patients with commercial insurance, complete the following, staple them together and send with the specimen:

- Patient Demographics and Third Party Billing Information form (required)
- Letter of Medical Necessity (required)
- Copy of front and back of insurance card (if available)

Note: The Advanced Beneficiary Notice of Noncoverage (ABN) form is not required for commercial insurance-covered patients.

Medicare

For patients with Medicare, complete the following, staple them together and send with the specimen:

- Patient Demographics and Third Party Billing Information form (required)
- Advanced Beneficiary Notice of Noncoverage (ABN) form (required – see separate ABN form: MC2934-212)
- Copy of front and back of secondary insurance card (if applicable)

Attach the ABN form and copy of the secondary insurance card to the Patient Demographics and Third Party Billing Information form and send with the specimen.

Note: The Letter of Medical Necessity and a copy of the Medicare card are not required for Medicare-covered patients.

Medicaid

Mayo Clinic Laboratories may be able to file claims for your Medicaid-covered patients. Before ordering, contact the MCL Business Office at 800-447-6424 to discuss. Have the patient's Medicaid information available when calling.

Note: These instructions are subject to change at any time. Call the MCL Business Office at 800-447-6424 with any questions.

Complete and print.

Reset Form

MAYO CLINIC LABORATORIES

Prior Authorization Patient Demographics and Third Party Billing Information

Client Order Number

Patient Demographics and Insurance Information

Patient Name *(Last, First, Middle)*		Gender ☐ Male ☐ Female	Birth Date *(mm-dd-yyyy)*
Patient Mailing Address		City	State / ZIP Code
Primary Insurance Company Name	Insurance Subscriber ID No. / Policy No.		Insurance Group No. (if applicable)
Primary Insurance Company Mailing Address		City	State / ZIP Code
Primary Insurance Company Phone	Subscriber Name (if different than patient) and Relationship to Patient		

Order Information

MCL Test ID **BRCRC**	Name of desired MCL test **Hereditary Breast and Colorectal Cancer Panel, Next-Generation Sequencing, Varies**
ICD-10 Codes (use number codes to highest specificity)	Service Date (Collection Date)
Referring Provider Name	Referring Provider's National Provider ID (NPI)

Client Account and Client Contact Information

MCL Client Account Number (if known)	Referring Client Facility Name
Contact Name	Contact Phone
Contact Email	Date Today *(mm-dd-yyyy)*

Attach the Following to This Completed Form

- Letter of Medical Necessity (required except for Medicare patients) – template provided on page 3
- Advanced Beneficiary Notice of Noncoverage (ABN) form (required for Medicare patients only) – see separate form: MC2934-212
  - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for Hereditary Breast and Colorectal Cancer Panel

Patient Name *(Last, First, Middle)* _____

Birth Date *(mm-dd-yyyy)* _____

Member Number _____

Group _____

ICD-10 Codes _____

To Whom It May Concern:
We are requesting preauthorization for the Hereditary Breast and Colorectal Cancer Panel, Next-Generation Sequencing, Varies (BRCRC)

performed by Mayo Clinic Laboratories for (insert patient name) _____

Patient's personal medical history is significant for _____

Patient's family history is significant for _____

Due to the patient's (medical or family) history, a hereditary breast and colon cancer syndrome is suspected and genetic testing is recommended. Testing is being requested for germline evaluation of 11 genes associated with hereditary breast and colon cancer: BRCA1, BRCA2, TP53, PTEN, CDH1, STK11, MLH1, MSH2, MSH6, PMS2 and EPCAM.

Lynch syndrome (associated with MLH1, MSH2, MSH6, PMS2 and EPCAM gene mutations) is the most common inherited colon cancer predisposition syndrome and accounts for 2% to 3% of all colorectal cancers and 2% of all endometrial cancers. The highest cancer risks associated with Lynch syndrome include colon cancer (up to a 70% lifetime risk), endometrial cancer (up to a 60% lifetime risk), gastric cancer (up to a 20% lifetime risk), and ovarian cancer (up to a 10% lifetime risk). Other cancers associated with Lynch syndrome include cancers of the small intestine, urinary tract, hepatobiliary tract, pancreas, skin (sebaceous carcinoma), and brain.[1]

Hereditary breast cancer accounts for about 10% of all female breast cancer, the majority of which is associated with BRCA1 and BRCA2 mutations. The reported cancer risks associated with BRCA1 and BRCA2 are up to a 60% to 80% lifetime risk for breast cancer and up to a 40% lifetime risk of ovarian cancer. Mutations in TP53, PTEN, CDH1, and STK11 are also associated with hereditary cancer syndromes in which there is an increased risk for breast cancer (Li-Fraumeni syndrome, Cowden syndrome, Hereditary Diffuse Gastric Cancer and Peutz-Jeghers syndrome, respectively). The risk for developing an invasive breast cancer associated with these syndromes is up to an 85% lifetime risk.[1,4] Individuals with a pathogenic variant in one of these genes may develop multiple primary cancers or bilateral cancers. Therefore, testing for mutations in these 6 genes is useful when there is a suspicion of a hereditary susceptibility to breast cancer.[1]

Rationale: The American Society of Clinical Oncology recommends that genetic testing be offered to individuals with suspected inherited cancer risk in which test results will aid in medical management decision-making.[2] Visit NCCN.org to see screening recommendations provided by the National Comprehensive Cancer Network. Because an aggressive approach to medical management is necessary for individuals identified as having a genetic mutation, test results are important in reducing cancer risk and promoting early cancer detection.

A positive test result would allow the utilization of appropriate screening guidelines[3] and help guide decisions toward possible preventative measures. For this patient in particular, the genetic test results are needed in order to consider:

- ☐ Increased colon surveillance (colonoscopy every 1–2 years) or prophylactic surgery
- ☐ Increased breast surveillance (clinical breast exam every 6–12 months and annual breast MRI and/or mammogram) beginning at age 25
- ☐ Prophylactic bilateral mastectomy
- ☐ Prophylactic hysterectomy and bilateral salpingo-oophorectomy
- ☐ Urine analysis (annually)
- ☐ Other _____

Test requested: BRCRC / Hereditary Breast and Colorectal Cancer Panel, Next-Generation Sequencing, Varies is a cost-effective test that utilizes next-generation sequencing (NGS), array comparative hybridization (aCGH), multiplex ligation-dependent probe amplification (MLPA), and other technologies to evaluate 11 genes for pathogenic mutations and deletions associated with hereditary breast and colon cancer including: BRCA1, BRCA2, TP53, PTEN, CDH1, STK11, MLH1, MSH2, MSH6, PMS2 and EPCAM. Visit NCCN.org to see personal and/or family history criteria and testing recommendations provided by the National Comprehensive Cancer Network.

Laboratory information: Testing would be performed at Mayo Clinic Laboratories (**TIN#** 411346366 / **NPI#** 1093792350), a CAP-accredited and CLIA-certified laboratory, using 2020 CPT codes: 81162, 81228, 81292, 81295, 81298, 81317, 81319, 81321, 81351, 81403, and 81406.

Thank you for your thoughtful consideration of our preauthorization request. We look forward to hearing back from you.

Sincerely,

Ordering Clinician Name _____

Contact information _____

1. Concise handbook of familial cancer susceptibility syndromes-second edition. Journal of the National Cancer Institute. Monographs 2008;(38):1-93
2. ASCO Policy Statement Update: genetic testing for cancer susceptibility. Journal of Clinical Oncology 2003;21(12):2397-2406
3. American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. CA A Cancer Journal for Clinicians 2007; Mar–Apr;57(2):75-89
4. Lifetime cancer risks in individuals with germline PTEN mutations. Clin Cancer Res 2012 Jan 15;18(2):400-407

Print

MAYO CLINIC
200 First Street SW
Rochester, Minnesota 55905
507-284-2511

Patient Name *(First, Middle, Last)*	Mayo Clinic Number

Advance Beneficiary Notice of Noncoverage (ABN)

Note: If Medicare doesn't pay for Items and Services below, you may have to pay.
Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the Items and Services below.

Items and Services	Reason Medicare May Not Pay	Estimated Cost
BRCRC / Hereditary Breast and Colorectal Cancer Panel, Next-Generation Sequencing, Varies	Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test.	$3,059.00

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the Items and Services listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

Options: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the Items and Services listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the Items and Services listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

☐ **OPTION 3.** I don't want the Items and Services listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY**: 1-877-486-2048).
Signing below means that you have received and understand this notice. You also receive a copy.

Signature ▶	Date *(mm-dd-yyyy)*

CMS does not discriminate in its programs and activities. To request this publication in an alternative format, please call: 1-800-MEDICARE or email: AltFormatRequest@cms.hhs.gov.