



*BRCA1/BRCA2 Genes,
Full Gene Analysis (BRCAZ)
Prior Authorization Ordering Instructions*

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our BRCA1/BRCA2 Genes, Full Gene Analysis, Varies (BRCAZ). 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 BRCAZ with prior authorization services, complete this document as instructed below by insurance type. **You must order test code BRCAZ 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 BRCAZ 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 BRCAZ 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: MC2934-209)
- 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.



*Prior Authorization
Patient Demographics and
Third Party Billing Information*

Client Order Number

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Patient Demographics and Insurance Information

Patient Name <i>(Last, First, Middle)</i>		Gender <input type="checkbox"/> Male <input type="checkbox"/> Female		Birth Date <i>(mm-dd-yyyy)</i>	
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 BRCAZ	Name of desired MCL test BRCA1/BRCA2 Genes, Full Gene Analysis, 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 <i>(mm-dd-yyyy)</i>

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: MC2934-209
 - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for BRCA1/BRCA2 Genes, Full Gene Analysis

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 BRCA1/BRCA2 Genes, Full Gene Analysis, Varies (BRCAZ) 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, Hereditary Breast and Ovarian Cancer (HBOC) syndrome is suspected and genetic testing is recommended. Testing is being requested for germline evaluation of the BRCA1 and BRCA2 genes associated with HBOC.

BRCA1/BRCA2 associated HBOC syndrome is the most common inherited breast cancer and ovarian cancer predisposition syndrome and accounts for 5% of all female breast cancer diagnosed before the age of 50 and 10% to 15% of all ovarian cancer diagnoses. The reported cancer risks associated with HBOC are up to a 60% to 80% lifetime risk for breast cancer and up to a 40% lifetime risk of ovarian cancer. Other cancers associated with HBOC syndrome include pancreatic cancer, prostate cancer, fallopian tube cancer, primary peritoneal cancer, melanoma, male breast cancer, and others.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 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 and management guidelines³ and help guide decisions toward possible preventative measures. Visit NCCN.org to see screening recommendations provided by the National Comprehensive Cancer Network. For this patient in particular, the genetic test results are needed in order to consider:

- 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 bilateral salpingo-oophorectomy
- Other _____

Test requested: BRCAZ / BRCA1/BRCA2 Genes, Full Gene Analysis, Varies is a cost-effective test that utilizes next-generation sequencing (NGS), and multiplex ligation-dependent probe amplification (MLPA) technologies to evaluate the BRCA1 and BRCA2 genes for pathogenic mutations and deletions associated with Hereditary Breast and Ovarian Cancer syndrome. 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 code: 81162.

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

Patient Name <i>(First, Middle, Last)</i>	Mayo Clinic Number
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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
BRCA1/BRCA2 Genes, Full Gene Analysis, Varies	Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test.	\$1969.80

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.
<input type="checkbox"/> 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.
<input type="checkbox"/> 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.
<input type="checkbox"/> 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 <i>(mm-dd-yyyy)</i>
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