MAYO CLINIC LABORATORIES

FBN1, Full Gene Sequence
Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our FBN1, Full Gene Sequence, Varies (FBN1B). 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 FBN1B with prior authorization services, complete this document as instructed below by insurance type. **You must order test code FBN1B 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 FBN1B 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 FBN1B 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: MC2934-257)
- 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 **FBN1B**	Name of desired MCL test **FBN1, Full Gene Sequence, 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: MC2934-257
  - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for FBN1 Genetic Testing for Marfan Syndrome

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 FBN1, Full Gene Sequence, Varies (FBN1B) 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 history, a diagnosis of Marfan syndrome or a related disorder is suspected and genetic testing is recommended.

Rationale: The use of genetic testing to distinguish the gene involved in Marfan syndrome and related disorders is supported by experts in the field and summarized by the 2010 Ghent nosology for Marfan syndrome, "In order to avoid persistent ambiguity even under the proposed criteria, molecular testing should be strongly considered because it influences the clinical management."* Test results will have a direct impact on this patient's medical management, screening, and prevention of potential complications, including sudden cardiac death.

Genetic testing is used to confirm a diagnosis and/or identify at-risk individuals. This testing would allow for the unequivocal diagnosis of a gene mutation causative of the patient's medical history, and would have significant implications for the patient's clinical management with regard to decision making for ongoing imaging and surveillance, surgery, as well as medical management. For example, identification of an FBN1 mutation would confirm the diagnosis of Marfan syndrome and warrant ongoing echocardiographic screening to monitor the size of the aorta and prevent serious complications such as aortic dissection. Additionally, identification of a mutation in FBN1 would provide guidance regarding the best timing for surgical intervention on the aorta, given that different genes are known to have higher or lower risk of aortic dissection at different aortic dimensions. A positive genetic test result would provide a definitive cause for this patient's history and would ensure this patient is being treated appropriately.

A negative FBN1 test result could also be informative. It could help to reinforce that the patient does not have Marfan syndrome, or alternatively it could indicate that additional genetic testing for genes known to cause similar disorders (TGFBR1, TGFBR2, SMAD3, TGFB2, ACTA2, etc.) should be considered to confirm the diagnosis and allow for gene-specific management and screening.

Marfan syndrome and related disorders are typically inherited in an autosomal dominant fashion; therefore, each child is at a 50% risk to inherit the mutation from an affected parent. When a familial mutation has been identified, genetic testing can identify family members who are not at increased risk to develop disease (non-mutation carriers). No other test can reliably differentiate unaffected family members, who do not require further screening, from presymptomatic affected family members, who must be followed closely by a cardiologist.

Test requested: FBN1B / FBN1, Full Gene Sequence, Varies is a cost-effective test that utilizes next-generation sequencing (NGS), to evaluate the FBN1 gene for pathogenic mutations associated with Marfan syndrome and related disorders.

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: 81408.

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

Sincerely,

Ordering Clinician Name _____

Contact information _____

* Loeys BL, Dietz HC, Braverman AC, et al: 2010. The revised Ghent nosology for the Marfan syndrome. J Med Genet 47:476-485

Print

MAYO CLINIC LABORATORIES
200 First Street SW
Rochester, Minnesota 55905
800-447-6424

Patient Name *(First, Middle, Last)*	MCL Order 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
FBN1B / FBN1, Full Gene Sequence, Varies	Patient's personal and family history does not meet Medicare's medical necessity coverage criteria for this laboratory test.	$2,085.60

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.