MAYO CLINIC LABORATORIES

Whole Exome Sequencing (WESDX) Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Whole Exome Sequencing for Hereditary Disoders, Varies (WESDX). 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 WESDX with prior authorization services, complete this document as instructed below by insurance type. **You must order test code WESDX 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 WESDX 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 WESDX 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: MC2934-307)
- 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)*		Sex ☐ 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 **WESDX**	Name of desired MCL test **Whole Exome Sequencing for Hereditary Disorders, 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: MC2934-307
  - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for Whole Exome Sequencing for Hereditary Disorders (WESDX) Testing

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 Whole Exome Sequencing for Hereditary Disorders, Varies (WESDX) performed by

Mayo Clinic Laboratories for (insert patient name)

It is my professional determination that this testing is medically necessary, and will have a direct impact on this patient's treatment and management.

Patient's personal medical history is significant for

Patient's family history is significant for

Rationale: Whole Exome Sequencing (WES) is a widely used, standard of care genetic test that analyzes the exons, or coding regions, of over 20,000 genes via next generation sequencing in patients with suspected underlying hereditary disorders. WES can be used as a first-tier test to identify a genetic diagnosis in patients with suspected genetic disorders or as a second-tier test for patients in whom previous genetic testing was negative. Advantages of whole exome sequencing include:

1. WES is an **effective first-tier** method for identifying a diagnosis: Based on a meta-analysis of published reports, a diagnosis is identified by WES in approximately 36% of cases.[1,2] Furthermore, WES reduces the time to diagnosis, shortening the diagnostic odyssey experienced by patients and supporting its use early in the diagnostic trajectory.[3,4,5]
2. WES **changes clinical management**: In a systematic evidence-based review of outcomes from exome and genome sequencing, more than half of patients experienced a reported clinical impact related to the diagnosis. WES eliminated the need for additional (invasive) medical procedures in almost a quarter of patients[6] and resulted in direct changes to treatment recommendations in about 18% of patients with diagnostic results.[7] Additional changes to clinical management can include changes to surveillance strategies, changes in medication, alterations to a patient's diet, access to clinical trials, changes to reproductive counseling, and withdrawal of care or initiation of palliative care.[8]
3. WES results in **cost savings**: Using WES as a first-tier test is a cost-effective alternative to traditional/standard diagnostic pathways.[5] Using WES as a first- or second-tier test (in lieu of multiple other tests) yields more diagnoses at an equal or lower cost.[6,9] Additionally, WES reduced downstream costs by eliminating the need for additional medical procedures in almost a quarter of patients.[6]

Not only is WES effective, medically impactful, and financially beneficial, but the American College of Medical Genetics and Genomics (ACMG) recently published evidence-based clinical guidelines that formally recommend WES for the following indications[9]:

- Patients with one or more congenital anomalies
- Patients with developmental delay or intellectual disability with onset prior to age 18 years

Testing may also be considered in the following situations:

- Patients with a phenotype and/or family history that strongly suggests an underlying genetic cause, yet genetic tests for that phenotype have failed to arrive at a diagnosis (diagnostic odyssey)
- Patients with a phenotype and/or family history that strongly suggests an underlying genetic cause, but the phenotypes appear unrelated or do not fit with one specific disorder (numerous individual genetic tests would be required for evaluation)
- Patients with a suspected genetic disorder that has numerous underlying genetic causes, making analysis of numerous genes simultaneously a more practical approach than single-gene testing (condition is genetically heterogeneous)
- Patients with a suspected genetic disorder for which specific molecular genetic testing is not yet available
- Patients with an atypical presentation of a genetic disorder

In summary, there is a large body of evidence that recommends WES as either a first- or second-tier test in patients with one or more congenital anomalies, neurodevelopmental disorders, or a phenotype for which a single clear diagnostic test is not available. Identification of an underlying genetic diagnosis for any of these indications can lead to changes in medical management that will influence mortality, morbidity, and reduce the burden on patients and families searching for answers. The Whole Exome Sequencing for Hereditary Disorders test at Mayo Clinic is a highly sensitive, cost-effective genetic test that interrogates both single nucleotide and copy number variants allowing for tailored medical management and treatment for this patient.

Test requested: WESDX / Whole Exome Sequencing for Hereditary Disorders, Varies uses next-generation sequencing to test for variants in the exons, or coding-regions, of an individual's DNA.

Laboratory information: Testing would be performed at Mayo Clinic Laboratories (TIN# 411346366 / NPI# 1093792350), a CAP-accredited and CLIA-certified laboratory, using 2022 CPT code: 81415 and 81416.

Thank you for your thoughtful consideration of our preauthorization request. If you have questions, or if I can be of further assistance, please do not hesitate to call me.

Sincerely,

Ordering Clinician Name

Contact information

References

1. Clark MM, Stark Z, Farnaes L, et al: Meta-analysis of the diagnostic and clinical utility of genome and exome sequencing and chromosomal microarray in children with suspected genetic diseases. NPJ Genom Med. 2018;3:16. Published 2018 Jul 9
2. Srivastava S, Love-Nichols JA, Dies KA, et al: Correction: Meta-analysis and multidisciplinary consensus statement: exome sequencing is a first-tier clinical diagnostic test for individuals with neurodevelopmental disorders. Genet Med. 2020;22(10):1731-1732
3. Cordoba M, Rodriguez-Quiroga SA, Vega PA, et al: Whole exome sequencing in neurogenetic odysseys: An effective, cost- and time-saving diagnostic approach. PLoS One. 2018;13(2):e0191228. Published 2018 Feb 1
4. Powis Z, Farwell Hagman KD, Speare V, et al: Exome sequencing in neonates: diagnostic rates, characteristics, and time to diagnosis. Genet Med. 2018;20(11):1468-1471
5. Tan TY, Dillon OJ, Stark Z, et al: Diagnostic Impact and Cost-effectiveness of Whole-Exome Sequencing for Ambulant Children With Suspected Monogenic Conditions. JAMA Pediatr. 2017;171(9):855-862
6. Vissers LELM, van Nimwegen KJM, Schieving JH, et al: A clinical utility study of exome sequencing versus conventional genetic testing in pediatric neurology. Genet ed. 2017;19(9):1055-1063
7. Kuperberg M, Lev D, Blumkin L, et al: Utility of whole exome sequencing for genetic diagnosis of previously undiagnosed pediatric neurology patients. J Child Neurol. 2016;31(14):1534-1539
8. Malinowski J, Miller DT, Demmer L, et al: Systematic evidence-based review: outcomes from exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability. Genet Med. 2020;22(6):986-1004
9. Manickam K, McClain MR, Demmer LA, et al: Exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability: an evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2021;23(11):2029-2037

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
WESDX / Whole Exome Sequencing for Hereditary Disorders, Varies	Patient's personal and family history does not meet Medicare's medical necessity coverage criteria for this laboratory test.	$4,500.00
CMPRE / Family Member Comparator Specimen for Exome Sequencing, Varies (Per family member)		$1,100.00

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.