



Whole Exome Sequencing for Hereditary Disorders (WESDX) Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on Whole Exome Sequencing for Hereditary Disorders, 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.



**Prior Authorization
Patient Demographics and
Third Party Billing Information**

Client Order Number

| |
|--|
| |
|--|

Patient Demographics and Insurance Information

| | | | |
|---|---|--|----------------|
| Patient Name (Last, First Middle) | | Birth Date (mm-dd-yyyy) | |
| Sex Assigned at Birth <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown <input type="checkbox"/> Choose not to disclose | | Legal/Administrative Sex <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Nonbinary | |
| 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/Collection Date (mm-dd-yyyy) | |
| Referring Provider Name (Last, First) | | 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.³⁻⁵
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 patients⁶ 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 indications⁹:

- 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 Provider 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

Advance Beneficiary Notice of Non-coverage (ABN)

Medicare doesn't pay for everything, even some care you or your health care provider think you need. **We expect Medicare may not pay for the item, test, service or care listed below.** If Medicare doesn't pay, you may have to pay.

| Item, Test, Service or Care | 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 to do now

- Read this notice to make an informed decision about your care.
- Ask any questions you have.
- Choose one option below to let us know if you still want to get the item, test, service or care.

Choose ONE option below. We can't choose for you.

If you choose Option 1 or 2, we may help you use any other insurance you might have, but Medicare can't require us to do this.

- OPTION 1: I want the item, test, service or care listed above, and I want Medicare to be billed for an official decision on payment, which I'll get on a Medicare Summary Notice (MSN).** You can ask to be paid now. I understand that if Medicare doesn't pay, I'm responsible to pay, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you'll refund any payments I made to you, minus co-pays or deductibles.
- OPTION 2: I want the item, test, service or care listed above, but don't bill Medicare.** You can ask to be paid now and I'm responsible to pay. I understand that I can't appeal, since Medicare isn't billed.
- OPTION 3: I don't want the item, test, service or care listed above.** I understand I'm not responsible for payment and I can't appeal to see if Medicare would pay.

Additional Information:

This notice gives our opinion, not an official Medicare decision. For other questions about this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227). TTY users can call 1-877-486-2048. Signing below means you received and understand this notice. You can ask to get a copy.

Signature

Date (mm-dd-yyyy)

You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you feel you've been discriminated against. Visit [Medicare.gov/about-us/accessibility-nondiscrimination-notice](https://www.medicare.gov/about-us/accessibility-nondiscrimination-notice).

PRA Disclosure Statement: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. This information collection is for providers, suppliers, Hospice and Religious Non-medical HealthCare Institutes and Home Health Agencies to notify original Medicare beneficiaries of their potential financial liability under specific conditions. The time required to complete this information collection is estimated to average less than 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is mandatory under Section 1879 of the Social Security Act, 42 CFR 411.404(b) and (c) and 411.408(d)(2) and (f). If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.