XomeDx Medical Necessity Attestation Form
for patients eligible under the
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) benefit

Date	
Patient name	
Date of birth	
Medicaid plan	
Medicaid ID number	

Under **Section 1905(a)(29) of the Social Security Act**, states must cover medically necessary healthcare services for Medicaid beneficiaries under **EPSDT** to correct or improve medical conditions, even if not typically covered by the state plan.[1]

Exome sequencing, including XomeDx, is eligible for coverage under relevant **state biomarker laws** and is recognized as the standard of care for diagnosing complex rare diseases, as supported by multiple evidence-based professional society guidelines.

I, the undersigned provider, certify that exome sequencing (ES) is medically necessary for this patient under EPSDT and that all the following are true:

- ✓ The patient is under age 21
- ✓ The patient has undergone informed consent and genetic counseling with a qualified clinician
- ✓ The patient's symptoms do not fit a well-defined syndrome for which a single-gene or targeted panel test is available, but a genetic cause is strongly suspected
- ✓ ES is supported by clinical guidelines and/or peer-reviewed medical literature for this indication

Test results will impact medical management, including treatment or care decisions as follows:

Ordering provider signature
(or authorized representative)

Printed name

I authorize GeneDx to appeal any denial of coverage for genetic testing services on my behalf or on behalf of my legal dependent. I also consent to my health insurance provider sharing relevant medical information with GeneDx and communicating directly with GeneDx regarding this appeal. I understand that GeneDx will not charge me for handling the appeal process.

Patient/Guardian signature

Date

Printed name

GeneDx

Why exome sequencing?

Exome sequencing (ES) is a highly efficient diagnostic test that evaluates all protein-coding genes, which contain the majority of disease-causing mutations. It is the most effective first-line approach when a patient's symptoms suggest an underlying genetic condition but do not match a well-defined syndrome. ES replaces the use of multiple other tests and procedures, shortening time to diagnosis and reducing healthcare cost.

Advantages of ES:

- **Efficiency:** ES is more efficient than single-gene or multi-gene panels, reducing unnecessary testing and delays in care.
- **Clinical recommendations:** Leading evidence-based clinical guidelines from the American College of Medical Genetics and Genomics (ACMG), the National Society of Genetic Counselors (NSGC), and the American Epilepsy Society (AES) recommend ES for children with unexplained neurodevelopmental disorders, epilepsy, or congenital anomalies.[2–5]
- **Insurance coverage:** ES is covered by nearly all commercial insurers and Medicaid in most states for suspected genetic diseases, reflecting its growing recognition as the prevailing standard of care.

Evidence-based guidelines:

American College of Medical Genetics and Genomics (ACMG) Guideline

Recommends ES as a first-line test for patients with congenital anomalies, intellectual disability, or developmental delay. Highlights the clinical utility in establishing diagnoses that guide medical management.[2,3]

National Society of Genetic Counselors (NSGC) Guideline

Endorsed by the American Epilepsy Society (AES)

Supports ES as a first-tier test for unexplained epilepsy across all ages. Emphasizes that genetic diagnoses can lead to targeted treatments and reduce healthcare disparities.[4,5]

References

1. Social Security Act, 42 U.S.C. § 1396d(a)(29)
2. Manickam, K., McClain, M.R., Demmer, L.A. *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.* 23,2029–2037 (2021). https://doi.org/10.1038/s41436-021-01242-6
3. Malinowski, J., Miller, D.T., 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.* 22, 986–1004 (2020). https://doi.org/10.1038/s41436-020-0771-z
4. Sheidley, B. R., Malinowski, J., Bergner, A. L., Bier, L., Gloss, D. S., Mu, W., Mulhern, M. M., Partack, E. J., & Poduri, A. (2022). Genetic testing for the epilepsies: A systematic review. *Epilepsia*. 63(2), 375-387. https://doi.org/10.1111/epi.17141
5. Smith, L., Malinowski, J., Ceulemans, S., Peck, K., Walton, N., Sheidley, B. R., & Lippa, N. (2022). Genetic testing and counseling for the unexplained epilepsies: An evidence-based practice guideline of the National Society of Genetic Counselors. *J Genet Couns*. https://doi.org/10.1002/jgc4.1646