**Letter of Medical Necessity**

Baylor Genetics Whole Genome Sequencing (WGS) Test

Date:

Patient Name:

Patient DOB:

Patient Insurance:

Insurance: (***ID# and Group #***)

Policy Holder’s Name: (***if different from patient)***

Expected Date of Service:

To Whom It May Concern:

This letter is written on behalf of patient, ***[Patient’s Full Name]****,* a **[age, in years, months, days**] **-**year-old child who is undergoing evaluation for a suspected rare genetic disorder. I am requesting coverage for Whole Genome Sequencing (WGS) as a medically necessary test to determine the underlying genetic cause of their complex clinical presentation.

***[Patient Name]*** *has a significant clinical history consistent with a suspected rare genetic disease including:*

* ***Primary symptoms:*** *[List symptoms and corresponding ICD10 codes, e.g. global developmental delays, seizures, failure to thrive]*
* ***Onset and duration:*** *[detail onset, progression and duration of symptoms]*
* ***Family history:*** *[include relevant family history findings]*

*No definitive diagnosis has been achieved despite multiple medical evaluations including:*

* ***Laboratory testing****: [add test and results]*
* ***Imaging****: [add tests and results]*

**Clinical Rationale, Supporting Evidence and Guidelines for WGS:**

Whole Genome Sequencing (WGS) is medically necessary and the most appropriate next step for **[Patient Name]** because:

1. **It can impact time to diagnosis** - WGS identifies 30-40% of genetic causes on initial testing, with higher diagnostic rates in specific indications,7. Establishing a diagnosis early can decrease the total number of specialist visits as well as avoid unnecessary procedures and their associated costs.
2. **It can affect the diagnostic odyssey** - Providing an answer alleviates stress and anxiety associated with the uncertainty of the prognosis, cost and risk to other family members including future offspring1.
3. **It can change clinical management** - A rare disease diagnosis facilitated by WGS demonstrates clinical utility through higher rates of precision medicine interventions and changes in clinical management as compared with standard genetic testing approaches including evidence-based treatment strategies associated with the identified condition2,4-5.
4. **It can provide cost-neutral/cost-savings** - Studies evaluating the economic benefit of WGS have demonstrated overall cost-savings when implemented early in the diagnostic testing process6. Multiple studies have shown an overall median cost-savings of $16,504 per child tested ($35,580-$133,333 per affected child) which more than offsets the median cost of WGS testing2-4,6.

In 2021, the American College of Medical Genetics and Genomics (ACMG) published an evidence-based guideline strongly recommending Whole Exome or Whole Genome Sequencing as a first- or second-tier diagnostic test for patients with one or more congenital anomalies diagnosed before one year of age or developmental delay/intellectual disability diagnosed prior to 18 years of age. Trio analysis was recommended as best practice,and WGS performed more favorably (43%) than WES (34%) when comparing diagnostic rates to standard genetic testing.

**Test and Laboratory Information**

* **Test Requested:** Whole Genome Sequencing
* **Performing Laboratory:** Baylor Genetics

The Baylor Genetics Whole Genome Sequencing tests are intended to **establish or** **confirm a diagnosis in individuals with clinical feature(s) suggestive of a rare disease** caused by one or more underlying genetic etiologies. Baylor Genetics offers both standard and rapid WGS options for trio, duo, and proband only analysis.

In conclusion, Whole Genome Sequencing is the most appropriate and comprehensive test to identify the underlying cause of **[Patient Name]’s** condition. This testing will not only inform and guide medical management and clinical care but also provide answers to my patient’s family and allow for a better understanding of the long-term outcomes.

I respectfully request coverage of this critical test for **[PATIENT NAME].** Please feel free to contact me if any additional information is required to ensure its prompt approval.

Thank you for your consideration.

Sincerely,

***[Ordering Physician’s Signature]***

***[Ordering Physician’s Full Name, Title, Department]***

***[Ordering Physician’s email]***
***[Ordering Physician’s phone number]***

**Attachments:**

* Clinical notes
* Prior laboratory and/or imaging test results
* Family history / pedigree

Peer-Reviewed References:

1. 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). Genetics in Medicine. 2021;23(11):2029-2037. doi:10.1038/s41436-021-01242-6
2. Farnaes L, Hildreth A, Sweeney NM, et al. Rapid whole-genome sequencing decreases infant morbidity and cost of hospitalization. NPJ Genom Med. 2018;3(1). doi:10.1038/s41525-018-0049-4
3. Dimmock D, Caylor S, Waldman B, et al. Project Baby Bear: Rapid precision care incorporating rWGS in 5 California children’s hospitals demonstrates improved clinical outcomes and reduced costs of care. Am J Hum Genet. 2021;108(7):1231-1238. doi:10.1016/j.ajhg.2021.05.008
4. Kingsmore SF, Nofsinger R, Ellsworth K. Rapid genomic sequencing for genetic disease diagnosis and therapy in intensive care units: a review. NPJ Genom Med. 2024;9(1). doi:10.1038/s41525-024-00404-0
5. Jobanputra V, Schroeder B, Rehm HL, et al. Advancing access to genome sequencing for rare genetic disorders: recent progress and call to action. NPJ Genom Med. 2024;9(1). doi:10.1038/s41525-024-00410-2
6. Incerti D, Xu XM, Chou JW, Gonzaludo N, Belmont JW, Schroeder BE. Cost-effectiveness of genome sequencing for diagnosing patients with undiagnosed rare genetic diseases. Genetics in Medicine. 2022;24(1):109-118. doi:10.1016/j.gim.2021.08.015
7. Wojcik MH, Lemire G, Berger E, et al. Genome Sequencing for Diagnosing Rare Diseases. New England Journal of Medicine. 2024;390(21):1985-1997. doi:10.1056/nejmoa2314761