Letter of Medical Necessity Test Code 5000

<<Today’s Date>>

<<Insurance Company Name>>

<<Address 1>>

<<Address 2>>

<<City, State ZIP>>

**Regarding:** <<Patient full name>>

**DOB:** <<MM/DD/YYYY>>

**Subscriber ID:** <<Member ID#>>

**Group ID:** <<Group ID#>>

**Re:** Request for prior authorization coverage for PreventionGenetics’ Whole Exome Sequencing Assay (PGxome). Billing is through <<billing institution>> with testing performed at PreventionGenetics, LLC. CPT codes for PreventionGenetics test code #5000 include: <<81415 (Proband) and 81416 (for each additional family member)>>. The ICD 10 code(s) associated with the patient’s diagnosis include <<ICD code(s)>>.

**Rationale for Whole Exome Sequencing (WES)**

Nearly 50% of patients with specific genetic diseases are left undiagnosed using traditional genetic testing methods1.Whole Exome Sequencing can benefit undiagnosed patients by sequencing nearly all genes found in the human genome that are known to be associated with human disease, ultimately leading to the potential detection of disease causing variants. WES is useful in cases in which clinical features are confounding or non-informative, or where previous testing is unclear or fails to provide a diagnosis. Disease-causing variants detected by WES can be beneficial in determining appropriate treatment as well as giving closure to those seeking answers regarding the undiagnosed condition.

WES is capable of identifying multiple variants that result in genetic disease that may have non-specific phenotype features including dysmorphic features, multiple congenital anomalies, birth defects, developmental delay, and intellectual disability2, 3, 4. It is also useful in identifying complex disorders with high levels of genetic heterogeneity, or diseases in which multiple loci contribute to the phenotype. WES is especially valuable for detecting complex variants not usually associated with a specific phenotype or disorder. In some cases, certain disease diagnoses could not have been made using any other method5.

<<**For family/trio testing only; if proband only/singleton testing is desired, remove the following paragraph**>> In addition to testing the proband, two immediate relatives (most commonly the biological mother and father) will also be tested. By sequencing three family members, or a trio, the accuracy in deciphering the inheritance pattern and pathogenicity of variants within the protein coding regions is greatly increased2, 6.

In the case of incidental findings, the American College of Medical Genetics and Genomics’7, 8 guidelines will be followed. Appropriate consent forms allow for discussion and disclosure of incidental findings where needed.

**Personal History**

<<Personal Medical History: Include details of patient’s relevant medical history>>

<<Insert a relevant work up including previous testing and negative results and/or further rationale for the WES request>>

**Family History**

<<Family History: Include list of relevant family history information if applicable. Appropriate risk assessment models or limited history should be noted >>

Given <<Mr/Mrs/Ms/Miss patient’s last name’s>> personal and family history, at this point in the patient’s care, the most efficient and cost effective method that would result in a potentially conclusive diagnosis would be WES.

The laboratory providing the genetic testing is PreventionGenetics, LLC, (Tax ID: 83 0343803) who is a sponsor of Pediatric Lab Utilization Guidance Services ([PLUGS®](http://www.seattlechildrenslab.org/plugs.aspx)).  PreventionGenetics is committed to providing comprehensive, high quality, and affordable genetic testing that adds value to patient care.  Through utilization management strategies at PreventionGenetics, over 1.3 million healthcare dollars are saved annually.

I am hopeful that we can work together for <<Mr/Mrs/Ms/Miss patient’s last name’s>> benefit.  Please contact me at <<Phone #>> with the result of this prior authorization and/or if you need additional information.

Sincerely,

<<Name, credentials>>

<<Title>>

<<Institution>>

References

1. Shashi, V., et al. (2014). *Genetics in Medicine, 16*, 176-182. PubMed ID: 23928913
2. Megahed, H., et al. (2016). Orphanet Journal of Rare Diseases, 11, 57. PubMed ID: 27146152
3. Pronicka, E., et al. (2016). Journal of Translational Medicine, 14, 174. PubMed ID: 27290639
4. Sener, E. F., et al. (2016). *Psychiatry Investigation, 13*, 255-264.

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1. Iglesias, A., et al. (2014). *Genetics in Medicine, 16*, 922-931.

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1. Farwell, K. D., et al. (2015). *Genetics in Medicine, 17*, 578-586.

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1. Allyse, M., & Michie, M. (2013). *Trends in Biotechnology, 8*, 439-441.

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