**CLINICAL GAP / OUT-OF-NETWORK EXCEPTION REQUEST**

To: Insurer
Re: Patient’s Name
DOB: XXXX
Insurance ID #: XXXX

Dear Insurance Authorization Representative:

This letter is to request a gap exception (or out-of-network exception) authorization for the above-named patient for the GeneAware test. The patient was referred to our laboratory by her physician. It was determined that the patient would strongly benefit from expanded carrier screening through GeneAware.

The American Congress of Obstetrics and Gynecology (ACOG) recommends testing for cystic fibrosis, spinal muscular atrophy, thalassemias, and hemoglobinopathies for all patients who are pregnant or considering pregnancy, regardless of ethnic background.1 Further, ACOG issued a joint statement with the American College of Medical Genetics and Genomics, Society for Maternal-Fetal Medicine, National Society of Genetic Counselors, and Perinatal Quality Foundation, supporting the use of expanded carrier screening as a tool for improved pre-conception counseling and disease prevention in offspring.2

To this end, GeneAware expanded carrier screening utilizes next-generation sequencing and copy number variant analysis to test for over 150 genetic conditions simultaneously. GeneAware is exceptional for the amount of sequence covered in the targeted genes, for the inclusion of gene dosage analysis for alpha-thalassemia and silent carriers for spinal muscular atrophy as well as the inclusion of Duchenne muscular dystrophy. In greater than 90% of conditions, GeneAware can report a detection rate of over 90%. Baylor Genetics provides live curation for variants of unknown significance as well as access to a genetic counselor. High detection rates coupled with a robust database of curated variants and a specialized team of carrier lab directors and genetic counselors, allows patients to obtain a highly comprehensive report that includes the most accurate reproductive risk estimates available.

Baylor Genetics can work with small and limited specimens while still providing in-depth results. There is not another in-network provider to provide this level of comprehensive screening in our patient’s geographical area. **[Name of patient]** would like to be able to utilize his/her in-network benefits. As there is not an in-network provider for his/her who can provide the same comprehensive carrier screening, we are requesting a network gap exception authorization for treatment.

Thank you for your prompt attention to this matter.

For additional questions, please contact us by phone at 1-800-411-4363, by fax at 1-866-399-3559 or email at billing@baylorgenetics.com.

Sincerely,

Your Name

1. American College of Obstetricians and Gynecologists. Carrier screening for genetic conditions. Committee Opinion No. 691. Obstet Gynecol. 2017;129:e41–e55. |
2. Edwards, J.G., Feldman, G., Goldberg, J., Gregg, A.R., Norton, M.E., Rose, N.C. et al, Expanded carrier screening in reproductive medicine—points to consider. A joint statement of the American College of Medical Genetics and Genomics, American College of Obstetricians and Gynecologists, National Society of Genetic Counselors, Perinatal Quality Foundation, and Society for Maternal-Fetal Medicine. Obstet Gynecol. 2015;1225:653–662.