**LETTER OF MEDICAL NECESSITY**

To: ***[Insurance Company Name]***

**STAT Review Request**

***[Address]***

***[City, State, ZIP]***

***[Fax]***

Re: ***[Patient Name, DOB]***

***[Member ID Number]***

August 15, 2016

Dear Medical Director:

I am writing on behalf of my patient, listed above, to request coverage for PreSeek, the non-invasive prenatal screen that detects predominately de novo changes in genes related to disorders (such as Noonan Syndrome, SYNGAP1 related developmental delay, thanatophoric dysplasia, osteogenesis imperfecta, Apert syndrome, Crouzon syndrome, etc.) that have significant implications and are not currently detected through any other prenatal screening test. De novopoint mutations are associated with the most deleterious genetic disorders and although individually rare, as a whole have incidence rates great than that of Down Syndrome.1

In 2008, The American College of Genetics and Genomics published a policy statement discussing the increased risk for spontaneous autosomal dominant disorders with advanced paternal age (APA).  As per ACMG, “ The conditions most strongly associated with advanced paternal age are those caused by mutations in the form of single base substitutions in the *FGFR*2, *FGFR*3, and *RET*genes, and include Pfeiffer syndrome, Crouzon syndrome, Apert syndrome, achondroplasia, thanatophoric dysplasia….”. At the time, no prenatal screen for these conditions was clinically available.2,3  PreSeek was designed to detect de novo changes with special emphasis on disorders that increase with advanced paternal age and disorders that are difficult to differentiate by ultrasound findings alone.

This letter provides relevant information about the patient’s pregnancy history, which makes her an appropriate candidate for this test. I am recommending the test be covered for this patient because her pregnancy has been determined to be at increased risk for the fetus based on the below mentioned criteria.

**Patient Diagnosis:**

***[Patient name]*** is a ***[insert age]*** year old female with the following diagnoses:

1. ***[ICD10 code]***

2. ***[ICD10 code]***

**Clinical History:**

\_\_\_\_ an increased risk for the fetus to be affected with genetic disorders based on prenatal screening

\_\_\_\_ has a history of a prior pregnancy affected with \_\_\_\_\_\_\_\_\_\_\_\_, which puts the fetus at increased risk

\_\_\_\_ parent is known to be affected with genetic disorder screened for by PreSeek, which puts the fetus at up to 50% risk to be affected.

\_\_\_\_ Father of pregnancy is of advanced paternal age (>40 years old) conferring a 4-5x greater risk (ACMG policy guidelines for APA, 2008) for specific autosomal dominant conditions that can only be screened using PreSeek

\_\_\_\_\_ abnormal ultrasound suggestive of disorders screened for by PreSeek

*Ultrasound Details:*

I have recommended the non-invasive prenatal test in order to further counsel and guide the care of this patient and to aid in medical management for this pregnancy.

Thank you for your consideration. I look forward to receiving a timely response given the time sensitive nature of my patient’s condition. Please feel free to contact me at ***[Phone number]*** for additional information.

Sincerely,

***[GC Name]***

Genetic Counselor

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***[Signature of ordering physician]***

***[Name of Ordering Physician]***

*CPT Codes:* ***[Insert CPT codes]***

*Laboratory: Baylor Molecular Genetics Laboratories*

References

1. Veltman JA and Brunner HG. De novo mutations in human genetic disease. Nature Review Genetics, et al. 2012 August; 13: 565-575.
2. Toriello HV and Meck JM. Statement on guidance for genetic counseling in advanced paternal age. Genetics in Medicine. 2008 June; 10(6): 457-460.
3. Kong A, Frigge ML, Masson G. Rate of de novo mutations, father’s age, and disease risk. Nature. 2012 August; 488(7412): 471-475.