[DATE]

**Patient:** [PATIENT\_FIRST\_NAME] [PATIENT\_LAST\_NAME]

**Insurance Company:** [INSURANCE\_COMPANY\_NAME]

**Subscriber Name:** [POLICY\_HOLDER\_NAME]

**Policy #:** [POLICY\_NUMBER]

Dear Claims Specialist,

I am writing this letter of medical necessity on behalf of the patient [PATIENT\_FIRST\_NAME] [PATIENT\_LAST\_NAME] to request coverage for genetic testing for mitochondrial disorders offered through GeneDx, a high complexity CLIA certified laboratory located in Gaithersburg, Maryland. The purpose of this test is to identify a pathogenic mutation(s) in the mitochondrial and nuclear genome, and the methodology used by this laboratory is able to find these mutations with a very high degree of sensitivity. **Results of this test will allow better care and treatment of the patient. In addition, it will allow for proper genetic counseling and family planning.** This test is performed by next generation sequencing (aka massive parallel sequencing), which has a detection rate of 99%.

**Information on Mitochondrial Disorders:**

Mitochondrial disorders are clinically heterogeneous group of genetic disorders characterized by multiple organ system involvement affecting systems that require high amounts of energy (brain, skeletal muscle, heart, kidney, endocrine system, etc). The signs and symptoms of mitochondrial disorders vary greatly from patient to patient making an accurate clinical diagnosis very difficult. Additionally, the prognosis varies considerably, from treatable to early death between these variable genotypes.

**Diagnosing Mitochondrial Disorders**

Gene testing can confirm the clinical diagnosis from among an extensive group of widely different genetic conditions with efficiency, economy, and certainty.

**Clinical Utility of Mitochondrial Disorders Genetic Testing**

**Results of this genetic test will help determine the diagnosis so that the physician can proceed with the proper treatment and management necessary for cost effective care.** This requested test is far more beneficial, cost effective, and accurate than other current means or methods in determining if a mitochondrial disease is present. The benefits and cost effectiveness of this mitochondrial genetic testing are extensive and includes:

* Accurate genetic diagnosis which cannot be made by other means1. If found to be present, provides the exact gene that is causing the Mitochondrial Disease without the false negatives/false positives of tissue biopsies.
* Eliminates the need for expensive and inconclusive tissue biopsies with their associated cost and risk of general anesthesia. This test is not an interpretation as a biopsy is.
* Enables clinicians to establish a specific diagnosis that can put an end to the quest (often lengthy and costly) for an accurate diagnosis.
* Ability to sequence large numbers of genes inexpensively that locates the exact gene that may be effective. This is critical in the future as treatment and protocols for mitochondrial diseases are and will be based on knowing the exact gene that is effective.
* Counseling will be far more targeted regarding recurrence risk, prognosis, 1 and involvement with other organs as well as providing valuable family planning counseling.
* Elimination of the ongoing cost of further low-specificity and low sensitivity testing that is often repeated many times and is expensive in its own right (Lumbar punctures, biomarker testing, MRI, etc).
* Choice of appropriate therapy1

Thank you for your review and consideration. I hope you will support this request for genetic testing coverage for [PATIENT\_FIRST\_NAME] [PATIENT\_LAST\_NAME]. If you have questions, or if I can be of further assistance, please do not hesitate to call me at [PHYSICIAN\_PHONE\_NUMBER].

Sincerely,

[PHYSICIAN\_FIRST\_NAME] [PHYSICIAN\_LAST\_NAME], MD

cc: [PATIENT\_FIRST\_NAME] [PATIENT\_LAST\_NAME]

Reference:

1. Chinnery, P. Gene Reviews (2006) Mitochondrial Disorders Overview