#######, 2019

Patient Name: #####, #####

Patient DOB: ##/##/####

I’m writing this letter on behalf of patient **#####** to request coverage for performing the UCSF cerebrospinal fluid (CSF) metagenomic next-generation sequencing (mNGS) infectious disease diagnostic test, a clinically validated molecular test performed by the University of California San Francisco Medical Center’s Microbiology Laboratory.

This patient has a meningoencephalitis of unclear etiology despite extensive diagnostic testing for many infectious and non-infectious etiologies. As a result of this condition, the patient has developed ###disabilities#### and has not responded to empiric therapies for ####diseases####. Given ##his/her## current clinical trajectory, I am concerned that this life-threatening illness will only progress. Molecular testing on the UCSF CSF mNGS assay is medically essential for this patient for two purposes:

1. Based on the patient’s clinical presentation, I am very suspicious of an infectious etiology, but the diagnostic tests I have sent thus far, each for specific organisms, have failed to identify an etiology. Unlike other infectious disease diagnostic tests, the CSF mNGS assay has the ability to identify any class of organism (DNA and RNA viruses, bacteria, fungi and parasites) in a single test whether the treating physician has suspicion for a particular organism or not. As a result, this test will be particularly useful for my patient’s diagnostically challenging presentation.
2. There is a possibility that my patient has a **non-infectious** cause of ##his/her## meningoencephalitis which may be effectively treated with empiric immunosuppression. To facilitate the institution of empiric immunosuppression, I need to first exhaustively rule out an occult infection which could be exacerbated by immune suppressing medications. The CSF mNGS assay is the most effective and efficient way to do this since it can detect a huge range of infections.

For the performance characteristics of this validated diagnostic test, please refer to the following manuscript (https://doi.org/10.1101/330381). In addition, a recent prospective, multi-center trial of 204 patients with idiopathic meningoencephalitis found that this CSF mNGS assay increased the number of identified infections by 22% and that the assay was 80% sensitive and 98% specific compared to all other direct detection testing on CSF ordered by treating physicians (e.g., pathogen-specific PCR, culture and antigen testing). More than half of the additional infections detected by CSF mNGS had clinical impact, especially with regard to guiding treatment.

I hope that you please consider this request for coverage of this molecular test that is considered essential to help either identify the infectious diagnosis in my patient or to exhaustively exclude an underlying infection and thereby enable me to pursue alternate treatment modalities to avoid further neurologic deterioration and permanent disability. Please let me know if there are any questions.

Laboratory Information:

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Test CPT: 81479 (DEX-Z Code ZB6T9, Lab Test ID P710)

Test HCPC: G0452

Sincerely,