Letter of Medical Necessity for Lynch Syndrome

Physician Name, MD
Institution
Address
City, State and Zip Code

Date

Medical Director/Physician Name, MD
Insurance Company Name
Address
City, State and Zip Code

Re: Patient Name DOB: MM/DD/YYYY

Member ID: Group ID:

Dear Medical Director:

I am writing this letter on behalf of the above-referenced patient to request coverage of genetic testing for Lynch syndrome available through Sonora Quest Laboratories and performed by Quest Diagnostics. This test includes comprehensive analysis of the *MLH1*, *MSH2*, *MSH6*, and *PMS2* genes and *EPCAM* deletion/duplication analysis. This multi-gene test is the most cost-effective and efficient way to analyze multiple genes associated with Lynch syndrome. This letter documents the medical necessity for this test and, as such, provides information about the patient's medical history and treatment options.

The relevant CPT codes for this service are 81295, 81297, 81292, 81294, 81298, 81300, 81317, 81319, and 81403.

Lynch syndrome, otherwise known as Hereditary Nonpolyposis Colorectal Cancer (HNPCC), is the most common cause of hereditary colon cancer and the second most common cause of hereditary ovarian cancer.[1] Lynch syndrome is caused by mutations in mismatch repair genes (*MLH1*, *MSH2*, *MSH6*, *PMS2*) and *EPCAM*.[1] A mutation in one of these genes is associated with up to an 80% lifetime risk of colorectal cancer, as compared to the general population risk of 5.5%.[1] Women with Lynch syndrome have up to a 60% lifetime risk of endometrial cancer and up to a 24% lifetime risk of ovarian cancer, as compared to the general population risk of 2.7% and 1.6%, respectively.[1] Individuals with Lynch syndrome also have an increased risk to develop extracolonic cancers including: small bowel, biliary system, pancreatic, renal pelvis, brain, and ureteral cancer.[1] For individuals who have already been diagnosed with cancer, Lynch syndrome is associated with a significantly increased risk of developing a second primary cancer.[1]

Patient and Family Medical History
Significant aspects of my patient's personal and/or family history that are strongly suggestive of hereditary cancer are listed below.

Patient History

- ☐ The patient has a personal history of Type of Cancer diagnosed at age .
- ☐ The patient does not have a personal history of cancer, but has a very strong family history of cancer as detailed below.
- ☐ o If the patient does not have a personal history of cancer, please indicate if any of the following apply:
  - ☐ The patient's affected relatives are deceased.
  - ☐ Patient does not have any contact with the affected relatives.
  - ☐ The affected relatives have refused genetic testing or have refused to share their testing history and/or test results with my patient.

Family History

☐ The patient has a family history that includes the following relatives and their conditions: *[for relatives, include both maternal and paternal sides of the family]*

1. Relationship	Cancer	Age
2. Relationship	Cancer	Age
3. Relationship	Cancer	Age

☐ A mutation was previously identified in the gene in the patient's blood relative Relationship
☐ Other:

The relevant ICD-10 codes for this patient are .

Medical Necessity
I have determined that this test is medically necessary for the above-referenced patient. The American Society of Clinical Oncology recommends that genetic testing be offered to individuals with suspected inherited cancer risk for whom test results would aid in medical management decision-making. In addition, several professional societies, including those listed below, have published guidelines for managing patients with elevated cancer risks due to a gene mutation.

- National Comprehensive Cancer Network
- American College of Obstetricians and Gynecologists
- American Society of Clinical Oncology
- International Gastric Cancer Linkage Consortium
- International Cancer of the Pancreas Screening Consortium

Ultimately, if a mutation is found in a gene associated with Lynch syndrome, it would help clarify the patient's cancer risk and prompt a change in the patient's medical management due to the increased risk for multiple malignancies. Individuals with Lynch syndrome have specialized treatment options to decrease their risk of cancer, including increased surveillance, surgery, and chemoprevention. Therefore, test results are necessary in choosing the most appropriate course of treatment and/or surveillance for this patient. A positive result will provide a genetic diagnosis of Lynch syndrome, which would help ensure my patient is managed appropriately.

Management changes may include[1]:

- Colonoscopy every 1-2 years starting at age 20-25, or earlier depending on the youngest diagnosis in the family
- More aggressive colorectal cancer surgery
- Risk-reducing hysterectomy and bilateral salpingo-oophorectomy
- Annual urinalysis starting at age 25-30
- Annual physical/neurological exam starting at age 25-30
- Other:

Explanation of Need
Hereditary cancer syndromes associated with these genes present with a wide spectrum of cancers with variable penetrance, severity and ages of onset, which makes it difficult to determine appropriate single-syndrome testing. Therefore, a multi-gene test increases the opportunity for at-risk individuals to be appropriately identified and receive necessary medical management. The National Comprehensive Cancer Network (NCCN) guidelines specify that multi-gene tests should be included, when appropriate, in the evaluation of high risk patients, because multiple genes may contribute to increased cancer risk.[1] Multiple professional societies have published statements that recognize the advantages of multi-gene tests in decreasing cost and improving efficiency of cancer genetic testing as compared to other approaches to genetic testing, such as a tiered approach.

I am specifying Quest Diagnostics as the performing laboratory because Quest has extensive experience in molecular genetics and offers a highly-sensitive and cost-effective test for Lynch syndrome.

Informed Consent
The patient has provided informed consent after being counseled about the cancer risks associated Lynch syndrome, the meaning of possible test results and available treatment options.

Please contact me at Phone Number if you have any additional questions.

Thank you,

Physician Name, MD

References:

[1] National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines). Genetic/familial high-risk assessment: colorectal. Version 2.2015.