INVITAE

PROVIDENCE Express Care | at Home

Providence Health Plan Statement of Medical Necessity Form	**Genetic Testing for Hereditary Colorectal Cancer (Lynch Syndrome)**
Patient Information	**Physician Information**
Name:	Physician Name:
Gender: ☐ Male ☐ Female	Tax ID Number:
Providence Health Plan ID Number: ☐ HMO ☐ PPO/ASO	Specialty: ☐ PCP ☐ Specialist ☐ Genetic Counselor (Please Identify):
Birth Date (mm/dd/yy):	Rendering Provider (Laboratory): Invitae Corporation
Date of Service (mm/dd/yy):	Rendering Provider ID Number: NPI: 1316206220
Has the patient undergone prior Lynch Syndrome or FAP testing? ☐ Yes ☐ No	

Coding Information

MLH1, MSH2, MSH6, PMS2 and EPCAM CPT Codes (check all that apply):
☑ **81435** (Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel)

ICD-10 Codes (list all applicable codes):

Medical Necessity Criteria

Mutation Testing: Genetic testing for MLH1, MSH2, MSH6, PMS2, and/or EPCAM mutations in adults (at least 18 years of age or older) may be considered **medically necessary** when **any** of the following criteria are met (please check all applicable boxes):

☐ **I am ordering *MLH1, MSH2, MSH6, PMS2,* and *EPCAM* testing and my patient has a personal history of a Lynch-syndrome related cancer (*colorectal, endometrial, ovarian, gastric, pancreas, ureter & renal pelvis, biliary tract, brain (usually glioblastoma), sebaceous gland carcinoma, and small intestine cancer)* or a Lynch-syndrome related benign tumor *(sebaceous gland adenoma or keratoacanthomas)* and meets one of following criteria:**

- ☐ Lynch-syndrome related cancer or tumor was diagnosed at less than 50 years of age
- ☐ Patient has history of two or more Lynch syndrome-associated tumors, regardless of age
- ☐ Patient has one or more first-degree relatives with a Lynch syndrome associated tumor, with one of the tumors being diagnosed under age 50 years
- ☐ Patient has two or more first- or second-degree relatives with Lynch syndrome-associated tumors, regardless of age
- ☐ Patient has first, second or third degree relative with known clinical diagnosis of Lynch syndrome
- ☐ Patient has an MMRPro, PREMM, or MMRpredict model score of 5% or more

If there is colorectal or endometrial tumor available from my patient,
- ☐ the tumor is MSI-H
- ☐ the tumor shows absent MSH2 and/or MSH6 and/or PMS2 protein by IHC
- ☐ Lynch-syndrome related cancer shows absent MLH1 protein in the tumor and the tumor has been shown not to haveMLH1 promoter methylation or not to have a BRAF V600E mutation

☐ **I am ordering *MLH1, MSH2, MSH6, PMS2,* and *EPCAM* testing. My patient does not have a personal history of a Lynch-syndrome related tumor but meets one of following criteria:**

- ☐ Has one or more first-degree relatives with a Lynch syndrome associated cancer, with one of the cancers being diagnosed under age 50 years
  Family Member: _____ *Age*: _____(years) *Tumor type:* _____
- ☐ Has two or more first- or second-degree relatives with Lynch syndrome-associated cancers, regardless of age
  Family Member: _____ *Age*: _____(years) *Tumor type:* _____
  Family Member: _____ *Age:* _____(years) *Tumor type:* _____
- ☐ Has a first, second or third degree relative with a clinical diagnosis of Lynch syndrome
  Family Member: _____ *Age*: _____(years) *Tumor type:* _____
- ☐ Has an MMRPro, PREMM, or MMRpredict model score of 5% or more

☐ **I am ordering specific *MLH1, MSH2, MSH6, PMS2, or EPCAM* testing for** a known *MLH1, MSH2, MSH6, PMS2,* or *EPCAM* gene mutation first, second or third degree relative.
Family Member: _____ *Identify gene and mutation*: _____

I confirm that this test is medically necessary in accordance with (*Providence Health Plan*) medical policy and that the information provided is accurate and factual based on the patient's medical records and history. I confirm that this test is medically necessary for the risk and assessment, diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will determine my patient's medical management and treatment decisions. I confirm that I have been trained to provide genetic counseling, and that I have conducted a full personal and family history which includes a first, second and third degree pedigree. I have provided genetic testing information and pre-test counseling to the patient and they have consented to genetic testing. I have scheduled post-test counseling to review the test results and determine future medical management and treatment plans.

Ordering Provider Signature:_____ Date (mm/dd/yy): _____

Please print name: _____ NPI number: _____

Date of genetic counseling (mm/dd/yy): _____