LETTER OF MEDICAL NECESSITY
HEREDITARY CANCER GENETIC TESTING (Advanced Lab Solutions Hereditary Cancer Panel)

Date: Date of service/claim

To: Utilization Review Department
Insurance Company Name, Address, City, State

Re: Patient Name, DOB, ID #:

ICD-10 Codes:

The ICD-10 codes listed below are commonly received by Advanced Lab Solutions LLC from ordering providers for the testing described in this letter. Ambry provides this information as a customer service but makes no recommendations regarding the use of any diagnosis codes. As a reminder, it is the ordering provider's responsibility to always determine, for the specific date of service, the appropriate diagnostic codes based on the patient's signs and symptoms.

ACTIVE DIAGNOSIS:

- ☐ C21.0-C21.8 Anal cancer
- ☐ C24.0-C24.9 Bile duct cancer
- ☐ C71.0-C71.9 Brain cancer
- ☐ C50.011-C50.929 Breast cancer (male or female)
- ☐ C18.0-C18.9, C19, C20 Colorectal cancer
- ☐ C57.00-C57.03 Fallopian Tube Cancer
- ☐ C22.0-C22.9 Liver cancer
- ☐ C56.1-C56.9 Ovarian cancer
- ☐ C25.0-C25.9 Pancreatic cancer
- ☐ C48.1-C48.2 Peritoneal Cancer
- ☐ C61 Prostate cancer
- ☐ C64.1-C64.9, C65.1-C65.9 Renal cancer
- ☐ C16.0-C16.9 Stomach cancer
- ☐ C17.0-C17.9 Small intestine cancer
- ☐ C73 Thyroid cancer
- ☐ C66.1-C66.9 Ureteral cancer
- ☐ C54.0-C54.9, C55 Uterine cancer

PERSONAL HISTORY:

- ☐ Z85.09 Bile duct cancer, personal history
- ☐ Z85.841 Brain cancer, personal history
- ☐ Z85.3 Breast cancer, personal history
- ☐ Z85.038, Z85.048 Colorectal OR anal cancer, personal history
- ☐ Z85.05 Liver cancer, personal history
- ☐ Z85.43 Ovarian/Fallopian Tube/Peritoneal cancer, Personal history
- ☐ Z85.07 Pancreatic cancer, Personal history
- ☐ Z85.46 Prostate cancer, Personal history
- ☐ Z85.528, Z85.53 Renal cancer, personal history
- ☐ Z85.068 Small intestinal cancer, personal history
- ☐ Z85.028 Stomach cancer, personal history
- ☐ Z85.850 Thyroid cancer, personal history
- ☐ Z85.54 Ureteral cancer, personal history
- ☐ Z85.42 Uterine cancer, Personal history

FAMILY HISTORY:

- ☐ Z80.0 Bile Duct OR colorectal OR anal OR pancreatic OR stomach OR small intestinal OR liver cancer, Family history
- ☐ Z80.8 Brain OR thyroid cancer, family history
- ☐ Z80.3 Breast cancer, family history
- ☐ Z80.0 Colorectal OR anal OR pancreatic OR bile duct OR stomach OR small intestinal OR liver cancer, Family history
- ☐ Z80.0 Liver or colorectal OR anal OR pancreatic OR bile duct OR stomach OR small intestinal cancer, Family history
- ☐ Z80.41 Ovarian/Fallopian Tube/Peritoneal cancer, Family history
- ☐ Z80.0 Pancreatic OR colorectal OR anal OR bile duct OR stomach OR small intestinal OR liver cancer, Family history
- ☐ Z80.42 Prostate cancer, family history
- ☐ Z80.51 Renal cancer, family history
- ☐ Z80.0 Small intestinal OR colorectal OR anal OR pancreatic OR bile duct OR stomach OR liver cancer, Family history

- ☐ Z80.0 Stomach OR colorectal OR anal OR pancreatic OR bile duct OR small intestinal OR liver cancer, Family history
- ☐ Ureteral cancer, family history
- ☐ Uterine cancer (other genital organs), Family history

This letter is regarding my patient and your subscriber, referenced above, to request full coverage of medically indicated genetic testing for hereditary cancer (**(Advanced Lab Solutions Hereditary Cancer Panel**) to be performed by Advanced Lab Solutions LLC.

Cancer is thought to have a hereditary component in up to 10% of cases. Mutations in multiple genes cause hereditary cancer, which markedly increases the lifetime risk for many types of cancer.[1] Evaluating personal and family histories is a major part of hereditary cancer risk assessment. **Significant aspects of my patient's personal and/or family medical history that suggest a reasonable probability of hereditary cancer include** [check all that apply]**:**

- ☐ A history clearly suggestive of hereditary cancer
- ☐ An individual with multiple primary cancers
- ☐ Cancer diagnosed at a younger age than expected (≤ 50 years, for most cancers)
- ☐ Multiple people with genetically related cancers on the same side of the family
- ☐ A family history of cancer that is typical of a known hereditary cancer syndrome
- ☐ A family history with features of several hereditary cancer syndromes
- ☐ Multiple cancers in the family that do not seem to fit a particular hereditary cancer syndrome (demonstrating a need for a multi-gene testing approach)
- ☐ Other:_____

Based on this, I am requesting coverage for this test (Hereditary Cancer Panel). Hereditary Cancer Panel includes comprehensive analysis of 32 genes associated with hereditary cancer:*, APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1,CDH1,CDKN2A, CHEK2,EPCAM, FH, FLCN, MLH1, MRE11A,MSH2, MSH6, MUTYH, NBN, , PALB2,PMS2,PTEN, RAD50, RAD51C,RAD51D, RINT1, SDHB, SMAD4,STK11,TP53, VHL, XRCC2.* According to published guidelines, more than one gene may explain an inherited cancer syndrome; thus, multi-gene testing can be more efficient and/or cost-effective than a sequential single gene testing approach.[2,3]

This genetic testing will help estimate my patient's risk to develop cancer/another primary cancer and could directly impact my patient's medical management. Many of the genes in this test have published clinical practice guidelines to reduce the risk for cancer and/or detect cancer early, thus reducing morbidity and mortality. Management options may include:

- ✓ Increased breast screening including self-examinations, clinical breast examinations, mammogram, ultrasound, and MRI
- ✓ Breast cancer risk reduction using prophylactic mastectomies and/or chemoprevention
- ✓ Risk-reducing bilateral salpingo-oophorectomy and/or hysterectomy
- ✓ More frequent and/or earlier colonoscopy screening

- ✓ Prostate cancer screening (PSA and DRE)[4,5]
- ✓ Avoidance of radiation treatment when possible
- ✓ To aid in systemic therapy decision-making
- ✓ Consideration of other MRI-based screening/technologies[6]
- ✓ Other: _____

[For affected patients:] This testing may also impact the surgical and/or medical options available to treat my patient's current cancer.

Based on these factors, this testing is medically necessary, and I request that you approve coverage of genetic testing for hereditary cancer in my patient.

Thank you for your time, and please don't hesitate to contact me with any questions.

Sincerely,

Ordering Clinician Name (Signature Provided on Test Requisition Form)
(MD/DO, Clinical Nurse Specialist, Nurse-Midwives, Nurse Practitioner, Physician Assistant, Genetic Counselor*)

*Authorized clinician requirements vary by state

Test Details

CPT codes: 81162, and 81201, 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, 81321, 81403, or 81432, 81433, or 81435, 81436, or 81479

Laboratory: ADVANCED LAB SOLUTIONS LLC, a CLIA-certified laboratory located at 3729 Easton Nazareth Hwy, LL2, Easton, PA,18045

References:

1. Chen S and Parmigiani G. Meta-analysis of *BRCA1* and *BRCA2* penetrance. J Clin Oncol. 2007 Apr 10;24(1):1329-33.
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic. Version 2.2022, 3/9/2022.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/Familial High-Risk Assessment: Colorectal. Version 1/2022, 6/8/2022.
4. Kirchhoff T, *et al.* BRCA mutations and risk of prostate cancer in Ashkenazi Jews. Clin Cancer Res. 2004 May;10(9):2918-2921.
5. Castro E, *et al.* Germline BRCA mutations are associated with higher risk of nodal involvement, distant metastasis, and poor survival outcomes in prostate cancer. J Clin Oncol. 2013 May;31(14):1748-1757.
6. Villani A, *et al.* Biochemical and imaging surveillance in germline *TP53* mutation carriers with Li-Fraumeni syndrome: a prospective observational study. Lancet Oncol. 2011 Jun;12(6):559-67