**LETTER OF MEDICAL NECESSITY**

**HEREDITARY BREAST/GYNECOLOGIC CANCER GENETIC TESTING (BRCANext-Expanded)**

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 Ambry 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

C17.0-C17.9 Small intestine cancer

C16.0-C16.9 Stomach 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 instestinal 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 instestinal OR liver cancer, Family history

Z80.0 Liver or colorectal OR anal OR pancreatic OR bile duct OR stomach OR small instestinal 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 instestinal OR liver cancer, Family history

Z80.42 Prostate cancer, family history

Z80.51 Renal cancer, family history

Z80.0 Small instestinal 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 instestinal OR liver cancer, Family history

Z80.59 Ureteral cancer, family history

Z80.49 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 breast/gynecologic cancer (BRCANext-Expanded) to be performed by Ambry Genetics Corporation.

Breast and gynecologic cancers (*e.g.* ovarian and uterine) are thought to have a hereditary component in up to 10% and 25% of cases respectively. **Significant aspects of my patient’s personal and/or family medical history that suggest a reasonable probability of hereditary breast/gynecologic cancer are below** [check all that apply]:

* Ovarian, triple negative breast, male breast, pancreatic, or metastatic or high/very high-risk group prostate cancer at any age
* Early-onset breast cancer (diagnosed before 45) or uterine cancer (diagnosed before 50)
* Multiple primary cancers in one person (*e.g*., uterine and breast or thyroid cancer)
* Close family members with ovarian or uterine and other cancers
* Cancer histories that are suspicious for both hereditary breast and ovarian cancer and Lynch syndrome
* A known mutation in a cancer susceptibility gene within the family
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Based on the personal and/or family history, my patient is suspicious for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ syndrome(s).* **According to published guidelines, germline genetic testing is warranted.**2,3

Therefore, I am requesting coverage for this test (BRCANext-Expanded), which analyzes 23 genes associated with hereditary breast/gynecologic cancer: *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, DICER1, EPCAM, MLH1, MSH2, MSH6, NBN, NF1, PALB2, PMS2, PTEN, RAD51C, RAD51D,* *RECQL*, *SMARCA4*, *STK11*, *TP53.* According to published guidelines, more than one gene may explain an inherited cancer syndrome, thus multi-gene testing may be more efficient and/or cost-effective.2-4

**This genetic testing will help estimate my patient’s risk to develop [choose one] cancer/another primary cancer and could directly impact my patient’s medical management. All of the genes in this test have published clinical practice guidelines** to reduce the risk for cancer and/or detect cancer early, in order to reduce morbidity and mortality. Management options may include2,3 [check all that apply]:

* Increased breast screening including, clinical breast examinations, mammogram, ultrasound, MRI
* Breast cancer risk reduction using anti-estrogen therapy or prophylactic mastectomies
* Gynecologic cancer risk reduction using risk-reducing salpingo-oophorectomy and/or hysterectomy
* More frequent colonoscopy
* Prostate cancer screening (PSA and DRE)5,6
* Avoidance of radiation treatment when possible
* Consideration of other MRI-based screening/technologies7
* 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 diagnostic genetic testing for hereditary breast/gynecologic 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 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, or 81479

Laboratory: Ambry Genetics Corporation (TIN 33-0892453 / NPI 1861568784), a CAP-accredited and CLIA-certified laboratory located at 7 Argonaut, Aliso Viejo, CA 92656

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. Lancaster JM, *et al*. Society of Gynecologic Oncology statement on risk assessment for inherited gynecologic cancer predispositions. Gynecol Oncol. 2015 Jan;136(1):3-7.
5. Kirchhoff T, *et al.* BRCA mutations and risk of prostate cancer in Ashkenazi Jews. Clin Cancer Res. 2004 May;10(9):2918-2921.
6. 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.
7. 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.