**LETTER OF MEDICAL NECESSITY TEMPLATE**

**HEREDITARY BREAST/GYNECOLOGIC CANCER GENETIC TESTING (BRCANext®)**

Date: Date of service/claim

To: Utilization Review Department

 Insurance Company Name, Address, City, State

Re: Patient Name, DOB, ID #

ICD-10 Codes: (Quick reference suggestions)

ACTIVE DIAGNOSIS:

C50.919 BREAST, FEMALE cancer

C50.929 BREAST, MALE cancer

C18.9 COLON cancer

C56.9 OVARY cancer

C25.9 PANCREAS cancer

C61 PROSTATE cancer

C55 UTERUS cancer

PERSONAL HISTORY:

Z80.3 BREAST cancer (female or male), Personal history

Z83.71 COLON cancer. Personal history

Z85.43 OVARIAN cancer, Personal history

Z85.07 PANCREATIC cancer, Personal history

Z85.46 PROSTATE cancer, Personal history

Z85.42 UTERUS cancer, Personal history

FAMILY HISTORY:

Z85.3 BREAST cancer. Family history

Z80.0 COLON (digestive organ) cancer, Family history

Z80.41 OVARIAN cancer, Family history

Z90.0 PANCREATIC (digestive organ) cancer, Family history

Z85.46 PROSTATE cancer; Family history

Z80.49 UTERUS 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) 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 respectively1. **Significant aspects of my patient’s personal and/or family medical history that suggest a reasonable probability of hereditary breast/gynecologic cancer are below:**

* 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 by age 50) 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, we are requesting coverage for this test (BRCANext), which analyzes 19 genes associated with hereditary breast/gynecologic cancer: *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NF1, PALB2, PMS2, PTEN, RAD51C, RAD51D,* STK11, *TP53* (with an option to add on 7 additional genes: *ATRIP, CDC73, FH, NTHL1, POLE, POLD1, RAD51B).* 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.1-3

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)
* Avoidance of radiation treatment when possible
* Consideration of other MRI-based screening/technologies
* 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

**Test Details**

CPT codes: 81432,81433 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 1.2025, 9/11/2024.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/Familial High-Risk Assessment: Colorectal, Endometrial and Gastric. Version 2.2024. 10/3/2024.