**LETTER OF MEDICAL NECESSITY**

**HEREDITARY CANCER GENETIC TESTING (CancerNext-*Expanded®*)**

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 cancer (CancerNext-*Expanded*) to be performed by Ambry Genetics Corporation.

Cancer is thought to have a hereditary component in up to 10% of cases. Mutations in multiple genes cause hereditary cancer, which markedly increase 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)
* Ovarian, triple negative breast, male breast, pancreatic, or metastatic or high/very high-risk group prostate cancer at any age
* Close family members with any of the above cancers
* Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Based on this, I am requesting coverage for this test (CancerNext-*Expanded*). CancerNext-*Expanded* includes comprehensive analysis of 77 genes associated with hereditary cancer: *AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CEBPA, CHEK2, CTNNA1, DDX41, DICER1, EGFR, EPCAM, ETV6, FH, FLCN, GATA2, GREM1, HOXB13, KIT, LZTR1, MAX, MBD4, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD51C, RAD51D, RB1, RET, RPS20, RUNX1, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TMEM127, TP53, TSC1, TSC2, VHL, WT1.* 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/technologies6
* 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

**Test Details**

CPT codes: 81479, or 81432/81433, 81435/81436, 81162, 81292, 81295, 81298, 81317, 81201, or 81406

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.
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