**LETTER OF MEDICAL NECESSITY**

**HEREDITARY PROSTATE CANCER GENETIC TESTING (ProstateNext)**

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:

C61 PROSTATE cancer

PERSONAL HISTORY:

Z85.46 PROSTATE 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

Z80.3 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

Z80.0 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

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 prostate cancer (ProstateNext) to be performed by Ambry Genetics Corporation.

Prostate cancer is thought to have a hereditary component in approximately 10% of cases. Mutations in multiple genes cause hereditary prostate cancer, which markedly increase the lifetime risk for prostate cancer. Most of these gene mutations also increase the lifetime risk for other cancers (such as male breast, pancreatic, ovarian, uterine, colorectal, sarcomas, brain, leukemia, gastric, thyroid, and kidney).1,2

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 prostate cancer are below** [check all that apply]:

* Metastatic prostate cancer
* Intraductal/cribriform prostate cancer
* NCCN high- or very-high risk group prostate cancer
* Prostate cancer (any age or type) and:
  + A close relative with ovarian, pancreatic or male breast cancer at any age, or early onset breast, colon or endometrial cancer (<50 yo)
  + Two close relatives with breast and/or prostate cancer of any type or age
  + Three close relatives with a Lynch syndrome cancer (biliary tract, brain, colorectal, endometrial, gastric, ovarian, pancreatic, small intestine and/or urothelial cancers or sebaceous adenomas, carcinomas or keratoacanthomas)
  + Ashkenazi Jewish ancestry
* A child, sibling or parent meeting any of the above criteria
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Based on this, I am requesting coverage for this test (ProstateNext), which analyzes 14 genes associated with hereditary prostate cancer: *ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, RAD51D,* and *TP53.* Due to the history stated above, there is a reasonable probability of detecting a mutation in my patient. This multi-gene test is the most efficient and cost-effective way to analyze these genes.**According to published guidelines, germline genetic testing is warranted.**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:

* Prostate cancer screening starting at age 40
* Increased breast screening including clinical breast examinations, mammogram, ultrasound, MRI
* Prophylactic mastectomies and/or chemoprevention
* Prophylactic hysterectomy
* Risk-reducing salpingo-oophorectomy
* More frequent and/or earlier colonoscopy
* Avoidance of radiation treatment when possible
* 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 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319

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. Pritchard CC *et al.* Inherited DNA-Repair Gene Mutations in Men with Metastatic Prostate Cancer. N Engl J Med. 2016 Aug 4;375(5):443-53.
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®). Prostate Cancer. Version 4.2022, 5/10/2022.