**LETTER OF MEDICAL NECESSITY**

**HEREDITARY PANCREATIC CANCER GENETIC TESTING (PancNext)**

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:

C50.011-C50.929 Breast cancer (male or female)

C18.0-C18.9, C19, C20 Colorectal cancer

C57.00-C57.03 Fallopian Tube Cancer

C43.0-C43.9 Melanoma (skin)

C56.1-C56.9 Ovarian cancer

C25.0-C25.9 Pancreatic cancer

C48.1-C48.2 Peritoneal Cancer

C61 Prostate cancer

C54.0-C54.9, C55 Uterine cancer

PERSONAL HISTORY:

Z85.3 Breast cancer, personal history

Z85.038, Z85.048 Colorectal cancer, personal history

Z85.820 Melanoma (skin), Personal History

Z85.43 Ovarian/Fallopian Tube/Peritoneal cancer, Personal history

Z85.07 Pancreatic cancer, Personal history

Z85.46 Prostate 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

Z80.3 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

Z80.8 Melanoma (skin) OR brain 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

Z85.46 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

Z80.59 Ureteral 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 pancreatic cancer (PancNext) to be performed by Ambry Genetics Corporation.

Pancreatic cancer is thought to have a hereditary component in approximately 10% of cases. Mutations in multiple genes cause hereditary pancreatic cancer, which markedly increase the lifetime risk for pancreatic cancer (such as a 17-25% or higher risk for those with *CDKN2A* mutations).1,2 Most of these gene mutations also increase the lifetime risk for other cancers (such as breast, colorectal, ovarian, uterine, melanoma, sarcoma, brain, thyroid, and prostate).3,4

According to published guidelines, **all individuals with exocrine pancreatic cancer in themselves or a parent, sibling or child should be offered genetic testing**.3

**In addition, individuals from families with pancreatic cancer and close relatives with any of the following features should also consider genetic testing:**

* Multiple cases of pancreatic cancer
* Melanoma and pancreatic cancer in the same or related individuals
* Ovarian, breast, or metastatic or high/very high-risk group prostate cancer at any age
* Early-onset colorectal or endometrial cancer (diagnosed <50 years of age)
* Colorectal or endometrial cancer at any age and one or more relatives with a Lynch syndrome tumor (biliary tract, brain, colorectal, endometrial, gastric, ovarian, pancreatic, small intestine and/or urothelial cancers or sebaceous adenomas, carcinomas or keratoacanthomas)
* Multiple primary cancers in one person (*e.g*., uterine and pancreatic cancer)
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Based on this, I am requesting coverage for this test (PancNext), which analyzes 13 genes associated with hereditary pancreatic cancer: *APC, ATM, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, 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.**3-5

**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:

* Pancreatic screening utilizing endoscopic ultrasound and/or MRI/MRCP
* Risk-reducing salpingo-oophorectomy and/or hysterectomy
* More frequent colonoscopy
* Increased breast screening including, clinical breast examinations, mammogram, ultrasound, MRI
* Breast cancer risk reduction using prophylactic mastectomies and/or chemoprevention
* Prostate cancer screening (PSA and DRE)
* Avoidance of radiation treatment when possible
* Consideration of 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 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

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. Vasen HF, *et al*. Risk of developing pancreatic cancer in families with familial atypical multiple mole melanoma associated with a specific 19 deletion of *p16* (p16-Leiden). Int J Cancer. 2000 Sep 15:87(6):809-11.
2. McWilliams RR, *et al*. Prevalence of *CDKN2A* mutations in pancreatic cancer patients: implications for genetic counseling. Eur J Hum Genet. 2011 Apr;19(4):472-8.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic. Version 2.2022, 3/9/2022.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/Familial High-Risk Assessment: Colorectal. Version 1/2022, 6/8/2022.
5. Syngal S, *et al*. ACG clinical guideline: Genetic testing and management of hereditary gastrointestinal cancer syndromes. Am J Gastroenterol. 2015 Feb;110(2):223-62.