**LETTER OF MEDICAL NECESSITY**

**HEREDITARY MELANOMA GENETIC TESTING (MelanomaNext)**

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:

C71.0-C71.9 Astrocytoma

C44.01-C44.91\* Basal Cell Carcinoma

C22.1 Cholangiocarcinoma

C22.0 Hepatocellular carcinoma

C43.0-C43.9 Melanoma (skin)

C69.30-C69.32, C69.40-C69.42 Melanoma of eye (choroid/ciliary body/uvea)

D32.0-D32.9 Meningioma

C45.0-C45.9 Mesothelioma

C25.0-C25.9 Pancreatic cancer

C64.1-C64.9 Renal cancer

\*Code range is mixed with other skin cancer types by site

PERSONAL HISTORY:

Z85.841 Astrocytoma, personal history

Z85.828 Basal Cell Carcinoma, personal history

Z85.05 Cholangiocarcinoma OR Hepatocellular carcinoma

Z86.011 Brain tumor, Benign, personal history

Z85.89 Mesothelioma, personal history

Z85.528 Renal cancer, personal history

Z85.840 Melanoma of eye (choroid/ciliary body/uvea)

Z85.820 Melanoma (skin), Personal History

Z85.07 Pancreatic cancer, Personal history

FAMILY HISTORY:

Z80.8 Melanoma OR Astrocytoma, Family history

Z80.0 Pancreatic cancer, family history

This letter is regarding my patient and your subscriber, referenced above, to request full coverage of medically indicated genetic testing for hereditary melanoma (MelanomaNext) to be performed by Ambry Genetics Corporation.

Melanoma is thought to have a hereditary component in 5-10% of cases. Mutations in multiple genes cause hereditary melanoma, which markedly increase the lifetime risk for melanoma and other cancers (such as up to a 74% lifetime risk for malignant melanoma by age 50 with *CDK4* mutations, or up to a 67% lifetime risk for melanoma with a *CDKN2A* mutation).1-3 While melanoma accounts for less than 1% of skin cancers, it accounts for the majority of skin cancer related deaths. Early detection is essential for increased screening and survival, given that the survival rates decrease significantly for more advanced stage melanoma. Additionally, mome of these gene mutations also increase the lifetime risk for other cancers (such as breast, ovarian, pancreatic, uterine, renal, sarcoma, brain, thyroid, and prostate) and additional cancer screening may be indicated.

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 an inherited predisposition to melanoma are below** [check all that apply]**:**

* 3 or more primary melanomas in a patient and/or family members
* A person with melanoma and a first-degree relative with pancreatic cancer
* A mix of melanoma, pancreatic cancer and/or astrocytoma in an individual or family
* Melanoma and other *BAP1*-related cancers (basal cell carcinoma, cholangiocarcinoma, hepatocellular carcinoma, meningioma, mesothelioma, renal cell carcinoma or uveal/eye melanoma) or BAP-1-inactivated nevi in the patient and/or relatives on the same side of the family

Based on this, I am requesting coverage for this test (MelanomaNext), which analyzes 9 genes associated with hereditary melanoma: *BAP1, BRCA2, CDK4, CDKN2A, MITF, POT1, PTEN, RB1, 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.**4-6

**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:

* Earlier and more frequent skin examination by a dermatologist
* Pancreatic screening utilizing endoscopic ultrasound and/or MRI/MRCP
* Risk-reducing bilateral salpingo-oophorectomy and/or hysterectomy
* Increased breast screening including self-examinations, clinical breast examinations, mammogram, ultrasound, MRI
* Breast cancer risk reduction using prophylactic mastectomies and/or chemoprevention
* Prostate cancer screening (PSA and DRE)
* Renal ultrasounds
* 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: 81216, 81321, 81404, 81405, 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. Begg CB, *et al*., Lifetime risk of melanoma in *CDKN2A* mutation carriers in a population-based sample. J Natl Cancer Inst. 2005. 97(20): p. 1507-15.
2. Goldstein AM, *et al.*, High-risk melanoma susceptibility genes and pancreatic cancer, neural system tumors, and uveal melanoma across GenoMEL. Cancer Res. 2006. 66(20): p. 9818-28.
3. Ward KA, Lazovich D, and Hordinsky MK. Germline melanoma susceptibility and prognostic genes: a review of the literature. J Am Acad Dermatol. 2012. 67(5): p. 1055-67.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Melanoma: Cutaneous. Version 3.2022, 4/11/2022.
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Melanoma: Uveal. Version 2.2022, 4/5/2022.
6. Swetter, SM, *et al*. Guidelines for the management of primary cutaneous melanoma. J Am Acad Dermatol. 2019;80:208-50.