**LETTER OF MEDICAL NECESSITY**

**HEREDITARY BRAIN TUMOR GENETIC TESTING (BrainTumorNext)**

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 Brain Cancer

D33.0-D33.2 Brain tumor, benign

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

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

C57.00-C57.03 Fallopian tube cancer

C90.00-C95.92 Leukemia

C7A.00-C7A.8 Neuroendocrine Tumor (malignant)

D3A.00-D3A.8 Neuroendocrine Tumor (benign)

C56.1-C56.9 Ovarian cancer

C25.0-C25.9 Pancreatic cancer

C48.1-C48.2 Peritoneal Cancer

C49.0-C49.9 Sarcoma, Soft tissue

C41.0-C41.9 Sarcoma, Bone

C73 Thyroid cancer

C54.0-C54.9, C55 Uterine cancer

PERSONAL HISTORY:

Z85.841 Brain cancer, personal history

Z86.011 Brain tumor, Benign, personal history

Z85.3 Breast cancer, personal history

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

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

Z85.07 Pancreatic cancer, Personal history

Z85.831 Sarcoma, Soft tissue, Personal history

Z85.830 Sarcoma, Bone, Personal history

Z85.42 Uterine cancer, Personal history

FAMILY HISTORY:

Z80.0 Colon OR pancreatic (digestive organ) cancer, Family history

Z80.8 Brain cancer OR sarcoma, family history

Z80.3 Breast cancer, family history

Z80.41 Ovarian/Fallopian Tube cancer, Family history

Z80.0 Pancreatic OR colon (digestive organ) 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 brain tumors (BrainTumorNext) to be performed by Ambry Genetics Corporation.

Brain tumors are thought to have a hereditary component and evaluating personal and family histories is a major part of hereditary cancer/tumor risk assessment. Mutations in multiple genes cause hereditary brain tumors, which markedly increase the lifetime risk for brain tumors. Most of these gene mutations also increase the lifetime risk for other cancers/tumors as well.1,2 **Significant aspects of my patient’s personal and/or family medical history that suggest an inherited predisposition to brain tumors include** [check all that apply]**:**

* Early-onset brain tumor(s) (diagnosed <50 years of age)
* Multiple primary cancers in one person (e.g., brain tumor and colorectal cancer)
* Multiple close relatives on the same side of the family with brain tumors or related cancers such as breast, pancreatic, ovarian, uterine, colorectal, sarcomas, leukemia, thyroid, and neuroendocrine tumors.

Based on this, I am requesting coverage for this test (BrainTumorNext), which analyzes 29 genes associated with hereditary brain tumors: *AIP, ALK, APC, CDKN1B, CDKN2A, DICER1, EPCAM, LZTR1, MEN1, MLH1, MSH2, MSH6, NBN, NF1, NF2, PHOX2B, PMS2, POT1, PRKAR1A, PTCH1, PTEN, SMARCA4, SMARCB1, SMARCE1, SUFU, TP53, TSC1, TSC2, VHL.* Due to the history stated above, there is a reasonable probability of detecting a mutation in my patient. As well, the significant clinical overlap associated with mutations in the above-mentioned genes makes this multi-gene test the most efficient and cost-effective way to analyze these genes. **Therefore, germline genetic testing is warranted.**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:

* Consideration of MRI-based screening/technologies
* Biochemical screening for metanephrine levels
* Increased breast screening including clinical breast examinations, mammogram, ultrasound, and/or MRI
* Breast cancer risk reducting prophylactic mastectomies and/or chemoprevention
* Risk-reducing bilateral salpingo-oophorectomy
* Annual thyroid ultrasound and exam
* More frequent 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: 81201, 81292, 81295, 81298, 81317, 81321, 81403, 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. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic. Version 2.2022, 3/9/2022.
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/Familial High-Risk Assessment: Colorectal. Version 1.2022, 6/8/2022.
3. Meldrum C, Doyle MA, Tothill RW. Next-generation sequencing for cancer diagnostics: a practical perspective. Clin Biochem Rev. 2011 Nov;32(4):177-95.