**LETTER OF MEDICAL NECESSITY**

**HEREDITARY COLORECTAL CANCER GENETIC TESTING (ColoNext)**

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:

C21.0-C21.8 Anal cancer

C24.0-C24.9 Bile duct cancer

C71.0-C71.9 Brain cancer

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

K36.5, D12.0-D12.9 Colon POLYPS

C57.00-C57.03 Fallopian Tube Cancer

C22.0-C22.9 Liver cancer

C56.1-C56.9 Ovarian cancer

C25.0-C25.9 Pancreatic cancer

C48.1-C48.2 Peritoneal Cancer

C64.1-C64.9, C65.1-C65.9 Renal cancer

C16.0-C16.9 Stomach cancer

C17.0-C17.9 Small intestine cancer

C66.1-C66.9 Ureteral cancer

C54.0-C54.9, C55 Uterine cancer

PERSONAL HISTORY:

Z85.09 Bile duct cancer, personal history

Z85.841 Brain cancer, personal history

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

Z86.010 Colon Polyps, Personal history

Z85.05 Liver cancer, personal history

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

Z85.07 Pancreatic cancer, Personal history

Z85.528, Z85.53 Renal cancer, personal history

Z85.068 Small intestinal cancer, personal history

Z85.028 Stomach cancer, personal history

Z85.54 Ureteral 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

Z80.8 Brain OR thyroid 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

Z80.51 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 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 colorectal cancer (ColoNext) to be performed by Ambry Genetics Corporation.

Colorectal cancer is thought to have a hereditary component in up to 10% of cases. **Significant aspects of my patient’s personal and/or family medical history that suggest a reasonable probability of hereditary colorectal cancer are below** [check all that apply]:

Cancer:

* Early-onset colorectal or endometrial cancer (diagnosed <50 years of age)
* Colorectal or endometrial cancer at any age with:
  + A second primary Lynch syndrome tumor\* at any age
  + One first- or second-degree relative with a Lynch syndrome tumor\* diagnosed < 50 yo
  + Two first- or second-degree relatives on the same side of the family with a Lynch syndrome tumor\* diagnosed at any age.

\* Lynch syndrome tumors include biliary tract, brain, colorectal, endometrial, gastric, ovarian, pancreatic, small intestine and/or urothelial cancers or sebaceous adenomas, carcinomas or keratoacanthomas

* An unaffected individual with a first- or second-degree relative meeting the above criteria.
* Colorectal or endometrial cancer at any age with evidence of mismatch repair deficiency in the tumor (abnormal microsatellite instability or immunohistochemistry)
* Individuals with >5% risk for having a Lynch syndrome gene mutation based on the PREMM, MMRpro or MMRpredict risk models.

Polyposis:

* 10 or more cumulative GI adenomatous polyps during one’s lifetime
* 2 or more Peutz-Jeghers type polyps in a person with characteristic mucocutaneous hyperpigmentation or a family history of Peutz-Jeghers syndrome.
* 5 or more cumulative hamartomatous or juvenile polyps in the colon, or multiple throughout the GI tract, or any number in patients with a family history of Juvenile Polyposis syndrome.
* 5 or more cumulative hyperplastic or serrated polyps/lesions >5mm (with 2 being >10 mm) proximal to the rectum or 20 of any size throughout the large bowel (with >5 proximal to the rectum)
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Based on the personal and/or family history, my patient is suspicious for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ syndrome(s).* **According to published guidelines, germline genetic testing is warranted.**1

Therefore, I am requesting coverage for this test (ColoNext), which analyzes 20 genes associated with hereditary colorectal cancer: *APC, AXIN2, BMPR1A, CDH1, CHEK2, EPCAM, GREM1, MLH1, MSH2, MSH3, MSH6, MUTYH, NTHL1, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53*.According to published guidelines, more than one gene may explain an inherited cancer syndrome, thus multi-gene testing may be more efficient and/or cost-effective.1-3

**This genetic testing will help estimate my patient’s risk to develop [choose one] cancer/another primary cancer and could directly impact my patient’s medical management. Most of the genes in this test have published clinical practice guidelines** to reduce the risk for cancer and/or detect cancer early, in order to reduce morbidity and mortality. Management options may include2,3 [check all that apply]:

* Earlier and/or more frequent colonoscopy
* Colectomy
* Upper endoscopy
* Risk-reducing hysterectomy and/or bilateral salpingo-oophorectomy
* Annual urinalysis
* 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 colorectal 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, 81294, 81295, 81297, 81298, 81300, 81317, 81319, or 81435, 81436, 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: Colorectal. Version 1.2022 6/8/2022.
2. Meldrum C, Doyle MA, Tothill RW. Next-generation sequencing for cancer diagnostics: a practical perspective. Clin Biochem Rev. 2011 Nov;32(4):177-95.
3. Cragun D, *et al*. Panel-based testing for inherited colorectal cancer: a descriptive study of clinical testing performed by a US laboratory. Clin Genet. 2014 Dec;86(6):510-20.