**LETTER OF MEDICAL NECESSITY TEMPLATE**

**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: (Quick reference suggestions)

ACTIVE DIAGNOSIS:

C18.9 COLON cancer

K36.5 Colon POLYPS

C56.9 OVARY cancer

C25.9 PANCREAS cancer

C55 UTERUS cancer

PERSONAL HISTORY:

Z83.71 COLON cancer. Personal history

Z86.010 Colon POLYPS, Personal history

Z85.43 OVARIAN cancer, Personal history

Z85.07 PANCREATIC cancer, Personal history

Z85.42 UTERUS cancer, Personal history

FAMILY HISTORY:

Z80.0 COLON (digestive organ) cancer, Family history

Z83.71 Colon POLYPS, family history

Z80.41 OVARIAN cancer, Family history

Z90.0 PANCREATIC (digestive organ) 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 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, endometrial or other Lynch syndrome tumor\* (diagnosed <50 years of age)
* Colorectal, endometrial or other Lynch syndrome tumor\* 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, endometrial or other tumor 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 21 genes associated with hereditary colorectal cancer: *APC, AXIN2, BMPR1A, CDH1, EPCAM, GREM1, MBD4, MLH1, MSH2, MSH3, MSH6, MUTYH, NTHL1, PMS2, POLD1, POLE, PTEN, RPS20, 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: 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.