**LETTER OF MEDICAL NECESSITY**

**HEREDITARY KIDNEY CANCER GENETIC TESTING (RenalNext)**

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:

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

PERSONAL HISTORY:

Z85.528 Renal cancer, Personal History

FAMILY HISTORY:

Z80.51 Renal 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 kidney cancer (RenalNext) to be performed by Ambry Genetics Corporation.

Kidney cancer is thought to have a hereditary component in 3-5% of cases. Mutations in multiple genes cause hereditary kidney cancer, which markedly increase the lifetime risk for kidney cancer (such as up to a 70% risk for kidney cancer for individuals with von Hippel-Lindau disease (VHL)).1-3 Most of these gene mutations also increase the lifetime risk for other cancers (such as adrenal, brain, colorectal, ovarian, prostate, sarcomas, thyroid, and uterine).

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 kidney cancer are below:**

**An individual with renal cell carcinoma (RCC) and any of the following criteria:**

* Diagnosed at age ≤46 y
* Bilateral or multifocal tumors
* ≥1 first- or second-degree relative with RCC
* **A kidney tumor with any of the following characteristics:**
* Multifocal papillary histology
* Hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated RCC, RCC with fumarate hydratase (FH) deficiency or other histologic features associated with HLRCC
* Birt-Hogg-Dubé syndrome (BHDS)-related histology (multiple histologies in same tumor: chromophobe, oncocytoma, or oncocytic hybrid)
* Angiomyolipomas of the kidney and one additional tuberous sclerosis complex criterion in the same person
* Succinate dehydrogenase (SDH)-deficient RCC histology

Based on this, I am requesting coverage for this test (RenalNext), which analyzes 20 genes associated with hereditary kidney cancer: *BAP1, CHEK2, EPCAM, FH, FLCN, MET, MITF, MLH1, MSH2, MSH6, PMS2, PTEN, SDHA, SDHB, SDHC, SDHD, TP53, TSC1, TSC2, VHL.* 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

**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. Most 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:

* Kidney cancer screening with CT, MRI or ultrasound
* Earlier or more frequent colonoscopy
* Risk-reducing bilateral salpingo-oophorectomy and/or hysterectomy
* Increased breast screening including clinical breast exams, mammogram, MRI
* Prophylactic mastectomies and/or chemoprevention
* 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: 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, 81321, 81323, 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. Maher ER. Hereditary renal cell carcinoma syndromes: diagnosis, surveillance and management. World J Urol 2018;36:1891-1898.
2. Van Leeuwaarde RS, Ahmad S, Links TP, Giles RH. Von Hippel-Lindau Syndrome. 2000 May 17 [Updated 2018, Sept 6]. In: Pagon RA, Adam MP, Ardinger HH, *et al*., editors. GeneReviews®. [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022.
3. Shuch B, *et al*. Defining early-onset kidney cancer: implications for germline and somatic mutation testing and clinical management. J Clin Oncol. 2014 Feb 10;32(5)431–7.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer. Version 2.2022, 8/3/2022.