

**LETTER OF MEDICAL NECESSITY**

**Guideline-based Hereditary Cancer Panel**

**Instructions for Healthcare Provider:**

1. This letter template is being provided as a tool for clinicians to assist in communications with payers
2. Include specific patient information in the letter for this tool to be effective. The areas that must be edited/deleted are indicated in gray on the template
3. Print the template on the physician’s letterhead, **NOT** Quest letterhead. There should be no Quest branding on the letter

LMN: Guideline-based Hereditary Cancer Panel (1/18/21)

<Date>

ATTN: <Medical Director/ Physician Name>, M.D.

<Institution/Insurance Company>

<Street Address>

<City>**,** <State> <Zip>

RE: <Patient Name>

DOB: <MM/DD/YYYY>

Member ID: <Insurance ID Number>

Group #: <Enter Group #>

Dear Doctor <Medical Director/ Physician Name>:

I am writing this letter on behalf of my patient <Patient Name> to request that you approve the Guideline-based Hereditary Cancer Panel as part of his/her care. This test includes analysis of 32 cancer-susceptibility genes (listed in Appendix 1) for inherited pathogenic/likely pathogenic variants or mutations. I am choosing multigene panel testing at this juncture over targeted genetic testing because <**CHOOSE**: no targeted genetic test is well-suited for this phenotype – **OR** –targeted gene testing was done and found to be negative>.

<Patient Name> is a <age>-year-old <gender> with <list symptoms and clinical findings>.

1. <Symptom #1 with ICD-10 code>

2. <Symptom #2 with ICD-10 code>

…

<Add family/personal history as relevant. Consider indicating the following as applicable.>

* The patient has a personal history of <type of cancer> diagnosed at age <age>.
* The patient is of Ashkenazi Jewish decent.
* The patient does not have a personal history of cancer but has a very strong family history of cancer.

<If the patient does not have a personal history of cancer, consider indicating if any of the following apply:>

* + The patient’s affected relatives are deceased.
  + Patient does not have any contact with the affected relatives.
  + The affected relatives have refused genetic testing or have refused to share their testing history and/or test results with my patient.
* The patient has a family history that includes the following relatives and their conditions: *[for relatives, include both maternal and paternal sides of the family]*

|  |  |  |
| --- | --- | --- |
| 1. Relationship | Cancer | Age |
| 2. Relationship | Cancer | Age |

* A mutation was previously identified in the <gene> gene in the patient’s <blood relative relationship>.

**Rationale for Testing**

Hereditary cancer syndromes present with a wide spectrum of cancers with variable and overlapping phenotypes, which can make it challenging to determine appropriate single-gene or single-syndrome testing.1 Therefore, a multigene test increases the opportunity for at-risk individuals to be appropriately identified and receive necessary medical management. The National Comprehensive Cancer Network® (NCCN®) guidelines state that multigene tests can be used as a more efficient approach when more than 1 gene or syndrome may explain the increased cancer risk observed in an individual’s personal and/or family history.2,3 Other professional societies have also published statements that recognize the advantages of multigene tests.4,5

Studies of patients who underwent hereditary cancer testing further highlight the importance of multigene tests. These studies demonstrate that many pathogenic/likely pathogenic variants occur in genes other than those traditionally associated with the most common hereditary cancer syndromes (ie, *BRCA1/2* forhereditary breast and/or ovarian cancer syndrome [HBOC] and *MLH1*, *MSH2*, *MSH6*, *EPCAM*, and *PMS2* for Lynch syndrome).6-8 In addition, some patients carry pathogenic/likely pathogenic variants associated with other cancer syndromes than those originally indicated for genetic testing.7,8 For example, a study that tested 32 cancer-susceptibility genes in 33,987 patients found that less than half of pathogenic variants among patients meeting testing criteria for only HBOC or only Lynch syndrome occurred in the respective syndrome-specific genes.7 Considering specifically the pathogenic variants among patients meeting only Lynch syndrome criteria, 9% occurred in *BRCA1/2*, 36% occurred in other breast or ovarian cancer genes, and 9% occurred in other cancer susceptibility genes.7 Results such as these support multigene testing as an appropriate approach for effectively detecting pathogenic/likely pathogenic variants that confer increased cancer risk.

If a pathogenic/likely pathogenic variant is found in one or more genes on the Guideline-based Hereditary Cancer Panel, it would provide a diagnosis of a hereditary cancer syndrome, thereby helping to clarify the patient’s cancer risk and prompting a change in the patient’s medical management due to the increased risk for multiple malignancies. Therefore, test results are necessary in choosing the most appropriate course of treatment and/or surveillance for this patient.

Individuals with a hereditary predisposition to cancer have specialized treatment options available to them to decrease their risk to develop cancer.2,3 Management changes may include:

* More aggressive surgical management of cancer
* Risk-reducing prophylactic surgery (ie, mastectomy, colectomy, hysterectomy, etc.)
* Enhanced surveillance of organs at higher risk for cancer
* Beginning cancer screening at an earlier age
* Chemoprevention
* Other:

In conclusion, I am requesting that <Patient Name> be approved for the Guideline-based Hereditary Cancer Panel (Test Code 38611; CPT codes listed in Appendix 2) offered by Quest Diagnostics®. I hope you will support this letter of medical necessity for <Patient Name>. Please feel free to contact me at <Physician Phone> if you have additional questions.

Sincerely,

<Physician Name>, MD

NPI #: <Physician NPI#>

Contact information:

< Address>

<City>**,** <State> <Zip>

Contact Phone: <phone number>

The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

**Appendix 1**

**Genes included on the Guideline-based Hereditary Cancer Panel**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| *APC* | *ATM* | *AXIN2* | *BMPR1A* | *BRCA1* | *BRCA2* | *BRIP1* | *CDH1* |
| *CDK4* | *CDKN2A* (p16, p14) | *CHEK2* | *EPCAM* | *GREM1* | *HOXB13* | *MLH1* | *MSH2* |
| *MSH3* | *MSH6* | *MUTYH* | *NBN* | *NF1* | *NTHL1* | *PALB2* | *PMS2* |
| *POLD1* | *POLE* | *PTEN* | *RAD51C* | *RAD51D* | *SMAD4* | *STK11* | *TP53* |

**Appendix 2**

**CPT codes for the Guideline-based Hereditary Cancer Panel**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Indication for testing** | **CPT codes** | | | | | | |
| Related to breast and/or ovarian cancer syndrome | **GSP codinga** | 81162 | 81295 | 81300 | 81323 | 81405 |  |
| 81432 | 81292 | 81297 | 81307 | 81351 | 81408 x2 |  |
| 81433 | 81294 | 81298 | 81321 | 81404 | 81479 |  |
| Related to colorectal cancer/Lynch syndrome | 81435 | 81201 | 81294 | 81298 | 81319 | 81351 | 81405 x2 |
| 81436 | 81203 | 81295 | 81300 | 81321 | 81403 | 81406 x2 |
|  | 81292 | 81297 | 81317 | 81323 | 81404 | 81479 |

a Genomic sequencing procedures and other molecular multianalyte assays.

**References**

**1.** Hall MJ, Forman AD, Pilarski R, et al. Gene panel testing for inherited cancer risk. *J Natl Compr Canc Netw*. 2014;12(9):1339-1346. doi:10.6004/jnccn.2014.0128

**2.** National Comprehensive Cancer Network®. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/familial high-risk assessment: colorectal. Version 1.2020. Published July 21, 2020. <www.nccn.org>

**3.** National Comprehensive Cancer Network®. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/familial high-risk assessment: breast, ovarian, and pancreatic. Version 2.2021. Published November 20, 2020. <www.nccn.org>

**4.** Robson ME, Bradbury AR, Arun B, et al. American Society of Clinical Oncology policy statement update: genetic and genomic testing for cancer susceptibility. *J Clin Oncol*. 2015;33(31):3660-3667. doi:10.1200/jco.2015.63.0996

**5.** Hereditary cancer syndromes and risk assessment: ACOG Committee Opinion, Number 793. *Obstet Gynecol*. 2019;134(6):e143-e149. doi:10.1097/aog.0000000000003562

**6.** Gardner SA, Weymouth KS, Kelly WS, et al. Evaluation of a 27-gene inherited cancer panel across 630 consecutive patients referred for testing in a clinical diagnostic laboratory. *Hered Cancer Clin Pract*. 2018;16:1. doi:10.1186/s13053-017-0083-8

**7.** LaDuca H, Polley EC, Yussuf A, et al. A clinical guide to hereditary cancer panel testing: evaluation of gene-specific cancer associations and sensitivity of genetic testing criteria in a cohort of 165,000 high-risk patients. *Genet Med*. 2020;22(2):407-415. doi:10.1038/s41436-019-0633-8

**8.** Rosenthal ET, Bernhisel R, Brown K, et al. Clinical testing with a panel of 25 genes associated with increased cancer risk results in a significant increase in clinically significant findings across a broad range of cancer histories. *Cancer Genet*. 2017;218-219:58-68. doi:10.1016/j.cancergen.2017.09.003