Sample letter of medical necessity (panel testing)

NOTE TO THE HEALTHCARE PROVIDER: The following is an example template for a letter of medical necessity for possible use when testing medically appropriate patients. This may not include all the information necessary to support the coverage request. You, the healthcare provider, are responsible for the accuracy and supportability of all information provided.

DATE: [MM/DD/YYYY]

ATTN: [Physician name, M.D.]
[Medical director]
[Insurance company/Institution]
[Street address]
[City, State, ZIP]

Re: [Patient name, date of birth, ID number]

Dear Medical Director:

I am writing to request coverage for the above patient using the Invitae Multi-Cancer Panel. I have determined that this test is medically necessary for the above patient due to the following history, which is suggestive of a hereditary cancer syndrome consistent with a mutation in multiple genes. The Invitae Multi-Cancer Panel has increased sensitivity compared with testing individually for only hereditary breast and ovarian cancer syndrome (BRCA1, BRCA2) and/or Lynch syndrome (MLH1, MSH2, MSH6, PMS2, EPCAM)[1,2]. Each of the genes on the panel is associated with a level of cancer risk that may indicate altered medical management of this patient.

PATIENT HISTORY *(Choose one or both of the following tables)*

Relevant cancers include: breast, ovarian, colorectal, endometrial, melanoma, pancreatic, gastric, and prostate; specify maternal or paternal relatives; specify bilateral or multiple primary cancers; indicate if breast tumors are triple-negative, or if colon/endometrial tumors are MSI-high or IHC abnormal.

Personal history

Cancer or polyp site (number/type of polyp)	Dx age

Family history

First-, second-, or third-degree relative (maternal or paternal side)	Relationship	Cancer or polyp site (number/type of polyp)	Dx age

[Skip if not applicable to your patient]

This patient has not been affected with cancer, but has a family history of cancer strongly suggestive of a hereditary cancer syndrome. My patient's relatives who have had an associated cancer are not available for testing because: *[Choose one]*

- ◯ They are deceased
- ◯ My patient does not have any contact with the affected relatives
- ◯ The affected relatives have refused testing or have specifically refused to share their testing history or results with my patient
- ◯ Other: _____

EXPLANATION OF NEED

Individuals who carry a mutation in one or more of these genes have an increased lifetime risk of breast, ovarian, colorectal, endometrial, melanoma, pancreatic, gastric, prostate, and/or other cancers. Several professional societies, including those listed below, have published guidelines for managing patients with elevated cancer risks that are associated with mutations in these genes. Therefore, test results are necessary for choosing the most appropriate course of treatment and/or surveillance for this patient.

- National Comprehensive Cancer Network
- American College of Obstetricians and Gynecologists
- American Society of Clinical Oncology
- International Gastric Cancer Linkage Consortium
- International Cancer of the Pancreas Screening Consortium

Hereditary cancer syndromes associated with these genes present a wide spectrum of cancers with variable penetrance and ages of onset, thus making it difficult to determine appropriate single-syndrome testing. Therefore, a multi-gene panel increases the opportunity for at-risk individuals to be appropriately identified and receive necessary medical management.Professional society guidelines provide the option of a multi-gene (panel) test, when appropriate, in the algorithm to evaluate a high-risk patient, because multiple genes may contribute to increased cancer risk. The Society for Gynecologic Oncology (SGO) also recognizes the advantages of cancer gene panels in decreasing costs and improving the efficiency of cancer genetic testing[3].

For this patient, the genetic test results are needed in order to consider the following medical management strategies: *[Please specify in the table below]*

Relevant management may include: breast surveillance, colonoscopy, upper endoscopy, surveillance for endometrial and ovarian cancer, prophylactic surgeries, chemoprevention strategies, etc.

Medical management considerations

INFORMED CONSENT

The patient has provided informed consent to pursue genetic testing based on my discussion of the personal and/or family history, the potential test results and the implications for medical management.

GENETIC COUNSELING

I attest that I have provided genetic counseling to my patient and, by signing below, I agree that I have satisfied the counseling requirements outlined below:

- Review and collection of personal and/or family history of cancer and/or genetic disorders (including history of previous genetic testing/availability for testing of family members with cancer)
- Ethnic background of the patient
- Evaluation of the patient's cancer risk
- Prepared the patient for possible outcomes of testing including positive (pathogenic/likely pathogenic), negative, and uncertain findings, and follow up medical management
- Description of the benefits, risks, and limitations of genetic testing
- Plan to engage in post test counseling

Please do not hesitate to contact me if I can provide you with any additional information.

Sincerely,

Ordering healthcare provider signature | Ordering healthcare provider printed name | Date (MM/DD/YYYY)

1. Tung N et al. Cancer. 2014.
2. Yurgelun MB et al. J Clin Oncol. 2014 (suppl; abstr 1509).
3. SGO Clinical Practice Statement: Next-generation cancer gene panels versus gene by gene testing. March 2014.