GenPath Medicare Criteria Form

Account Name _____ Account Number _____

Patient Name: _____
(Please Print) First Name Last Name

Phone #: (h)_____(c) _____

Ordering Physician: _____

Physician Signature: _____ Date: _____

1. For patients of Ashkenazi Jewish ancestry, the BRCA1/BRCA2 Ashkenazi Jewish Founder Panel (B361) **MUST BE ORDERED FIRST**. If negative, either BRCA1/BRCA2 Sequencing and Deletion/Duplication Analysis (B362) or one of the Hereditary Cancer Panel tests in the hereditary breast and ovarian cancer syndrome box below may be ordered if the patient meets the non-Ashkenazi Jewish HBOC criteria.
2. A test listed in the hereditary breast and ovarian cancer syndrome box and a test listed in the hereditary colorectal cancer box **MAY BOTH BE ORDERED** if the patient meets criteria in both sections. Patients that meet both criteria will have a history of at least two primary cancers including breast or ovarian cancer AND colon or endometrial cancer.
3. Medicare may deny a second test ordered in a reflex fashion. GenPath Customer Service will contact providers if an ABN is needed for reflex tests.

Please feel free to contact one of the GenPath Hereditary Cancer Customer Service Genetic Counselors with any questions at 888-729-1206.

Hereditary Breast and Ovarian Cancer (HBOC) Syndrome

Has your patient had prior germline genetic testing for breast cancer billed to Medicare? ❒ Yes ❒ No

If yes, Medicare coverage may be denied. To proceed with testing, please fill out and sign an Advance Beneficiary Notice (ABN) form.

To meet Medicare criteria for the following tests, at least one of the below criteria for hereditary breast and ovarian cancer must be met:

Test Ordered:

❒ B361 BRCA1/BRCA2 Ashkenazi Founder Panel

HBOC Criteria for BRCA1/BRCA2 Ashkenazi Founder Panel:

❒ Patient is of Ashkenazi Jewish descent and has or had breast, ovarian or pancreatic cancer

Medicare states: If the individual is of Ashkenazi Jewish descent, test the three common pathogenic variants first. Then if negative, consider comprehensive ("Reflex") testing based on assessment of individual and family history as if the individual is of non-Ashkenazi Jewish descent. Please review HBOC Criteria below.

Please check ONE test:

❒ B362 BRCA1/BRCA2 Sequencing and Deletion/Duplication Analysis
❒ B501 BRCA1/BRCA2 Deletion/Duplication Analysis
❒ B275 Comprehensive Cancer Panel
❒ B751 High/Moderate Risk Panel
❒ B273 Breast/Ovarian Cancer Panel
❒ J055 Breast Cancer High/Moderate Risk Panel
❒ B521 Breast Cancer High Risk Panel
❒ B343 Pancreatic Cancer Panel
❒ B344 Endometrial Cancer Panel
❒ B370 Testing for a previously identified familial pathogenic variant or mutation in BRCA1 or BRCA2

HBOC Criteria (Please check all that apply):

Personal history of breast cancer:

❒ Patient diagnosed with breast cancer ≤45y
❒ Patient diagnosed ≤60y with a triple negative breast cancer (ER-, PR-, HER2-)
❒ Male patient diagnosed with breast cancer at any age

Patient diagnosed with breast cancer ≤50y with one or more of the following:

❒ Diagnosis of a second breast primary (includes bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors)
❒ ≥1 close blood relative^ with breast cancer at any age
❒ Limited family history, defined as fewer than 2 first- or second-degree female relatives or female relatives surviving beyond 45y in either lineage

Patient diagnosed with breast cancer at any age with one or more of the following:

❒ ≥2 close blood relatives^ with breast cancer, pancreatic cancer, and/or prostate cancer with a Gleason score ≥7, at any age
❒ ≥1 close blood relative^ with breast cancer diagnosed ≤50y
❒ ≥1 close blood relative^ with ovarian/fallopian tube/primary peritoneal cancer
❒ ≥1 close male blood relative^ with breast cancer
❒ ≥1 close blood relative^ with a previously identified familial pathogenic variant or mutation in BRCA1 or BRCA2

Personal history of other cancer:

❒ Patient diagnosed with epithelial ovarian/fallopian tube/primary peritoneal cancer at any age

Patient diagnosed with pancreatic cancer at any age with one or more of the following:

❒ ≥1 close relatives^ with breast cancer ≤50y, ovarian/fallopian tube/primary peritoneal cancer, pancreatic cancer, or prostate cancer (Gleason score ≥7)
❒ ≥1 close relatives^ with a previously identified familial pathogenic variant or mutation in BRCA1 or BRCA2

Patient diagnosed with prostate cancer (Gleason score ≥7) at any age with one or more of the following:

❒ ≥1 close relatives^ with breast cancer ≤50y, ovarian/fallopian tube/primary peritoneal cancer, pancreatic cancer, or prostate cancer (Gleason score ≥7)
❒ ≥1 close relatives^ with a previously identified familial pathogenic variant or mutation in BRCA1 or BRCA2

Hereditary Colorectal Cancer

Has your patient had prior germline genetic testing for colorectal or endometrial cancer billed to Medicare? ❒ Yes ❒ No
If yes, Medicare coverage may be denied. To proceed with testing, please fill out and sign an Advance Beneficiary Notice (ABN) form.

To meet Medicare criteria for the following tests, at least one of the below criteria for hereditary colorectal cancer must be met:

Please check ONE test:

- ❒ B275 Comprehensive Cancer Panel
- ❒ B751 High/Moderate Risk Panel
- ❒ B274 Colorectal Panel
- ❒ B522 Lynch/Colorectal Panel
- ❒ B344 Endometrial Cancer Panel
- ❒ B890 Lynch Syndrome Custom Panel
- ❒ B370 Testing for a previously identified pathogenic variant or mutation in MLH1, MSH2, MSH6, PMS2, EPCAM, APC, or MUTYH

Hereditary Colorectal Cancer/Lynch Syndrome Criteria (Please check all that apply):

Patient has or had colorectal or endometrial cancer and meets one of the following criteria:

- ❒ Patient's colorectal tumor is MSI high or mutation of one of the mismatch repair genes is indicated by failure of IHC staining
- ❒ Patient has a close blood relative^ with a known Lynch syndrome related pathogenic variant
- ❒ Patient diagnosed with endometrial cancer ≤50y

Revised Bethesda Criteria:

Patient has been diagnosed with colorectal cancer AND meets one of the following:

- ❒ Patient diagnosed ≤50y
- ❒ Presence of synchronous or metachronous Lynch syndrome-associated cancers*
- ❒ Colorectal cancer with the MSI-H histology diagnosed in a beneficiary who is <60y
- ❒ Colorectal cancer with ≥1 first-degree relatives with a Lynch syndrome-associated cancer,* with one of the cancers being diagnosed <50y
- ❒ Colorectal cancer with ≥2 first- or second-degree relatives with Lynch syndrome-associated cancers, regardless of age

Amsterdam Criteria:

❒ Patient has or had colorectal or endometrial cancer AND has had at least two close relatives^ on the same side of the family who have or have had Lynch syndrome-associated cancer* AND all of the following criteria must be met:

- One must be a first-degree relative of the other two;
- At least two successive generations must be affected;
- At least one of the relatives or the beneficiary with cancer associated with Lynch syndrome should be diagnosed <50y;
- Familial adenomatous polyposis (FAP) should be excluded in the colorectal cancer case(s) (if any);
- Histologic diagnosis of tumors should be verified whenever possible.

Hereditary Colorectal Cancer/FAP/AFAP/MAP

❒ Patient with ≥20 cumulative colorectal adenomas over a lifetime

^1st, 2nd, or 3rd degree relatives (parents, siblings, children, aunts/uncles, nieces/nephews, grandchildren, grandparents, 1st cousins, great aunts/uncles, great grandparents)

* Lynch syndrome-associated cancers include colorectal, endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.

Compassionate Care Price

For patients who do not meet Medicare medical necessity criteria

B361	BRCA1/BRCA2 Ashkenazi Founder Panel	$295
B362	BRCA1/BRCA2 Sequencing and Deletion/Duplication Analysis	$1,495
B501	BRCA1/BRCA2 Deletion/Duplication	$350
B275	Comprehensive Cancer Panel	$1,500
B751	High/Moderate Risk Panel	$1,500
B273	Breast/Ovarian Cancer Panel	$1,500
J055	Breast Cancer High/Moderate Risk Panel	$1,500
B521	Breast Cancer High Risk Panel	$1,500
B274	Colorectal Cancer Panel	$1,500
B522	Lynch/Colorectal High Risk Panel	$1,500
B890	Lynch Syndrome Custom Panel	$1,500
B343	Pancreatic Cancer Panel	$1,500
B344	Endometrial Cancer Panel	$1,500
B370	Testing for a previously identified familial pathogenic variant or mutation	$245 (1 mutation)/$350 (2 mutations)