



Germline Genetic Testing Medicare Billing Criteria Form

Patient Name: _____ First Name Last Name
Phone: (H) _____ (C) _____
Ordering Physician: _____
Physician Signature: _____ Date: _____

For Patients of Ashkenazi Jewish ancestry:

- BRCA1/BRCA 2 Ashkenazi Jewish panel must be ordered first, if test is negative, BRCA1/BRCA2 sequencing and deletion duplication or one of Gopath’s other Hereditary Cancer panel tests (see testing options below) if patient meets NON-Ashkenazi HBOC testing criteria.
- If a patient meets testing criteria for both HBOC and Colorectal Cancer, testing from both lists may be ordered. Patients must however **meet criteria in both sections and have a history of at least two primary cancers; Breast, or Ovarian AND Colon or Endometrial.**
- Completed ABN must accompany every requisition for Medicare patients (see guide on how to complete a valid ABN).

Hereditary Breast and Ovarian Cancer (HBOC) Syndrome:

Has patient ever been tested for germline genetic testing for breast cancer that was billed to Medicare? Yes No
If yes, Medicare may deny coverage, to proceed with testing anyway, please complete Advanced Beneficiary Form (ABN).

To meet Medicare criteria for the following tests, at LEAST one of the HBOC criteria must be met:

HBOC Criteria for BRCA1/2 Ashkenazi Panel:

Patient is of Ashkenazi Jewish decent and has or had Breast, Pancreatic, or Ovarian Cancer

Medicare regulation: If patient is of Ashkenazi Jewish decent, it is the laboratory’s obligation to initially test the three most common variants, if negative, move forward with comprehensive panel as a “reflex” test based on family and individual history and assessment.

HBOC Criteria (Please indicate all that are applicable):

Personal history of Breast Cancer and one or more of the following indications:

- Patient diagnosed at 45 years of age or under;
- Patient diagnosed at 60 years of age or younger with Triple Negative Breast cancer (ER-, PR-, HER2-);
- Male patient diagnosed at any age;



Patient diagnosed with breast cancer at 50 years of age or younger with one of more of the following criteria:

- Diagnosed with an additional breast cancer primary;
- At least 1 close blood relative with breast cancer at any age;
- At least 1 close relative with pancreatic cancer;
- At least 1 relative with prostate cancer (Gleason score greater than 7);
- Inadequate family history (less than 2 first or second degree female relatives or female relatives surviving beyond 45 years in either lineage);

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

- At least 1 close blood relative with breast cancer, diagnosed at or before 50 years;
- At least 2 close blood relatives with breast cancer at any age;
- At least 1 close blood relative with invasive ovarian cancer (including fallopian tube and primary peritoneal cancer);
- At least 2 close blood relatives with pancreatic or prostate cancer (Gleason score greater than 7), at any age;
- Close male blood relative with breast cancer;
- Individual or ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish descent);

Personal history of other cancers:

- Personal history of invasive ovarian (includes fallopian tube and primary peritoneal cancers) cancer at any age;
- Personal history of male breast cancer;
- Personal history of pancreatic cancer at any age with at least 1 close blood relative diagnosed with breast, invasive ovarian, prostate and/or pancreatic cancer at 50 years or younger;
- Personal history of prostate cancer (Gleason score greater than 7) at any age with at least 1 close blood relative diagnosed with breast, invasive ovarian, pancreatic or prostate cancer at 50 years or younger;
- Personal history with prostate cancer or pancreatic cancer at any age with a previously recognized mutation in BRCA1/2;

BRCA1/2 genetic testing with next generation sequencing panel is covered as medically necessary when **ALL** of the following criteria is met:

- Pre & Post genetic counseling by a genetics professional that meets NCCN accreditation;
- All genes in the panel are appropriate to the individuals personal and family history;
- Criteria under “personal history or breast cancer” and/or “personal history of other cancers” are met;
- Individuals also meet criteria for at least one hereditary cancer syndrome.

**NCCN outlines blood relatives as first- (parents, siblings and children), second- (grandparents, aunts, uncles, nieces, nephews, grandchildren and half-siblings), third- (great-grandparents, great aunts/uncles, great grandchildren and cousins) on the same side of the family.*

**Medicare will also cover BRCA1/2 testing for an adopted individual diagnosed with breast cancer at 45 years or younger, 60 years or younger with triple negative breast cancer or has a personal history of another cancer mentioned above that is suspicious of being a BRCA related cancer.*



Hereditary Colorectal Cancer/Lynch Syndrome Criteria:

Has patient ever been tested for germline genetic testing for colorectal or endometrial cancer that was billed to Medicare? Yes No

If yes, Medicare may deny coverage, to proceed with testing anyway, please complete Advanced Beneficiary Form (ABN).

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

Hereditary colorectal cancer/Lynch Syndrome Criteria (Please indicate all that are applicable):

Patient diagnosed with colorectal or endometrial cancer and meets one of the following criteria:

- Colorectal tumor MSI elevated or know mutation of MMR genes by failure of IHC staining;
- Patient has a close blood relative with a known Lynch Syndrome mutation;
- Patient diagnosed with endometrial cancer at 50 years or younger;

Hereditary Colorectal Cancer/FAP/AFAP/MAP

- Patient with at least 20 or greater cumulative colorectal adenomas over a lifetime

**Lynch Syndrome associated cancers include colorectal, ovarian, endometrial, gastric, pancreas, ureter and renal pelvis, biliary tract, brain, small intestine cancers and adenomas/carcinomas and keratoacanthomas.*

- Patient meets Medicare Policy criteria for genetic testing
- Patient does not meet Medicare Policy criteria for genetic testing, as such, patient signed ABN is attached

Physician Signature: _____ Date: _____



GoPath Care Solutions

Available for patients who do not meet Medicare criteria

Hereditary Breast and Ovarian Germline Testing:

BRCAnow
BRCAnowPlus
BRCAnowExtended

Individual testing:

BRCA 1 Target Analysis
BRCA 2 Target Analysis
BRCA1/2 Ashkenazi Jewish Panel
BRCA1/2 del/dup Analysis

Lynch Syndrome Germline Testing:

Lynchnow
LynchnowPlus
LynchnowExtended

Individual testing:

MLH1 Comprehensive Analysis
PMS2 Comprehensive Analysis
MSH2 Comprehensive Analysis
MSH6 Comprehensive Analysis
EPCAM Comprehensive Analysis
MLH1 Target Analysis
MSH2 Target Analysis
MSH6 Target Analysis
PMS2 Target Analysis