

MEDICARE CHECKLIST FOR HEREDITARY CANCER

Hereditary Breast, Ovarian, Pancreatic and Prostate Cancer

- Summarized below are indications for germline *BRCA1/BRCA2* testing which apply to individuals with Medicare. Please visit the CMS website at www.cms.gov for the most up-to-date information and to view the complete coverage determination for *BRCA1/BRCA2* testing (LCD L36715).
- Individuals with a personal history of breast, ovarian, pancreatic and prostate cancer who meet one of the following criteria are eligible for Medicare coverage.
- In the following circumstances, individuals are not eligible for Medicare coverage and an Advance Beneficiary Notice (ABN) form is required to proceed with testing:
 - Individuals who had genetic testing including the *BRCA1/BRCA2* genes and was billed to their Medicare plan
 - Individuals without a personal history of cancer
 - Individuals not meeting one of the below criteria

Indications for *BRCA1/BRCA2* Testing

- Personal history of ovarian, fallopian tube, or primary peritoneal cancers
- Personal history of male breast cancer
- Individual with a history of breast, ovarian, pancreatic, or prostate cancer from a family with a known *BRCA1/BRCA2* pathogenic or likely pathogenic variant
- Personal history of breast cancer and one or more of the following indications:
 - Individual of ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish)**
 - Diagnosed at age 45 or under
 - Diagnosed at age 50 or under with any of the following:
 - An additional breast cancer primary
 - At least one close blood relative* with breast cancer at any age
 - Unknown or limited family history
 - Diagnosed at age 60 or under with a:
 - Triple negative breast cancer [estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative]
 - Diagnosed at any age with any of the following:
 - At least one close blood relative* with breast cancer diagnosed at age 50 or under
 - At least two additional diagnoses of breast cancer in the patient and/or close blood relative(s)* at any age
 - At least one close blood relative* with ovarian, fallopian tube, or primary peritoneal cancers
 - At least one close blood relative* with pancreatic cancer
 - At least one close blood relative* with prostate cancer (Gleason score ≥ 7 or metastatic)
 - At least one close blood relative* with male breast cancer
- Personal history of pancreatic cancer
- Personal history of prostate cancer (Gleason score ≥ 7) at any age with any of the following:
 - At least 1 close blood relative* with ovarian/fallopian tube/primary peritoneal cancer, pancreatic cancer, or metastatic prostate cancer
 - At least 1 close blood relative* with breast cancer at age 50 or under
 - At least 2 close blood relatives* with breast cancer or prostate cancer (any grade)
 - Ashkenazi Jewish ancestry**
- Personal history of metastatic prostate cancer
- Individual with a history of breast, ovarian, pancreatic, or prostate cancer and a *BRCA1/BRCA2* pathogenic variant detected by tumor profiling on any tumor type in the absence of germline variant analysis
- Personal history of breast, ovarian, pancreatic, or prostate cancer with either of the following:
 - First- or second-degree blood relative meeting any of the above criteria
 - Third-degree blood relative who has breast cancer or ovarian/fallopian tube/primary peritoneal cancer and who has at least two close blood relatives* with breast cancer (at least one who was diagnosed at age 50 or under) or ovarian/fallopian tube/primary peritoneal cancer

* Close blood relative are defined as first- (parents, siblings and children), second- (grandparents, aunts, uncles, nieces and nephews, grandchildren and half-siblings), and third degree-relatives (great-grandparents, great-aunts, great uncles, great grandchildren and first cousins) on the same side (either maternal or paternal) of the family.

** For individuals of Ashkenazi Jewish ancestry who only meet ancestry-related criteria, Medicare will only cover the *BRCA1/BRCA2* Ashkenazi Jewish Founder Panel (test code B361). For these individuals, testing beyond this test code may not be covered and requires a signed ABN.

For patients who meet one of the above criteria, Medicare coverage requires that the *BRCA1/BRCA2* genes are included in your test selection.

Healthcare providers are responsible for ensuring that any and all testing ordered on behalf of their patient(s) is/are reasonable and medically necessary.

Hereditary Colorectal Cancer

- Summarized below are indications for germline testing of Lynch syndrome, Familial adenomatous polyposis (FAP), Attenuated familial adenomatous polyposis (AFAP) and MYH associated polyposis (MAP). The following criteria are derived from national genetic testing guidelines.
- In the following circumstances, individuals may not be eligible for Medicare coverage and an Advance Beneficiary Notice (ABN) form is required to proceed with testing:
 - Individuals who had genetic testing including the Lynch syndrome genes (*MLH1*, *MSH2*, *MSH6*, *PMS2* and *EPCAM*), the FAP gene (*APC*) or the MAP gene (*MUTYH*) and was billed to their Medicare plan
 - Individuals not meeting one of the below criteria

Indications for Lynch Syndrome Testing

- Personal history of a Lynch syndrome related cancer** with one of the following:
 - A known *MLH1*, *MSH2*, *MSH6*, *PMS2* or *EPCAM* pathogenic or likely pathogenic variant in the family
 - ≥1 first-degree relative* with colorectal or endometrial cancer diagnosed under the age of 50
 - ≥1 first-degree relative* with colorectal or endometrial cancer and another synchronous or metachronous Lynch syndrome related cancer**
 - ≥2 first-degree or second-degree relatives* with Lynch syndrome related cancers**, including ≥1 diagnosed under the age of 50
 - ≥3 first-degree or second-degree relatives* with a Lynch syndrome related cancer** regardless of age
- Personal history of colorectal or endometrial cancer with one of the following:
 - Diagnosed under the age of 50
 - Another synchronous or metachronous Lynch syndrome related cancer**
 - ≥1 first-degree or second-degree relative* with a Lynch syndrome related cancer** diagnosed under the age of 50
 - ≥2 first-degree or second-degree relatives* with a Lynch syndrome related cancer** regardless of age
- Personal history of colorectal or endometrial cancer at any age with tumor showing evidence of mismatch repair (MMR) deficiency, either by microsatellite instability (MSI) or loss of MMR protein expression
- Personal history of a colorectal tumor with MSI-high (MSI-H) histology (i.e. presence of tumor-infiltrating lymphocytes, Crohn's-like lymphocytic reaction, mucinous/signet ring differentiation, or medullary growth pattern) diagnosed at age 60 or under
- Personal history of a Lynch syndrome related cancer** who has a ≥5% risk of having a Lynch syndrome mutation based on the MMRpro or MMRpredict models, or ≥2.5% risk of having a Lynch syndrome mutation based on the PREMM5 model

* Close blood relative are defined as first- (parents, siblings and children), second- (grandparents, aunts, uncles, nieces and nephews, grandchildren and half-siblings), and third degree-relatives (great-grandparents, great-aunts, great uncles, great grandchildren and first cousins) on the same side (either maternal or paternal) of the family.

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

For patients who meet one of the above criteria, Medicare coverage requires that one or more of the Lynch syndrome genes (*MLH1*, *MSH2*, *MSH6*, *PMS2* and *EPCAM*) are included in your test selection.

Indications for FAP/AFAP/MAP Testing

- Personal history of 10 or more adenomas
- Personal history of a desmoid tumor, hepatoblastoma, cribriform-morular variant of papillary thyroid cancer, or multifocal/bilateral CHRPE
- Multiple adenomas and one of the following:
 - 5 or more serrated polyps proximal to the sigmoid colon, with at least 2 being >10mm
 - ≥20 serrated polyps of any size, distributed throughout the colon

For patients who meet one of the above criteria, Medicare coverage requires that the *APC* and *MUTYH* genes are included in your test selection.

Healthcare providers are responsible for ensuring that any and all testing ordered on behalf of their patient(s) is/are reasonable and medically necessary.