otogenetics®

Medicare Genetic Test Requisition Gx™

Please submit both pages of this form.

LABORATORY USE ONLY:	DATE RECEIVED:	ACCESSION NO:	SPECIMEN ID:

1. PATIENT INFORMATION (REQUIRED)

First Name_____ Last Name_____

DOB(mm/dd/yyyy) _____ ☐ Male ☐ Female Age_____

Address_____

City_____ State_____ Zip Code _____

Phone _____ Email_____

2. ORDERING PHYSICIAN INFORMATION (REQUIRED)

First Name_____ Last Name_____

Medical Credentials_____ NPI#_____

Facility Name_____

Address_____

City_____ State_____ Zip_____

Direct Office Contact (Required) _____

Phone_____

3. ADDITIONAL RESULTS RECIPIENT

Healthcare Professional Name _____

Phone_____ Fax_____

Email (for notification of results only)_____

Mailing Address_____

City_____ State_____ Zip_____

4. SPECIMEN INFORMATION (REQUIRED)

Date of Collection_____ Collected By_____

Specimen Type ☐ Saliva ☐ Blood (Lavender Top)

5. MEDICARE CRITERIA – Please complete the Medicare Criteria Section on the Reverse Side of this Form

Medicare does not currently cover the cost of genetic testing in individuals who do not have a personal history of cancer.
Medicare may deny a second test order as a Reflex test. Otogenetics will contact providers if an ABN is required for reflex tests.
Please feel free to contact us at 855-686-4363 with any questions.

6. ANCESTRY (Select all that apply)

☐ African/African American	☐ East Indian	☐ Mediterranean	☐ Pacific Islander
☐ Ashkenazi Jewish	☐ French Canadian	☐ Middle Eastern	☐ Sephardic Jewish
☐ Caucasian	☐ Hispanic/Latin American	☐ Native American	☐ South East Asian
			☐ Other

7. ICD10 CODES: _____

_____

8. TEST PANELS

Hereditary Cancers

☐ **Comprehensive Inherited Cancer Panel –**
39 Genes linked to breast, ovarian, colon, pancreatic, and other major cancers. APC, ATM, BARD1,BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKn2A, CHEK2, ELAC2, EPCAM, FANCC,HRAS1, MEN1, METMLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, NTRK1, PALB2, PALLD, PMS2, PTCH,PTEN,RAD50,RAD51, RAD51C, RAD51D, RET, SMAD4, STK11, TP53, VHL

☐ **Comprehensive Inherited Cancer Panel with Confirmation for Lynch Syndrome – 39 Genes**

☐ **Breast and Ovarian Cancer – 15 Genes**
ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, PALB2 PTEN, RAD51C, RET, STK11, TP53, VHL

☐ **Colorectal, Endometrial and Ovarian Cancer –**
12 Genes APC, BMPR1A, CDH1, EPCAM, MLH1, MSH2 MSH6, MUTYH, PMS2, PTEN, SMAD4, STK11

9. PATIENT INFORMED CONSENT (Please sign here or the consent form)

☐ I have read the Informed Consent Form and give permission to Otogenetics to perform the genetic tests as described.
☐ **Optional**: I consent to use of my de-identified test samples for research.
☐ **Optional**: I consent to be contacted by Otogenetics for research opportunities.
☐ **Optional**: I am a New York State resident and I consent to storing my test samples at Otogenetics beyond 60 days for future use or testing

Patient Signature _____Date_____

10. CONFIRMATION OF INFORMED CONSENT AND MEDICAL NECESSITY

The tests ordered are medically necessary for the risk assessment, diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will determine the patient's medical management and treatment decision. The person listed as the Ordering Physician is legally authorized to order the test(s) requested herein. The patient was provided with information about genetic testing and has consented to genetic testing.

Ordering Physician Signature_____ Date_____

11. PATIENT PAYMENT OPTIONS

INSURANCE: Please attach a copy of front and back of insurance card
I am covered by insurance and understand and authorize:

- Otogenetics to give my health insurance plan information on this form and other information provided by my healthcare provider that is necessary for reimbursement.
- Otogenetics to inform my plan of my test result only if required for preauthorization or payment of additional or reflex testing.
- Plan benefits to be payable to Otogenetics.

Patient Signature _____Date_____

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12. HEREDITARY BREAST and OVARIAN CANCER (HBOC) SYNDROME

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

If Yes, then Medicare coverage may be denied. To proceed with testing, please fill out and sign the Advanced Beneficiary Notice (ABN) form.

To meet Medicare criteria, at least ONE of the below criteria for hereditary breast and ovarian cancer must be met.

13. HEREDITARY BREAST and OVARIAN CANCER (HBOC) CRITERIA Please check ALL that apply.

Personal History of Breast Cancer

- Patient diagnosed with breast cancer ≤45 yrs
- Patient diagnosed ≤60 yrs with a triple negative breast cancer (ER- PR- HER2-)
- Male patient diagnosed with breast cancer at any age
- A previously identified familial pathogenic variant or mutation in BRCA1 or BRCA2
- Patient diagnosed with breast cancer ≤50 yrs 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
  - ≥ 1 close relative with pancreatic cancer
  - ≥ 1 close relative with prostate cancer
  - Limited or unknown family history
- 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 of ≥7 at any age
  - ≥ 1 close blood relative with breast cancer diagnosed ≤50 yrs
  - ≥ 1 close blood relative with ovarian/fallopian tube/primary peritoneal cancer
  - ≥ 1 close male blood relative with breast cancer
  - Individual ethnicity associated with higher mutation frequency, including Ashkenazi Jewish, Icelandic, Swedish, Hungarian or other.

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 blood relative with breast cancer at ≤50 yrs or ovarian/fallopian tube/primary peritoneal cancer at any age
  - ≥ 1 close blood relative with a previously identified familial pathogenic variant or mutation in BRCA1 or BRCA2
  - An individual of Ashkenazi Jewish, Icelandic, Swedish, Hungarian or other ancestry.
  - ≥ 2 close blood relatives with breast cancer, pancreatic cancer, and/or prostate cancer with a Gleason score of ≥7 at any age
- Patient diagnosed with prostate cancer (Gleason score ≥7) at any age with **one or more** of the following:
  - ≥ 1 close blood relative with breast cancer at ≤50 yrs or ovarian/fallopian tube/primary peritoneal cancer at any age
  - ≥ 1 close blood relative with a previously identified familial pathogenic variant or mutation in BRCA1 or BRCA2
  - ≥ 2 close blood relatives with breast cancer, pancreatic cancer, and/or prostate cancer with a Gleason score of ≥7 at any age

Other:

- Individual with breast, prostate, (Gleason ≥ 7) or pancreatic cancer who has an affected first- or second-degree blood relative meeting any of the above criteria

14. 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 ≤50 yrs

15. HEREDITARY COLORECTAL CANCER/FAP/AFAP/MAP

- Patient with ≥20 cumulative colorectal adenomas over a lifetime

*Medicare will cover BRCA-testing for an adopted individual with breast or ovarian cancer diagnosed ≤45 y or ≤60 y with triple negative breast cancer, or has a personal history of an "other" cancer (see above) that is suspicious of being a BRCA-related cancer. Individuals with little known family health history, come from small families, and in the case of sex-specific conditions, have few female/male relatives at risk of developing a particular condition, may also be eligible for BRCA gene testing. Similar to all testing, these situations require explanation of medical necessity for BRCA testing in the patient's medical record, and documentation of genetic counseling prior to BRCA testing.

*NCCN defines blood relative 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 same side of family.