MyChoice® CDx and Germline Test Request Form

COMBO TRF

- Please submit both pages of this form
- Make sure information is complete and legible

FOR LAB USE

Blood/saliva specimen collection date (required)

(mm/dd/yyyy)

Note: Affix patient identifier label to specimen tube

At the time of specimen collection: ☐ Hospital outpatient ☐ Non-hospital patient ☐ Hospital inpatient (>24 hour stay) Discharge date: (mm/dd/yyyy)

1. Patient information (Complete information required)

Name (last)	Name (first)	(m.i.)	Gender ☐ Male ☐ Female	Birthdate (mm/dd/yyyy)	Patient ID #

Email	Cell phone	Daytime phone

Address	City	State	Zip

2. Ordering provider information (Only name and HCP Account # required unless you're a new customer or HCP # is unknown)

Name (last)	Name (first)	Myriad HCP account #	Degree	NPI #

Address	City	State	Zip

Office Contact Name	Phone	Fax	Email

3. Send results to (Optional - additional clinician can be listed to receive both germline and somatic test status updates and the patient's copy of the test results)

Name (last)	Name (first)	Myriad HCP account #	Degree	NPI #

Address	City	State	Zip

Office Contact Name	Phone	Fax	Email

4. Test requested (For test descriptions see page 4)

Tests ordered will be processed and billed based on payer criteria.
*When required by payer medical policy, myRisk® Update may be performed as a reflex.
BRCA1 and *BRCA2* may be analyzed separately if required by payer.

Hereditary cancer testing:

For patients meeting hereditary breast and ovarian cancer syndrome criteria:

Select both tests if both analyses encompassing all available genes are desired

- ☐ **Integrated BRCA*nalysis*®** (*BRCA1* and *BRCA2* only)
- ☐ **Myriad Genetics MyRisk® Hereditary Cancer Update Test*** (does not include *BRCA1* and *BRCA2*, see description on page 3)

For patients previously tested at myriad:

- ☐ **Myriad Genetics MyRisk® Hereditary Cancer Update Test** (Available to patients who have been tested with BRCA*nalysis*®, COLARIS®, and/or COLARIS *AP*®. Analysis of additional germline genes for patients tested with BRACAnalysis CDx® receiving a *BRCA1/2* status. Per payor medical policy, MyRisk Update Test may be performed as a reflex test.)

Somatic testing:

For somatic testing, please select only one option

- ☐ **Reflex to MyChoice® CDx only if *BRCA1/2* is negative on Integrated *BRACA*nalysis®**
- ☐ **Concurrently run Integrated BRCA*nalysis*® and MyChoice® CDx**

Myriad MyChoice® CDx - Next generation sequencing-based *in vitro* diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the *BRCA1* and *BRCA2* genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status who are eligible, because of a positive test result for deleterious or suspected deleterious mutations in *BRCA1* or *BRCA2* genes, or may become eligible, because of a positive test result for deleterious or suspected deleterious mutations in *BRCA1* or *BRCA2* genes or a positive Genomic Instability Score, for treatment with the approved targeted therapy for Zejula® (niraparib) or Lynparza® (olaparib). In addition, detection of deleterious or suspected deleterious *BRCA1* and *BRCA2* mutations and/or positive Genomic Instability Score in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula® (niraparib) maintenance therapy. *When GIS is unable to be analyzed, tumor mutation *BRCA1/2* status alone may be reported.

5. Confirmation of informed consent & statement of medical necessity

I affirm each of the following: I have provided genetic testing information to the patient and the patient has consented to genetic testing. This test is medically necessary for the diagnosis of a disease or syndrome. The results will be used in the patient's medical management and treatment decisions. I authorize Myriad Genetics to assist my patients in obtaining pre-test genetic counseling services if required by the patient's insurance provider (see reverse). The person listed as the ordering provider is authorized by law to order the test(s) requested herein.

Sign here: Medical Professional (required to process form) X _____ Date: _____ (mm/dd/yyy)

(Signature date is the specimen collection date if a different date is not provided above)

6. Billing/payment information

☐ **Option 1: Bill insurance** (Please attach copy of authorization/referral)

Name of policy holder: _____ **Name of insurance:** _____

DOB: ____ / ____ / _____ (mm/dd/yyyy) **Insurance ID#:** _____

Authorization/referral: _____

Sign here: Patient/responsible party I agree to the biling terms on reverse X _____ **Patient relation to policy holder:** ☐ Self ☐ Spouse ☐ Child ☐ Other

Reminder: Include a copy of both sides of your insurance card(s).

If you submit more than one card, indicate which is primary.

I understand that Myriad Genetics will contact me if I will be financially responsible for any non-covered service. To be considered for the Myriad Financial Assistance Program, please provide the following information: Annual household income $. Number of family members in household .

☐ **Option 2: Uninsured** (Please call Customer Service for questions regarding test prices or for credit card payment)

☐ **Option 3: Other billing** (To establish an account, submit billing information with this form)

☐ Bill our institutional account #: or established research project code #: or Authorization/Voucher #:

TM-0722-MR1

Continue on page 2

7. Patient information (Make sure information is the same as entered on page 1)

Name (last)	(first)	(m.i.)	Birthdate (mm/dd/yyyy)

8. Ancestry

Select all that apply: ☐ Ashkenazi Jewish ☐ Black / African ☐ Middle Eastern ☐ Pacific Islander ☐ Asian ☐ Hispanic / Latino ☐ Native American ☐ White / Non-Hispanic

9. Patient personal history of cancer & other clinical information (Select all that apply)

Patient has been diagnosed with:	Age at diagnosis	Patient is currently being treated	Pathology / other info
Ovarian cancer (Select applicable diagnosis/es): ☐ **Left ovary** ☐ **Right ovary** ☐ **Left fallopian tube** ☐ **Right fallopian tube** ☐ **Peritoneum** (cul-de-sac, mesentery, mesocolon, omentum, parietal, pelvic)		☐	☐ Date of ovarian biopsy or surgery: (mm/dd/yyyy) _____ **For Medicare patients only:** **At the time of biopsy or surgery:** ☐ Hospital outpatient ☐ Non-hospital patient ☐ Hospital inpatient (>24 hour stay) Discharge date: _____ (mm/dd/yyyy)
☐ **Breast cancer** (Primary diagnosis) ☐ Left ☐ Right		☐	☐ DCIS ☐ Ductal invasive ☐ Metastatic ☐ Lobular invasive ☐ High risk clinpath* ER status: ☐ + ☐ – PR status: ☐ + ☐ – HER2 status: ☐ + ☐ – If ER/PR+, previous endocrine therapy: ☐ Yes ☐ No ☐ N/A or inappropriate Previous chemotherapy: ☐ Yes ☐ No
☐ **Breast cancer** (Second primary diagnosis) ☐ Left ☐ Right		☐	☐ DCIS ☐ Ductal invasive ☐ Metastatic ☐ Lobular invasive ☐ High risk clinpath* ER status: ☐ + ☐ – PR status: ☐ + ☐ – HER2 status: ☐ + ☐ – If ER/PR+, previous endocrine therapy: ☐ Yes ☐ No ☐ N/A or inappropriate Previous chemotherapy: ☐ Yes ☐ No
☐ **Endometrial cancer - not sarcoma**		☐	☐ Tumor MSI-High or IHC abnormal - result: _____ ☐ Tumor not available for MSI or IHC testing
☐ Colon cancer ☐ Rectal cancer		☐	Type: ☐ Mucinous ☐ Signet ring ☐ Medullary growth pattern ☐ Tumor infiltrating lymphocytes ☐ Crohn's-like lymphocytic reaction ☐ Patient's tumor is MSI-high or IHC abnormal - Result: _____ ☐ Tumor not available for MSI or IHC testing
☐ Colon adenomas ☐ Rectal adenomas		☐	Cumulative adenomatous polyp #: ☐ 1 ☐ 2-5 ☐ 6-9 ☐ 10-19 ☐ 20-99 ☐ 100+
☐ Hematologic cancer		☐	
☐ **Pancreatic cancer**		☐	
☐ **Other cancer**		☐	**Type:**
☐ **Other cancer**		☐	**Type:**

Check if applicable to patient:	
	☐ Bone marrow transplant recipient **Type:** ☐ Autologous ☐ Allogeneic (If allogeneic please call 800-469-7423 x3850)
	☐ Blood transfusion recipient within 28 days of sample collection **Type:** ☐ Whole blood ☐ Packed red blood cells
	☐ Blood transfusion recipient within 12 months of sample collection **Date:** (mm/dd/yyyy)

10. Family history of cancer

Provide complete and specific information to ensure proper insurance reimbursement, determine cancer risk estimates, and optimize medical management recommendations.

☐ **No known family history of cancer**

☐ **Limited family structure** Limited family history available such as fewer than two female 1st or 2nd degree maternal or paternal relatives having lived beyond age 45

Relationship to patient	Maternal (mother's side)	Paternal (father's side)	Cancer site or polyp type (if colon/rectal adenomas, include total number)	Age at each diagnosis
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

11. Specimen information

# of block(s): **# of slide(s):**	**Tissue type submitted** (e.g., ovary):
Clinical stage: ☐ I ☐ II ☐ III ☐ IV	**Date specimen retrieved from archive:** (mm/dd/yyyy)
Clinical status: ☐ Recurrent ☐ Metastatic ☐ Relapsed ☐ Refractory ☐ Other	**Specimen Identification Number** as it appears on the tissue block(s) or slides submitted to Myriad Genetics:
Sample fixative: (check one): ☐ Fixed tissue ☐ Other (describe):	

12. Specimen retrieval

Pathology report must be submitted with this test request form.

☐ **I want Myriad Genetic Laboratories, Inc. to request the specimen.** (Complete the information below.)

Location of specimen	Phone	Fax

Contact name

*'High-risk' is defined as either 1) TNBC treated with either (a) adjuvant chemotherapy with axillary node-positive disease or an invasive primary tumor ≥2 cm on pathology analysis, or (b) neoadjuvant chemotherapy with residual invasive breast cancer in the breast or resected lymph nodes, or 2) hormone receptor positive disease treated with either (a) adjuvant chemotherapy with ≥4 positive pathologically confirmed lymph nodes, or (b) neoadjuvant chemotherapy which did not have a complete pathologic response, with a CPS+EG score of 3 or higher.

Important information for patient†

Billing terms: I represent that I am covered by insurance and authorize Myriad Genetic Laboratories, Inc. (MGL) to give my designated insurance carrier, health plan, or third party administrator (collectively "Plan") the relevant health information necessary for reimbursement. I authorize Plan benefits to be payable to MGL. I understand MGL will contact me if I will be financially responsible for any non-covered service. By agreeing to testing I also authorize Myriad to obtain a consumer credit report on me from a consumer reporting agency selected by Myriad. I understand and agree that Myriad may use my consumer credit report to confirm whether my income qualifies me for financial assistance. I further understand that this is not a credit application and will not impact my credit score. I agree to assist MGL in resolving insurance claim issues and if I don't assist, I may be responsible for the full test cost. I permit a copy of this authorization to be used in place of the original.

Non-discrimination: Federal law (GINA) and laws in most states prohibit discrimination regarding employment eligibility, health benefits, or health insurance premiums based solely on genetic information. Myriad Genetic Laboratories, Inc. (Myriad) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

Affordability: Myriad Promise™

- The majority of appropriate patients pay $0
- Myriad Genetics will work with your insurance provider to help you get the appropriate coverage
- Myriad is committed to provide patients with access to accurate and affordable genetic results.
- For more information please refer to the billing information at www.MyriadPromise.com

†Translation of billing terms are available in Mandarin and Spanish at MyriadPromise.com. Myriad also provides free language services to people whose primary language is not English through qualified interpreters. If you need these services, contact Customer Service at 800-469-7423.

Test descriptions (For a full list of tests offered, visit **www.myriadmyrisk.com**.)

Integrated BRCA*analysis*®: Analysis of *BRCA1*, and *BRCA2* for susceptibility to Hereditary Breast and Ovarian Cancer syndrome.
Multisite 3 BRCA*analysis*®: Three-mutation *BRCA1* and *BRCA2* analysis for individuals of Ashkenazi Jewish ancestry: BRCA1 c.68_69del (p.Glu23Valfs*17) (aka *BRCA1* 185delAG, 187delAG); *BRCA1* c.5266dupC (p.Gln1756Profs*74) (aka BRCA1 5382insC, 5385insC); *BRCA2* c.5946del (p.Ser1982Argfs*22) (aka BRCA2 6174delT).
COLARIS®PLUS: Analysis of *MLH1*, *MSH2*, *MSH6*, *PMS2*, *MUTYH*, and *EPCAM* for susceptibility to Lynch syndrome (HNPCC) and *MYH*-Associated Polyposis (MAP).
COLARIS *AP*®PLUS: Analysis of *APC* for susceptibility to FAP/AFAP.
Single Site Testing: Analysis of single, familial mutation.
Myriad MyRisk® Hereditary Cancer Update Test: Analysis of additional germline genes for patients who have been tested with BRCA*analysis* CDx® receiving a *BRCA1/2* status. Per payor medical policy, MyRisk Update may be performed as a reflex test.

Certain payers do not cover genetic testing when Single Nucleotide Polymorphisms (SNPs) are a component of the test. For payers who do not reimburse for a hereditary cancer test due to SNP analysis inclusion, Myriad will report the MyRisk Hereditary Cancer Test without SNPs and these patients will not receive a SNP based RiskScore®. Please visit **www.myriadmyrisk.com/payeroptout** to determine if your patient's payer does not reimburse for hereditary cancer genetic testing with SNP analysis.

To view the full list of genes available on the MyRisk™ panel, please visit: www.myriadmyrisk.com/gene-table/

The genes associated with MyRisk™ Hereditary Cancer Panel are subject to change. To ensure you have a current version of the TRF please visit **www.myriadmyrisk.com/documents-and-forms**.

The MyRisk Management Tool and RiskScore may not be reported without an accurate and specific personal and family history included on the patient cancer family history in **sections 9-10**.

For the latest RiskScore® eligibility criteria, please visit Myriad's official technical specification webpage at: **http://www.myriad.com/technical-specifications.**

RiskScore® and Tyrer-Cuzick model will not be calculated if provider indicates that they are not appropriate for the patient by selecting the check box in **section 4**. Not all data collected on the TRF is incorporated into Tyrer-Cuzick or RiskScore® calculations. Some fields may be used for anonymized, internal validation studies only.

Turnaround time:
- The majority of MyRisk™ results are completed within 14 days
- We will notify you in the unusual event results take longer than 21 days

MyRisk™ Report includes:
- MyRisk™ Genetic Result
- RiskScore® Result
  - Personalized breast cancer risk assessment based on an analysis of biomarkers combined with patient clinical and family history data
- MyRisk™ Management tool
  - Guideline based (NCCN, CAPS, Amsterdam, and others) cancer management for both positive and negative results
  - Includes a Tyrer-Cuzick breast cancer risk estimate

Completing the test request form:
- Please include:
  - Age, cancer diagnosis, ancestry, gender, and cancer family history

For additional information visit **www.mysupport360.com** and **www.myriadmyrisk.com**

Authorization of referral to genetic counseling

In signing **section 5** of the test request form, you hereby authorize Myriad to assist your patient in obtaining genetic counseling from a third-party service. The specific process will vary by third-party counseling service but in most situations the genetic counselor will be added as the healthcare provider receiving a copy of the patient's results, and also be allowed to change the test order should there be a clinical or payer-related reason to do so. You authorize the genetic counselor to facilitate the completion of any test requisition forms and/or submit any prior authorization, if necessary, on your behalf and identifying you as the ordering provider in any such forms by including your name and NPI.

Special instructions (if applicable): *Please note: some options may not be possible if an alternate is required by the patient's insurance or if the patient requests otherwise.

☐ Expedite genetic counseling for immediate management decision

☐ Maintain my test as ordered

☐ Allow me to review results with my patient prior to their follow-up counseling session

☐ Other: _____