Medical Necessity Guidelines: Genetic Testing: BRCA-Related Breast and/or Ovarian Cancer Syndrome

Effective: September 16, 2020

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☒ No ☐**

Applies to:
COMMERCIAL Products
☒Tufts Health Plan Commercial products; Fax: 617.972.9409
☒Tufts Health Freedom Plan products; Fax: 617.972.9409
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products
☒Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055
☒Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
☒Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) **–** Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW

Predisposition to breast cancer and ovarian cancer has been related to mutations found in the BRCA1 (Breast Cancer 1, early onset) and BRCA2 (Breast Cancer 2, early onset) genes. The risk of developing cancer associated with these mutations is not known and appears to be variable even within families of similar ethnic background with the same mutation. Ashkenazi descent refers to Jews of Eastern European descent. The majority of BRCA mutations in people of Ashkenazi descent occur in one of three sites along the BRCA1 and BRCA2 genes, therefore Multi-site BRCA3 testing, which looks for these common mutations, is usually completed before BRCA1 or BRCA2 testing.

For the purposes of genetic testing, the following definitions[1] are used:
- First-Degree Relatives: An individual's parents, siblings, and children.
- Second-Degree Relatives: An individual's grandparents, aunts, uncles, half-siblings, nieces, nephews, and grandchildren.
- Third-Degree Relatives: An individual's great grandparents, great aunts, great uncles, great-grandchildren and first cousins.

Also for the purposes of genetic testing, these relatives are on the same side of the family.

The Genetic and Molecular Diagnostics Testing Authorization Request Form must be completed and faxed to the appropriate fax number listed above according to Plan. Include all relevant clinical information as applicable.

CLINICAL COVERAGE CRITERIA

NOTE: **Medical necessity letters or genetic testing request forms submitted by the performing lab and signed by the requesting provider will not be accepted as sole documentation.**

[1] From The National Health Services National Genetics and Genomics Education Centre, available at geneticseducation.nhs.uk/

Tufts Health Plan may authorize coverage for BRCA1 & BRCA2, Multi-site BRCA3, or single-site BRCA1 or BRCA2 testing for Members at high risk for breast cancer.

Tufts Health Plan may authorize coverage of this testing when **both A and B** are met. In addition, the Member must meet one of the criteria listed under **C or D.**

A. The results of the genetic test will significantly alter the medical management of the Member (documentation required).
B. The recommendation for testing is based on a review of risk factors, clinical presentation and family history, and is supported by consultation with a healthcare provider with expertise in genetic counseling (documentation required).

C. Multi-site 3 BRCA Genetic Testing For Members of Ashkenazi Descent with or without a Personal History of Breast Cancer:

Tufts Health Plan may authorize for Members with **ONE** of the following risks:

1. Personal history of a primary breast cancer, epithelial ovarian/fallopian tube/primary peritoneal cancer, pancreatic cancer, or aggressive prostate cancer (defined as having a Gleason score of 7 or greater) at any age.
2. No personal history of breast or epithelial ovarian/fallopian tube/primary peritoneal cancer and **ONE** of the following risks:
    i. Family history of breast or epithelial ovarian/fallopian tube/primary peritoneal cancer, diagnosed at any age, in any first-degree relative.
    ii. Family history of breast or epithelial ovarian/fallopian tube/primary peritoneal cancer, diagnosed at any age, in at least two second-degree relatives.
    iii. A first-degree relative with a known BRCA1or BRCA2 mutation

D. Full Panel BRCA1 & BRCA2 Genetic Testing for Members not of Ashkenazi Descent

Tufts Health Plan may authorize for Members when **ONE** of the following is met:

1. A known BRCA 1 /2 pathogenic/likely pathogenic variant within the family (see "Type of BRCA Testing Ordered")
2. Personal history of male breast cancer
3. Personal history of breast cancer **and one or more** of the following:
    a. Diagnosis at or before age 45
    b. Diagnosis after age 45 and at or before age 50 **and one** of the following risks:
        i. An additional breast cancer primary at any age*
        ii. Family history of breast cancer, diagnosed at any age, in one or more first, second or third-degree relatives
        iii. Family history of one or more first, second, or third-degree relatives with aggressive prostate cancer (defined as having a Gleason score of 7 or greater)
        iv. An unknown or limited family history. A limited family history is defined as an individual with fewer than two first or second degree female relatives having lived beyond age 45 in either lineage.
    c. Diagnosed at or before age 60 with triple negative breast cancer. Triple negative breast cancer is defined as breast cancer in which the tumor does not have receptors for any of the following; estrogen, progesterone or human epidermal growth factor receptor 2 (HER2)
    d. Diagnosed at any age **and one** of the following:
        i. One or more first, second or third-degree relative with breast cancer diagnosed at or before age 50
        ii. One or more first, second, or third degree relative with epithelial ovarian/fallopian tube/primary peritoneal cancer
        iii. One or more first, second, or third degree relative with male breast cancer
        iv. One or more first, second, or third degree relative with metastatic prostate cancer
        v. One or more first, second, or third degree relative with pancreatic cancer
        vi. Two or more additional breast cancer diagnoses for Member at any age.*
        vii. Two or more breast cancer diagnoses (individuals or breast cancer primaries*) in a first, second or third-degree relative at any age

*Two breast cancer primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors diagnosed at either the same or different times.

1. Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer
2. Personal history of pancreatic cancer

3. Personal history of metastatic prostate cancer
4. Personal history of aggressive (Gleason score of 7 or greater) prostate cancer and one of the following:
    a. One or more first, second, or third degree relative with epithelial ovarian/fallopian tube/primary peritoneal cancer, pancreatic cancer, or metastatic prostate cancer diagnosed at any age
    b. One or more first, second, or third degree relative with breast cancer diagnosed before age 50
    c. Two or more first, second, or third degree relatives with breast or prostate cancer (any grade) diagnosed at any age
5. BRCA 1 /2 pathogenic/likely pathogenic variant detected by tumor profiling on any tumor type in the absence of germline pathogenic/likely pathogenic variant analysis
6. A Member who does not meet any of the criteria outlined above but who has one or more first or second-degree relative meeting any of the above criteria
7. A combination of three or more first or second-degree relatives with breast cancer regardless of age at diagnosis
8. A third degree blood relative who has breast cancer and/or ovarian/fallopian tube/primary peritoneal cancer AND who has two or more first, second or third-degree relatives with breast cancer (one or more at or before age 50) and/or ovarian/fallopian tube/primary peritoneal cancer

Type of BRCA Testing Ordered

- Tufts Health Plan may authorize single site analysis only for Members who have a relative with a known BRCA1or BRCA2 mutation, regardless of personal history or descent.
- For Members who are of Ashkenazic descent who meet the criteria for Multi-site BRCA3 testing and who have a negative Multi-site BRCA3 test, Tufts Health Plan may authorize full panel BRCA1 & BRCA2 genetic testing (reflex testing).
- For Members who are of a partial Ashkenazic or non-Ashkenazic descent if the Member meets the Ashkenazic criteria above and the family history of breast and/or ovarian cancer occurred predominantly in non-Ashkenazic relatives, Tufts Health Plan may authorize full panel BRCA1 & BRCA2 genetic testing.
- All testing must be performed at a contracting laboratory facility when available.

myRISK™ Hereditary Cancer Test

If specifically requested, Tufts Health Plan may authorize coverage of the myRISK™ Hereditary Cancer Test or the myRISK™ Update Test if the criteria for full panel BRCA1/BRCA2 testing outlined in this Medical Necessity Guideline are met, or if the guidelines outlined in the InterQual® Clinical Evidence Summary for Lynch Syndrome are met (refer to Genetic and Molecular Diagnostic Testing Medical Necessity Guidelines).

LIMITATIONS

None

CPT/HCPCS CODES

The following CPT/HCPCS codes for BRCA testing require prior authorization:

Code	Description
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (ie, detection of large gene arrangements)
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements

Code	Description
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81212	185delAG, 5385insC, 6174delT variants
81215	known familial variant
81216	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	known familial variant

For myRISK™ Hereditary Cancer Test or myRisk Update Test, the following CPT/HCPCS codes require prior authorization: Refer to Genetic and Molecular Diagnostic Testing Medical Necessity Guidelines

Code	Description
81406	Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia) (when used for myRISK™ Update Test)
81479	Unlisted molecular pathology procedure (when used for myRISK™ Hereditary Cancer Test)

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19. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Genetic/Familial High-Risk Assessment, Breast and Ovarian, Version 2.2016. Accessed on August 30, 2016 at www.nccn.org.
20. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Genetic/Familial High-Risk Assessment, Breast and Ovarian, Version 2.2019. Accessed on November 28, 2018 at nccn.org.

APPROVAL HISTORY

January 23, 2004: Reviewed by the Clinical Coverage Criteria Committee

Subsequent endorsement date(s) and changes made:

- February 27, 2004: Criteria for the authorization of multi-site BRCA3 test for female Members of Ashkenazi descent changed from requiring personal history of two primary breast cancers, each diagnosed before age 50, to personal history of a single primary breast cancer diagnosed before age 50.
- April 1, 2004: D. 6. a. Criteria for authorization of full panel BRCA 1 & BRCA 2 genetic test for female Members who are not of Ashkenazi descent and have the following risk factor was changed to reflect that both relatives need to be on the same side of the family to receive authorization for testing with no personal history of breast or ovarian cancer.
- April 15, 2005: Criteria expanded to cover single site BRCA1 and BRCA 2 testing for Members who have a 1st degree relative with a known mutation in BRCA1or BRCA2, coverage for testing when a male relative has been diagnosed with breast cancer at any age, and the addition of criteria to cover Large Rearrangement Panel testing for Members who meet the criteria for testing, tested negative and were tested prior to August 12, 2004.
- March 10, 2006: Several clarifications and additions were made: Definition of high risk as greater than ten percent risk of a positive test result added, use of the BRCAPRO and MYRIAD Models in determining Member's risk added, diagnosis of ductal cancer in situ as synonymous with a breast cancer diagnosis explained. Change D.6.b.: to include non-Ashkenazic Members with two or more 1st or 2nd degree relatives with a diagnosis of ovarian cancer at any age.
- January 1, 2007: Several clarifications were made to coverage for Members of Ashkenazi descent, BART testing was added to Limitations.
- November 13, 2007: Criteria for coverage clarified in cases where Members have 1st degree relatives with known BRCA 1or BRCA2 mutation.
- January 30, 2008: Criteria for coverage of BRCA testing for females, not of Ashkenazi descent, changed: Personal of history of primary breast cancer changed from before age 40 to before age 50. Definitions of first and second degree relatives added to Overview.
- February 11, 2009: For consideration, BRCAPRO calculation must be submitted by the requesting provider which shows that the calculated risk of the Member having the mutation is greater than ten percent.
- October 7, 2009 for an effective date of November 1, 2009: Coverage guidelines for BART™ testing added to the guideline.
- December 2009: limitations moved: placed within the body of the criteria.
- February 1, 2010: Reviewed by Medical Specialty Policy Advisory Committee (MSPAC), no content changes. Administrative process changed.
- May 2011: Reviewed by MSPAC. BRCAPro risk clarified to read; "≥ (**greater than or equal to**)."
- January 1, 2012: New CPT codes added.
- April 1, 2012: Coding update, HCPCS codes deleted by CMS.
- May 9, 2012: Added coverage of testing when the Member has a tumor which is triple negative.

- November 25, 2013: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC), no changes
- January 1, 2014: Coding update
- January 8, 2014: Reviewed by IMPAC, requirements for coverage for Ashkenazi and non-Ashkenazi Members was expanded to include additional combinations of 1st and 2nd degree relatives.
- April 9, 2014: Reviewed by IMPAC for a July 1, 2014 effective date. Changes were made to more closely align with the National Comprehensive Cancer Network's Version 4.2013 guidelines for Hereditary Breast and/or Ovarian Cancer while ensuring continued alignment with the USPSTF guidelines for women without a personal history of breast cancer. As a result, the age of diagnosis for personal history, with no other risk factors, for women not of Ashkenazi descent, was changed from age 50 or younger to age 45 or younger.
- September 30, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- November 19, 2014: Updates to align with the National Comprehensive Cancer Network Inc.'s version 1.2014: NCCN Guidelines 1.2014 Hereditary Breast and/or Ovarian Cancer Syndrome. As a result, additional changes were made to more closely align with these guidelines. Relatives were expanded to include third degree relatives, where indicated by NCCN. Also first, second and third-degree relatives are specified as on the same side of the family. References to ovarian cancer expanded to include fallopian tube and primary peritoneal cancers. Personal history expanded to include history of pancreatic or prostate cancer. Diagnosis age corrected in section D 2. Added criteria points D 3 and 4 and E 8 to be consistent with NCCN. Effective April 1, 2015.
- July 23, 2015: Reviewed at IMPAC. Additional criteria points, personal history of invasive ovarian cancer and known family mutation in a cancer susceptibility gene, added to section E.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- November 16, 2015: Reviewed by IMPAC, Criteria sections C.2, E, and F updated to be consistent with NCCN guidelines.
- December 31, 2015: Coding updated. Per AMA CPT®, effective January 1, 2016 the following code(s) added: 81162.
- February 5, 2016: Link to Myriad BART resource guide removed.
- March 9, 2016: Reviewed at IMPAC. Separate criteria for BART testing removed and name of guideline updated (formerly "Genetic Testing: Multisite BRCA3, Single Site BRCA1 or BRCA2, & BART"), effective on April 11, 2016 (date of posting). Effective July 1, 2016, language added for myRISK Hereditary Cancer Test.
- September 14, 2016: Reviewed by IMPAC, Criteria sections C.1, D.2, E.3, and F.3 updated to be consistent with NCCN guidelines, effective January 1, 2017.
- November 9, 2016: Reviewed by IMPAC, renewed without changes
- December 14, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- December 13, 2017: Reviewed by IMPAC, renewed without changes
- September 12, 2018: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- December 12, 2018: Reviewed by IMPAC, some formatting changes, updates to section D.5, D.6, D.8., and D.9 to align with NCCN guidelines.
- December 31, 2018: Coding updated. Per AMA CPT®, effective December 31, 2018 the following code(s) deleted: 81211, 81213, 81214 and effective January 1, 2019 the following code(s) added: 81163, 81164, 81165, 81166, 81167.
- September 18, 2019: Reviewed by IMPAC, renewed without changes
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- July 1, 2020: Coding updated. Per AMA CPT®, effective July 1, 2020 the following code(s) added:0172U.
- July 9, 2020: Fax number for Unify updated.
- July 29, 2020: CPT 0172U removed. Refer to Medical Necessity Guidelines: Genetic and Molecular Diagnostic Testing.
- September 16, 2020: Reviewed by IMPAC, renewed without changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.