Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Genetic Testing: BRCA1 and BRCA2 – Hereditary Breast, Ovarian, and Pancreatic Cancers

Effective: November 4, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; 888-415-9055
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☐ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Hereditary breast, ovarian and pancreatic cancers are frequently attributed to mutations in known susceptibility genes, including breast cancer susceptibility gene 1 (*BRCA1*) and breast cancer susceptibility gene 2 (*BRCA2*). Individuals with a personal and/or family history of breast, ovarian, or pancreatic cancer may benefit from genetic testing to determine their risk for these cancers or to guide medical management and treatment decisions. It is strongly recommended, but not required, that individuals receive genetic counseling prior to testing to discuss the potential benefits, limitations, and risks of genetic testing (e.g. variants of uncertain significance).

This policy is specific to BRCA1 and BRCA2 testing. Broader genetic testing may be indicated based on an individual's personal and/or family history. Other high penetrance breast, ovarian and pancreatic cancer susceptibility genes related to significantly increased likelihood of these cancers include CDH1, PALB2, PTEN, STK11, CDKN2A , ATM and TP53. Refer to Medical Necessity Guidelines: Molecular and Diagnostic Testing for additional gene testing, including multi-gene panel testing for breast and ovarian cancer.

Clinical Guideline Coverage Criteria

NOTE: 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. **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.

The Plan may authorize genetic testing for BRCA1 and/or BRCA2 gene(s) when **ONE** of the following criteria is met:

1. Member has a blood relative with known BRCA 1 or BRCA 2 pathogenic or likely pathogenic variant; or
2. Member is with an unknown or limited family history; or
3. Member has personal history of breast cancer and **ONE** of the following criteria is met:
    a. Member is ≤50 y; or
    b. Member is any age and **one** of the following criteria is met :
        i. Testing is requested to guide treatment management (e.g. use of PARP inhibitors, adjuvant treatment with Olaparib); or
        ii. Tumor genomic analysis has identified BRCA1/2 variant, which has clinical implications if also identified with germline testing; or
        iii. Member has triple-negative breast cancer; or
        iv. Member has multiple primary breast cancers; or
        v. Member has lobular breast cancer and a personal or family history of diffuse gastric cancer; or
        vi. Male member has breast cancer; or
        vii. Member is of Ashkenazi ancestry; or
        viii. Member's family history includes **one** or more of the following:
            - ≥1 close blood relative with:
                - breast cancer at age ≤50; or
                - male breast cancer; or
                - epithelial ovarian cancer; or
                - exocrine pancreatic cancer; or
                - prostate cancer: metastatic, intraductal, cribriform or high/very-high-risk group or;
            - ≥3 combined diagnoses of breast cancer in patient and/or close blood relatives; or
            - ≥2 close blood relatives with breast cancer; or
            - ≥2 close blood relatives with prostate cancer; or
4. Member has personal history of epithelial ovarian cancer (including fallopian tube cancer or primary peritoneal cancer) at any age; or
5. Member has a personal history of metastatic prostate cancer; or
6. Member has personal history of exocrine pancreatic cancer, including pancreatic adenocarcinoma or acinar cell carcinoma; or
7. Member has first-degree relative with pancreatic adenocarcinoma.
8. Member has a probability >5% of a BRCA1/2 pathogenic variant based on risk assessment tool (e.g., Tyrer-Cuzick, BRCAPro, CanRisk)
9. Member has first- or second-degree blood relative with epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer)
10. Member has a first- or second-degree blood relative meeting any criteria listed above, with exception of criterion 3bi. (NOTE: If relative has pancreatic adenocarcinoma or prostate cancer, Member should be offered testing only if Member is a first-degree relative of the affected family member)

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and

Code	Description
	ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81165	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81212	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81215	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81432	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least **10** genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53
0129U	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)

References:

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3. Genetic testing and management of individuals at risk of hereditary breast and ovarian cancer syndromes. UpToDate.com/login [via subscription only]. Published May 18, 2026. Accessed August 20, 2026.
4. Familial risk factors for pancreatic cancer and screening of high-risk patients. UpToDate.com/login [via subscription only]. Published April 12, 2024. Updated April 30, 2026. Accessed August 31, 2026
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Approval And Revision History

October 21, 2020: Reviewed by IMPAC, renewed without changes.

Subsequent endorsement date(s) and changes made:

- August 18, 2021: Reviewed by IMPAC, renewed without changes.
- October 20, 2021: Reviewed by IMPAC, renewed without changes.
- February 17, 2022: Freedom removed from template.
- March 16, 2022: Reviewed by Medical Policy Approval Committee (MPAC). Effective July 1, 2022, myRISK™ Hereditary Cancer Test is non-covered, considered investigational.
- December 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC). Updates to criteria for effective date February 1, 2023.
- March 15, 2023: Reviewed at MPAC. For effective date September 1, 2023, CPT codes 81432, 81433 and 0129U added.
- October 18, 2023: Reviewed by MPAC, renewed without changes.
- November 2023: Unify name changed to One Care effective January 1, 2024.
- November 21, 2024: Reviewed by MPAC, under criteria section, added personal history of metastatic prostate cancer; updated references, effective January 1, 2025.
- January 1, 2025: Coding updated per AMA CPT®, effective January 1, 2025, the following code removed 81433.
- September 17, 2025. Reviewed by MPAC, annual review no changes, effective November 1, 2025. References updated.
- October 21, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated; language for Carelink removed; Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template.
- October 21, 2026. Reviewed by MPAC, annual review no changes. Effective date November 4, 2026.

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. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.