Genetic testing: oncology - algorithmic testing

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Prior authorization is not required for the following tests as they are considered investigational/experimental and therefore not covered:

- Colorectal Cancer Prognostic Algorithmic Tests
- Emerging Evidence Cutaneous Melanoma Prognostic Algorithmic Tests
- Ovarian Cancer Diagnostic Algorithmic Tests
- Gynecologic Cancer Treatment Algorithmic Tests
- Emerging Evidence Lung Cancer Treatment Algorithmic Tests
- Emerging Evidence Lung Cancer Diagnostic Algorithmic Tests
- Emerging Evidence Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests
- Bladder/Urinary Tract Cancer Diagnostic Algorithmic Tests
- Cancer of Unknown Primary Gene Expression Profiling Tests
- PreciseDxTM Breast Cancer Test
- Emerging Evidence Pancreatic Cyst Risk Assessment Algorithmic Tests
- Gene Expression Profiling Breast Cancer Subtyping Tests
- Polygenic Risk Score Tests

Prior authorization is required for all other algorithmic testing including:

- Bladder/Urinary Tract Cancer Treatment and Recurrence Algorithmic Tests
- Cutaneous Melanoma Diagnostic Algorithmic Tests
- Cutaneous Melanoma Risk Assessment Algorithmic Tests
- Breast Cancer Treatment and Prognostic Algorithmic Tests
- Breast Cancer Extended Endocrine Therapy Algorithmic Tests
- Breast DCIS Prognostic Algorithmic Tests
- Prostate Cancer Treatment and Prognostic Algorithmic Tests
- Evidence Based Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests (except 84153 and 84154)
- Thyroid Cancer Diagnostic Algorithmic Tests
- Uveal Melanoma Prognostic Algorithmic Tests
- Evidence Based Cutaneous Melanoma Prognostic Algorithmic Tests
- Evidence Based Lung Cancer Diagnostic Algorithmic Tests
- Evidence Based Lung Cancer Treatment Algorithmic Tests
- Evidence Based Pancreatic Cyst Risk Assessment Algorithmic Tests
- Testing that is associated with a procedure code listed in “Box A”, below.

Prior authorization is not required for the following:

- Ovarian cancer treatment algorithmic tests

Tests that require prior authorization will be reviewed for medical necessity of the testing as a whole. That is, a single coverage decision will apply to all of the tests, services, and/or procedure codes associated with the genetic test, whether they are requested/billed together or separately.

Box A: Genetic testing procedure codes that require prior authorization
Molecular pathology procedures, Tier 2 or unlisted (CPT 81400-81408, 81479)
Unlisted multianalyte assays (CPT 81599)
Any other listed or unlisted laboratory/pathology CPT code when it is used in association with a genetic test.

Policy Reference Table

If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

HealthPartners

Coverage Criteria Sections	Example Tests, Labs	Common CPT Codes	Common ICD Codes
Breast Cancer			
Breast Cancer Treatment and Prognostic Algorithmic Tests	Oncotype Dx Breast Recurrence Score (Exact Sciences)	81519	C50.011-C50.92, Z17.0
Breast Cancer Extended Endocrine Therapy Algorithmic Tests	Breast Cancer Index (bioTheranostics)	81518	C50.011-C50.92, Z17.0
Breast Cancer Prognostic Algorithmic Tests	EndoPredict (Myriad)	81522	C50, Z17.0, Z17.1
	MammaPrint (Agendia, Inc.)	81521, 81523	
	Prosigna Assay (NeoGenomics)	81520	
Gene Expression Profiling Breast Cancer Subtyping Tests	BluePrint (Agendia, Inc.)	81599	C50-C50.929
Breast DCIS Prognostic Algorithmic Tests	Oncotype DX Breast DCIS Score (Exact Sciences)	0045U	D05.1
Colorectal Cancer			
Colorectal Cancer Prognostic Algorithmic Tests	Oncotype DX Colon Recurrence Score (Exact Sciences)	81525	C18.0-C18.9
	miR-31now (GoPath Laboratories)	0069U	
	Immunoscore (Veracyte)	0261U	
Prostate Cancer			
Prostate Cancer Treatment and Prognostic Algorithmic Tests	Oncotype DX Genomic Prostate Score (MDxHealth)	0047U	C61
	Decipher Prostate Biopsy Genomic Classifier (Veracyte)	81542	
	Decipher Prostate RP Genomic Classifier (Veractye)		
	Prolaris (Myriad Genetics)	81541	
	ArteraAI Prostate Test (Artera)	0376U	
Evidence-Based Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests	4K Prostate Score (Serum) (BioReference Laboratories)	81539	C61, Z12.5
	Prostate Health Index (ARUP Laboratories)	84153, 84154, 86316	
	SelectMDx for Prostate Cancer (MDx Health)	0339U	
	ExoDx Prostate Test (ExosomeDx)	0005U	
	IsoPSA (Cleveland Diagnostics, Inc)	0359U	
	MyProstateScore (Lynx DX)	0113U	
	ConfirmMDx for Prostate Cancer (MDxHealth)	81551	
	Prostate Cancer Gene 3 (Integrated Regional Laboratories)	81479	
Emerging Evidence Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests	PanGIA Prostate (Genetics Institute of America)	0228U	C61, Z12.5
	MyProstateScore 2.0 (Lynx Dx)	0403U	

	miR Sentinel Prostate Cancer Test (miR Scientific)	0343U, 0424U	
	EpiSwitch Prostate Screening Test (PSE) (Oxford BioDynamics)	0433U	
	Stockholm3 (BioAgilytix Diagnostics)	0495U	
	OncoAssure Prostate (DiaCarta, Inc.)	0497U	
	Tempus p-MSI (Tempus AI, Inc)	0512U	
	Tempus p-Prostate (Tempus AI, Inc)	0513U	
Thyroid Cancer			
Thyroid Cancer Diagnostic Algorithmic Tests	ThyroSeq Genomic Classifier (CBLPath)	0026U	C73, D44.0, E04.1
	ThyGeNEXT (Interpace Diagnostics)	0245U	
	ThyraMIR (Interpace Diagnostics)	0018U	
	Afirma Genomic Sequencing Classifier (Veracyte)	81546	
	Afirma Xpression Atlas (Veracyte)	0204U	
	ThyroSeq CRC (UPMC)	0287U	
Uveal Melanoma			
Uveal Melanoma Prognostic Algorithmic Tests	DecisionDX-UM (Castle Bioscience, Inc.)	81552	C69
Cutaneous Melanoma			
Evidence-Based Cutaneous Melanoma Prognostic Algorithmic Tests	DecisionDX-Melanoma (Castle Biosciences, Inc.)	81529	C43, D03.0-D03.9, Z12.83
	Merlin Melanoma (BioCartis)	81479	
	MelaNodal (Quest)	81599	
Emerging Evidence Cutaneous Melanoma Prognostic Algorithmic Tests	AMBL or (AMLo Biosciences)	0387U	C43, D03.0-D03.9, Z12.83
Cutaneous Melanoma Diagnostic Algorithmic Tests	myPath Melanoma (Castle Biosciences Inc.)	0090U	D22.0-D22.9, D48.5, D49.2, Z12.83
	DecisionDx-DiffDx-Melanoma (Castle Biosciences, Inc.)	0314U	
Cutaneous Melanoma Risk Assessment Algorithmic Tests	Pigmented Lesion Assay (DermTech)	0089U	D22-D23, Z12.83
Ovarian Cancer			
Ovarian Cancer Diagnostic Algorithmic Tests	OVA1 (Aspira Women's Health)	81503	D27.0, D27.1, D27.9, D39.10-D39.12, D39.9, D49.59, D49.9
	Overa (Aspira Women's Health)	0003U	
	Risk of Ovarian Malignancy (ROMA) (Labcorp)	81500	
	OvaWatch (Aspira Women's Health)	0375U	
	Avantect Ovarian Cancer Test (ClearNote Health)	0507U	
Ovarian Cancer Treatment Algorithmic Tests	myChoice CDx (Myriad Genetics)	0172U	C48, C56, C57.0
Gynecologic Cancer			
	ChemoFx (Helomics Corporation)	81535	C51-C57

Gynecologic Cancer Treatment Algorithmic Tests	ChemoFx - Additional Drug (Helomics Corporation)	81536	
Lung Cancer			
Evidence-Based Lung Cancer Diagnostic Algorithmic Tests	Nodify XL2 (Biodesix)	0080U	R91.1
Emerging Evidence Lung Cancer Diagnostic Algorithmic Tests	REVEAL Lung Nodule Characterization (MagArray)	0092U	R91.1
	Percepta Lung Cancer Diagnostic (Veracyte)	81479	
	LungLB Test (LungLife AI)	0317U	
	Nodify CDT (Biodesix)	0360U	
	OncobiotaLUNGdetect (Mironoma)	0395U	
	CyPath Lung (Precision Pathology Laboratory)	0406U	
Evidence-Based Lung Cancer Treatment Algorithmic Tests	VeriStrat (Biodesix)	81538	C34, D38.1, D38.6
	Razor14/Risk Reveal (RazorGenomics)	81599	
	DetermaRx (Oncocyte Corporation)	0288U	
Emerging Evidence Lung Cancer Treatment Algorithmic Tests	LungOI (Imagene)	0414U	C34, D38.1, D38.6
	PROphet NSCLC Test (OncoHost Inc)	0436U	
Bladder and Urinary Tract Cancer			
Bladder/Urinary Tract Cancer Diagnostic Algorithmic Tests	CxBladder Detect+ (Pacific Edge)	0420U	R31.9
	Cxbladder Detect (Pacific Edge)	0012M	
	Oncuria Detect (DiaCarta Clinical Lab)	0365U	
Bladder/Urinary Tract Cancer Treatment and Recurrence Algorithmic Tests	Cxbladder Monitor (Pacific Edge)	0013M	C67, C68
	Decipher Bladder (Veracyte)	0016M	
	Cxbladder Triage (Pacific Edge)	0363U	
	Oncuria Monitor (DiaCarta Clinical Lab)	0366U	
	Oncuria Predict (DiaCarta Clinical Lab)	0367U	
Pancreatic Cancer			
Evidence-Based Pancreatic Cyst Risk Assessment Algorithmic Tests	PancraGEN (Interpace Diagnostics)	81479	D49, K86.2
Emerging Evidence Pancreatic Cyst Risk Assessment Algorithmic Tests	PancreaSeq Genomic Classifier (Univ of Pittsburgh Medical Center Molecular and Genomic Pathology Laboratory)	0313U	
Cancer of Unknown Primary			
Cancer of Unknown Primary Gene Expression Profiling Tests	CancerTYPE ID (Biotheranostics)	81540	C79.9, C80.0, C80.1
Polygenic Risk Score Tests			
Breast Cancer Polygenic Risk Score Tests	geneType for Breast Cancer (Genetic Technologies)	81599	Z13.71, Z13.79 Z80.3

HealthPartners

Coverage

Breast Cancer

Breast Cancer Treatment and Prognostic Algorithmic Tests

1. The use of the breast cancer treatment and prognostic algorithmic test Oncotype DX Breast Recurrence Score is considered **medically necessary** when:
    - A. The member has primary breast cancer that is ductal/NST, lobular, mixed or micropapillary, **and**
    - B. The member's tumor is hormone receptor-positive (estrogen receptor-positive or progesterone receptor-positive), **and**
    - C. The member's tumor is human epidermal growth factor receptor 2 (HER2)- negative, **and**
    - D. The member is considering treatment with adjuvant therapy (e.g., tamoxifen, aromatase inhibitors, immunotherapy), **and**
    - E. The member is status post tumor resection and surgical axillary nodal staging and meets one of the following (regardless of menopausal status):
        - i. Tumor is greater than 0.5 cm and node negative (pN0), **or**
        - ii. Lymph nodes are pN1mi (2mm or smaller axillary node metastases), **or**
        - iii. Lymph nodes are pN1 (1-3 positive nodes)
2. The use of the breast cancer treatment and prognostic algorithmic test Oncotype DX Breast Recurrence Score is considered **investigational** for all other indications.

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Breast Cancer Extended Endocrine Therapy Algorithmic Tests

1. The use of the breast cancer extended endocrine therapy test Breast Cancer Index (BCI) is considered **medically necessary** when:
    - A. The member has primary breast cancer that is ductal/NST, lobular, mixed or micropapillary, **and**
    - B. The member's tumor is hormone receptor-positive (estrogen receptor-positive or progesterone receptor-positive), **and**
    - C. The member's tumor is HER2-negative, **and**
    - D. The member has no distant metastases, **and**
    - E. The member has completed at least 4 years of endocrine therapy, **and**
    - F. The member is considering extended treatment with adjuvant therapy (e.g., tamoxifen, aromatase inhibitors, immunotherapy), **and**
    - G. The member meets one of the following (regardless of menopausal status):
        - i. Tumor is greater than 0.5 cm and node negative (pN0), **or**
        - ii. Lymph nodes are pN1mi (2mm or smaller axillary node metastases), **or**
        - iii. Lymph nodes are pN1 (1-3 positive nodes)
2. The use of the breast cancer extended endocrine therapy test Breast Cancer Index (BCI) is considered **investigational** for all other indications.

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Breast Cancer Prognostic Algorithmic Tests

1. The use of a breast cancer prognostic algorithmic test (i.e., Endopredict, Prosigna, MammaPrint) is considered **medically necessary** when:
    - A. The member meets at least one of the following:
        - i. Postmenopausal status, **or**
        - ii. Greater than 50 years of age, **and**
    - B. The member has primary breast cancer that is ductal/NST, lobular, mixed or micropapillary, **and**
    - C. The member's tumor is estrogen receptor-positive, **and**
    - D. The member's tumor is human epidermal growth factor receptor 2 (HER2)-negative; **and**
    - E. The member is considering treatment with adjuvant therapy (for example, tamoxifen, aromatase inhibitors, immunotherapy), **and**
    - F. The member has had axial nodal staging and has the following node status:
        - i. pN0, nodes negative pathologically, **or**
        - ii. pN1mi or pN1 (1-3 nodes positive pathologically *).
2. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) in individuals with 4 or more positive nodes is considered **investigational**.
3. The use of the breast cancer prognostic algorithmic test Prosigna in individuals with 1-3 node positive breast cancer is considered **investigational**.
4. The use of a breast cancer prognostic algorithmic test (i.e., Endopredict, Prosigna, MammaPrint) is considered **investigational** for all other indications.

*Prosigna is indicated for node negative disease, but **not** for disease with 1-3 positive nodes. EndoPredict and Mammaprint are indicated for node negative disease and for disease with 1-3 positive nodes.

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Gene Expression Profiling Breast Cancer Subtyping Tests

1. Gene expression profiling breast cancer subtyping tests (e.g., BluePrint) are considered **investigational**.

Breast DCIS Prognostic Algorithmic Tests

1. Breast DCIS prognostic algorithmic tests are considered **medically necessary** when:
   - A. The member has ductal carcinoma in situ (DCIS), **and**
   - B. The tumor specimen contains at least 0.5 mm of DCIS, **and**
   - C. The result of testing would aid in treatment decision-making (i.e., pursuing additional surgery or radiation therapy), **and**
   - D. The patient's DCIS was not removed via mastectomy (i.e., there is residual ipsilateral breast tissue).
2. Breast DCIS prognostic algorithmic tests are considered **investigational** for all other indications.

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Colorectal Cancer

Colorectal Cancer Prognostic Algorithmic Tests

1. Colorectal cancer prognostic algorithmic tests are considered **investigational**.

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Prostate Cancer

Prostate Cancer Treatment and Prognostic Algorithmic Tests

1. The use of a prostate cancer treatment and prognostic algorithmic test (i.e., Oncotype DX Prostate, Prolaris, Decipher, ArteraAI) is considered **medically necessary** when:
   - **A.** The member has a life expectancy of 10 years or more, **and**
   - B. The member does not have either of the following:
     - i. Very low-risk prostate cancer, **or**
     - ii. Very high-risk prostate cancer.
2. The use of the prostate cancer treatment and prognostic algorithmic test Decipher assay is considered **medically necessary** when:
   - A. The member has a life expectancy of more than 5 years, **and**
     - i. The member has had radical prostatectomy, **and**
       - a) There are no lymph node metastases, **and**
       - b) There is PSA persistence/recurrence.
3. The use of a prostate cancer treatment and prognostic algorithmic test is considered **investigational** for all other indications.

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Evidence-Based Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests

1. Prostate cancer risk assessment and diagnostic algorithmic tests with sufficient evidence of clinical validity and utility are considered **medically necessary** when:
   - A. The member meets all of the following:
     - i. The member has not had a prostate biopsy, **and**
     - ii. The member has at least one of the following:
       - a) Prostate specific antigen (PSA) of >3 ng/ml, **or**
       - b) A digital rectal exam (DRE) that is suspicious for cancer, **and**
     - iii. The test is one of the following:
       - a) Prostate Health Index (PHI), **or**
       - b) SelectMDx, **or**
       - c) 4Kscore, **or**
       - d) ExoDx Prostate Test, **or**
       - e) MyProstateScore (MPS), **or**
       - f) IsoPSA, **or**
   - B. The member meets all of the following:
     - i. The member has had a prostate biopsy, **and**
     - ii. The result is one of the following:
       - a) Atypia, suspicious for cancer, **or**
       - b) High-grade prostatic intraepithelial neoplasia (PIN), **or**
       - c) Benign, **and**
     - iii. The test is one of the following:
       - a) Prostate Health Index (PHI), **or**
       - b) 4Kscore, **or**
       - c) ExoDx Prostate Test, **or**
       - d) MyProstateScore (MPS), **or**

e) IsoPSA, **or**
f) ConfirmMDx, **or**
g) PCA3.

2. The use of prostate cancer risk assessment algorithmic tests with sufficient evidence of clinical validity and utility are considered **investigationa**l for all other indications where clinical validity and utility have not been demonstrated.

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Emerging Evidence Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests

1. Prostate cancer risk assessment and diagnostic algorithmic tests with insufficient guidance for use are considered **investigational**.

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Thyroid Cancer

Thyroid Cancer Diagnostic Algorithmic Tests

1. The use of a thyroid cancer diagnostic algorithmic test in fine needle aspirates of thyroid nodules is considered **medically necessary** when:
   A. The fine needle aspirate showed indeterminate cytologic findings (i.e., Bethesda diagnostic category III or IV), **and**
   B. The result of the test would affect surgical decision making.
2. The use of a thyroid cancer diagnostic algorithmic test in fine needle aspirates of thyroid nodules is considered **investigational** for all other indications.

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Uveal Melanoma

Uveal Melanoma Prognostic Algorithmic Tests

1. The use of a uveal melanoma prognostic algorithmic test is considered **medically necessary** when:
   A. The member has primary, localized uveal melanoma.
2. The use of a uveal melanoma prognostic algorithmic test is considered i**nvestigational** for all other indications.

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Cutaneous Melanoma

Evidence Based Cutaneous Melanoma Prognostic Algorithmic Tests

1. Cutaneous melanoma prognostic algorithmic tests with sufficient evidence of clinical validity and utility are considered **medically necessary** when:
   A. The member has either of the following:
      i. Stage I melanoma (staging based on AJCC (American Joint Committee on Cancer)), **or**
      ii. Stage II melanoma (staging based on AJCC (American Joint Committee on Cancer)), **and**
   B. The member does not have metastatic disease, **and**
   C. The results of the testing will inform subsequent biopsy decisions, use of adjuvant therapy(ies), or follow-up screening protocols.
2. Cutaneous melanoma prognostic algorithmic tests with sufficient evidence of clinical validity and utility are considered **investigational** for all other indications where clinical validity and utility have not been demonstrated.

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Emerging Evidence Cutaneous Melanoma Prognostic Algorithmic Tests

1. Cutaneous melanoma prognostic algorithmic tests with insufficient evidence of clinical validity are considered **investigational**.

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Cutaneous Melanoma Diagnostic Algorithmic Tests

1. Cutaneous melanoma diagnostic algorithmic tests are considered **medically necessary** when:
   A. The member has a melanocytic neoplasm that is diagnostically uncertain or equivocal after histopathology.
2. Cutaneous melanoma diagnostic algorithmic tests are considered **investigational** for all other indications, including:
   A. A melanocytic neoplasm that has pathology definitive for melanoma, desmoplastic melanoma, or sclerosing nevus.

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Cutaneous Melanoma Risk Assessment Algorithmic Tests

1. Cutaneous melanoma risk assessment algorithmic tests are considered **medically necessary** when:
   A. The member has a melanocytic neoplasm that shows at least one ABCDE (asymmetry, border irregularity, color variegation, diameter >6 mm, and evolution) feature, **and**

B. A biopsy is being considered but has not yet been performed, **and**
C. The use of the test is limited to a maximum of 2 times per visit.

2. Cutaneous melanoma risk assessment algorithmic tests are considered **investigational** for all other indications.

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Ovarian Cancer

Ovarian Cancer Diagnostic Algorithmic Tests

1. Ovarian cancer diagnostic algorithmic tests (i.e., OVA1, Overa, ROMA, and OvaWatch) are considered **investigational** for all indications, including but not limited to:
   A. Preoperative evaluation of adnexal masses to triage for malignancy
   B. Screening for ovarian cancer
   C. Selecting patients for surgery for an adnexal mass
   D. Evaluation of patients with clinical or radiologic evidence of malignancy
   E. Evaluation of patients with nonspecific signs or symptoms suggesting possible malignancy
   F. Postoperative testing and monitoring to assess surgical outcome and/or to detect recurrent malignant disease following treatment.

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Ovarian Cancer Treatment Algorithmic Tests

1. Ovarian cancer treatment algorithmic tests are considered **medically necessary** when:
   A. The member has a diagnosis of ovarian cancer, **and**
   B. The member is being considered for PARP inhibitor therapy.
2. Ovarian cancer treatment algorithmic tests are considered **investigational** for all other indications.

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Gynecologic Cancer

Gynecologic Cancer Treatment Algorithmic Tests

1. Gynecologic cancer treatment algorithmic tests in the assessment of gynecological cancers are considered **investigational.**

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Lung Cancer

Evidence Based Lung Cancer Diagnostic Algorithmic Tests

1. Lung cancer diagnostic algorithmic tests with sufficient evidence of clinical validity and utility are considered **medically necessary** when:
   A. The member is age 40 years or older, **and**
   B. The member has a single lung nodule between 8 and 30 mm in diameter, **and**
   C. The member has a risk of cancer of 50% or less according to the Mayo risk prediction algorithm, **and**
   D. The member does **not** have a diagnosis of cancer (except for nonmelanoma skin cancer) within 5 years of the lung nodule detection.
2. Lung cancer diagnostic algorithmic tests with sufficient evidence of clinical validity and utility are considered **investigational** for all other indications where clinical validity and utility have not been demonstrated.

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Emerging Evidence Lung Cancer Diagnostic Algorithmic Tests

1. Lung cancer diagnostic algorithmic tests with insufficient evidence of clinical validity are considered i**nvestigational**.

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Evidence-Based Lung Cancer Treatment Algorithmic Tests

1. Lung cancer treatment algorithmic tests with sufficient evidence of clinical validity and utility are considered **medically necessary** when:
   A. The member has a non-squamous non-small cell lung cancer (NSCLC), **and**
   B. The member's tumor size less than 5 cm, **and**
   C. The member has no positive lymph nodes (stages I and IIa), **and**
   D. The member is considering adjuvant platinum-containing chemotherapy.
2. Lung cancer treatment algorithmic tests with sufficient evidence of clinical validity and utility are considered **investigational** for all other indications where clinical validity and utility have not been demonstrated.

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Emerging Evidence Lung Cancer Treatment Algorithmic Tests

1. Lung cancer treatment algorithmic tests with insufficient evidence of clinical validity are considered **investigational**.

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Bladder and Urinary Tract Cancer

Bladder/Urinary Tract Cancer Diagnostic Algorithmic Tests

1. Bladder /urinary tract cancer diagnostic algorithmic tests are considered **investigational** for all indications.

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Bladder/Urinary Tract Cancer Treatment and Recurrence Algorithmic Tests

1. The use of bladder/urinary tract cancer treatment and recurrence algorithmic test is considered **medically necessary** when:
   A. The member has a diagnosis of bladder cancer, **and**
   B. Results of algorithmic testing will affect management decisions for the member's bladder cancer, **and**
   C. The member has not previously undergone bladder cancer treatment and recurrence algorithmic testing for the current cancer diagnosis.
2. The use of bladder/urinary tract cancer treatment and recurrence algorithmic test is considered **investigational** for all other indications.

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Pancreatic Cancer

Evidence-Based Pancreatic Cyst Risk Assessment Algorithmic Tests

1. Pancreatic cyst risk assessment algorithmic tests with sufficient evidence of clinical validity and utility are considered **medically necessary** when:
   A. The member has a pancreatic cyst, **and**
   B. Initial testing (for example, CEA measurement, cytopathology and/or radiology) has been inconclusive for malignancy, **and**
   C. The results of the test will impact treatment decisions (e.g., surgery, more aggressive treatment).
2. Pancreatic cyst risk assessment algorithmic tests with sufficient evidence of clinical validity and utility are considered **investigational** for all other indications where clinical validity and utility have not been demonstrated.

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Emerging Evidence Pancreatic Cyst Risk Assessment Algorithmic Tests

1. Pancreatic cyst risk assessment algorithmic tests with insufficient evidence of clinical validity are considered **investigational**.

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Cancer of Unknown Primary

Cancer of Unknown Primary Gene Expression Profiling Tests

1. The use of a cancer of unknown primary gene expression profiling test to evaluate the site of origin of a tumor of unknown primary, or to distinguish a primary from a metastatic tumor is considered **investigational**.

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Polygenic Risk Score Tests

Breast Cancer Polygenic Risk Score Tests

1. The use of a breast cancer polygenic risk score test is considered **investigational**.

Definitions

1. **Ductal/NST breast cancer** is ductal cancer that is no special type (NST), meaning the cancer cells have no features that class them as a special type of breast cancer when examined by microscope.
2. **Thyroid nodules with indeterminate findings** include Bethesda diagnostic category III (atypia/follicular lesion of undetermined significance) or Bethesda diagnostic category IV (follicular neoplasm/suspicion for a follicular neoplasm)
3. **Adjuvant** therapy refers to medication (such as chemotherapy or endocrine therapy) given after the surgical removal of a cancerous tumor.
4. **PSA persistence/recurrence** is defined in the NCCN Prostate Cancer guidelines (4.2024) as failure of PSA to fall to undetectable levels (PSA persistence) or undetectable PSA after a radical prostatectomy with a subsequent detectable PSA that increases on 2 or more determinations (PSA recurrence) or that increases to PSA greater than 0.1 ng/mL (p. PROS-10)
5. **ABCDE** criteria is an acronym for examining patients with a lesion that is suspicious for melanoma: asymmetry, border irregularity, color variegation, diameter >6 mm, and evolution.
6. **Very high-risk prostate cancer**: Defined by NCCN as an individual who has no very-high-risk features but has at least one of the following high-risk features:
   A. cT3a
   B. Grade Group 4 or Grade Group 5
   C. PSA >20ng/ml
7. **Very low risk prostate cancer**: Defined by NCCN as clinical stage T1c, Grade Group 1, PSA <10 mg/nl and density <0.15 ng/mL/g, biopsy shows <3 positive cores/fragments and <50% cancer in each core/fragment)

Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria do not apply to Medicare Products. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7272 or 1-877-778-8384.

Approved Medical Director Committee 6/16/2021; Revised 11/17/2021, 4/12/22, 10/3/22, 3/31/23, 9/26/23, 03/13/2024, 9/17/2024; Reviewed 10/2021, 1/2022, 7/2022, 1/2023, 7/2023, 1/2024, 7/2024, 1/2025

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