Medica Central Coverage Policy

Policy Name:	**Genetic Testing – Oncology Testing: Algorithmic Assays MP9605**
Effective Date:	**01/01/2026**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

OVERVIEW

This policy addresses the use of tests that combine biomarkers and/or clinical data into an algorithm to generate a disease risk assessment, prognostic result, or clinical recommendation for treatment.

In keeping with the language used in National Comprehensive Cancer Network (NCCN) guidelines, the terms "male" and "female" refer to sex assigned at birth.

For additional information see the Rationale and References section.

The tests, CPT codes, and ICD codes referenced in this policy are not comprehensive, and their inclusion does not represent a guarantee of coverage or non-coverage. Please see the Concert Platform for additional registered tests.

POLICY REFERENCE TABLE

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Breast Cancer			

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Breast Cancer Treatment and Prognostic Algorithmic Tests	Oncotype Dx Breast Recurrence Score - 81519 (Exact Sciences Laboratories)	81519, S3854, C50.011-C50.92, Z17.0	Rationale/ References
Breast Cancer Extended Endocrine Therapy Algorithmic Tests	Breast Cancer Index - 81518 (bioTheranostics)	81518, S3854, C50.011-C50.92, Z17.0	Rationale/ References
Breast Cancer Prognostic Algorithmic Tests	EndoPredict - 81522 (Myriad Genetics)	81520, 81521, 81522, 81523, S3854, C50, Z17.0, Z17.1	Rationale/ References
	MammaPrint - 81521, 81523 (Agendia, Inc.)		
	Prosigna Breast Cancer Prognostic Gene Signature Assay(LabCorp)		
Gene Expression Profiling Breast Cancer Subtyping Tests	BluePrint (Agendia, Inc.)	81599, S3854, 0153U, C50-C50.929	Rationale/ References
	Insight TNBCtype - 0153U (Insight Molecular Labs)		
Breast DCIS Prognostic Algorithmic Tests	Oncotype DX Breast DCIS Score - 0045U (Exact Sciences Laboratories)	0045U, D05.1	Rationale/ References
Colorectal Cancer			
Colorectal Cancer Prognostic Algorithmic Tests	Oncotype DX Colon Recurrence Score - 81525 (Exact Sciences Laboratories)	81525, 0069U, 0261U, C18.0-C18.9	Rationale/ References
	miR-31now - 0069U (GoPath Laboratories)		
	Immunoscore - 0261U (Veracyte)		
Prostate Cancer			

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Prostate Cancer Treatment and Prognostic Algorithmic Tests	ArteraAI Prostate Test - 0376U (Artera)	81541, 81542, 0047U, 0376U, C61	Rationale/ References
	Oncotype DX Genomic Prostate Score - 0047U (MDxHealth)		
	Prolaris - 81541 (Myriad Genetics)		
	Decipher Prostate Biopsy Genomic Classifier - 81542 (Veracyte)		
Evidence-Based Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests	4K Prostate Score (Serum) - 81539 (BioReference Laboratories)	81479, 81539, 84153, 84154, 81551, 86316, 0005U, 0339U, 0359U, 0403U, C61, Z12.5	Rationale/ References
	Prostate Health Index (ARUP Laboratories)		
	SelectMDx for Prostate Cancer - 0339U (MDxHealth)		
	ExoDx Prostate Test - 0005U (ExosomeDx)		
	IsoPSA - 0359U (Cleveland Diagnostics, Inc.)		
	MyProstateScore 2.0 - 0403U (LynxDX)		
	ConfirmMDx for Prostate Cancer - 81551 (MDxHealth)		
	Prostate Cancer Gene 3 (Integrated Regional Laboratories)		

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Emerging Evidence Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests	Apifiny - 0021U (Armune Bioscience)	0021U, 0228U, 0343U, 0424U, 0433U, 0495U, 0497U, 0512U, 0513U, 0550U, C61, Z12.5	Rationale/ References
	PanGIA Prostate - 0228U (Genetics Institute of America)		
	miR Sentinel Prostate Cancer Test - 0343U or 0424U (UmiR Scientific)		
	EpiSwitch Prostate Screening Test (PSE) - 0433U (Oxford BioDynamics)		
	Stockholm3 - 0495U (BioAgilytix Diagnostics)		
	OncoAssure Prostate - 0497U (DiaCarta, Inc.)		
	Tempus p-MSI - 0512U (Tempus AI, Inc.)		
	Tempus p-Prostate - 0513U (Tempus AI, Inc.)		
	ClairtyDx Prostate - 0550U (Protean BioDiagnostics)		
Thyroid Cancer			
Thyroid Cancer Diagnostic Algorithmic Tests	ThyroSeq Genomic Classifier - 0026U (CBLPath)	81546, 0018U, 0026U, 0204U, 0245U, 0287U, C73, D44.0, E04.1	Rationale/ References
	ThyGeNEXT - 0245U (Interpace Diagnostics)		
	ThyraMIR - 0018U (Interpace Diagnostics)		

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
	Afirma Genomic Sequencing Classifier - 81546 (Veracyte)		
	Afirma Xpression Atlas - 0204U (Veracyte)		
	ThyroSeq CRC - 0287U (Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center)		
Uveal Melanoma			
Uveal Melanoma Prognostic Algorithmic Tests	DecisionDx-UM - 81552 (Castle Biosciences, Inc.)	81552, C69	Rationale/ References
Cutaneous Melanoma			
Cutaneous Melanoma Prognostic Algorithmic Tests	DecisionDx-Melanoma - 81529 (Castle Biosciences, Inc.)	81479, 81529, 81599, 0387U, C43, D03.0-D03.9, Z12.83	Rationale/ References
	Merlin Melanoma (BioCartis)		
	MelaNodal (Quest Diagnostics)		
	AMBLor - 0387U (AMLo Biosciences)		
Cutaneous Melanoma Diagnostic Algorithmic Tests	myPath Melanoma - 0090U (Castle Biosciences, Inc.)	0090U, 0314U, D22.0-D22.9, D48.5, D49.2, Z12.83	Rationale/ References
	DecisionDx DiffDx-Melanoma - 0314U (Castle Biosciences, Inc.)		

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Cutaneous Melanoma Risk Assessment Algorithmic Tests	Pigmented Lesion Assay - 0089U (DermTech)	0089U, D22-D23, Z12.83	Rationale/ References
Ovarian Cancer			
Ovarian Cancer Diagnostic Algorithmic Tests	OVA1 - 81503 (Aspira Women's Health)	81500, 81503, 0003U, 0375U, 0507U, D27.0, D27.1, D27.9, D39.10-D39.12, D39.9, D49.59, D49.9	Rationale/ References
	Overa - 0003U (Aspira Women's Health)		
	Risk of Ovarian Malignancy (ROMA) - 81500 (LabCorp)		
	OvaWatch - 0375U (Aspira Women's Health)		
	Avantect Ovarian Cancer Test - 0507U (ClearNote Health)		
Ovarian Cancer Treatment Algorithmic Tests	myChoice CDx - 0172U (Myriad Genetics)	0172U, C48, C56, C57.0	Rationale/ References
Gynecologic Cancer			
Gynecologic Cancer Treatment Algorithmic Tests	ChemoFx - 81535 (Helomics Corporation)	81535, 81536, C51-C57	Rationale/ References
	ChemoFx - Additional Drug - 81536 (Helomics Corporation)		
Lung Cancer			
Evidence-Based Lung Cancer Risk Assessment Algorithmic Tests	Nodify XL2 - 0080U (Biodesix)	0080U, R91.1	Rationale/ References

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Emerging Evidence Lung Cancer Diagnostic Algorithmic Tests	REVEAL Lung Nodule Characterization - 0092U (MagArray)	81479, 0092U, 0317U, 0360U, 0395U, 0406U, R91.1	Rationale/ References
	Percepta Lung Cancer Diagnostics (Veracyte)		
	LungLB Test - 0317U (LungLife AI)		
	Nodify CDT - 0360U (Biodesix)		
	OncobiotaLUNGdetect - 0395U (Micronoma)		
	CyPath Lung - 0406U (Precision Pathology Laboratory)		
Evidence-Based Lung Cancer Treatment Algorithmic Tests	Veristrat - 81538 (Biodesix)	81538, 81599, 0288U, C34, D38.1, D38.6	Rationale/ References
	Razor14/Risk Reveal (RazorGenomics)		
	DetermaRx - 0288U (Oncocyte Corporation)		
Emerging Evidence Lung Cancer Treatment Algorithmic Tests	LungOI - 0414U (Imagene)	0414U, 0436U, C34, D38.1, D38.6	Rationale/ References
	PROphet NSCLC Test - 0436U (OncoHost, Inc)		
Bladder and Urinary Tract Cancer			
Bladder/Urinary Tract Cancer Diagnostic Algorithmic Tests	CxBladder Detect+ - 0420U (Pacific Edge)	0012M, 0363U, 0365U, 0420U, 0549U, R31.9	Rationale/ References
	Cxbladder Detect - 0012M (Pacific Edge)		
	Oncuria Detect - 0365U (DiaCarta Clinical Lab)		

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
	Bladder CARE - 0549U (Pangea Laboratory)		
	Cxbladder Triage - 0363U (Pacific Edge)		
Bladder Cancer Treatment and Recurrence Algorithmic Tests	Cxbladder Monitor - 0013M (Pacific Edge)	0013M, 0016M, 0363U, 0366U, 0367U, 0549U, C67, C68	Rationale/ References
	Decipher Bladder Genomic Test - 0016M (Veracyte)		
	Oncuria Monitor - 0366U (DiaCarta Clinical Lab)		
	Oncuria Predict - 0367U (DiaCarta Clinical Lab)		
	Bladder CARE - 0549U (Pangea Laboratory)		
Pancreatic Cancer			
Pancreatic Cyst Risk Assessment Algorithmic Tests	PancreaSeq Genomic Classifier - 0313U (Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center)	0313U, D49, K86.2	Rationale/ References
Cancer of Unknown Primary			
Cancer of Unknown Primary Gene Expression Profiling Tests	CancerTYPE ID - 81540 (Biotheranostics)	81540, C79.9, C80.0, C80.1	Rationale/ References
Esophageal Cancer			
Barrett's Esophagus Risk Assessment and Diagnostic Algorithmic Tests	TissueCypher - 0108U (Cernostics Lab)	0108U, 0114U, 0398U, 0506U	Rationale/ References
	EsoGuard - 0114U (Lucid Diagnostics)		

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
	ESOPREDICT Barrett's Esophagus Risk Classifier Assay - 0398U (Capsulomics Inc. d/b/a Previse)		
	EndoSign Barrett's Esophagus Test - 0506U (Cyted Health)		

RELATED POLICIES

This policy document provides coverage criteria for testing related to diagnosis and prognosis for cancer. Please refer to:

- ***Oncology Testing: Solid Tumor Molecular Diagnostics*** for coverage criteria related to molecular profiling of a known or suspected cancer (e.g., broad molecular profiling, including Minimal Residual Disease (MRD) Testing, Tumor Mutational Burden (TMB), and cytogenetic/fusion testing).
- ***Oncology Testing: Hematologic Malignancy Molecular Diagnostics*** for coverage criteria related to molecular profiling of a known or suspected blood cancer (e.g., broad molecular profiling, including Minimal Residual Disease (MRD) Testing, Tumor Mutational Burden (TMB), and cytogenetic/fusion testing).
- ***Oncology Testing: Hereditary Cancer*** for coverage criteria related to genetic testing for hereditary cancer predisposition syndromes.
- ***Oncology Testing: Cancer Screening and Surveillance*** for coverage criteria related to screening and biomarker cancer tests.
- ***General Approach to Laboratory Testing*** for coverage criteria related to oncology, including known familial variant testing, that is not specifically discussed in this or another non-general policy.

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COVERAGE CRITERIA

BREAST CANCER

Breast Cancer Treatment and Prognostic Algorithmic Tests

I. The use of the breast cancer treatment and prognostic algorithmic test Oncotype Dx Breast Recurrence Score is considered **medically necessary** in all members, regardless of gender, 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**

1. The member meets one of the following (regardless of menopausal status):

a) Tumor is greater than 0.5 cm and node negative (pN0), **OR**

b) Lymph nodes are pN1mi (2mm or smaller axillary node metastases), **OR**

c) Lymph nodes are pN1 (1-3 positive nodes).

II. 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

I. The use of the breast cancer extended endocrine therapy test Breast Cancer Index (BCI) is considered **medically necessary** when:

A. The member is female (sex assigned at birth), **AND**

B. The member has primary breast cancer that is ductal/NST, lobular, mixed or micropapillary, **AND**

C. The member's tumor is hormone receptor-positive (estrogen receptor-positive or progesterone receptor-positive), **AND**

D. The member's tumor is human epidermal growth factor receptor 2 (HER2)-negative, **AND**

E. The member has no distant metastases, **AND**

F. The member has completed at least 4 years of endocrine therapy, **AND**

G. The member is considering extended treatment with adjuvant therapy (e.g., tamoxifen, aromatase inhibitors, immunotherapy), **AND**

H. The member meets one of the following (regardless of menopausal status):

1. Tumor is greater than 0.5 cm and node negative (pN0), **OR**

2. Lymph nodes are pN1mi (2mm or smaller axillary node metastases), **OR**

3. Lymph nodes are pN1 (1-3 positive nodes).

II. The use of the breast cancer extended endocrine therapy test Breast Cancer Index (BCI) in men (sex assigned at birth) with breast cancer is considered **investigational**.

III. 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

I. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) is considered **medically necessary** when:

A. The member is female (sex assigned at birth), **AND**

B. The member meets at least one of the following:

1. Postmenopausal status, **OR**

2. Greater than 50 years of age, **AND**

C. The member has primary breast cancer that is ductal/NST, lobular, mixed or micropapillary, **AND**

D. The member's tumor is estrogen receptor-positive, **AND**

E. The member's tumor is human epidermal growth factor receptor 2 (HER2)-negative, **AND**

F. The member is considering treatment with adjuvant therapy (e.g., tamoxifen, aromatase inhibitors, immunotherapy), **AND**

G. The member has had axillary nodal staging and has the following node status:

1. pN0 (nodes negative pathologically), **OR**

2. pN1mi or pN1 (1-3 nodes positive pathologically)[1].

II. 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**.

III. The use of the breast cancer prognostic algorithmic test Prosigna in individuals with 1-3 node positive breast cancer is considered **investigational**.

IV. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) in men (sex assigned at birth) with breast cancer is considered **investigational**.

V. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) is considered **investigational** for all other indications.

[1] 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

I. Gene expression profiling breast cancer subtyping tests (e.g., BluePrint, Insight TNBCtype) are considered **investigational** for all indications.

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Breast DCIS Prognostic Algorithmic Tests

I. 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 member's DCIS was not removed via mastectomy (i.e., there is residual ipsilateral breast tissue).

II. Breast DCIS prognostic algorithmic tests are considered **investigational** for all other indications.

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COLORECTAL CANCER

Colorectal Cancer Prognostic Algorithmic Tests

I. Colorectal cancer prognostic algorithmic tests are considered **investigational** for all indications.

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PROSTATE CANCER

Prostate Cancer Treatment and Prognostic Algorithmic Tests

I. The use of a prostate cancer treatment and prognostic algorithmic test (i.e., Genomic Prostate Score Test, Prolaris, Decipher, ArteraAI) is considered **medically necessary** when:

   A. The member has prostate cancer, **AND**

   B. The member has a life expectancy of 10 years or more, **AND**

   C. The member does **not** have either of the following:

      1. Very low-risk prostate cancer, as defined by all of the following characteristics:

         a) cT1c

         b) Grade Group 1

         c) PSA less than 10 mg/nl and density less than 0.15 ng/mL/g

         d) Biopsy shows less than 3 positive cores/fragments and less than or equal to 50% cancer in each core/fragment, **OR**

      2. Very high-risk prostate cancer, as defined by all of the following characteristics:

         a) cT3-cT4

         b) PSA greater than 40 ng/mL

         c) Grade Group 4 or 5.

II. 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

I. 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:

1. The member has not had a prostate biopsy, **AND**
2. The member has at least one of the following:
    a) Prostate specific antigen (PSA) greater than 3 ng/ml, **OR**
    b) A digital rectal exam (DRE) that is suspicious for cancer, **AND**
3. 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 2.0 (MPS2), **OR**
    f) IsoPSA, **OR**

B. The member meets all of the following:

1. The member has had a prostate biopsy, **AND**
2. The result is one of the following:
    a) Atypia, suspicious for cancer, **OR**
    b) High-grade prostatic intraepithelial neoplasia (PIN)**, OR**
    c) Benign, **AND**
3. The test is one of the following:
    a) Prostate Health Index (PHI), **OR**
    b) 4Kscore, **OR**
    c) ExoDx Prostate Test, **OR**
    d) MyProstateScore 2.0 (MPS2), **OR**
    e) IsoPSA, **OR**
    f) ConfirmMDx, **OR**
    g) PCA3.

II. The use of prostate cancer risk assessment and 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 Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests

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

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THYROID CANCER

Thyroid Cancer Diagnostic Algorithmic Tests

I. 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.

II. 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

I. The use of a uveal melanoma prognostic algorithmic test is considered **medically necessary** when:

A. The member has primary, localized uveal melanoma.

II. The use of a uveal melanoma prognostic algorithmic test is considered **investigational** for all other indications.

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CUTANEOUS MELANOMA

Cutaneous Melanoma Prognostic Algorithmic Tests

I. Cutaneous melanoma prognostic algorithmic tests with insufficient evidence of clinical validity are considered **investigational** for all indications.

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Cutaneous Melanoma Diagnostic Algorithmic Tests

I. 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.

II. 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

I. Cutaneous melanoma risk assessment algorithmic tests are considered **medically necessary** when:

   A. The member has a melanocytic neoplasm that shows at least one ABCDE feature (**a**symmetry, **b**order irregularity, **c**olor variegation, **d**iameter greater than 6 mm, and **e**volution), **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.

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

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OVARIAN CANCER

Ovarian Cancer Diagnostic Algorithmic Tests

I. Ovarian cancer diagnostic algorithmic tests (i.e., OVA1, Overa, ROMA, and OvaWatch) are considered **investigational** for all indications, including:

A. Preoperative evaluation of adnexal masses to triage for malignancy

B. Screening for ovarian cancer

C. Selecting members for surgery for an adnexal mass

D. Evaluation of members with clinical or radiologic evidence of malignancy

E. Evaluation of members 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

I. 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.

II. Ovarian cancer treatment algorithmic tests are considered **investigational** for all other indications.

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GYNECOLOGIC CANCER

Gynecologic Cancer Treatment Algorithmic Tests

I. Gynecologic cancer treatment algorithmic tests in the assessment of gynecological cancers are considered **investigational** for all indications**.**

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LUNG CANCER

Evidence-Based Lung Cancer Risk Assessment Algorithmic Tests

I. Lung cancer risk assessment 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.

II. Lung cancer 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 Lung Cancer Diagnostic Algorithmic Tests

I. Lung cancer diagnostic algorithmic tests with insufficient evidence of clinical validity are considered **investigational** for all indications.

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Evidence-Based Lung Cancer Treatment Algorithmic Tests

I. 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 is 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.

II. 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

I. Lung cancer treatment algorithmic tests with insufficient evidence of clinical validity are considered **investigational** for all indications**.**

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BLADDER AND URINARY TRACT CANCER

Bladder/Urinary Tract Cancer Diagnostic Algorithmic Tests

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

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Bladder Cancer Treatment and Recurrence Algorithmic Tests

I. The use of bladder cancer treatment and recurrence algorithmic tests is considered **medically necessary** when:

   A. The member has a diagnosis of bladder cancer, **AND**

   B. The 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.

II. The use of bladder cancer treatment and recurrence algorithmic test is considered **investigational** for all other indications.

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PANCREATIC CANCER

Pancreatic Cyst Risk Assessment Algorithmic Tests

I. Pancreatic cyst risk assessment algorithmic tests with insufficient evidence of clinical validity are considered **investigational** for all indications.

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CANCER OF UNKNOWN PRIMARY

Cancer of Unknown Primary Gene Expression Profiling Tests

I. 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** for all indications.

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ESOPHAGEAL CANCER

Barrett's Esophagus Risk Assessment and Diagnostic Algorithmic Tests

I. Barrett's esophagus risk assessment and diagnostic algorithmic tests are considered **investigational** for all indications.

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PRIOR AUTHORIZATION

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

RATIONALE AND REFERENCES

Breast Cancer Treatment and Prognostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Breast Cancer (4.2025)

Oncotype DX for breast cancer is a 21-gene expression assay and is one of many gene expression assays used to aid in determining adjuvant systemic therapy. This guideline recommends the 21-gene expression assay for both prognosis and treatment decisions in patients of either sex (p. BINV-J 1 of 2, BINV-N 1 of 5). Per NCCN, the breast tumor must be either ductal/NST, lobular, mixed, or micropapillary, and it also must be hormone receptor positive (either Estrogen receptor or Progesterone receptor), and HER2 negative (p. BINV-6, BINV-7, BINV-8).

Females (sex assigned at birth) with postmenopausal breast tumors must be considering chemotherapy and have one of the following:

- A tumor that is 0.5 cm or larger (p. BINV-6)
- A tumor that is pN1mi (2 mm or smaller axillary node metastases) (p. BINV-6)
- A tumor that is pN1 (1–3 positive nodes) (p. BINV-6).

Females (sex assigned at birth) with premenopausal breast tumors must be a candidate for chemotherapy and have one of the following:

- A tumor that is 0.5 cm or larger and pN0 (p. BINV-7)
- A tumor that is pN1mi (2 mm or smaller axillary node metastasis) (p. BINV-7)
- A tumor that is pN1 (1-3 positive nodes) (p. BINV-7).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

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Breast Cancer Extended Endocrine Therapy Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Breast Cancer (4.2025)

The BCI (Breast Cancer Index) is recommended by these guidelines for both indications of prognosis as well as predicting treatment for extended adjuvant endocrine therapy (p. BINV-N 1 of 5). Appropriate patients for this test include pre and postmenopausal women with HR positive, HER2 negative breast cancer (either ductal/NST, lobular, mixed, or micropapillary) (BINV-6, BINV-7, BINV-8).

Postmenopausal breast tumors must be one of the following:

- 0.5 cm or larger
- pN1mi (2 mm or smaller axillary node metastases)
- pN1 (1–3 positive nodes) (p. BINV-6, BINV-N 1 of 5).

Premenopausal tumors must be one of the following:

- 0.5 cm or larger and pN0 (p. BINV-7)
- pN1mi (2 mm or smaller axillary node metastasis) (BINV-8)
- pN1 (1–3 positive nodes) (BINV-8).

NCCN guidelines also state that there is limited data regarding the use of these tests in males with breast cancer who are being considered for chemotherapy (p. BINV-J 1 of 2).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

American Society of Clinical Oncology (ASCO)

In 2022, ASCO issued a guideline regarding the use of Breast Cancer Index testing for extended endocrine therapy for ER-positive HER2-negative breast cancer. They recommend consideration of the Breast Cancer Index (BCI) test for either node-negative cancer or cancer with 1-3 positive nodes, which has been treated with primary endocrine therapy for 5 years with no evidence of recurrence (Recommendation 1.24., p. 1819).

The guideline cites a lack of sufficient evidence for the BCI test to guide decisions about extended endocrine therapy in individuals with node-positive breast cancer with 4 or more positive nodes following 5 years of endocrine therapy (Recommendation 1.25, p. 1819).

Andre F, Ismaila N, Allison KH, et al. Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update [published correction appears in J Clin Oncol. 2022 Aug 1;40(22):2514]. J Clin Oncol. 2022;40(16):1816-1837. doi:10.1200/JCO.22.00069

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Breast Cancer Prognostic Algorithmic Tests

American Society of Clinical Oncology (ASCO)

The 2022 ASCO guideline update for Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer provides guidance for the diagnostic indications for several breast cancer prognostic algorithmic tests, including EndoPredict, MammaPrint, and Prosigna (among others).

Figure 1 (p. 1821) includes an algorithm that acts as a guide for prognostic test choice in women with early-stage invasive breast cancer. In summary, a female patient must have the following in order to recommend EndoPredict, Prosigna, or MammaPrint testing:

- Postmenopausal **OR** older than age 50 years
- Early-stage invasive breast cancer
- Node negative disease,
- HER2 negative tumor
- ER positive tumor

Of note, per the guide, if the patient has 1 to 3 positive node disease then only MammaPrint or EndoPredict may be ordered. The algorithm also shows that there is "Insufficient evidence to recommend a biomarker for use" in women with 4 or more positive nodes (p. 1821).

Andre F, Ismaila N, Allison KH, et al. Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update [published correction appears in J Clin Oncol. 2022 Aug 1;40(22):2514]. J Clin Oncol. 2022;40(16):1816-1837. doi:10.1200/JCO.22.00069

National Comprehensive Cancer Network (NCCN): Breast Cancer (4.2025)

This guideline recommends consideration of other prognostic gene expression assays to help assess risk of recurrence in pre- and postmenopausal patients with either ductal/NST, lobular, mixed, or micropapillary breast cancer that is HR-positive, Her2-negative, pT1-3 and pN0 or pN+. However, these other tests have not been validated to predict response to chemotherapy (p. BINV-6, BINV-7, BINV-8).

A footnote on page BINV-N 3 of 5 states: "Gene expression assays can provide prognostic and treatment-predictive information that can be used with T,N,M and biomarker information". These prognostic gene expression assays can provide prognostic information but there is limited evidence for prediction of chemotherapy benefit (p. BINV-N 3 of 5).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

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Gene Expression Profiling Breast Cancer Subtyping Tests

National Comprehensive Cancer Network (NCCN): Breast Cancer (4.2025)

This guideline does not reference gene expression profiling tests (i.e., Blueprint) for the purpose of subtyping breast cancer to provide information for clinical decision-making.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

American Society of Clinical Oncology (ASCO)

The ASCO Guideline Update on Biomarkers for Adjuvant Endocrine and Chemotherapy in Early Stage Breast Cancer (2022) does not include breast cancer subtyping tests (i.e., BluePrint) as recommended biomarker tests for guiding adjuvant therapy.

Andre F, Ismaila N, Allison KH, et al. Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update [published correction appears in J Clin Oncol. 2022 Aug 1;40(22):2514]. J Clin Oncol. 2022;40(16):1816-1837. doi:10.1200/JCO.22.00069

Concert Note

There is insufficient evidence of clinical utility to support the routine use of these tests in clinical care. A search for guidelines, position statements, systematic reviews, and consensus statements regarding the use of the Blueprint and Insight TNBCtype was performed in May 2025, and no conclusive, objective support was identified. The following guideline bodies were assessed for relevant guidance: NCCN and ASCO.

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Breast DCIS Prognostic Algorithmic Tests

Centers for Medicare and Medicaid Services (CMS)

The CMS local coverage determination (LCD) entitled “MolDX: Oncotype DX Breast Cancer for DCIS (Genomic Health)” includes the following coverage criteria for OncotypeDX DCIS:

“The Oncotype DX DCIS assay is covered only when the following clinical conditions are met:

- Pathology (excisional or core biopsy) reveals ductal carcinoma in situ of the breast (no pathological evidence of invasive disease), and
- FFPE specimen with at least 0.5 mm of DCIS length, and
- Patient is a candidate for and is considering breast conserving surgery alone as well as breast conserving surgery combined with adjuvant radiation therapy, and
- Test result will be used to determine treatment choice between surgery alone vs. surgery with radiation therapy, and

- Patient has not received and is not planning on receiving a mastectomy."

Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Local Coverage DeterminationMolDX: Oncotype DX Breast Cancer for DCIS (Genomic Health) (L36912). Effective Date 11/25/2021. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36912

Muktar, et al.

This single center prospective clinical trial aimed to study whether adjuvant radiation therapy recommendations would change for women with DCIS based on results of Oncotype DX Breast DCIS testing. The paper found that "in 28% of patients (20/71), the RT [radiotherapy] recommendation changed as a result of the Oncotype test, with the majority of the change being from recommending RT to omitting RT" (p. 5).

Muktar S, Kirby A, Locke I, et al. Oncotype DX Breast DCIS Score® Test: Impact on Radiotherapy Recommendations and Patient Decisional Anxiety. Clin Oncol (R Coll Radiol). 2025 Jun:42:103839. Published online April 4, 2025. doi:10.1016/j.clon.2025.103839

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Colorectal Cancer Prognostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Colon Cancer (4.2025)

This guideline does not recommend multigene panel assays to assist in making clinical decisions about adjuvant therapy, citing insufficient evidence for their use (p. COL-4).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colon Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf

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Prostate Cancer Treatment and Prognostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Prostate Cancer (2.2025)

This guideline recommends use of advanced risk stratification tools (i.e., gene expression biomarkers, AI digital pathology) for disease management, most commonly for men with localized prostate cancer and life expectancy of 10 yrs or more (p. PROS-4, 5, 6 of 7). The most common reasons to use these tools are for deciding between active surveillance and radical treatment, or use of radiation alone vs radiation with androgen deprivation therapy (short or long term) (p. PROS-H 2 and 3 of 7).

These tests should not be used for very low risk or very high risk disease as they have not been validated in these populations and there are no current treatment implications based on the results (p. PROS-H 1 of 7 and PROS-H 3, 4, 5, 6, of 7). The following tumor-based assays are called out for use: Decipher, Genomic Prostate Score (GPS), ArteraAI Prostate and Prolaris (p. PROS-H 3 of 7).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer 2.2025
https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

American Society of Clinical Oncology (ASCO)

ASCO issued a guideline called “Molecular Biomarkers in Localized Prostate Cancer: ASCO Guideline” (2020). The guideline overall states that tissue-based biomarker testing “may improve risk stratification”, but results should be interpreted in combination with other routine clinical factors (p. 1474) and in situations where the results are likely to affect medical management (p. 1475).

Eggener SE, Rumble RB, Armstrong AJ, et al. Molecular biomarkers in localized prostate cancer: ASCO Guideline. J Clin Oncol. 2020;38(13):1474-1494. doi:10.1200/JCO.19.02768

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Evidence-Based Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests

American Urological Association (AUA)and Society of Urologic Oncology (SUO)

The AUA/SUO published guidelines on the early detection of prostate cancer (2023). They state that clinicians and patients may use adjunctive urine or serum markers to inform the shared decision making process regarding prostate biopsy (initial and/or repeat biopsy). It is imperative clinicians are familiar with biomarkers, understand what information or data each test provides, and consider whether additional information will impact management decisions before ordering a test (conditional recommendation, evidence level C) (p. 21-22, 24).

Of note, conditional recommendations are non-directive statements used when the evidence indicates that there is no apparent net benefit or harm, or when the balance between benefits and risks/burden is unclear. For evidence level C, the balance between benefits and risks is unclear but net benefit or net harm is comparable to other options.

Wei JT, Barocas D, Carlsson S, et al. Early Detection of Prostate Cancer: AUA/SUO Guideline Part I: Prostate Cancer Screening. J Urol. 2023;210(1):46-53. doi:10.1097/JU.0000000000003491

Wei JT, Barocas D, Carlsson S, et al. Early Detection of Prostate Cancer: AUA/SUO Guideline Part II: Considerations for a Prostate Biopsy. J Urol. 2023;210(1):54-63. doi:10.1097/JU.0000000000003492

National Comprehensive Cancer Network (NCCN): Prostate Cancer Early Detection (2.2025)

This guideline recommends consideration of biomarkers that improve the specificity of screening in patients considering biopsy after abnormal PSA and/or DRE. Specifically, NCCN recommends further evaluation for individuals with PSA “greater than 3 ng/ml and/or a very suspicious DRE” (p. PROSD-2). Biomarker testing is mentioned as part of this additional evaluation, and NCCN specifies the following tests as options for risk stratification: Prostate Health Index (PHI), SelectMDx, 4Kscore, ExoDx Prostate Test, MyProstateScore (MPS), and IsoPSA (p. PROSD-3 and PROSD-A).

On page PROSD-4, NCCN also recommends consideration of biomarker tests to improve specificity when considering a repeat biopsy for biopsy results showing the following: atypia, suspicious for cancer; high-grade prostatic intraepithelial neoplasia (PIN); benign. These tests include those listed above (except for SelectMDX) plus PCA3 and ConfirmMDX.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection 2.2025
https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf

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Emerging Evidence Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Prostate Cancer Early Detection (2.2025)

This guideline comments on the usefulness of biomarker testing to assist in biopsy decision making. The guidelines do not mention the following tests as part of recommended clinical care: EpiSwitch Prostate Screening Test (PSE), miR Sentinel Prostate Cancer Test, PanGIA Prostate, Stockholm3, OncoAssure Prostate, Tempus p-MSI, or Tempus p-Prostate.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection 2.2025
https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf

Concert Note

Tests that have limited established clinical utility or validity as defined in the Concert policy for General Approach to Genetic and Molecular testing do not meet the threshold for coverage. Evidence for validity may include a Technology Assessment conducted by an independent third party (e.g. MolDx Tech, ECRI, Optum Genomic) and/or evidence-based guidelines published by professional societies. Such evidence was not identified for the tests referenced by this policy.

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Thyroid Cancer Diagnostic Algorithmic Tests

American Thyroid Association (ATA)

The ATA developed evidence-based guidelines on the management of thyroid nodules and differentiated thyroid cancer in adults (2016). They state that molecular testing may be used to aid in risk stratification for nodules with AUS/FLUS [atypia of undetermined significance/follicular lesion of undetermined significance] in place of the more traditional strategy of surveillance or diagnostic surgery (p. 21).

Haugen BR, Alexander EK, Bible KC, et al. American Thyroid Association management guidelines for adult patients with thyroid nodules and differentiated thyroid cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2016;26(1):1-133. doi:10.1089/thy.2015.0020

National Comprehensive Cancer Network (NCCN): Thyroid Carcinoma (1.2025)

This guideline recommends consideration of molecular diagnostics on fine needle aspirate (FNA) results of thyroid nodules which are classified as Bethesda III or Bethesda IV if there is not high clinical and/or radiographic suspicion of malignancy (p. THYR-1 and THYR-2).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma 1.2025
https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf

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Uveal Melanoma Prognostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Uveal Melanoma (1.2025)

This guideline recommends consideration of biopsy of the primary tumor before radiation for prognostic analysis. Molecular testing for prognostication is recommended over cytology alone (p. UM-2A). Tumor class defined by gene expression profiling was more strongly associated with risk of metastasis than any other prognostic factor (p. UM-4).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Melanoma: Uveal 1.2025
https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf

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Cutaneous Melanoma Prognostic Algorithmic Tests

Society of Surgical Oncology (SSO)

The SSO, in its 2024 consensus statement “Assessing the Evidence for and Utility of Gene Expression Profiling of Primary Cutaneous Melanoma”, does not recommend the use of gene expression profiling (GEP) in adults with pT1a-pT4b primary cutaneous melanoma for predicting sentinel lymph node (SLN) status, guiding surveillance or follow-up approaches, or informing the use of adjuvant therapy due to insufficient high-level evidence (p. 2). These conclusions were reached through a rigorous process involving 20 experts, who used the PICOT framework to refine clinical questions and systematically reviewed 50 studies selected from over 130 articles. The recommendations were developed through the Modified Delphi process, achieving consensus with at least 80% agreement among a diverse panel of specialists (p. 4-6).

Bartlett EK, O'Donoghue C, Boland G, et al. Society of Surgical Oncology Consensus Statement: Assessing the Evidence for and Utility of Gene Expression Profiling of Primary Cutaneous Melanoma. Ann Surg Oncol. 2025;32(3):1429-1442. doi:10.1245/s10434-024-16379-2

ECRI Genetic Test Assessment

A review completed by ECRI (2023) found evidence for the DecisionDx-Melanoma 31-gene profiling (31-GEP) test to be somewhat favorable based on the available data pertaining to clinical validity, and potential clinical utility of the test. Specifically, the available studies demonstrated that they may improve patient outcomes (e.g., overall survival), by informing decisions to escalate surveillance when the test is added to best available care (i.e., tumor staging, SLNB). The review determined that current research does not provide sufficient evidence to conclude whether DecisionDx-Melanoma allows patients to safely skip sentinel lymph node biopsy (SLNB). Additional longitudinal studies are necessary to assess long-term health outcomes, such as recurrence, in patients who opt out of the biopsy.

ECRI. DecisionDx-Melanoma (Castle Biosciences, Inc.) for Evaluating Prognosis and Guiding Management of Cutaneous Melanoma. Genetic Test Assessment. Published October 2023.

Concert Note

Cutaneous melanoma prognostic testing is addressed by the Local Coverage Determination (LCD), MolDX: Melanoma Risk Stratification Molecular Testing - L38016, which provides a path to coverage for the DecisionDx-Melanoma and Merlin test assays. However, these recommendations

were established prior to the release of the Society of Surgical Oncology (SSO) guidelines, which represent the latest expert consensus in the field. Given the rapidly evolving landscape of precision medicine and the methodological rigor applied in developing these guidelines, we place greater weight on the SSO's recommendations as a more current and comprehensive standard for clinical practice.

Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MolDX: Melanoma Risk Stratification Molecular Testing (L38016). Revision effective May 15, 2025. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38016&ver=19&

Bartlett EK, O'Donoghue C, Boland G, et al. Society of Surgical Oncology Consensus Statement: Assessing the Evidence for and Utility of Gene Expression Profiling of Primary Cutaneous Melanoma. Ann Surg Oncol. 2025;32(3):1429-1442. doi:10.1245/s10434-024-16379-2

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Cutaneous Melanoma Diagnostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Cutaneous Melanoma (2.2025)

This guideline recommends gene expression profiling (GEP) as an available test for diagnosing indeterminate melanocytic neoplasms by histopathology, along with several other ancillary tests (p. ME-C 1 of 8). NCCN recommends against the use of GEP testing during the initial workup of a stage 0 in situ, T1a, or T1b melanoma (p. ME-2 and ME-2A).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf

American Academy of Dermatology

In 2019, the American Academy of Dermatology published an article titled “Guidelines of care for the management of primary cutaneous melanoma”. The guidelines consider diagnostic testing for cutaneous melanoma to be “largely investigative” and do not recommend them for routine use; however, it may be an appropriate ancillary test for equivocal melanocytic neoplasms. This includes gene expression profiling (GEP) as a routine diagnostic test for individuals with cutaneous melanoma (p. 219).

Swetter SM, Tsao H, Bichakjian CK, et al. Guidelines of care for the management of primary cutaneous melanoma. J Am Acad Dermatol. 2019;80(1):208-250. doi:10.1016/j.jaad.2018.08.055

American Society of Dermatopathology

The American Society of Dermatopathology (AUC Committee Members, 2022) published clinical scenarios where a 23 gene qRT-PCR test (MyPath Melanoma) was determined by a review of published evidence to be “majority usually appropriate”. The guideline also found that qRT-PCR testing for individuals with confirmed melanoma or nevus and adults with sclerosing (desmoplastic) nevus and desmoplastic melanoma were classified as “rarely inappropriate” clinical scenarios (p. 238 and Table 2, starting on p. 239).

AUC Committee Members, Fung MA, Vidal CI, et al. Appropriate use criteria for ancillary diagnostic testing in dermatopathology: New recommendations for 11 tests and 220 clinical

scenarios from the American Society of Dermatopathology Appropriate Use Criteria Committee. J Cutan Pathol. 2022;49(3):231-245. doi:10.1111/cup.14135

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Cutaneous Melanoma Risk Assessment Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Cutaneous Melanoma (2.2025)

This guideline recommends consideration of "prediagnostic noninvasive patch testing" to help inform decisions regarding biopsy for patients with melanocytic neoplasms that are clinically/dermoscopically suspicious for melanoma (p. ME-12).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf

ECRI Genetic Test Assessment

A recent review completed by ECRI (2023) found evidence for the Pigmented Lesion Assay (PLA) to be somewhat favorable based on the available data demonstrating clinical validity and utility to improve patient outcomes when added to standard of care (p. 1).

ECRI. Pigmented Lesion Assay (DermTech) for Aiding Melanoma Diagnosis. Genetic Test Assessment. Published March 2023.

American Academy of Dermatology

In their 2019 publication, the American Academy of Dermatology states that skin biopsy should be the initial step in establishing a diagnosis of cutaneous melanoma. The article mentions consideration of newer noninvasive techniques, including gene expression analysis (p. 211).

Swetter SM, Tsao H, Bichakjian CK, et al. Guidelines of care for the management of primary cutaneous melanoma. J Am Acad Dermatol. 2019;80(1):208-250. doi:10.1016/j.jaad.2018.08.055

UpToDate

Per UpToDate, "patients with a pigmented lesion that is changing and has additional ABCDE (**a**symmetry, **b**order irregularity, **c**olor variegation, **d**iameter >6 mm, **e**volution) criteria" should be strongly considered for dermatology referral.

Swetter S, Geller A. Melanoma: Clinical features and diagnosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. Last update Oct 04, 2023. https://www.uptodate.com/contents/melanoma-clinical-features-and-diagnosis

Centers for Medicare & Medicaid Services (CMS)

Per MolDX: Pigmented Lesion Assay LCD (L38051), this test is used to determine whether a biopsy should be performed. The LCD lists characteristics for the skin lesion that are appropriate for testing, which includes having at least 1 ABCDE criteria.

The LCD also states that "Only 1 test may be used per patient per clinical encounter, in most cases. In roughly 10% of patients, a second test may be indicated for the same clinical encounter.

For rare cases where more than 2 tests are indicated in a single clinical encounter, an appeal with supporting documentation may be submitted for additional tests".

Centers for Medicare & Medicaid Services. MolDX: Pigmented Lesion Assay (LCD L38051). Original effective date: 02/10/2020. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38151

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Ovarian Cancer Diagnostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer (3.2025)

This guideline recognizes several biomarker tests and algorithms using multiple biomarker test results that have been proposed for preoperatively distinguishing benign from malignant tumors in patients who have an undiagnosed adnexal/pelvic mass (p. MS-7).

In the NCCN Panel discussion section regarding Biomarker Tests, there is a comment stating "the NCCN panel does not recommend the use of these biomarker tests for determining the status of an undiagnosed adnexal/pelvic mass" (p. MS-10, 11). The discussion section includes OVA1 and ROMA as test examples.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer 3.2025 https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

American College of Obstetrics and Gynecology (ACOG)

In 2016, ACOG released practice bulletin 174 regarding the Evaluation and Management of Adnexal Masses. They recommend consultation or referral to a gynecologic oncologist for any women with an adnexal mass who also had other elevated risk factors, one of which may be an "elevated score on a formal risk assessment test" (p. e217). However, ACOG considers this a Level B recommendation, which is based on "limited or inconsistent scientific evidence" (p. e219).

American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Practice Bulletin No. 174: evaluation and management of adnexal masses. Obstet Gynecol. 2016;128(5):e210-e226. doi:10.1097/AOG.0000000000001768

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Ovarian Cancer Treatment Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer (3.2025)

This guideline recommends molecular analysis for alterations that might impact clinical decision making. This testing should include *BRCA1/2* status, as there are specific post primary treatment recommendations based on *BRCA1/2* status (OV-1, 2, 3, and 5; OV-B 1 of 3).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer 3.2025 https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

American Society of Clinical Oncology (ASCO)

In 2020, ASCO issued a guideline for the use of PARP inhibitors in the management of ovarian cancer, which they updated via a targeted literature review in 2022. Per their updated recommendations, PARPi maintenance therapy “should be offered” to all patients with newly diagnosed stage III-IV EOC (epithelial ovarian, tubal, or primary peritoneal cancer, high-grade serous or endometrioid type), whose disease is in complete or partial response to first-line, platinum-based chemotherapy (p. 3879).

Tew WP, Lacchetti C, Ellis A, et al. PARP Inhibitors in the Management of Ovarian Cancer: ASCO Guideline. J Clin Oncol. 2020;38(30):3468-3493. doi:10.1200/JCO.20.01924

Tew WP, Lacchetti C, Kohn EC; PARP Inhibitors in the Management of Ovarian Cancer Guideline Expert Panel. Poly(ADP-Ribose) Polymerase Inhibitors in the Management of Ovarian Cancer: ASCO Guideline Rapid Recommendation Update. J Clin Oncol. 2022;40(33):3878-3881. doi:10.1200/JCO.22.01934

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Gynecologic Cancer Treatment Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer (3.2025)

This guideline states that chemosensitivity/resistance assays have been proposed for informing decisions related to future chemotherapy if there are multiple similar treatment options being considered. However, there is insufficient evidence to recommend these tests at this time (p. OV-C, 1 of 12).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer 3.2025 https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

National Comprehensive Cancer Network (NCCN): Cervical Cancer (4.2025)

This guideline does not mention chemosensitivity or chemoresistance assays as part of clinical care.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf

National Comprehensive Cancer Network (NCCN): Uterine Neoplasms (3.2025)

This guideline does not mention chemosensitivity or chemoresistance assays as part of clinical care.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms 3.2025 https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

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Evidence-Based Lung Cancer Risk Assessment Algorithmic Tests

Centers for Medicare and Medicaid Services (CMS)

The CMS local coverage determination (LCD) entitled BDX-XL2 (L37031) includes the following coverage criteria for the NodifyXL2 test for the management of a lung nodule:

- Nodule must be between 8 and 30mm in diameter
- Patients must be 40 years or older
- Patients must have a pre-test cancer risk (as assessed by the Mayo Clinic Model for Solitary Pulmonary Nodules) of 50% or less.

“The intended use of the test is to assist physicians in the management of lung nodules by identifying those lung nodules with a high probability of being benign. These lung nodules would then be candidates for non-invasive computed tomography (CT) surveillance instead of invasive procedures.”

Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Local Coverage Determination. MolDX: BDX-XL2 (L37031). Effective Date 04/28/2022. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37031

Pritchett, et al.

A 2023 study titled: “Assessing a biomarker's ability to reduce invasive procedures in patients with benign lung nodules: Results from the ORACLE study” aimed to assess the clinical impact of proteomic integrated classifier (IC) tests (specifically, NodifyXL2), following confirmation of clinical validity (PANOPTIC trial) in 2018. The study included a matched cohort and ultimately found that “[p]atients with a benign nodule in the IC group underwent fewer invasive procedures (n = 8, 5%) compared to patients in the untested control group (n = 30, 19%), yielding…[a] relative reduction of 74%” (p. 6).

Pritchett MA, Sigal B, Bowling MR, Kurman JS, Pitcher T, Springmeyer SC; ORACLE Study Investigators. Assessing a biomarker's ability to reduce invasive procedures in patients with benign lung nodules: Results from the ORACLE study. PLoS One. 2023 Jul 11;18(7):e0287409. PMID: 37432960; PMCID: PMC10335667 doi:10.1371/journal.pone.0287409.

Kheir, et al.

A 2023 retrospective study titled: “Impact of an integrated classifier using biomarkers, clinical and imaging factors on clinical decisions making for lung nodules” compared individuals with lung nodules who were evaluated with the integrated classifier (IC) test (NodifyXL2) versus individuals receiving standard of care. The findings showed that invasive procedures were decreased by 57.5% in individuals with indeterminate lung nodules “without missing a malignant diagnosis at 1-year follow-up)”, when compared to the control arm (p. 3563).

Kheir F, Uribe JP, Cedeno J, et al. Impact of an integrated classifier using biomarkers, clinical and imaging factors on clinical decisions making for lung nodules. J Thorac Dis. 2023;15(7):3557-3567. doi:10.21037/jtd-23-42

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Emerging Evidence Lung Cancer Diagnostic Algorithmic Tests

Concert Evidence Review for Coverage Determination (Published 08/15/2025)

This review focused on a search for evidence-based guidelines and peer-reviewed, published evidence of the clinical utility of lung cancer diagnostic algorithmic tests from 07/15/2024 - 07/30/2025. A total of 9 full text publications were fully reviewed and 2 met the inclusion criteria and were added to the evidence review (Long, et al. and Tahvilian, et al.).

There is **INSUFFICIENT EVIDENCE** in published guidelines and peer-reviewed literature to definitively demonstrate improved health outcomes from the use of NodifyCDT, Percepta, LungLB, and CyPath Lung as compared to the current standard of care. At this time, the available evidence does not support health plan coverage of these tests, in part due to lack of evidence for their clinical utility compared to other, guideline-supported testing methodologies. See below for a summary of the literature.

NodifyCDT

Several validation studies were previously published to assess the performance of EarlyCDT-Lung (now called NodifyCDT) in individuals with indeterminate pulmonary nodules. A review from 2020 (Ostrin, et al.) summarizes these studies, stating that the initial results of a six-autoantibody panel validation study showed a specificity of about 90% and sensitivity of about 40%. Further validation studies of a related seven-autoantibody panel, which ultimately became the EarlyCDT-Lung test, showed a sensitivity of 41%. According to the review article, a double-blinded randomized trial was performed in 2020 by Sullivan, et al. to study the use of EarlyCDT-Lung testing to reduce the incidence of later stage (III/IV/unspecified) lung cancer at the time of diagnosis. After a two year period, the test was not shown to increase the frequency of lung cancer detection, and mortality reduction was not statistically significant. The authors note that although individuals who received the intervention (EarlyCDT-Lung testing with follow-up low-dose CT) were diagnosed with lung cancer at an earlier stage, the authors state that “further large-scale studies on the outcomes of the test compared to low-dose CT alone are required to clarify effectiveness and cost benefits”.

A 2025 study by Long, et al. studied a blood-based autoantibody test performed similarly in 2 separate cohorts, both composed of patients aged ≥ 40 years with indeterminate pulmonary nodules 8 to 30 mm in diameter found on a recent (within 60 days) CT scan. Out of the 447 total participants, the testing demonstrated an overall specificity of 90%, a positive predictive value of 66%, sensitivity of 16%, and a false-positive rate of 10%. Further study is warranted to assess the test’s clinical utility alongside FDG-PET imaging, and its effect on the timeliness of care and appropriate utilization of procedures in patients presenting with indeterminate PNs.

CyPath

A retrospective validation study for CyPath Lung performed by Lemieux, et al. (2023) showed an 82% sensitivity and 88% specificity in individuals known to be affected or unaffected with lung cancer, and 92% sensitivity and 87% specificity in individuals with lung nodules <20mm. The performance of the test also differed based on tumor type and stage. Limitations of this study included small sample size, with underrepresentation of minorities and females, as well as lack of long-term followup of unaffected individuals to determine if they were diagnosed with lung cancer. The researchers discuss an intention to conduct a larger, prospective clinical trial.

In an updated search conducted in July 2025, no new peer-reviewed articles and/or guidelines were found that address the clinical validity or utility of CyPath.

Percepta (aka Percepta Lung Cancer Diagnostics or Percepta Bronchial Genomic Classifier)

Multiple studies have been published on Percepta and its ability to identify risk of cancer in patients with lung nodules. This body of literature includes studies meant to assess clinical validity for each test. Overall, these studies inadequately demonstrate the clinical validity of these tests for distinguishing high risk nodules from low risk nodules.

Percepta originally had a cost-effectiveness study published in 2017. A new validation study for this test was published in 2021 and it is not clear if the new test would also be cost-effective.

There are a few studies that include some characterization of clinical utility for the Percepta test and its ability to identify risk of cancer in patients with lung nodules. These studies have significant flaws, including small population sizes, and potential bias due to authors with conflict of interest. The studies were each published with authors from the company that developed or currently offers the test. Additionally, studies regarding the costs of these tests compared to costs of under- and over-diagnosis of lung cancer in patients with lung nodules needs to be completed.

In an updated search conducted in July 2025, no new peer-reviewed articles and/or guidelines were found that address the clinical validity or utility of Percepta.

LungLB

A 2023 prospective validation study by Tahvilian, et al. included 151 patients with indeterminate pulmonary nodules, with 112 cases determined to be malignant and 39 benign. The test achieved a sensitivity of 71% and a specificity of 72%. Larger cohort studies are needed to further validate the test's clinical validity and assess the test's clinical utility.

Concert. Evidence Review for Coverage Determination for Lung Cancer Diagnostic Algorithmic Tests. Published 08/15/2025.

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Evidence-Based Lung Cancer Treatment Algorithmic Tests

Centers for Medicare and Medicaid Services (CMS)

The CMS local coverage determination (LCD) entitled "MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer" includes the following coverage criteria for lung cancer treatment algorithmic tests:

- "The patient has a non-squamous NSCLC with a tumor size < 5cm, and there are no positive lymph nodes (i.e., American Joint Committee on Cancer (AJCC) Eighth Edition Stages I and IIa)
- The patient is sufficiently healthy to tolerate chemotherapy
- Adjuvant platinum-containing chemotherapy is being considered for the patient".

Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer (L38238). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38238

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Emerging Evidence Lung Cancer Treatment Algorithmic Tests

Concert Note

Tests that have limited established clinical utility or validity as defined in the Concert policy for General Approach to Genetic and Molecular testing do not meet the threshold for coverage. Evidence for validity may include a Technology Assessment conducted by an independent third party (e.g., MolDx Tech, ECRI, Optum Genomic) and/or evidence-based guidelines published by professional societies. Such evidence was not identified for the tests referenced by this policy.

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Bladder/Urinary Tract Cancer Diagnostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Bladder Cancer (1.2025)

The NCCN considers cystoscopy a “critical diagnostic tool” for bladder cancer, and supports the use of biomarker testing to delay or skip cystoscopy only if there is demonstrated non-inferiority to cystoscopy in a prospective randomized clinical trial (p. BL-I 2 of 3).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer 1.2025
https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf

The American Urological Association (AUA) / American Society of Clinical Oncology (ASCO) / Society of Urologic Oncology (SUO)

The updated AUA/SCO/SUO guideline highlights several key areas for which further evidence is needed. Included in this section is a statement regarding the need to identify and validate both prognostic and predictive markers to improve clinical outcomes, including therapeutic decision-making.

Holzbeierlein J, Bixler BR, Buckley DI, et al. Treatment of non-metastatic muscle-invasive bladder cancer: AUA/ASCO/SUO guideline (2017; amended 2020, 2024). J Urol. Published online April 25, 2024. doi:10.1097/JU.0000000000003981

The American Urological Association (AUA) / Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)

This joint clinical practice guideline states that urine-based tumor markers should not be routinely used when deciding whether to proceed to cystoscopy for low/negligible or high-risk patients, *or* as an adjunct to normal cystoscopy (p. 15) and does not include such tests in their associated “Microhematuria Diagnostic Algorithm.” For intermediate-risk patients, the guideline suggests that urine-based tumor markers could be used to support decision making about cystoscopy, but cautions that there is risk to this and that such patients must still undergo other imaging (ultrasound) (p. 20).

Barocas DA, Lotan Y, Matulewicz RS, et al. Updates to Microhematuria: AUA/SUFU Guideline (2025). *J Urol*. 2025;213(5):547-557. doi:10.1097/JU.000000000000449
https://www.auajournals.org/doi/abs/10.1097/JU.0000000000004490

Concert Note

There is insufficient evidence of clinical utility to support the routine use of these tests in clinical care. A search for guidelines, position statements, systematic reviews, and consensus statements regarding the use of bladder/urinary tract cancer diagnostic algorithmic tests was performed in April 2025, and no conclusive, objective support was identified. The following guideline bodies were assessed for relevant guidance: National Comprehensive Cancer Network, American Urological Association, American Society of Clinical Oncology, Society of Urologic Oncology.

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Bladder Cancer Treatment and Recurrence Algorithmic Tests

Centers for Medicare and Medicaid Services (CMS)

The CMS local coverage determination (LCD) entitled “MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer” states the following regarding bladder cancer molecular diagnostic tests, including algorithmic tests:

“This contractor will cover molecular diagnostic tests for use in a beneficiary with bladder cancer when all of the following conditions are met:

1. The beneficiary is being actively managed for bladder cancer.
2. At least 1 of the 2 criteria are met:
    a. The patient is a candidate for multiple potential treatments, which could be considered to have varied or increasing levels of intensity based on a consensus guideline, and the physician and patient must decide among these treatments. OR
    b. The patient is a candidate for multiple therapies, and the test has shown that it predicts response to a specific therapy among accepted therapy options based on nationally recognized society consensus guidelines
3. The test successfully completes a Molecular Diagnostic Services Program (MolDX) technical assessment that ensures the test is reasonable and necessary as described above.
4. Only 1 test may be performed prior to the initiation of therapy UNLESS a second test that interrogates different genomic content AND meets all the criteria established herein, is reasonable and necessary.
5. The genomic content interrogated by the test must be relevant to the therapy under consideration”.

Centers for Medicare & Medicaid Services., Dep't of Health & Human Services (CMS), Medicare Coverage Database: Local Coverage Determination MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (L38576). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38576

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Pancreatic Cyst Risk Assessment Algorithmic Tests

Concert Note

Tests that have limited established clinical utility or validity as defined in the Concert policy for General Approach to Genetic and Molecular testing do not meet the threshold for coverage. Evidence for validity may include a Technology Assessment conducted by an independent third party (e.g. MolDx Tech, ECRI, Optum Genomic) and/or evidence-based guidelines published by professional societies. Such evidence was not identified for the tests referenced by this policy.

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Cancer of Unknown Primary Gene Expression Profiling Tests

National Comprehensive Cancer Network (NCCN): Occult Primary (Cancer of Unknown Primary) (2.2025)

This guideline states that testing to predict tissue of origin is not recommended (p. OCC-1). There has been no clinical benefit from gene expression profiling to identify tissue of origin (p. MS-5).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Occult Primary 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/occult.pdf

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Barrett's Esophagus Risk Assessment and Diagnostic Algorithmic Tests

Centers for Medicare and Medicaid Services (CMS)

The CMS local coverage determination (LCD) entitled "MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia" states that molecular diagnostic tests that identify individuals with upper gastrointestinal metaplasia, dysplasia, and neoplasia are not covered.

Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia (L39256). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39256

American College of Gastroenterology (ACG)

In their 2022 guidelines for diagnosis and management of Barrett's esophagus, the ACG suggests that a swallowable, nonendoscopic capsule sponge device combined with biomarker testing is an acceptable alternative to endoscopy for screening for BE in those with risk factors, including chronic reflux. However, the strength of the recommendation is categorized as "conditional," and the quality of evidence is categorized as "very low" (p. 10).The ACG also states they are unable to make a recommendation about the TissueCypher and WATS-3D tests based on either current evidence showing low sensitivity and specificity, or lack of data, respectively (p. 18-21).

Shaheen NJ, Falk GW, Iyer PG, et al. Diagnosis and Management of Barretts esophagus: an updated ACG guideline. The American Journal of Gastroenterology. 2022;117(4):559-587. doi:10.14309/ajg.0000000000001680

American Society of Gastrointestinal Endoscopy (ASGE)

The ASGE Technology Committee published a technology status evaluation report in 2019, which discussed several biomarker and molecular tests (including TissueCypher) related to risk stratification for Barrett's esophagus. The committee stated that further study and clarification is needed to determine the best strategies for management following a positive molecular testing result in the setting of a negative EGD. In addition, the committee acknowledges that many of these molecular tests are expensive, and cost-effectiveness analyses would be useful to better understand how widely these new technologies should be adopted into routine clinical care (p. 332).

ASGE Technology Committee, Trindade AJ, Navaneethan U, et al. Advances in the diagnosis and surveillance of Barrett's esophagus (with videos). Gastrointest Endosc. 2019;90(3):325-334. doi:10.1016/j.gie.2019.05.004

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DEFINITIONS

1. **ABCDE feature** is an acronym for examining patients with a lesion that is suspicious for melanoma: **a**symmetry, **b**order irregularity, **c**olor variegation, **d**iameter greater than 6 mm, and **e**volution.
2. **Adjuvant** therapy is a medication (such as chemotherapy or endocrine therapy) given after the surgical removal of a cancerous tumor.
3. **Ductal/NST** is a ductal breast cancer of no special type (NST), meaning the cancer cells have no features that classify them as a specific type of breast cancer when examined by microscope.
4. **Indeterminate cytologic findings** include Bethesda diagnostic category III (atypia/follicular lesion of undetermined significance) or Bethesda diagnostic category IV (follicular neoplasm/suspicion for a follicular neoplasm)

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Note: The Health Plan uses the genetic testing clinical criteria developed by Concert Genetics, an industry-leader in genetic testing technology assessment and policy development.

	Committee/Source	Date(s)
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Medica Central Coverage Policy

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