ONCOLOGY: ALGORITHMIC TESTING

OVERVIEW

Oncology prognostic and algorithmic tests are developed to aid in determining the likelihood that an individual has cancer, the prognosis for a patient diagnosed with cancer, and/or surveillance for recurrence. These tests may be used to guide clinical decision making for an individual diagnosed with cancer. The testing methodologies include gene expression profiling (GEP), which analyzes messenger RNA (mRNA) typically of multiple genes simultaneously, multimarker serum analysis, single-nucleotide variant testing, plasma-based proteomic analysis, and incorporation of other clinical data into test outputs.

In addition to the tests previously mentioned, proteogenomic testing is an emerging area. Proteogenomic testing combines the analysis of DNA with RNA and/or protein analysis. The current focus of proteogenomics is primarily on diagnostic and prognostic analyses in various cancers. Results also seek to provide potential treatment options, and to which treatments the cancer may be resistant.

Polygenic risk score (PRS) tests are another emerging area. These tests combine information from population SNP analysis with clinical and family history and aim to give additional insight into an individual's lifetime risk to develop a specific cancer.

Results of prognostic and algorithmic tests are often reported as a recurrence score, probability of distant disease recurrence, malignant potential, probable site of origin, or cancer risk score. Additionally, the output of these prognostic and algorithmic tests may be useful to assist in surgical and management decision-making and to identify individuals who may benefit from adjuvant chemotherapy.

POLICY REFERENCE TABLE

Coverage Criteria Sections	Example Tests, Labs	Common CPT Codes	Common ICD Codes	Ref
Breast Cancer				

Breast Cancer Treatment and Prognostic Algorithmic Tests	OncotypeDx Breast Recurrence Score (Genomic Health, Inc.)	81519	C50.011-C50.929, Z17.0	1, 2, 3, 10
Hormone Receptor Positive Breast Cancer Prognostic Algorithmic Tests	EndoPredict, Sividon Diagnostics (Myriad)	81522, S3854	C50.011-C50.929, D05.00-D05.92, Z17.0	1, 2, 3, 10
	Breast Cancer Index Prognostic (Biotheranostics)	81518		
	Prosigna (NanoString Technologies)	81520,		
Hormone Receptor Agnostic Breast Cancer Prognostic Algorithmic Tests	MammaPrint (Agendia, Inc.)	81521, 81523, S3854	C50.011-C50.929, D05.00-D05.92, Z17.0	1, 2, 3, 10
Gene Expression Profiling Breast Cancer Subtyping Tests	BluePrint (Agendia, Inc.)	81599, S3854		1, 2, 3, 10
	Insight TNBCtype™ (Insight Molecular Labs)	0153U		
Breast DCIS Prognostic Algorithmic Tests	OncotypeDX Breast DCIS (Genomic Health, Inc.)	0045U	D05.1, Z17.0	1, 2, 3
Colorectal Cancer				
Colorectal Cancer Prognostic Algorithmic Tests	Oncotype DX Colon Recurrence Score (Genomic Health, Inc.)	81525	C18.0-C18.9	4
	GeneFx Colon, Helomics Therapeutics (aka ColDx) (Almac Diagnostics)	81599		
	miR-31now™ (GoPath Laboratories)	0069U		
Prostate Cancer				
Prostate Cancer Treatment and Prognostic Algorithmic Tests	Oncotype DX Genomic Prostate (Genomic Health, Inc.)	0047U	C61	5, 6, 7 9, 23, 26, 27
	Decipher Prostate Cancer Classifier (GenomeDX Biosciences, Inc.)	81542		
	Prolaris (Myriad Genetics)	81541		

	ProMark (Metamark Genetics)	81599		
	Prostate Cancer Risk Panel (Mayo Medical Laboratories	0053U		
Prostate Cancer Risk Assessment Algorithmic Tests	Kallikrein markers (e.g. 4Kscore Test, OPKO Lab)	81539	C61, Z12.5	6, 7, 8, 9
	Prostate Health Index (Beckman Coulter)	84153, 84154, 86316		
	SelectMDx (MDx Health)	81599		
	ExoDx Prostate Test (ExosomeDx)	0005U		
Prostate Cancer Diagnostic Algorithmic Tests	ConfirmMDX (MDxHealth)	81551	C61, Z12.5	5, 6, 7, 9, 23
	PCA3 testing (e.g. Progensa PCA3 Assay)	81313		
	MiPS (Mi-Prostate), University of Michigan MLabs	0113U		
	Prostate Core Mitomics Test	81479		
Thyroid Cancer				
Thyroid Cancer Diagnostic Algorithmic Tests	ThyroSeq Genomic Classifier (University of Pittsburgh)	0026U	C73, D44.0, E04.1	11, 12, 13
	ThyGeNEXT (Interpace Diagnostics)	0245U		
	ThyraMIR (Interpace Diagnostics)	0018U		
	Afirma Genomic Sequencing Classifier (Veracyte)	81546		
	Afirma Xpression Atlas (Veracyte)	0204U		
Uveal Melanoma				
Uveal Melanoma Prognostic Algorithmic Tests	DecisionDX-UM (Castle Bioscience, Inc.)	81552, 0081U	C69.00-C69.92	14
	Uveal Melanoma Prognostic	81599		

	Test (LabCorp)			
Cutaneous Melanoma				
Cutaneous Melanoma Prognostic Algorithmic Tests	DecisionDX-Melanoma (Castle Biosciences, Inc.)	81529	C43.0-C43.9, C44.0-C44.99, C4A.0-C4A.9, D03.0-D03.9, D04.0-D04.9, Z12.83	15, 16
Cutaneous Melanoma Diagnostic Algorithmic Tests	myPath Melanoma (Castle Biosciences Inc)	0090U	D22-D23, Z12.83	15, 16
Cutaneous Melanoma Risk Assessment Algorithmic Tests	Pigmented Lesion Assay (DermTech)	0089U	D22-D23, Z12.83	15, 16, 34
Ovarian Cancer				
Ovarian Cancer Diagnostic Algorithmic Tests	OVA1 (Aspira)	81503	D27.0-D27.9, D39.10-D39.12, D39.9, D49.59, D49.9	17
	Overa (Aspira)	0003U		
	ROMA (Risk of Ovarian Malignancy Algorithm) (Roche Diagnostics)	81500		
Ovarian Cancer Treatment Algorithmic Tests	myChoice CDx (Myriad Genetics)	0172U	C56	17, 29
	Tempus HRD (Tempus Clinical Laboratory)	81479		
Gynecologic Cancer				
Gynecologic Cancer Treatment Algorithmic Tests	ChemoFx	81535	C51-C57	17, 24, 25, 28
	ChemoFx - Additional Drug	81536		
Lung Cancer				
Lung Cancer Treatment Algorithmic Tests	VeriStrat (Biodesix)	81538	C34, D38.1, D38.6	32, 35
	DetermaRx (Oncocyte)	81599		
Lung Cancer Diagnostic Algorithmic	Nodify XL2 (Biodesix)	0080U	R91.1	32, 36
	REVEAL Lung Nodule	0092U		

Tests	Characterization (MagArray)			
	Percepta Bronchial Genomic Classifier (Veracyte)	81599		
Bladder and Urinary Tract Cancer				
Bladder Cancer Diagnostic and Recurrence Algorithmic Tests	Cxbladder Triage (Pacific Edge)	81599	C67.0-C67.9, D09.0, D49.4, R31.9, Z85.51	18, 19, 20
	Cxbladder Detect (Pacific Edge)	0012M		
	Cxbladder Monitor (Pacific Edge)	0013M		
	Xpert Bladder Cancer Monitor (Cepheid)	81599		
	BTA *stat*® (Polymedco)	86294		
Urinary Tract Cancer Recurrence Algorithmic Tests	Alere NMP22® (Alere)	86386	C67.0-C67.9, D09.0, D49.4, R31.9, Z85.51	
	Alere NMP22® BladderChek® (Alere)	86386		
Pancreatic Cancer				
Pancreatic Cyst Risk Assessment Algorithmic Tests	PancraGEN (Interpace Diagnostics)	81479	C25	30, 31
Cancer of Unknown Primary				
Cancer of Unknown Primary Gene Expression Profiling Tests	Tissue of Origin (Cancer Genetics Inc.)	81504	C79.9, C80.0, C80.1	22
	CancerTYPE ID (Biotheranostics)	81540		
Polygenic Risk Score Tests				
Breast Cancer Polygenic Risk Score Tests	riskScore (Myriad Genetics)	81599	Z13.71-Z13.79 Z80.3	21, 33
	AmbryScore-Breast (Ambry Genetics)			
	BrevaGen (Pathogen Sciences Laboratories)			
	BrevaGen*plus* (Pathogen Sciences Laboratories)			

Prostate Cancer Polygenic Risk Score Tests	AmbryScore-Prostate (Ambry Genetics)	81599	C61, R97.2, Z19.1-Z19.2, Z80.42	21, 33
Multiple Myeloma Polygenic Risk Score Tests	MyPRS (Signal Genetics)	81599	C90.00-C90.02	21, 33
Oncology: Test-Specific Not Covered Algorithmic Tests				
Oncology: Test-Specific Not Covered Algorithmic Tests	Onco4D (Animated Dynamics, Inc.)	0083U		
	LC-MS/MS Targeted Proteomic Assay (OncoOmicDx laboratory)	0174U		
	BBDRisk Dx (Silbiotech)	0067U		
	PreciseDx Breast Cancer Test (PreciseDx)	0220U		
	Lymph3Cx Lymphoma Molecular Subtyping Assay	0120U		

OTHER RELATED POLICIES

This policy document provides coverage criteria for tests that determine the risk for or the prognosis for cancer. For other oncology related testing, please refer to:

- ***Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies*** for criteria related to DNA testing of a solid tumor or a blood cancer.
- ***Genetic Testing: Hereditary Cancer Susceptibility Syndromes*** for criteria related to genetic testing to determine if an individual has an inherited cancer susceptibility syndrome.
- ***Oncology: Cancer Screening*** for criteria related to the use of non-invasive fecal, urine or blood tests for screening for cancer.
- **Oncology: *Circulating Tumor DNA and Circulating Tumor Cells (Liquid Biopsy)*** for criteria related to circulating tumor DNA (ctDNA) or circulating tumor cell

testing performed on peripheral blood for cancer diagnosis, management and surveillance.

- ***Genetic Testing: General Approach to Genetic Testing*** for coverage criteria related to algorithmic testing in oncology 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 a breast cancer treatment and prognostic algorithmic test (i.e.,, Oncotype DX Breast Recurrence Score) (81519, S3854) is considered **medically necessary** when:

   A. The member has primary breast cancer, **AND**

   B. The tumor meets **all** of the following characteristics:

      1. Hormone receptor-positive (ie, estrogen receptor-positive or progesterone receptor-positive), **AND**

      2. Human epidermal growth factor receptor 2 (HER2)- negative, **AND**

      3. Anatomic stage I or II, **AND**

      4. Node-negative (lymph nodes with micrometastases [≤2 mm in size] are considered node-negative for this policy statement) or 1 - 3 lymph node positive, **AND**

   C. The member is considering treatment with adjuvant endocrine therapy (eg, tamoxifen, aromatase inhibitors).

II. The use of a breast cancer treatment and prognostic algorithmic test (e.g., Oncotype DX Breast Recurrence Score) (81519, S3854) is considered **investigational** for all other indications.

Hormone Receptor Positive Breast Cancer Prognostic Algorithmic Tests

I. The use of a hormone receptor positive breast cancer prognostic algorithmic test (i.e., Endopredict, Prosigna, Breast Cancer Index) (S3854, 81522, 81520, 81518) is considered **medically necessary** when:

   A. The member is a female with primary breast cancer, **AND**

   B. The tumor meets **all** of the following characteristics:

      1. Hormone receptor-positive (i.e., estrogen receptor-positive or progesterone receptor-positive); **AND**

      2. Human epidermal growth factor receptor 2 (HER2)- negative; **AND**

      3. Anatomic stage I or II; **AND**

      4. Node negative or one to three positive nodes; **AND**

   C. The member is considering treatment with adjuvant endocrine therapy (eg, tamoxifen, aromatase inhibitors).

II. The use of a hormone receptor positive breast cancer prognostic algorithmic test (i.e.., Endopredict, Prosigna, Breast Cancer Index) (S3854, 81522, 81520, 81518,) in men with breast cancer is considered **investigational**.

III. The use of a hormone receptor positive breast cancer prognostic algorithmic test (i.e., Endopredict, Prosigna, Breast Cancer Index) (S3854, 81522, 81520, 8151) is considered **investigational** for all other indications.

Hormone Receptor Agnostic Breast Cancer Prognostic Algorithmic Tests

I. The use of a hormone receptor agnostic breast cancer prognostic algorithmic test (i.e, Mammaprint) (S3854, 81521) is considered **medically necessary** when:

A. The member is a female with primary breast cancer, **AND**

B. The tumor meets **all** of the following characteristics:

1. Hormone receptor-positive (i.e., estrogen receptor-positive or progesterone receptor-positive) or hormone receptor-negative; **AND**
2. Human epidermal growth factor receptor 2 (HER2)- negative; **AND**
3. Anatomic stage I or II; **AND**
4. Node-negative or one to three positive nodes; **AND**

C. The member is considering treatment with adjuvant endocrine therapy (eg, tamoxifen, aromatase inhibitors).

II. The use of a hormone receptor agnostic breast cancer prognostic algorithmic test (i.e., Mammaprint) (81521) in men with breast cancer is considered **investigational**.

III. The use of a hormone receptor agnostic breast cancer prognostic algorithmic test (i.e, Mammaprint) (81521) is considered **investigational** for all other indications.

Gene Expression Profiling Breast Cancer Subtyping Tests

I. Gene expression profiling breast cancer subtyping tests (e.g., BluePrint, Insight TNBCtype) (0153U, 81599) are considered **investigational**.

Breast DCIS Prognostic Algorithmic Tests

I. Breast DCIS prognostic algorithmic tests (e.g., OncotypeDX Breast DCIS Score) (0045U) are considered **investigational**.

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COLORECTAL CANCER

Colorectal Cancer Prognostic Algorithmic Tests

I. Colorectal cancer prognostic algorithmic tests (e.g. OncotypeDx Colon Recurrence Score, GeneFX Colon) (81525, 81599) are considered **investigational**.

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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. Prolaris, Decipher Prostate Cancer Genomic Classifier, Oncotype DX Prostate) (81541, 81542, 0047U) is considered **medically necessary** when:
   II. The member meets all of the following:
      III. The member has low or favorable intermediate-risk prostate cancer, **AND**
      IV. The member has a life expectancy of ≥ 10 years, **OR**
V. The use of a prostate cancer treatment and prognostic algorithmic test (i.e. Prolaris, Decipher Prostate Cancer Genomic Classifier) (81541, 81542) is considered **medically necessary** when:
   VI. The member meets all of the following:
      VII. The member has unfavorable intermediate- and high-risk prostate cancer **AND**
      VIII. The member has a life expectancy of ≥ 10 years
IX. The use of the Decipher assay (81542) to inform adjuvant treatment and counseling for risk stratification is considered **medically necessary** when the member meets the following:
   A. Adverse features are found post-radical prostatectomy, including but not limited to PSA resistance/recurrence .
X. The use of a prostate cancer treatment and prognostic algorithmic test (e.g. Prolaris, Decipher Prostate Cancer Genomic Classifier) (81541, 81542) is considered **investigational** for all other indications.

Prostate Cancer Risk Assessment Algorithmic Tests

I. Prostate cancer risk assessment algorithmic tests (e.g., 4Kscore (81539), Prostate Health Index (84153, 84154, 86316), SelectMDx (81599), ExoDx Prostate Test (0005U), Apfinity (0021U)) are considered **investigational**.

Prostate Cancer Diagnostic Algorithmic Tests

I. Prostate cancer diagnostic algorithmic tests (e.g. ConfirmMDx (81551), Progensa PCA3 Assay (81313), MiPS (0013U), Prostate Core Mitomics Test (81479)) are considered **investigational**.

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THYROID CANCER

Thyroid Cancer Diagnostic Algorithmic Tests

I. The use of a thyroid cancer diagnostic algorithmic test (e.g., ThyroSeq Genomic Classifier, ThyGeNEXT, ThyraMIR, Afirma Genomic Sequence Classifier, Afirma Gene Expression Classifier, Afirma MTC, Afirma Xpression Atlas) (0026U, 0018U, 0208U, 0204U, 0245U, 0287U, 81546) in fine needle aspirates of thyroid nodules is considered **medically necessary** when:

   A. The fine needle aspirates showed indeterminate or suspicious cytologic findings, **AND**

   B. Clinical and/or radiologic findings of the thyroid nodules are indeterminate or suspicious of malignancy, **AND**

   C. The result of the test would affect surgical decision making.

II. The use of a thyroid cancer diagnostic algorithmic test (e.g., ThyroSeq Genomic Classifier, ThyGeNEXT, ThyraMIR, Afirma Genomic Sequence Classifier, Afirma Gene Expression Classifier, Afirma MTC, Afirma Xpression Atlas) (0026U, 0018U, 0208U, 0204U, 0245U, 81546) 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 (e.g., DecisionDX-UM or Uveal Melanoma Prognostic Test) (81552, 0081U, 81599) is considered **medically necessary** when:

   A. The member has primary, localized uveal melanoma.

II. The use of a uveal melanoma prognostic algorithmic test (e.g., DecisionDX-UM or Uveal Melanoma Prognostic Test) (81552, 0081U, 81599) is considered **investigational** for all other indications.

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CUTANEOUS MELANOMA

Cutaneous Melanoma Prognostic Algorithmic Tests

I. Cutaneous melanoma prognostic algorithmic tests (e.g., Decision-DX Melanoma) (81529) are considered **investigational**.

Cutaneous Melanoma Diagnostic Algorithmic Tests

I. Cutaneous melanoma diagnostic algorithmic tests (e.g. myPath) (0090U) are considered **investigational**.

Cutaneous Melanoma Risk Assessment Algorithmic Tests

I. Cutaneous melanoma risk assessment algorithmic tests (e.g. Pigmented Lesion Assay) (0089U) are considered **investigational**.

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OVARIAN CANCER

Ovarian Cancer Diagnostic Algorithmic Tests

I. Ovarian cancer diagnostic algorithmic tests (e.g., OVA1, Overa, and ROMA) (0003U, 81500, 81503) 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

Ovarian Cancer Treatment Algorithmic Tests

I. Ovarian cancer treatment algorithmic tests (e.g., myChoice CDx) (0172U, 81479) 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 (e.g., myChoice CDx) (0172U, 81479) are considered **investigational** for all other indications.

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GYNECOLOGIC CANCER

Gynecologic Cancer Treatment Algorithmic Tests

I. Gynecologic cancer treatment algorithmic tests (e.g. ChemoFX, ChemoFX - Additional Drug) (81535, 81536) in the assessment of gynecological cancers are considered **investigational.**

LUNG CANCER

Lung Cancer Treatment Algorithmic Tests

I. Lung cancer treatment algorithmic tests (e.g. Veristrat, DetermaRx) (81538, 81599) are considered **investigational**.

Lung Cancer Diagnostic Algorithmic Tests

I. Lung cancer diagnostic algorithmic tests (e.g. NodifyXL2, Reveal Lung Nodule Characterization, Percepta Bronchial Genomic Classifier) (0080U, 0092U, 81599) are considered **investigational**, including for members with undiagnosed pulmonary nodules.

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BLADDER AND URINARY TRACT CANCER

Bladder Cancer Diagnostic and Recurrence Algorithmic Tests

I. Bladder cancer diagnostic and recurrence algorithmic tests (e.g., Cxbladder Triage, Cxbladder Detect, Cxbladder Monitor, Xpert Bladder Cancer Monitor, BTAstat) (0012M, 0013M, 81599, 86294) are considered **investigational**.

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Urinary Tract Cancer Recurrence Algorithmic Tests

I. Urinary tract cancer recurrence algorithmic tests (e.g., Alere NMP22, Alere NMP22 BladderCheck) (86386) are considered **investigational**.

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PANCREATIC CANCER

Pancreatic Cyst Risk Assessment Algorithmic Tests

I. Pancreatic cyst risk assessment algorithmic tests (e.g., PancraGEN) (81479) are considered **investigational**.

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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 (81504, 81540) 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

I. The use of a breast cancer polygenic risk score test (81599) is considered **investigational**.

Prostate Cancer Polygenic Risk Score Tests

I. The use of a prostate cancer polygenic risk score test (e.g. AmbryScore) (81599) is considered **investigational**.

Multiple Myeloma Polygenic Risk Score Tests

I. The use of a multiple myeloma polygenic risk score test (e.g., myPRS) (81599) is considered **investigational**.

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ONCOLOGY: TEST-SPECIFIC NOT COVERED ALGORITHMIC TESTS

I. The use of these specific oncology algorithmic tests are considered **investigational**:

   A. BBDRisk Dx™ (0067U)
   B. Onco4D™ (0083U)
   C. Lymph3Cx Lymphoma Molecular Subtyping Assay (0120U)
   D. LC-MS/MS Targeted Proteomic Assay (0174U)
   E. PreciseDxTM Breast Cancer Test (0220U)

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CLINICAL CONSIDERATIONS

The Oncotype DX, EndoPredict, the Breast Cancer Index, MammaPrint, and Prosigna assays should only be ordered on a tissue specimen obtained during surgical removal of the tumor and after subsequent pathology examination of the tumor has been completed and determined to meet the above criteria (ie, the test should not be ordered on a preliminary core biopsy). The test should be ordered in the context of a physician-patient

discussion regarding risk preferences when the test result will aid in making decisions regarding chemotherapy.

For patients who otherwise meet the criteria for gene expression profiling for breast cancer but who have multiple ipsilateral primary tumors, a specimen from the tumor with the most aggressive histologic characteristics should be submitted for testing. It is not necessary to test each tumor; treatment is based on the most aggressive lesion.

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DEFINITIONS

1. **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)
2. **Somatic** mutations can occur in any of the cells of the body except the germ cells (sperm and egg) and therefore are not passed on to children. These alterations can (but do not always) cause cancer or other diseases.

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BACKGROUND AND RATIONALE

Practice Guidelines and Committee Statements

National Comprehensive Cancer Network (NCCN):

Adjuvant Chemotherapy for Node-Negative Breast Cancer

Current NCCN guidelines on the use of multigene assays for consideration of addition of adjuvant systemic chemotherapy to adjuvant endocrine therapy for breast cancer (v.8.2021) recognize that multigene assays provide prognostic and therapy-predictive information that compliments T,N,M biomarker information and based on higher level evidence there is uniform NCCN consensus that the intervention is appropriate (category 1) and support strong consideration 21-gene RT-PCR assay (specifically OncotypeDx) to help estimate the likelihood of recurrence and the benefit from chemotherapy and cites

this as the preferred test. The panel also recognizes other multigene expression assays to help predict risk of recurrence including MammaPrint (category 1), Endopredict, Breast Cancer Index and Prosignia (category 2A) for node-negative, ER+, HER2- breast cancer with pT1, pT2, or pT3; and pN0 and tumor less than 0.5 cm. They further state that only one of these assays should be ordered for an individual patient and tumor.

NCCN indicates that most breast cancer clinical trials have been performed in females, which necessitates extrapolation of the results to males with breast cancer. For molecular assays like Oncotype DX, the limited available data suggests that this 21-gene assay recurrence score for prognostic information is applicable to males with breast cancer.

Adjuvant Chemotherapy for Node-Positive Breast Cancer

Current NCCN guidelines on the use of multigene assays for consideration of addition of adjuvant systemic chemotherapy to adjuvant endocrine therapy for breast cancer (v.8.2021) recognize that multigene assays provide prognostic and therapy-predictive information that compliments T,N,M biomarker information and based on lower level evidence there is uniform NCCN consensus that the intervention is appropriate (category 2A) and support the consideration of multigene assay to assess prognosis and determine chemotherapy benefit for node-positive, ER+, HER2- breast cancer with pN1mi (≤2 mm axillary node metastasis) or N1 (<4 nodes).

Extended Endocrine Therapy for Breast Cancer

Current NCCN guidelines (v.8.2021) provides a flow chart on adjuvant endocrine therapy recommendations and considerations, based on menopausal status at diagnosis and after 5 years of therapy, and on prior therapy history.

Predicting Recurrence of Colon Cancer

Current NCCN guidelines (v.2.2021) recognize that the use of multigene assays to inform the risk of recurrence is an emerging technology to aid in determination of adjuvant therapy; however, there is currently insufficient data to recommend the use of multigene assays to determine adjuvant therapy for stage II or III colon cancer.

Prostate Cancer Prognosis and Management

Current NCCN guidelines (v.1.2022) support the consideration of gene expression profiling for prostate cancer prognosis and management in men with low or favorable intermediate clinically localized disease, at the time of initial risk stratification (i.e. before

treatment). Additionally, a subset of these tests are recommended for consideration in men with unfavorable intermediate- and high-risk disease.

Prostate Cancer Risk Assessment and Early Detection

Current NCCN guidelines (v.1.2021) support the consideration of biomarkers that improve the specificity of screening in patients with a PSA level greater than 3 ng/mL who have not yet had a biopsy and in men who had a negative biopsy but are thought to be at higher risk.

Current NCCN guidelines (v.1.2021) recommend considering the use of tests that improve specificity post-biopsy, including percent-free PSA, 4kscore, PHI, PCA3 and ConfirmMDx.

Thyroid Cancer

Current NCCN guidelines (v.2.2021) support the use of molecular diagnostics for thyroid nodules evaluated with FNA when lesions are suspicious for follicular or Hurthle cell neoplasms, atypia of undetermined significance or follicular lesions of undetermined significance.

Uveal Melanoma

Current NCCN guidelines (v.2.2021) support gene expression profiling and chromosome analysis in all patients with uveal melanoma and further state that molecular testing for prognostication is preferred over cytology alone.

Cutaneous Melanoma

Current NCCN guidelines (v.2.2021) recognize that the use of gene expression profiling as an emerging technology to differentiate melanomas at low versus high risk for metastasis, to clarify indeterminate melanocytic neoplasms following histopathology, and to classify cutaneous melanoma into separate categories based on metastasis; however, currently there is insufficient data to recommend the use of gene expression profiling for cutaneous melanoma as the impact of these tests has not been established.

Current NCCN guidelines (v.2.2021) also recognize that there are emerging technologies aiming to differentiate benign from malignant melanocytic neoplasms (e.g., IHC, CGH, FISH, GEP, SNP arrays, and NGS). The guideline states that these tests may facilitate interpretation of cases that are diagnostically uncertain and that these tests should be used as adjuncts to clinical and expert dermatopathologic examination and interpreted within the context of those findings.

Ovarian Cancer Risk

Current NCCN guidelines (v.1.2021) recognize the use of biomarker analysis for risk assessment for ovarian cancer in women with a pelvic mass as an emerging technology; however, there is currently insufficient data to recommend the use of biomarker analysis for determining risk for ovarian cancer.

Ovarian Cancer Treatment

Current NCCN guidelines for ovarian cancer (v2.2021) recommend genetic risk evaluation, and germline and somatic testing if not previously done, including BRCA1/2 to inform maintenance therapy for patients with ovarian, fallopian tube or primary peritoneal cancer. If a patient does not have a germline BRCA1/2 mutation, homologous recombination status may inform on the benefit of PARP inhibitor therapy.

The NCCN guideline for ovarian cancer (v.3.2021) recognizes that chemosensitivity/resistance assays are used in some situations where multiple equivalent chemotherapy options are available, however the current level of evidence is not sufficient to take the place of standard-of-care chemotherapy (category 3 recommendation).

Urinary Biomarkers for Bladder Cancer

Current NCCN guidelines (v.2.2021) support consideration for urinary urothelial tumor markers for high-risk patients with non-muscle-invasive bladder cancer (category 2b recommendation).

Pancreatic Cyst Risk Assessment Algorithmic Tests

Current NCCN guidelines (v.2.2021) discuss the use of endoscopic ultrasound to follow patients with pancreatic cysts and after the removal, citing that the risk of malignancy in mucinous cystic neoplasms is less than 15%. The guidelines do not include recommendation or discussion for the use of molecular analysis of pancreatic cysts to stratify risk of cancer.

Genetic/Familial High Risk Assessment: Breast, Ovarian and Pancreatic

Current NCCN guidelines (v.1.2022) recognize the use of polygenic risk scores as an emerging technology in the risk assessment of cancer; however, there are significant limitations in the interpretation of polygenic risk scores and therefore polygenic risk scores should not be used for clinical management at this time.

NCCN does recognize that laboratory variant reporting may differ between germline and somatic testing, so it is reasonable to perform germline testing for actionable mutations even if tumor testing is negative in order to identify patients at additional risk.

Cancers of Unknown Primary (Occult Primary)

Current NCCN guidelines (v.2.2021) recognize the use of gene expression profiling as a tool that may be beneficial for diagnosis, but not necessarily clinical benefit. Gene sequencing to predict tissue of origin is not recommended (category 3 recommendation).

American Society of Clinical Oncology (ASCO)

ASCO (2020) issued a guideline for the use of PARP inhibitors in the management of ovarian cancer, which included the following summary of recommendations:

> "The guideline pertains to patients who are PARPi naïve. All patients with newly diagnosed, stage III-IV EOC whose disease is in complete or partial response to first-line, platinum-based chemotherapy with high-grade serous or endometrioid EOC should be offered PARPi maintenance therapy with niraparib. For patients with germline or somatic pathogenic or likely pathogenic variants in BRCA1 (g/sBRCA1) or BRCA2 (g/sBRCA2) genes should be treated with olaparib. The addition of olaparib to bevacizumab may be offered to patients with stage III-IV EOC with g/sBRCA1/2 and/or genomic instability and a partial or complete response to chemotherapy plus bevacizumab combination. Maintenance therapy (second line or more) with single-agent PARPi may be offered for patients with EOC who have not received a PARPi and have responded to platinum-based therapy regardless of BRCA mutation status. Treatment with a PARPi should be offered to patients with recurrent EOC that has not recurred within 6 months of platinum-based therapy, who have not received a PARPi and have a g/sBRCA1/2, or whose tumor demonstrates genomic instability. PARPis are not recommended for use in combination with chemotherapy, other targeted agents, or immune-oncology agents in the recurrent setting outside the context of a clinical trial. Recommendations for managing specific adverse events are presented. Data to support reuse of PARPis in any setting are needed."

ASCO (2019) issued a guideline for the use of molecular biomarkers in localized prostate cancer that included the following summary of recommendations:

> "Tissue-based molecular biomarkers (evaluating the sample with the highest volume of the highest Gleason pattern) may improve risk stratification when added

to standard clinical parameters, but the Expert Panel endorses their use only in situations in which the assay results, when considered as a whole with routine clinical factors, are likely to affect a clinical decision. These assays are not recommended for routine use as they have not been prospectively tested or shown to improve long-term outcomes—for example, quality of life, need for treatment, or survival."

ASCO (2017) updated its evidence-based guidelines on the use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer and published a focused update of those guidelines in 2019[1]. The recommendations state that gene expression profiling biomarkers have been found to demonstrate clinical utility to guide decisions on the need for adjuvant systemic therapy in women with early-stage invasive breast cancer and known estrogen and progesterone and *HER2* status and are as follows:

Node-Negative

- For patients older than 50 years and whose tumors have Onco*type* DX recurrence scores of less than 26 and for patients age 50 years or younger whose tumors have Onco*type* DX recurrence scores of less than 16, there is little to no benefit from chemotherapy. Clinicians may offer endocrine therapy alone.
- For patients 50 years of age or younger with Onco*type* DX recurrence scores of 16 to 25, clinicians may offer chemoendocrine therapy.
- Patients with Onco*type* DX recurrence scores of greater than 30 should be considered candidates for chemoendocrine therapy.
- Based on Expert Panel consensus, oncologists may offer chemoendocrine therapy to patients with Onco*type* DX scores of 26 to 30.
- Clinician may use the EndoPredict 12-gene risk score to guide decisions on adjuvant systemic chemotherapy
- Clinician may use the Breast Cancer Index to guide decisions on adjuvant systemic therapy
- Clinician may use the MammaPrint 70-gene assay to guide decisions on adjuvant systemic therapy in women with high clinical risk per MINDACT categorization
- Clinician should **not** use the MammaPrint 70-gene assay to guide decisions on adjuvant systemic therapy in women with low clinical risk per MINDACT categorization
- Clinician may use the Prosigna PAM50 risk of recurrence score, in conjunction with other clinicopathologic variables, to guide decisions on adjuvant systemic therapy

Node-Positive (1-3 nodes)

- Clinician may use the MammaPrint 70-gene assay to guide decisions on adjuvant systemic therapy in women with high clinical risk per MINDACT categorization

ASCO (2011) published a clinical practice guideline update on the use of chemotherapy sensitivity and resistance assays which included the following summary recommendation:

> "The use of [chemotherapy sensitivity and resistance assays] CSRAs to select chemotherapeutic agents for individual patients is not recommended outside of the clinical trial setting. Oncologists should make chemotherapy treatment recommendations based on published reports of clinical trials and a patient's health status and treatment preferences. Because the in vitro analytic strategy has potential importance, participation in clinical trials evaluating these technologies remains a priority."

American Urological Association

Prostate Cancer Management

The American Urological Association, American Society for Radiation Oncology, and the Society of Urologic Oncology (2017, 2018) published joint guidelines on the management of clinically localized prostate cancer which state that among most low-risk localized prostate cancer patients, genomic biomarkers have not demonstrated a clear role in the selection of active surveillance or in the follow-up of patients on active surveillance.

Prostate Cancer Early Detection

The American Urological Association (2013; confirmed 2018) published guidelines on the early detection of prostate cancer and concluded that the literature supporting the use of genetic and protein biomarkers for prostate cancer screening and risk assessment provides little evidence for routine use at this time. However, the guidelines did recognize that multiple approaches subsequent to a PSA test (e.g., urinary and serum biomarkers, imaging, risk calculators) are available for identifying men more likely to harbor prostate cancer and/or one with an aggressive phenotype. The use of such tools can be considered in men with a suspicious PSA level to inform prostate biopsy decisions.

The American Urological Association and the Society of Abdominal Radiology (2016) published joint guidelines on prostate magnetic resonance imaging and magnetic

resonance imaging-targeted biopsy. The associations commented that there may be value in using genetic and protein biomarkers for prostate cancer risk in patients warranting repeat biopsy; however, further research is needed to fully assess the utility.

Urinary Biomarkers for Bladder Cancer

The American Urological Association and Society of Urologic Oncology (2016) addressed the diagnosis and treatment of non-muscle-invasive bladder cancer, based on a systematic review and includes the following statements on the use of urine markers after the diagnosis of bladder cancer:

- Urinary biomarker analysis should not replace cystoscopic evaluation in the surveillance of NMIBC.
- Urinary biomarker analysis or cytology should not routinely be used during surveillance In a patient with a history of low-risk cancer and a normal cystoscopy
- Urinary biomarker analysis may be used to assess response to intravesical BCG (UroVysion® FISH) and adjudicate equivocal cytology (UroVysion® FISH and ImmunoCyt™) in a patient with NMIBC.

American Association of Clinical Endocrinologists

The American Association of Clinical Endocrinologists, American College of Endocrinology, and Associazone Medici Endocrinologi (2016) updated their joint guidelines on molecular testing for cytologically indeterminate thyroid nodules and endorsed the following:

- *TERT* mutational analysis may improve the diagnostic sensitivity of molecular testing on cytologic samples.
- There is insufficient evidence to recommend either in favor of or against the use of gene expression classifiers for cytologically indeterminate nodules.
- With the exception of mutations such as BRAFV600E, there is insufficient evidence to recommend in favor of or against the use of mutation testing to determine the extent of surgery.

American Thyroid Association

The American Thyroid Association (2016) updated its guidelines on the management of thyroid nodules and differentiated thyroid cancer in adults. These guidelines made the following statements on molecular diagnostics in thyroid nodules:

- For nodules with AUS/FLUS, molecular testing may be used to supplement malignancy risk assessment in lieu or proceeding directly with either surveillance or diagnostic surgery.
- Molecular testing may be used to supplement risk assessment in lieu of proceeding directly with surgery.

American Academy of Dermatology

The American Academy of Dermatology (2019) published guidelines of care for the management of primary cutaneous melanoma. The guidelines state the following regarding GEP tests:

- Diagnostic molecular techniques are still largely investigative and may be appropriate as ancillary tests in equivocal melanocytic neoplasms, but they are not recommended for routine diagnostic use in CM. These include comparative genomic hybridization (CGH), fluorescence in situ hybridization (FISH), gene expression profiling (GEP), and (potentially) next-generation sequencing.
- Ancillary diagnostic molecular techniques (eg, CGH, FISH, GEP) may be used for equivocal melanocytic neoplasms.
- There is insufficient evidence of benefit to recommend routine use of currently available prognostic molecular tests, including GEP, for prognosis of CM.
- Routine molecular testing, including GEP, for prognostication is discouraged until better use criteria are defined. The application of molecular information for clinical management is not recommended.

American College of Gastroenterology

The American College of Gastroenterology (2018) published guidelines for the diagnosis and management of pancreatic cysts, which included the following:

- “A number of DNA, RNA, protein, and metabolomic markers have been evaluated in cyst fluid. The majority of these are still early in development and not yet ready

for translation into clinical practice. However, analysis of DNA mutations in cyst fluid has shown promise in identifying IPMNs and MCNs."

Cutaneous Melanoma Prognostic Algorithmic Tests

Concert Genetics

This review focused on peer-reviewed, published evidence of the clinical utility of DermTech PLA through August, 2021. PubMed and ECRI Guidelines Trust searches were performed. Search terms included pigmented lesion assay, DermTech, 0089U, PRAME, LINC00518, cutaneous melanoma risk. References were also identified from the performing laboratory's website. A total of 110 abstracts from these sources were reviewed, and 30 full text publications were evaluated. At the present time, the DermTech Pigmented Lesion Assay has not been adequately shown in peer-reviewed publications to effectively result in improved health outcomes compared to the current standard of care.

Lung Cancer Treatment Algorithmic Tests

Concert Genetics

This review focused on peer-reviewed, published evidence of the clinical utility of VeriStrat® through September 2021. PubMed and ECRI Guidelines Trust searches were performed. Search terms included VeriStrat®, proteomic non-small cell lung cancer, prognosis, and survival. References were also identified from the performing laboratory's website. A total of 69 abstracts from these sources were reviewed, and 44 full text publications were evaluated. At the present time, the VeriStrat® test has not been adequately shown in peer-reviewed publications to effectively result in improved health outcomes compared to the current standard of care.

Lung Cancer Diagnostic Algorithmic Tests

Concert Genetics

This review focused on peer-reviewed, published evidence of the clinical utility of NodifyXL2, Percepta Bronchial Genomic Classifier, and Reveal Lung Nodule Characterization through October 2021. PubMed and ECRI Guidelines Trust searches were performed. Search terms included Nodify, Percepta, lung nodule, plasma-protein and multiplex. References were also identified from the performing laboratory's website. A total of 53 abstracts from these sources were reviewed, and 15 full text publications were evaluated. At the present time, NodifyXL2, Percepta Bronchial Genomic Classifier, and Reveal Lung Nodule Characterization have not been adequately shown in peer-reviewed publications to effectively result in improved health outcomes compared to the current standard of care.

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