

<b>Department of Origin:</b> Integrated Healthcare Services	<b>Effective Date:</b> 12/05/24
<b>Approved by:</b> Medical Policy Quality Management Subcommittee	<b>Date Approved:</b> 03/05/24
<b>Clinical Policy Document:</b> Molecular Testing, Tumor/Neoplasm Biomarkers	<b>Replaces Effective Clinical Policy Dated:</b> 03/21/24
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## PURPOSE:

The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

## POLICY:

Benefits must be available for health care services. Healthcare services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

## GUIDELINES:

Medical Necessity Criteria - Must satisfy all of the following: I – III

### I. Characteristics of covered tests

- A. Each test has been approved for its intended use by the appropriate *regulatory/oversight body* (implies *analytic validity*).
- B. Each test has sufficient sensitivity and specificity (*clinical validity*) for targeting the member's specific clinical condition.
- C. The results of each molecular test will directly impact clinical decision-making and clinical care (*clinical utility*) for the individual.

### II. Unless otherwise noted, molecular testing is allowed once per member for the targeted condition and duplicate testing is not allowed.

### III. Request is appropriate per the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines or NCCN Biomarkers Compendium®, unless otherwise noted, which includes, but is not limited to any of the following: A - H

- A. Bladder Cancer<sup>23,26,27</sup> - can allow requests for surveillance testing of urinary urothelial markers mRNA MDK, HOXA13, CDC2 [CDK1], IGFBP5, CXCR20 (Cxbladder Monitor [0013M]) in members with high-risk non-muscle invasive bladder cancer (NMIBC) (see Table 2).
- B. Breast Cancer<sup>5</sup> – can allow requests for any of the following: 1 or 2
  1. Breast Cancer Index<sup>SM</sup> (BCI [CPT 81518]), EndoPredict® (CPT 81522), MammaPrint™ microarray/NGS [Amsterdam signature] (CPTs 81521/81523) Oncotype DX® Breast Recurrence Score (CPT 81519), or Prosigna™ [PAM50] Breast Cancer Gene Signature assay (CPT 81520) to make a treatment decision regarding adjuvant systemic therapy in members (female or male) with invasive breast cancer – must satisfy all of the following: a – e
    - a. Member is newly diagnosed (within the last 6 months); and
    - b. Lymph node negative or 1- 3 positive ipsilateral lymph nodes; and
    - c. No distant metastasis; and
    - d. Hormone receptor positive (HR [estrogen receptor, progesterone receptor or both]); and
    - e. Human epidermal growth factor receptor (HER2) negative.

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2. Breast Cancer Index<sup>SM</sup> (BCI [CPT 81518]) to make a treatment decision regarding extended adjuvant systemic therapy in members (female or male) with invasive breast cancer – must satisfy all of the following: a – c
  - a. Member is currently receiving adjuvant endocrine therapy (eg, Tamoxifen or an aromatase inhibitor) for breast cancer; and
  - b. Hormone receptor positive (HR [estrogen receptor, progesterone receptor or both]); and
  - c. Human epidermal growth factor receptor (HER2) negative.

[Note: Testing on more than one tumor may be medically necessary for members with two or more histologically distinct tumors and the above indications are met.]

[Note: with the exception of BCI, use of more than one Gene Expression test for the same tumor in an individual with breast cancer is unproven and not medically necessary due to insufficient evidence of efficacy.]

- C. Hematological Cancers – can allow requests that satisfy any of the following: 1 – 6
  1. Clonality assessment testing at initial diagnosis (eg, ClonoSeq Clonality [ID]) in any of the following: a - b
    - a. Acute lymphoblastic leukemia (ALL)<sup>28</sup> ;or
    - b. Multiple myeloma (MM)<sup>30</sup>
  2. Minimal residual disease (MRD) testing for acute lymphoblastic leukemia (ALL)<sup>28</sup> (eg, ClonoSeq Tracking [MRD] 0364U) – must satisfy any of the following: a – d
    - a. Upon completion of initial induction; or
    - b. End of consolidation; or
    - c. Additional time points as guided by the regimen used; or
    - d. Serial monitoring in patients with molecular relapse or persistent low-level disease burden.
  3. MRD testing of bone marrow aspirate for acute myeloid leukemia (AML)<sup>31</sup> (eg, FLT ITD MRD [0046U], MyMRD [0171U]) – must satisfy any of the following: a - c
    - a. Upon completion of initial induction; or
    - b. Before allogeneic transplantation; or
    - c. Additional time points as guided by the regimen used.
  4. MRD testing of peripheral blood samples for AML<sup>31</sup> (eg, FLT ITD MRD [0046U], MyMRD [0171U]) - must satisfy any of the following: a – c
    - a. Upon completion of initial induction; or
    - b. Before allogeneic transplantation; or
    - c. Additional time points as guided by the regimen used
  5. MRD testing of bone marrow aspirate for chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL)<sup>29</sup> (eg, ClonoSeq Tracking [MRD] 0364U) - upon completion of first-line therapy.
  6. MRD testing for multiple myeloma (MM)<sup>30</sup> (eg, ClonoSeq Tracking [MRD] 0364U) - must satisfy any of the following: a - b
    - a. During follow-up/surveillance after response to primary therapy; or

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- b. After each treatment state (eg, after induction, high-dose therapy/autologous stem-cell transplantation [ASCT], consolidation, and maintenance).
  - D. Melanoma, cutaneous<sup>9</sup> – can allow diagnostic (post-biopsy) molecular testing in indeterminate melanocytic neoplasms that are diagnostically uncertain or controversial by histopathology (eg, MyPath PLA 0090U, DiffDx-Melanoma PLA 0314U)
  - E. Melanoma, uveal (ocular)<sup>6</sup> - can allow prognostic (risk stratification) molecular testing in localized uveal (ocular) melanoma (post-biopsy) (eg, DecisionDX-UM CPT 81552) .  
[Note: does not apply to prognostic testing of cutaneous melanoma - see below for investigative position]
  - F. Prostate – can allow requests that satisfy any of the following: 1 - 4
    1. Post-biopsy, to manage the treatment of newly diagnosed prostate cancer<sup>7</sup> – must satisfy any of the following: a - b
      - a. Decipher® Prostate [Biopsy Genomic Classifier] (CPT 81542), Oncotype DX Prostate (PLA 0047U), or Prolaris (CPT 81541) for low, favorable intermediate, unfavorable intermediate, or high-risk prostate cancer (see Table 1)
      - b. ArteraAI Prostate (multi-modal AI biomarker [PLA 0376U]) for clinically localized disease (N0,M0)
    2. Post radical prostatectomy for prostate cancer<sup>7</sup> – can allow Decipher® Prostate [RP Genomic Classifier] (CPT 81542]) if not already performed post-biopsy.
- [Note: Decipher® Prostate Biopsy Genomic Classifier and Decipher® Prostate RP Genomic Classifier are the same test and are billed with the same CPT code]
3. For further evaluation to determine need for biopsy<sup>24</sup> – must satisfy both of the following: a and b
    - a. Pre-biopsy PSA and/or digital rectal exam (DRE) findings reveal either of the following: 1) or 2)
      - 1) PSA greater than 3ng/mL; or
      - 2) *Very suspicious digital rectal exam.*
    - b. Requesting one of the following biomarkers: 1) – 7)
      - 1) Percent-free PSA (%fPSA) (CPT 84154); or
      - 2) Prostate Health Index (PHI) (CPTs 84153, 84154, 86316); or
      - 3) Select MDx (2-gene mRNA test) (CPT 0339U); or
      - 4) 4Kscore (CPT 81539); or
      - 5) ExoDx Prostate (ExosomeDx, IntelliScore, EPI) Test (PLA 0005U); or
      - 6) MyProstateScore (MPS, MiPS) (2-gene expression profile) (PLA 0113U); or
      - 7) IsoPSA (PLA 0359U).
  4. For further evaluation post-biopsy<sup>24</sup> – must satisfy all of the following: a - c
    - a. Pre-biopsy PSA and/or digital rectal exam findings reveal either of the following: 1) or 2)
      - 1) PSA greater than 3ng/mL; or
      - 2) *Very suspicious digital rectal exam.*
    - b. Biopsy results reveal any of the following: 1) - 3)
      - 1) Atypia, suspicious for cancer; or
      - 2) High-grade prostatic intraepithelial neoplasia (PIN); or
      - 3) Benign.

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- c. Requesting one of the following biomarkers: 1) - 7)
  - 1) Percent-free PSA (%fPSA) (CPT 84154); or
  - 2) 4Kscore (CPT 81539); or
  - 3) Prostate Health Index (PHI) (CPTs 84153, 84154, 86316); or
  - 4) PCA3 (Progenesa) (CPT 81313); or
  - 5) ConfirmMDx (CPT 81551); or
  - 6) ExoDx Prostate Test (ExosomeDx, IntelliScore, EPI) Test (PLA 0005U); or
  - 7) MyProstateScore (MPS/ MiPS) (2-gene expression profile) (PLA 0113U); or
  - 8) IsoPSA (PLA 0359U).
- G. Thyroid<sup>8,17,18</sup>— can allow testing post fine needle aspiration biopsy (FNAB) in findings are of undetermined significance (*Bethesda III/IV*) - can allow any of the following: Afirma Genomic Sequencing Classifier ([CPT 81546], ThyGeNEXT/ThyGenX (PLA 0245U) ThyraMIR (PLA 0018U), ThyroSeq V3 Genomic Classifier (PLA 0026U, 0287U)

[Note: Afirma Medullary Thyroid Carcinoma (MTC) Classifier (previously billed with PLA 0208U) is now part of the Afirma Genomic Sequencing Classifier test]

- H. Requests for simultaneous testing of multiple markers through genomic *next generation sequencing* (NGS), PCR-based, or methylation-based gene panels (includes ctDNA or cfDNA liquid biopsy testing panels) can be allowed when they satisfy the following: 1 or 2
  - 1. The panel test is a companion diagnostic or required test, as listed on the U.S. Food and Drug Administration (FDA) List of Cleared or Approved Companion Diagnostic Devices; or

[Note: hyperlink to US. Food and Drug Administration In Vitro Diagnostics list of cleared or approved companion diagnostic device]

<https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools>

- 2. Broad, broad-based, comprehensive, expanded tumor/somatic, or targeted genomic panel is recommended in the NCCN Clinical Practice Guidelines or NCCN Biomarkers Compendium®

## EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description.

The following tests are considered investigative (see Investigative List): I – XXIII

- I. Afirma Xpression Atlas
- II. HeproDX
- III. Lymph2Cx
- IV. MI Cancer Seek™ (Caris)
- V. Molecular Intelligence® Comprehensive Tumor Profiling /MI Tumor Seek™ / MI Profile® (Caris)
- VI. Molecular testing, blood-based testing (including algorithmic analyses) of autoantibody or protein/proteomic biomarkers for differentiation of benign pulmonary nodule from malignant nodule, in

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lung cancer screening. Investigative testing includes, but is not limited to:

- A. BDX-XL2
- B. EarlyCDT® Lung (Oncimmune)
- C. Nodify CDT
- D. Nodify XL2
- E. OncobiotaLUNG Micronoma™
- F. REVEAL Lung Nodule Characterization

VII. Molecular testing, chemotherapy/ chemosensitivity/ tumor resistance (cytotoxicity) assay testing (in vitro assays challenging tumor cells against chemotherapy agents). Investigative testing includes, but is not limited to:

- A. Adenosine triphosphate bioluminescence assay (ATP)
- B. ChemoFx Assay\* (\*note may be allowed in recurrent ovarian cancer disease with two or less previous chemotherapy regimens, and re-biopsy of tissue)
- C. ChemOD Assay
- D. Extreme drug-resistance assay (EDRA)
- E. Methyl-thiazolyl-diphenyltetrazolium bromide assay (MTT)
- F. Onco4D
- G. 3D Predict Ovarian Doublet panel
- H. 3D Predict Ovarian PARP panel

VIII. Molecular testing, circulating tumor cell (CTC) assays in the management of cancer conditions.

Investigative testing includes, but is not limited to:

- A. CELLSEARCH® System
- B. CELLSEARCH® Circulating Multiple Myeloma Cell (CMMC)
- C. CELLSEARCH® HER2 Circulating Tumor Cell (CTC- HER2)
- D. FirstSightCRC and CellMax Life
- E. LungLB®, LungLife AI®, LungLife AI®

IX. Molecular testing, circulating tumor cell (CTC), circulating tumor DNA (ctDNA) and cell-free DNA (cfDNA) testing in the detection of/screening for undiagnosed cancer conditions. Investigative testing includes, but is not limited to:

- A. Galleri®
- B. Avantect™ Pancreatic Cancer Test

X. Molecular testing, gene expression profiling in bladder cancer detection and management for indications not included in clinical policy Molecular Testing, Tumor Neoplasm Biomarkers (MC/L012). Investigative testing includes, but is not limited to:

- A. CxBladder Detect
- B. CxBladder Detect+
- C. CxBladder Triage
- D. Decipher Bladder TURBT
- E. Oncuria Detect
- F. Oncuria Monitor
- G. Oncuria Predict

XI. Molecular testing, gene expression profiling in breast cancer not included in this clinical policy.

Investigative testing includes, but is not limited to:

- A. 41-gene signature assay
- B. BBDRisk DX

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- C. BluePrint® (80-gene profile)
- D. Breast Cancer Gene Expression Ratio (also known as Theros H/I<sup>sm</sup>)
- E. BreastOncPx™ or Breast Cancer Prognosis Gene Expression Assay
- F. BreastPRS
- G. DCISionRT®
- H. DiviTum® TKa
- I. Genomic Grade Index (also known as MapQuant Dx™)
- J. HERmark® Breast Cancer Assay
- K. Insight™ DX Breast Cancer Profile
- L. Insight TNBCtype™
- M. Mammostrat™
- N. NexCourse® Breast IHC4
- O. Oncotype DX® DCIS
- P. PreciseDx Breast biopsy test
- Q. PreciseDx Breast cancer test
- R. Rotterdam signature assay (76-gene assay)
- S. SYMPHONY™ Genomic Breast Cancer Profile
- T. TargetPrint®

XII. Molecular testing, gene expression profiling in cancers of unknown primaries/occult primary tumors. Investigative testing includes, but is not limited to:

- A. CancerTYPE ID® Test
- B. ProOnc TumorSourceDX™ Test
- C. ResponseDX: Tissue of Origin Test™ (Pathwork® Tissue of Origin)
- D. Rosetta Cancer Origin Test™ (miRview® mets and miRview® mets2 tests)

XIII. Molecular testing, gene expression profiling in colorectal cancer. Investigative testing includes, but is not to:

- A. ColDx
- B. ColoPrint
- C. Colorectal Cancer DSA®
- D. Colosense™
- E. GeneFx Colon®
- F. miR-31 now™
- G. OncoDefender-CRC®
- H. Oncotype DX® Colon Cancer Assay
- I. Polyp DX

XIV. Molecular testing, gene expression profiling in cutaneous melanoma, post-biopsy (prognostic). Investigative testing includes, but is not limited to:

- A. AMBLor® melanoma
- B. DecisionDX-Melanoma

XV. Molecular testing, gene expression profiling in idiopathic pulmonary fibrosis. Investigative testing includes, but is not limited to: Envisia® Genomic Classifier

XI. Molecular testing, gene expression profiling in indeterminate cutaneous lesions, pre-biopsy. Investigative testing includes, but is not limited to: Pigmented Lesion Assay

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- XII. Molecular testing, gene expression profiling/molecular testing in predicting malignancy in women with adnexal mass. Investigative testing includes, but is not limited to:
- A. OVA1
  - B. OvaWatch
  - C. Overa
  - D. Risk of Ovarian Malignancy Algorithm (ROMA)
- XIII. Molecular testing, gene expression profiling/molecular testing in prostate cancer for indications not included in this clinical policy. Investigative testing includes, but is not limited to:
- A. Apify
  - B. miR Sentinel™ Prostate Cancer Test (53 sncRNAs)
  - C. miR Sentinel™ Prostate Cancer Test (442 sncRNAs)
  - D. MyProstate Score 2.0
  - E. NeoLAB Prostate liquid biopsy
  - F. PanGIA Prostate
  - G. ProstaVysion®
- XIX. MSK-Impact
- XX. MyAML NGS panel
- XXI. OncoTarget/OncoTreat
- XXII. Oncotype MAP™ Pan Cancer Tissue Test
- XXIII. Topographic Genotyping. Investigative testing includes, but is not limited to: PathfinderTG® from RedPath Integrated Pathology

## DEFINITIONS:

### Analytic Validity:

How accurately and reliably the test measures the genotype of interest. A major component in the validation of an analytical technique is the technique's ability to accurately determine the presence of the substance it is seeking. It must measure the target substance without a great range of variation over a number of trials. The technique also must be proven to work reliably at multiple labs to be validated by this testing.

### Bethesda III:

Atypia of undetermined significance (AUS) or follicular lesion of undetermined significance (FLUS)

### Bethesda IV:

Follicular neoplasm or suspicious for a follicular neoplasm

### Biomarker:

Any characteristic of an organism that can be objectively measured and evaluated to indicate the presence of a disease or drug reaction.

### Clinical Staging terms for Breast Cancer indications:

Pathologic node (pN) stage of pN0 and pN1mi:

- pN0 - No regional lymph node metastasis histologically

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- pN1mi - Micrometastases (greater than 0.2mm and/or more than 200 cells, but none greater than 2.0mm)

Pathologic tumor (pT) stage of pT1, pT2, and pT3:

- pT1 – Tumor is less than or equal to 20mm or less in greatest dimension
- pT2 – Tumor is greater than 20mm but less than or equal to 50mm in greatest dimension
- pT3 – Tumor is greater than 50mm in greatest dimension

#### Clinical TNM Staging System for Prostate Cancer:

T1 Clinically inapparent tumor that is not palpable

- T1a Tumor incidental histologic finding in 5% or less of tissue resected
- T1b Tumor incidental histologic finding in more than 5% of tissue reported
- T1c Tumor identified by needle biopsy found in one or both sides, but not palpable

T2 – Tumor is palpable and confined within prostate

- T2a – Tumor involves one-half of one side or less
- T2b – Tumor involves more than one-half of one side but not both sides
- T2c – Tumor involves both sides

T3 – Extraprostatic tumor that is not fixed or does not invade adjacent structures

- T3a – Extraprostatic extension (unilateral or bilateral)
- T3b – Tumor invades seminal vesicle(s)

T4 – Tumor is fixed or invades adjacent structures other than seminal vesicles such as sphincter, rectum, bladder, levator muscles, and/or pelvic wall

#### Clinical Utility:

How likely the test is to significantly improve patient outcomes. The evidence of improved measurable clinical outcomes, and its usefulness and added value to patient management decision-making compared with current management without the testing.

#### Clinical Validity:

How consistently and accurately the test detects or predicts the intermediate or final outcomes of interest.

#### Companion Diagnostic:

A companion diagnostic is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. The test helps a health care professional determine whether a particular therapeutic product's benefits to patients will outweigh any potential serious side effects or risks. Companion diagnostics can:

- identify patients who are most likely to benefit from a particular therapeutic product;
- identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or
- monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness.

#### Estrogen receptor (ER):

A protein that allows estrogen to attach and may be present in some cells

#### Gene expression:

The process by which a gene gets turned on in a cell to make RNA and proteins. Gene expression may be measured by looking at the RNA, or the protein made from the RNA, or what the protein does in a cell.

#### Gleason Score

The Gleason scoring system is the most common prostate cancer grading system used. The pathologist looks at how the cancer cells are arranged in the prostate and assigns a score on a scale of 3 to 5 from 2



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different locations. Cancer cells that look similar to healthy cells receive a low score. Cancer cells that look less like healthy cells or look more aggressive receive a higher score. To assign the numbers, the pathologist determines the main pattern of cell growth, which is the area where the cancer is most obvious, and then looks for another area of growth. The doctor then gives each area a score from 3 to 5. The scores are added together to come up with an overall score between 6 and 10.

Human epidermal growth factor receptor (HER2):  
Protein expressed by and involved in some breast cancers

Ipsilateral:  
Occurring on the same side of the body.

Molecular test:  
In medicine, a laboratory test that checks for certain genes, proteins, or other molecules in a sample of tissue, blood, or other body fluid. Molecular tests also check for certain changes in a gene or chromosome that may cause or affect the chance of developing a specific disease or disorder, such as cancer. A molecular test may be done with other procedures, such as biopsies, to help diagnose some types of cancer. It may also be used to help plan treatment, find out how well treatment is working, or make a prognosis.

Nadir or PSA nadir in prostate cancer:  
Lowest prostate specific antigen (PSA) level post-prostatectomy

Next Generation Sequencing (NGS):  
Used to analyze specimens for the four main classes of genomic alterations (base substitutions, insertions and deletions, copy number alterations, and rearrangements)

Progesterone receptor (PR):  
Intracellular receptor that binds to progesterone and is often over-expressed in individuals with breast cancer

Regulatory/oversight body:  
Such as, but not limited to, Clinical Laboratory Improvement Amendments (CLIA), Food and Drug Administration (FDA) or The Joint Commission

Tumor Marker:  
A biomarker that can identify a specific malignancy.

Very suspicious digital rectal exam of prostate:  
A hard mass or nodule, induration or asymmetry

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Table 1. Risk Group for Prostate Cancer

Risk Group	Clinical/Pathologic Features	
Very Low	<ul style="list-style-type: none"> <li>• cT1c; and</li> <li>• Grade Group 1; and</li> <li>• PSA less than 10ng/mL; and</li> <li>• Fewer than 3 prostate biopsy fragments/cores positive, less than or equal to 50% cancer in each fragment/core; and</li> <li>• PSA density less than 0.15ng/mL/g</li> </ul>	
Low	<ul style="list-style-type: none"> <li>• Does not qualify for very low risk; and</li> <li>• cT1-cT2a; and</li> <li>• Grade Group 1; and</li> <li>• PSA less than 10ng/mL</li> </ul>	
Intermediate	<ul style="list-style-type: none"> <li>• No high-or very high-risk group features; and</li> <li>• Has one or more intermediate risk factors (IRFs): <ul style="list-style-type: none"> <li>○ cT2b-cT2c; or</li> <li>○ Grade Group 2 or 3; or</li> <li>○ PSA 10-20 ng/mL</li> </ul> </li> </ul>	Favorable Intermediate <ul style="list-style-type: none"> <li>• 1 IRF; and</li> <li>• Grade Group 1 or 2; and</li> <li>• Less than 50% biopsy cores positive (eg, less than 6 of 12 cores)</li> </ul>
		Unfavorable Intermediate <ul style="list-style-type: none"> <li>• 2 or 3 IRFs; or</li> <li>• Grade Group 3; or</li> <li>• Greater than or equal to 50% biopsy cores positive (eg, equal to or greater than 6 of 12 cores)</li> </ul>
High	<ul style="list-style-type: none"> <li>• No very high-risk features; and</li> <li>• Exactly one high-risk feature; <ul style="list-style-type: none"> <li>○ cT3a; or</li> <li>○ Grade Group 4 or 5; or</li> <li>○ PSA greater than 20ng/mL</li> </ul> </li> </ul>	
Very High	<ul style="list-style-type: none"> <li>• cT3b-cT4; or</li> <li>• Primary Gleason pattern 5; or</li> <li>• 2 or 3 high-risk features; or</li> <li>• Greater than 4 cores with Grade Group 4 or 5</li> </ul>	

Retrieved from National Comprehensive Cancer Network (NCCN) Guidelines. Prostate Cancer. 4.2023, 09/07/23. PROS-2. Accessed 01-26-24.

Table 2. AUA Risk Stratification for Non-Muscle Invasive Bladder Cancer

Low Risk	Intermediate Risk	High Risk
<ul style="list-style-type: none"> <li>• Papillary urothelial neoplasm of low malignant potential</li> <li>• Low grade urothelial carcinoma <ul style="list-style-type: none"> <li>➢ Ta and</li> <li>➢ ≤3 cm and</li> <li>➢ Solitary</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Low grade urothelial carcinoma <ul style="list-style-type: none"> <li>➢ T1 or</li> <li>➢ &gt;3 cm or</li> <li>➢ Multifocal or</li> <li>➢ Recurrence within 1 year</li> </ul> </li> <li>• High grade urothelial carcinoma <ul style="list-style-type: none"> <li>➢ Ta and</li> <li>➢ ≤3 cm and</li> <li>➢ Solitary</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• High grade urothelial carcinoma <ul style="list-style-type: none"> <li>➢ CIS or</li> <li>➢ T1 or</li> <li>➢ &gt;3 cm or</li> <li>➢ Multifocal</li> </ul> </li> <li>• Very high risk features (any): <ul style="list-style-type: none"> <li>➢ BCG unresponsive</li> <li>➢ Variant histologies</li> <li>➢ Lymphovascular invasion</li> <li>➢ Prostatic urethral invasion</li> </ul> </li> </ul>

Retrieved from National Comprehensive Cancer Network (NCCN) Guidelines. Bladder Cancer. 3.2023, 05/25/23. BL-2. Accessed 01-26-24.

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Prior Authorization: Yes, per network provider agreement.

## CODING:

CPT® or HCPCS

81168 CCND1/IDH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed

81175 ASXL 1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence

81176 ASXL 1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; targeted sequence analysis (eg, exon 12)

81191 NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis

81192 NTRK2 (neurotrophic receptor tyrosine kinase 2) (eg, solid tumors) translocation analysis

81193 NTRK3 (neurotrophic receptor tyrosine kinase 3) (eg, solid tumors) translocation analysis

81194 NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation

81218 CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence

81218 CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence

81233 BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)

81261 IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (eg, polymerase chain reaction)

81262 IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); direct probe methodology (eg, Southern blot)

81263 IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma, B-cell), variable region somatic mutation analysis

81264 IGK@ (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)

81270 JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant

81276 KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)

81278 IGH@/BCL2 (t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative

81279 JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)

81305 MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant

81309 PIK3CA (phosphatidylinositol-4, 5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)

81309 PIK3CA (phosphatidylinositol-4, 5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)

81313 PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 2 [prostate specific antigen]) (eg, prostate cancer)

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81315 PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative

81316 PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative

81320 PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)

81327 SEPT9 (Septin9) (eg, colorectal cancer) promoter methylation analysis

81334 RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (eg, exons 3-8)

81338 MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), common variants (eg, W515A, W515K, W515L, W515R)

81339 MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), exon 10 sequence

81340 TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, polymerase chain reaction)

81341 TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using direct probe methodology (eg, Southern blot)

81342 TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)

81345 TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)

81347 SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)

81348 SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)

81357 U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)

81357 U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)

81400 Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP], by techniques such as restriction enzyme digestion or melt curve analysis)

81401 Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using non-sequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat )

81402 Molecular pathology procedure, Level 3 (eg, >10 SNPs, 2-10 methylated variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene arrangements, duplication/deletion variants of 1 exon, loss of heterozygosity [LOH], uniparental disomy [UPD])

81403 Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)

81404 Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)

81405 Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis)

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81406 Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)

81407 Molecular pathology procedure, Level 8 (eg, analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of > 50 exons, sequence analysis of multiple genes on 1 platform)

81408 Molecular pathology procedure, Level 9 (eg, analysis of > exons in a single gene by DNA sequence analysis, full gene sequence)

81445 Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis

81449 Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis

81450 Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis

81451 Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis

81455 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis

81456 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis

81518 Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue

81519 Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score

81520 Oncology (breast), mRNA, gene expression by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported

81521 Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm

81522 Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported

81523 Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis

81538 Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival

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81539 Oncology (high-grade prostate cancer), biochemical assay of the four proteins (Total PSA, Free PSA, Intact PSA and human kallikrein-2 [hK2]), utilizing plasma or serum

81541 Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score (Prolaris ®, Myriad Genetic Laboratories, Inc.)

81542 Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk s

81546 Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)

81551 Oncology (prostate), promoter methylation profiling by real-time RT-PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported

81552 Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis

84153 Prostate specific antigen (PSA); total

84154 Prostate specific antigen (PSA); free

86316 Immunoassay for tumor antigen, other antigen, quantitative

S3854 Gene expression profiling panel for use in the management of breast cancer treatment

0005U Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score

0017U Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected

0018U Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate

0022U DNA and RNA targeted sequencing analysis of 1-23 genes associated with non-small cell lung cancer, reported as presence/absence of variants and associated therapies to consider (Oncomine Dx Target Test)

0026U Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result

0027U JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15

0037U Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden (FoundationOne CDx)

0047U Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue

0049U NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative

0057U Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank

0171U Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence (MyMRD NGS)

0090U mRNA gene expression profiling of 23 genes in skin melanoma tissue sample

0111U RAS detection of 56 specific mutations in RAS genes [KRAS (exons 2, 3, and 4) and NRAS (exons 2, 3, and 4)] (Praxis Extended RAS panel)

0113U Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as a risk score

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0179U Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)

0239U Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations (FoundationOne Liquid CDx)

0242U Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements ic, 1 mCi (Guardant360 CDx )

0245U Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage

0287U Oncology (thyroid), DNA and mRNA, next-generation sequencing analysis of 112 genes, fine needle aspirate or formalin-fixed paraffin-embedded (FFPE) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result (low, intermediate, high)

0288U Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score

0306U Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient specific panel for future comparisons to evaluate for MRD

0314U Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)

0326U Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden

0332U Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint-inhibitor therapy

0333U Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in highrisk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gammaprothrombin (DCP), algorithm reported as normal or abnormal result

0334U Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden

0339U Oncology (prostate), mRNA expression profiling of HOXC6 and DLX1, reverse transcription polymerase chain reaction (RT-PCR), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer

0340U Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate

0342U Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline

0356U Oncology (oropharyngeal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence

0364U Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as

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presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate

0376U Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate

0379U Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by next-generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden

0388U Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection

0391U Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice-site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score

0409U Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability

0013M Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma

0428U Oncology (breast), targeted hybrid-capture genomic sequence analysis panel, circulating tumor DNA (ctDNA) analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden

0448U Oncology (lung and colon cancer), DNA, qualitative, next-generation sequencing detection of single-nucleotide variants and deletions in EGFR and KRAS genes, formalin-fixed paraffin-embedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options

0478U Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET, NTRK 1/2/3, ERBB2, and MET) in formalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection (Lung HDPCR™)

0481U IDH1 (isocitrate dehydrogenase 1 [NADP+]), IDH2 (isocitrate dehydrogenase 2 [NADP+]), and TERT (telomerase reverse transcriptase) promoter (eg, central nervous system [CNS] tumors), next-generation sequencing (single-nucleotide variants [SNV], deletions, and insertions) (IDH1, IDH2, and TERT Mutation Analysis, NextGeneration Sequencing, Tumor [IDTRT])

0498U Oncology (colorectal), next-generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation (OptiSeq™ Colorectal Cancer NGS Panel)

0499U Oncology (colorectal and lung), DNA from formalin-fixed paraffin-embedded (FFPE) tissue, next-generation sequencing of 8 genes (NRAS, EGFR, CTNNB1, PIK3CA, APC, BRAF, KRAS, and TP53), mutation detection (OptiSeq™ Dual Cancer Panel Kit)

0501U Oncology (colorectal), blood, quantitative measurement of cell-free DNA (cfDNA) (QuantiDNA™ Colorectal Cancer Triage Test)



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## PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist  
PreferredOne Community Health Plan  
PO Box 59052  
Minneapolis, MN 55459-0052  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂບດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ፡ የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013 ) .

ဟ်သ့ဟ်သး- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၤ, နမၤန့ၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢၣ်ဘျဉ်လၢၣ်စၢၤ နီၣ်တမံၤဘၣ်သ့န့ၣ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

**ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

## PreferredOne Insurance Company Nondiscrimination Notice

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- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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- Information written in other languages

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If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist  
PreferredOne Insurance Company  
PO Box 59212  
Minneapolis, MN 55459-0212  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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ប្រែសម្រួល: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).

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ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လည်း ကိ: 1.800.940.5049 (TTY: 763.847.4013).

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