MEDICAL POLICY	Genetic Testing: Thyroid Nodules (Medicare Only)
Effective Date: 12/1/2022  12/1/2022 Medical Officer Date	Medical Policy Number: 40 Medical Policy Committee Approved Date: 2/18; 8/19; 12/19; 9/2020; 11/2020; 12/2020; 03/2021; 10/2021; 11/2021; 9/2022

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
Afirma™ Gene Expression Classifier Assay or Afirma™ Genomic Sequencing Classifer (GSC) (Veracyte, California; *Prior to 1/1/2021, CPT 81545, As of 1/1/2021, CPT 81546)*	Local Coverage Article (LCA): Billing and Coding: MolDX: Afirma™ Assay by Veracyte (A54358)

Afirma Xpression Atlas (Veracyte, California; *as of 10/1/2020, CPT 0204U)* Afirma Medullary Thyroid Carcinoma (MTC) Classifier (Veracyte, California; *Between 10/1/2020 and 1/1/2022, CPT 0208U, As of 1/1/2022, unlisted codes (e.g., CPT 81599)*	These tests are considered **not medically necessary**, based on Medicare guidelines. *See "Policy Guidelines" below*
NRAS Gene Testing for Proliferative Thyroid Lesions	Testing performed in OR, WA, AK, ID, UT, AZ, MT, ND, SD, WY: Local Coverage Determination (LCD): MolDX: NRAS Genetic Testing (L36339)
• ThyraMIR *(Interpace Diagnostics, Pittsburgh, PA; CPT 0018U)* • ThyGeNEXT Thyroid Oncogene Panel test (*Interpace Diagnostics, Pittsburgh, PA; Prior to 04/01/2021, CPT 81455, As of 04/01/2021, CPT 0245U*) • ThyroSeq *(CBLPath, Inc. & Univ of Pittsburgh Medical Center, testing performed in Pittsburgh, PA; CPT 0026U and 0287U)*	LCD: Biomarkers for Oncology (L35396)

POLICY GUIDELINES

Medicare and Medical Necessity

Laboratories performing tests in service areas which have adopted guidelines or coverage determinations made by the Medicare Molecular Diagnostics (MolDX) Program contractor are required to submit a technology assessment (TA) to establish analytical and clinical validity (AV/CV) and clinical utility (CU). Supporting LCDs regarding TA reviews include, but are not limited to, the following:

- Laboratories in CA & NV: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L35160)

- Laboratories in NC, SC, GA, TN, AL, VA, & WV: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L35025)
- Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, & WY: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L36256)

Coverage or non-coverage determinations made by MolDX are maintained in the DEX™ Diagnostics Exchange registry catalog and are available for public viewing. Some tests are listed in the registry as being "Not covered." However, if a test does not have any coverage determination by the MolDX Program documented in the registry, then AV/CV and CU is considered to have **not** been established and the test is also considered not medically reasonable and necessary under *SSA §1862(a)(1)(A)* until a MolDX review is complete and coverage is indicated by MolDX or Noridian. Tests identified in this policy as not meeting this requirement will be denied as not medically reasonable or necessary for Medicare under *SSA §1862(a)(1)(A).*

BILLING GUIDELINES

See related local coverage articles (LCAs) for additional coding and billing assistance.

- LCA: Billing and Coding: MolDX: NRAS Genetic Testing (A57487)
- LCA: Billing and Coding: Biomarkers for Oncology (A52986)

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
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 to high risk of malignancy *(For the ThyraMir, by Interpace Diagnostics)*
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 ("Positive, high probability of malignancy" or "Negative, low probability of malignancy") *(For the Thyroseq Genomic Classifier, by CBL Path Inc.)*
~~0208U~~	TERMED 12/31/2021 ~~Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma *(For the Afirma Medullary Thyroid Carcinoma [MTC] Classifier, by Veracyte Inc.)*~~
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 *(For the ThyGeNEXT® test, by Interpace Diagnostics)*

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) *(For the ThyroSeq® CRC, by CBL Path, Inc.)*
81311	NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)
81401	Molecular Pathology Procedure Level 2
81403	Molecular Pathology procedure, Level 4
81404	Molecular Pathology Procedure, Level 5
81405	Molecular Pathology Procedure, Level 6
81406	Molecular Pathology Procedure, Level 7
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
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) *(For the updated Afirma Genomic Sequence Classifier [GSC] test, by Veracyte)*
No Prior Authorization Required	
81210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)
Not Covered	
0204U	Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected *(For the Afirma Xpression Atlas, by Veracyte Inc.)*
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
81479	Unlisted molecular pathology procedure
81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.