Medical Coverage Policy | Laboratory Testing
Investigational Services

EFFECTIVE DATE: 08|01|2025
POLICY LAST REVIEWED: 04|02|2025

OVERVIEW

There are numerous commercially available genetic and molecular diagnostic, prognostic, and therapeutic tests for individuals with certain diseases or asymptomatic individuals with future risk. This review relates to genetic and molecular diagnostic tests not addressed in a separate review. If a separate evidence review exists, then conclusions reached there supersede conclusions here. The main criterion for inclusion in this review is the limited evidence on the clinical utility for the test. As these tests do not have clinical utility, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The following tests are addressed in this policy:

- Polygenic Risk Score (Many) (CPT code 81479)
- Apolipoprotein L1 (*APOL1*) Renal Risk Variant Genotyping (Quest Diagnostics) (CPT code 0355U)
- Thyroid GuidePx® (Protean Biodiagnostics) (CPT code 0362U)
- Oncuria® Detect (DiaCarta Clinical Lab) (CPT code 0365U)
- Oncuria® Monitor (DiaCarta Clinical Lab) (CPT code 0366U)
- Oncuria® Predict (DiaCarta Clinical Lab) (CPT code 0367U)
- Qlear UTI (Lifescan Labs of Illinois, Thermo Fisher Scientific) (CPT code 0371U)
- Qlear UTI - Reflex ABR (Lifescan Labs of Illinois, Thermo Fisher Scientific) (CPT code 0372U)
- ArteraAI Prostate Test (Artera Inc®, Artera Inc®) (CPT code 0376U)
- Liposcale® (CIMA Sciences, LLC) (CPT code 0377U)
- NaviDKD™ Predictive Diagnostic Screening for Kidney Health (Journey Biosciences, Inc) (CPT code 0384U)
- PromarkerD (Sonic Reference Laboratory, Proteomics International Pty Ltd) (CPT code 0385U)
- PEPredictDx (OncoOmicsDx Laboratory, mProbe) (CPT code 0390U)
- BTG Early Detection of Pancreatic Cancer (Breakthrough Genomics) (CPT code 0405U)
- CyPath® Lung (Precision Pathology Services/bioAffinity Technologies) (CPT code 0406U)
- Avantect Pancreatic Cancer Test (ClearNote Health) (CPT code 0410U)
- SmartVascular DX (SmartHealth DX) (CPT code 0415U)

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

There is no specific CPT coding for some of the services referenced in this policy. Therefore, an Unlisted CPT code should be used (see Coding Section for details). All Unlisted genetic testing CPT codes require prior authorization to determine what service is being rendered and if the service is covered or not medically necessary. See the Related Policies section.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

The following genetic or molecular tests to provide diagnostic, prognostic, therapeutic, or future risk assessment results are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products, as the evidence is insufficient to determine that the technology results in an improvement in net health outcome.

- Polygenic Risk Score

- Apolipoprotein L1 (*APOL1*) Renal Risk Variant Genotyping
- Thyroid GuidePx®
- Oncuria® Detect
- Oncuria® Monitor
- Oncuria® Predict
- Qlear UTI
- Qlear UTI - Reflex ABR
- Respiratory Pathogen with ABR (RPX)
- ArteraAI Prostate Test
- Liposcale®
- NaviDKD™ Predictive Diagnostic Screening for Kidney Health
- PromarkerD
- PEPredictDx
- BTG Early Detection of Pancreatic Cancer
- CyPath® Lung
- Avantect Pancreatic Cancer Test
- SmartVascular DX

Commercial Products
Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L. **§27-19-81** described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable laboratory benefits/coverage.

BACKGROUND
This policy applies if there is not a separate evidence review that outlines specific criteria for testing. If a separate evidence review does exist, then the criteria for medical necessity therein supersede the guidelines herein.

This policy addresses laboratory services considered to be investigational. These tests are often available on a clinical basis before the required and necessary evidence base to support clinical validity and utility is established. Because these tests are often proprietary, there may be no independent test evaluation data available in the early stages to support the laboratory's claims regarding test performance and utility. While studies using these tests may generate information that may help elucidate the biologic mechanisms of disease and eventually help design treatments, the tests listed in this policy are currently in a developmental phase, with limited evidence of clinical utility for diagnosis, prognosis, or risk assessment.

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

For individuals with various indications for diagnostic, prognostic, therapeutic, or future risk assessment testing who receive the genetic and molecular tests addressed in this review, the evidence on clinical utility is insufficient or non-evaluable. For each test addressed, a brief description is provided for informational purposes. No formal

evidence review was conducted. To sufficiently evaluate clinical utility, features of well-defined test, intended use, and clinical management pathway characteristics are summarized. If it is determined that enough evidence has accumulated to reevaluate its potential clinical utility, the test will be removed from this review and addressed separately. The lack of demonstrated clinical utility of these tests is based on the following factors: (1) there is no or extremely limited published data addressing the test; and/or (2) it is unclear where in the clinical pathway the test fits (replacement, triage, add-on); and/or (3) it is unclear how the test leads to changes in management that would improve health outcomes and/or avoiding existing burdensome and invasive testing; and/or (4) thresholds for decision making have not been established; (5) and/or the outcome from the test result does not result in a clinically meaningful improvement relative to the outcomes(s) obtained without the test.

CODING

Medicare Advantage Plans and Commercial Products

The following PLA codes are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

For Polygenic Risk Score CPT codes have not been assigned to the test. Therefore, an Unlisted code(s) should be used.

This code can be used for the Apolipoprotein L1 (*APOL1*) Renal Risk Variant Genotyping:

0355U APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)

This code can be used for the Thyroid GuidePx®

0362U Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture–enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, fine needle aspirate or formalin-fixed paraffin embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes

This code can be used for the Oncuria® Detect

0365U Oncology (bladder), 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1, and VEGFA) by immunoassays, urine, diagnostic, algorithm including patient's age, race and gender reported as a probability of harboring urothelial cancer (Text Revised Effective 1/1/2025)

This code can be used for the Oncuria® Monitor

0366U Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer.

This code can be used for Oncuria® Predict

0367U Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection.

This code can be used for Qlear UTI

0371U Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine

This code can be used for Qlear UTI - Reflex ABR

0372U Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score

This code can be used for ArteraAI Prostate Test

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

This code can be used for Liposcale®
0377U Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)

This code can be used for NaviDKD™ Predictive Diagnostic Screening for Kidney Health
0384U Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease

This code can be used for PromarkerD
0385U Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease

This code can be used for PEPredictDx
0390U Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score

This code can be used for BTG Early Detection of Pancreatic Cancer
0405U Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected

This code can be used for CyPath® Lung
0406U Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer

This code can be used for Avantect Pancreatic Cancer Test
04107U Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected

This code can be used for SmartVascular DX
0415U Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS

RELATED POLICIES
Biomarker Testing Mandate
Genetic Testing Services
Proprietary Laboratory Analyses (PLA)
Unlisted Procedures

PUBLISHED
Provider Update, June 2025
Provider Update, December 2024
Provider Update, November 2023

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