DRAFT Medical Coverage Policy | Laboratory Testing Investigational Services

EFFECTIVE DATE: 01|01|2024
POLICY LAST UPDATED: 10|02|2023

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)
- 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

Not applicable

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 (Many)
- Apolipoprotein L1 (*APOL1*) Renal Risk Variant Genotyping (Quest Diagnostics)
- Thyroid GuidePx® (Protean Biodiagnostics)
- Oncuria® Detect (DiaCarta Clinical Lab)
- Oncuria® Monitor (DiaCarta Clinical Lab)
- Oncuria® Predict (DiaCarta Clinical Lab)
- BTG Early Detection of Pancreatic Cancer (Breakthrough Genomics)
- CyPath® Lung (Precision Pathology Services/bioAffinity Technologies)
- Avantect Pancreatic Cancer Test (ClearNote Health)
- SmartVascular DX (SmartHealth 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 paraffinembedded (FFPE) tissue, algorithm reported as one of three molecular subtypes (Code text revision 10/01/2023)

This code can be used for the Oncuria® Detect
0365U 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 bladder cancer.

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 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 (New code effective 10/01/2023)

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 (New code effective 10/01/2023)

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 (New code effective 10/01/2023)

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 (New code effective 10/01/2023)

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

PUBLISHED

REFERENCES

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2. Quest Diagnostics. Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping. December 16, 2022; https://www.questdiagnostics.com/healthcare-professionals/clinical-education-center/faq/faq287#accordion-48070ca605- item-e92bca3e39. Accessed May 12, 2023.
3. Protean Biodiagnostics. Thyroid GuidePx. n.d.; https://www.proteanbiodx.com/thyroidguidepx. Accessed May 12, 2023.
4. Anger J, Lee U, Ackerman AL, et al. Recurrent Uncomplicated Urinary Tract Infections in Women: AUA/CUA/SUFU Guideline. J Urol. Aug 2019; 202(2): 282-289. PMID 31042112
5. Chang SS, Boorjian SA, Chou R, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline. J Urol. Oct 2016; 196(4): 1021-9. PMID 27317986
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Bladder Cancer Version 3.2023 May 25, 2023
7. Wand H, Lambert SA, Tamburro C, et al. Improving reporting standards for polygenic scores in risk prediction studies. Nature. Mar 2021; 591(7849): 211-219. PMID 3369255