MASSACHUSETTS

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Medical Policy

Laboratory Testing Investigational Services

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Policy Number: 165

BCBSA Reference Number: 2.04.159 (For Plan internal use only)
NCD/LCD: N/A

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Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

All tests listed in this policy are considered **INVESTIGATIONAL** as there is insufficient evidence to determine that the technology results in an improvement in the net health outcome.

Policy Guidelines

Test Name	Laboratory	PLA code
MicroGenDx	MicroGen Diagnostics	0112U See LCD for Medicare Advantage Biomarkers Overview (L35062)

Oncuria® Detect	DiaCarta Clinical Lab	0365U
Oncuria® Monitor	DiaCarta Clinical Lab	0366U
Oncuria® Predict	DiaCarta Clinical Lab	0367U
Qlear UTI	LifeScan Labs of Illinois, Thermo Fisher Scientific	0371U MP 045 Pathogen Panel Testing See LCD for Medicare Advantage MolDX: Molecular Diagnostic Tests (L35025)
Qlear UTI - Reflex ABR	LifeScan Labs of Illinois, Thermo Fisher Scientific	0372U MP 045 Pathogen Panel Testing See LCD for Medicare Advantage MolDX: Molecular Diagnostic Tests (L35025)
Respiratory Pathogen with ABR (RPX)	Lab Genomics LLC, Thermo Fisher Scientific	0373U MP 555 Identification of Microorganisms Using Nucleic Acid Probe See LCD for Medicare Advantage MolDX: Molecular Diagnostic Tests (L35025)
Urogenital Pathogen with Rx Panel (UPX)	Lab Genomics LLC, Thermo Fisher Scientific	0374U MP 045 Pathogen Panel Testing See LCD for Medicare Advantage MolDX: Molecular Diagnostic Tests (L35025)
ArteraAI Prostate Test	Artera Inc.	0376U
Liposcale Advanced Lipoprotein Test	CIMA Sciences LLC	0377U MP 283 Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease
NaviDKD® Predictive Diagnostic Screening for Kidney Health	Journey Biosciences, Inc	0384U

PromarkerD Diabetic Kidney Disease Risk Assessment	Sonic Reference Laboratory, Proteomics International	0385U
KawasakiDx™ (formerly PEPredictDx)	mProbe, Inc. (formerly OncoOmicsDx Laboratory)	0390U MP 163 Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
CyPath® Lung	Precision Pathology Services	0406U
SmartVascular Dx	SmartHealth DX	0415U
Prometheus® Crohn's Prognostic	Prometheus Laboratories	No specific code
Prometheus® IBD sgi Diagnostic®	Prometheus Laboratories	No specific code

Please refer to list of related evidence reviews for an assessment of other tests not listed in this policy.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene

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
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
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
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
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
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.
0386U	Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 methylation analysis, prognostic and predictive algorithm reported as a risk score for progression to high-grade dysplasia or esophageal cancer
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
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

Description

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.

Summary

Description

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.

Summary of Evidence
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.

Policy History

Date	Action
12/2024	Annual policy review. Policy updated with literature review through September 30, 2024; references added. Description for CPT code 0377U corrected in Policy Guidelines. Guidelines updated. Policy statement unchanged.
12/2023	Annual policy review. Policy updated with literature review through September 25, 2023. Policy statement unchanged. ▪ Codes 0376U, 0384U, 0385U, ongoing investigational were transferred from MP #400 Non-covered services list to MP #165. ▪ Codes 0368U, 0380U, 0405U, 0410U are managed by Carelon Genetic Testing program. Prior authorization is required through Carelon. These tests are managed by Carelon Genetic Testing program. Prior authorization is required through Carelon. ▪ Prometheus® Celiac PLUS ▪ DNA Methylation Pathway Profile ▪ know error®
10/2023	Coding information clarified.
8/2023	New medical policy describing ongoing investigational indications. Effective 8/2023. ▪ These investigational codes: 0112U; 0365U, 0366U, 0367U were transferred from MP #400 Non-covered services list to MP #165. ▪ Codes 0355U; 0362U are managed by Carelon Genetic Testing program. Prior authorization is required through Carelon.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Usereview.
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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