Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Laboratory Tests-Genetic, Molecular, and Other-Experimental/Investigational Status

Description/Background

The U.S. Food & Drug Administration defines laboratory tests as medical devices that are intended for use on samples of blood, urine, or other tissues or substances taken from the body to help diagnose disease or other conditions.[1]

Laboratory tests may detect the presence, absence, or amount of an analyte. Other tests reveal mutations in genes, or the presence of an infectious organism. Although we have the technology to test for many thousands of chemical or genetic substances, not every laboratory test is determined to be useful or necessary in medical care.[1]

Tests listed in Table 1 of this policy are discussed or listed in the associated medical policy or policies. This policy is a compilation of the test names that have been reviewed and determined to be experimental or investigational, based on medical policy status.

Regulatory Status

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

Medical Policy Statement

The tests listed in this policy have been determined to be Experimental/Investigational. They are not a covered benefit for all contracts that exclude reimbursement for investigational services.

Inclusionary and Exclusionary Guidelines

Note: Proprietary laboratory analyses tests are listed in a separate, related policy.

Exclusions:

Table 1. Laboratory Tests Determined by BCBSM Medical Policy to be Experimental/ Investigational

Note: This table list may not be all-inclusive.

Note: When the CPT code represents the Test Name, the code is considered E/I. Some CPT codes may be used for other testing that is considered established.

Test Name	Code(s)	Medical Policy
AdMark CSF Analysis	83520, 84999	Evaluation of Biomarkers for Alzheimer's Disease
AlloSure	81479	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
AlzheimAlert	81099, 86849	Evaluation of Biomarkers for Alzheimer's Disease
AlzoSure Predict	83520, 84999	Evaluation of Biomarkers for Alzheimer's Disease
Applied Genetics Cardiac Panel	81599, 84999	Cardiovascular Risk Panels
ARCHITECT HE4	86305	Serum Biomarker Human Epididymis Protein 4 (HE4)
ARK Methotrexate Assay	80204, 84999	Methotrexate (MTX) Polyglutamate Testing To Measure Response To Methotrexate Therapy
AVISE MTX	80204, 84999	Methotrexate (MTX) Polyglutamate Testing To Measure Response To Methotrexate Therapy
Axis-Shield HoloTC Assay (Active B-12 Test)	84999	Holotranscobalamin as a Marker of Vitamin B12 (Cobalamin) Status
BarreGEN	84999, 89240	Genetic Testing-Molecular Testing for the Diagnosis and Management of Pancreatic Cysts, Barrett Esophagus, and Solid Pancreaticobiliary Lesions (Eg, PathFinderTG, PancraGEN, BarreGEN)
BGM Galectin-3 Assay (Galectin-3 Assay, BG Medicine)	82777	Galectin-3 Testing in the Management of Chronic Heart Failure
BluePrint	S3854	Genetic Testing-Assays of Genetic Expression in Tumor Tissue as a Technique to Help Guide Decision-Making in Patients with Breast Cancer
BROCA Cancer Risk Panel	81479	Genetic Testing-Germline Genetic Testing for BRCA1, BRCA2, and PALB2 for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers, AND Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
Cardiac Panel	81599, 84999	Cardiovascular Risk Panels
Cardiac Risk Panel	81599, 84999	Cardiovascular Risk Panels
Cardiovascular Risk Panel	81599, 84999	Cardiovascular Risk Panels
CancerNext	81479	Genetic Testing-Genetic Cancer Susceptibility Panels Using Next Generation Sequencing

Cancer TYPE ID	81504, 81540	Genetic Testing-Microarray Testing for Cancers of Unknown Primary (CUP) Origin
Celiac PLUS (Prometheus)	81382, 82784, 83520, 86255 various	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests
CellMax-CRC Colorectal Cancer Early Detection Test	86152, 86153	Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (KRAS, NRAS,BRAF, NTRK, and HER2)
Cellsearch® CTC	86152, 86153	Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (KRAS, NRAS,BRAF, NTRK, and HER2)
cfDNA (Noninvasive prenatal screening for **microdeletions** using cell-free fetal DNA)	81422	Genetic Testing-Noninvasive Prenatal Screening for Fetal Aneuploides, Microdeletions, Single-Gene Disorders, and Twin Zygosity Using Cell-Free Fetal DNA
ColoNext	81479	Genetic Testing-Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
ColoPrint	81599, 84999, 88299	Genetic Testing-Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer (Eg, Coloprint, Colon PRS, GeneFx, OncoDefender, Oncotype Dx Colon Cancer Test)
Colon PRS	81599, 84999, 88299	Genetic Testing-Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer (Eg, Coloprint, Colon PRS, GeneFx, OncoDefender, Oncotype Dx Colon Cancer Test)
ColonSentry	81479	Genetic Testing-Serologic Genetic and Molecular Screening for Colorectal Cancer
ColoSeq Gene Panel	81479	Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
ColoVantage	81479	Genetic Testing-Serologic Genetic and Molecular Screening for Colorectal Cancer
Crohn's Prognostic (Prometheus)	83520, 86255 various	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests AND Serum Markers for the Diagnosis and Care of Inflammatory Bowel Disease
CV Health Plus Genomics Panel	81599, 84999	Cardiovascular Risk Panels
CV Health Plus Panel	81599, 84999	Cardiovascular Risk Panels
CVD Inflammatory Profile	81599, 84999	Cardiovascular Risk Panels
Cxbladder™Detect	81479, 0012M	Urinary Biomarkers for Bladder Cancer
Cxbladder™ Monitor	81479, 0013M	Urinary Biomarkers for Bladder Cancer
DCP (des-gamma-carboxy-prothrombin)	83591	Oncoprotein Des-gamma-carboxy Prothrombin (DCP) Immunoassay
DecisionDx-Melanoma	81479, 81529, 81599, 84999	Genetic Testing-Gene Expression Profiling for Cutaneous Melanoma
Dimension MPO Flex Reagent Cartridge	83876	Myeloperoxidase (MPO) Immunoassay for Cardiac Disease Risk
DNA Methylation Pathway Profile	81479, 84999 various	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests
Elecsys HE4	86305	Serum Biomarker Human Epididymis Protein 4 (HE4)
Enhanced Liver Fibrosis (ELF) test	81517	Noninvasive Techniques for the Evaluation and Monitoring of Patients With Chronic Liver Disease
Envisia™ Genomic Classifier	81479, 81554	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests
Epi proColon	81479	Genetic Testing-Serologic Genetic and Molecular Screening for Colorectal Cancer

eQ-PRC LightCycler Warfarin Genotype Kit	G9143, 81227, 81355	Genetic Testing-Genotype-Guided Warfarin Dosing
eSensor Warfarin Sensitivity Testing	G9143, 81227, 81355	Genetic Testing-Genotype-Guided Warfarin Dosing
FIBROSpect II	81599	Noninvasive Techniques for the Evaluation and Monitoring of Patients with Chronic Liver Disease
FirstSight	81479	Genetic Testing-Serologic Genetic and Molecular Screening for Colorectal Cancer
FMR2 (AFF2) variant testing	81171, 81172	Genetic Testing for FMR1 and FMR2 Variants (Including Fragile X and Fragile XE Syndromes)
Galleri (multicancer early detection test)	81479, 81599, 86849	Genetic Testing – Multicancer Early Detection Testing (eg, Galleri)
Genecept Assay	81225, 81226, 81227, 81230, 81231, 81291, 81401, 81479	Genetic Testing for Specified Conditions Using Testing Panels
GeneFX Colon	81599, 84999, 88299	Genetic Testing-Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer (Eg, Coloprint, Colon PRS, GeneFx, OncoDefender, Oncotype Dx Colon Cancer Test)
GeneSight Psychotropic Panel	81225, 81226, 81227, 81230, 81231, 81291, 81401, 81479	Genetic Testing for Specified Conditions Using Testing Panels
Genetiks Genetic Diagnosis and Research Center Cardiovascular Risk Panel	81599, 84999	Cardiovascular Risk Panels
GI Effects Stool Test	84999 various	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests
Guardant Reveal	81479	Genetic Testing-Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer (Eg, Coloprint, Colon PRS, GeneFx, OncoDefender, Oncotype Dx Colon Cancer Test)
Heartsbreath test	84999	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
HeartCare	81479	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
HE4 EIA	86305	Serum Biomarker Human Epididymis Protein 4 (HE4)
IBD sgi Diagnostic (Prometheus)	84999	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests, AND Serum Markers for the Diagnosis and Care of Inflammatory Bowel Disease
IDgenetix-branded tests	81225, 81226, 81227, 81230, 81231, 81291, 81401, 81479	Genetic Testing for Specified Conditions Using Testing Panels AND Genetic Testing for Pharmacogenomic Pain Management
Infiniti 2C9-VKORC1 Multiplex Assay for Warfarin	G9143, 81227, 81355	Genetic Testing-Genotype-Guided Warfarin Dosing
Know Error DNA test	81479, 84999	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests
Lumipulse G beta-amyloid	83520, 84999	Evaluation of Biomarkers for Alzheimer's Disease
Lumipulse G HE4	86305	Serum Biomarker Human Epididymis Protein 4 (HE4)
Macula Risk	81401, 81405, 81408, 81479	Genetic Testing for Macular Degeneration

Melaris	81404	Genetic Testing for Familial Cutaneous Malignant Melanoma (CDKN2A)
Mental Health DNA Insight panel	81225, 81226, 81227, 81230, 81231, 81291, 81401, 81479	Genetic Testing for Specified Conditions Using Testing Panels
Methotrexate	80204	Methotrexate (MTX) Polyglutamate Testing to Measure Response to Methotrexate Therapy
Millennium PGT (Pain Management) panel	81225, 81226, 81227, 81291, 81401, 81479	Genetic Testing for Pharmacogenetic Pain Management
miRview	81504, 81540	Genetic Testing-Microarray Testing for Cancers of Unknown Primary (CUP) Origin
MTHFR gene analysis	81291	Genetic Testing for Inherited Thrombophilias
My5-FU	84999, S3722	Genetic Testing-Genetic and Laboratory Testing for Use of 5-Fluorouracil in Patients with Cancer
myPath Melanoma	81479, 81529, 81599, 84999	Genetic Testing-Gene Expression Profiling for Cutaneous Melanoma
Myriad myRisk	81479	Genetic Testing-Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
Noonan Syndrome Genetic Testing	81442	Genetic Testing for Noonan Spectrum Disorders
OmePainMeds panel	81479	Genetic Testing for Pharmacogenetic Pain Management
OncoDefender	81599, 84999, 88299	Genetic Testing-Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer (Eg, Coloprint, Colon PRS, GeneFx, OncoDefender, Oncotype Dx Colon Cancer Test)
Oncoprotein DCP	83591	Oncoprotein Des-gamma-carboxy Prothrombin Immunoassay
Oncotype Dx Colon	81599, 84999, 88299	Genetic Testing-Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer (Eg, Coloprint, Colon PRS, GeneFx, OncoDefender, Oncotype Dx Colon Cancer Test)
PancraGEN	84999, 89240	Genetic Testing-Molecular Testing for the Diagnosis and Management of Pancreatic Cysts, Barrett Esophagus, and Solid Pancreaticobiliary Lesions (Eg, PathFinderTG, PancraGEN, BarreGEN)
PathFinder TG (includes any of the PathFinder TG tests (Barrett, biliary, pancreas, etc.)	84999, 89240	Genetic Testing-Molecular Testing for the Diagnosis and Management of Pancreatic Cysts, Barrett Esophagus, and Solid Pancreaticobiliary Lesions (Eg, PathFinderTG, PancraGEN, BarreGEN)
PathWork Tissue of Origin (FFPE)	81504, 81540	Genetic Testing-Microarray Testing for Cancers of Unknown Primary (CUP) Origin
PersonaGene Genetic Panel	81225, 81226, 81227, 81291, 81401, 81479	Genetic Testing for Pharmacogenomic Pain Management
PLAC Test	83698, 84999	Measurement of Lipoprotein-associated Phospholipase A2 (Lp-PLA2) and Secretory Type II Phospholipase A2 (sPLA2-IIA) in the Assessment of Cardiovascular Risk
Precivity	83520, 84999	Evaluation of Biomarkers for Alzheimer's Disease
Presage ST2 Assay	83006	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
PrognostiX CardioMPO	83876	Myeloperoxidase (MPO) Immunoassay for Cardiac Disease Risk
Prometheus Celiac PLUS	84999	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests

Prometheus Crohn's Prognostic Test	84999	Serum Markers for the Diagnosis and Care of Inflammatory Bowel Disease AND Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests
Prometheus IBD sgi Diagnostic	84999	Serum Markers for the Diagnosis and Care of Inflammatory Bowel Disease AND Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests
Proove Opioid Risk Panel	81225, 81226, 81227, 81291, 81401, 81479	Genetic Testing for Specified Conditions Using Testing Panels
Prospera™	81479	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
Prostate Core Mitomics Test	81479	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
Rapid Genotyping Assay	G9143, 81227, 81355	Genetic Testing-Genotype-Guided Warfarin Dosing
RetnaGene AMD	81401, 81405, 81408, 81479	Genetic Testing for Macular Degeneration
Rosetta Cancer Origin	81504, 81540	Genetic Testing-Microarray Testing for Cancers of Unknown Primary (CUP) Origin
RosettaGX Reveal	81479	Genetic Testing-Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid
Salivary Hormone Testing	S3650, S3652 (See policy for additional codes)	Salivary Testing for Hormone Levels
SEPT9 DNA methylation assay	81327	Genetic Testing-Serologic Genetic and Molecular Screening for Colorectal Cancer
SLCO1B1 Testing	81328	Genetic Testing for Statin-Induced Myopathy
SOMAmer	0019M	Cardiovascular Risk Panels
STA^{2}R test	81225, 81226, 81227, 81230, 81231, 81291, 81401, 81479	Genetic Testing for Specified Conditions Using Testing Panels
TDx/TDxFlx Assay	80204, 84999	Methotrexate (MTX) Polyglutamate Testing To Measure Response To Methotrexate Therapy
Telomerase Reverse Transcriptase (TERT)	81479	Genetic Testing-Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid
TGFBI Gene Analysis	81333	Genetic Testing-Gene Analysis for Corneal Dystrophy
Verigene Warfarin Metabolism Nucleic Acid	G9143, 81227, 81355	Genetic Testing-Genotype-Guided Warfarin Dosing
Vectra DA	81490	Multi-Biomarker Disease Activity (MBDA) Laboratory Testing (eg, Vectra DA Blood Test) for Rheumatoid Arthritis
Veracyte (Envisia™ Genomic Classifier)	81479	Genetic Testing-Miscellaneous and Genetic and Molecular Diagnostic Tests
VeriStrat	81538, 84999	Genetic Testing-Proteomic Testing for Non-Small-Cell Lung Cancer
Vistara	81479	Genetic Testing-Noninvasive Prenatal Screening for Fetal Aneuploidies, Microdeletions, Single-Gene Disorders, and Twin Zygosity Using Cell-Free Fetal DNA
VKOR1 gene analysis	81355	Genetic Testing-Genotype-Guided Warfarin Dosing
YouScript® Analgesic Panel	81225, 81226, 81227, 81291, 81401, 81479	Genetic Testing for Pharmacogenetic Pain Management

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

Multiple codes. Refer to Table 1. Under the exclusionary guidelines.

Rationale

ACCE Model Project
The Centers for Disease Control and Prevention's (CDC) Office of Public Health Genomics established and supported the ACCE Model Project, which from 2000 to 2004 developed an analytical process for evaluating scientific data on emerging genetic tests.[2] ACCE takes its name from the four main criteria for evaluating a genetic test: analytic validity, clinical validity, clinical utility and associated ethical, legal and social implications. The ACCE Project piloted an evidence evaluation framework of 44 questions, which defines the scope of the review (ie, disorder, genetic test, clinical scenario) and addresses the components of evaluation: analytic and clinical validity, clinical utility and associated ethical, legal, and social implications.

Analytic validity: The accuracy with which a particular genetic characteristic, such as a DNA sequence variant, chromosomal deletion, or biochemical indicator, is identified in a particular laboratory test. This includes the specific technical requirements of the assay, its reliability, the degree to which reliability varies from laboratory to laboratory, and the complexity of test interpretation. This refers to the technical performance of the test in test quality and reproducibility.[2,3]

Clinical validity: The accuracy with which a genetic test identifies or predicts a particular clinical condition or phenotype. It is described in terms of sensitivity (among those with a specific condition, the proportion who have a positive test result), specificity (among those who do not have the condition, the proportion who have a negative test result), positive predictive value (among those with a positive test result, the proportion who have the condition), and negative predictive value (among those with a negative test result, the proportion who do not have the condition). This refers to how well the variant accurately and reliably predicts the clinical disease.[2,3]

Clinical utility: The evidence that the genetic test improves clinical outcomes or has added value for patient management decisions. Clinical trials and studies show the test added value to standard care.[2,4]

The tests listed in Table 1 have not demonstrated definitive analytic validity, clinical validity and clinical utility; nor have they demonstrated a definitive and consistent impact on clinical outcomes. While some tests may provide information of interest or may involve interesting and useful technologies, the information obtained has not been definitively demonstrated to affect

clinical decision making or, ultimately, patient outcomes. Refer to the specific medical policy for test-specific information.

Government Regulations

Please refer to the MolDX: molecular diagnostic tests local coverage determinations at the Wisconsin Physicians Service (WPS) website for specific test coverage for Medicare.

www.wpsgha.com
Topic Center, Policies, Local Coverage Determinations (LCDs) and Billing and Coding/Policy Articles, Local Coverage Determination (LCD) and Billing and Coding/Policy Article Lookup

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [BCBSM, formerly HCFA] are updated and/or revised periodically. Therefore, the most current BCBSM information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Listed policies (in Table 1) for each individual test
- Genetic Testing and Counseling
- Proprietary Laboratory Analyses (PLA) Codes

References

1. U.S. Food & Drug Administration. Tests Used in Clinical Care. https://www.fda.gov/medical-devices/in-vitro-diagnostics/tests-used-clinical-care Accessed 01/06/25.
2. Centers for Disease Control and Prevention. ACCE Model Process for Evaluating Genetic Tests. Last reviewed December 28, 2010, archived.
3. Burke W. Genetic Tests: Clinical Validity and Clinical Utility. Curr Protoc Hum Genet. 2014; 81: 9.15.1-9.15.8. PMID 24763995
4. Bossuyt PM, et al. Beyond diagnostic accuracy: the clinical utility of diagnostic tests. Clin Chem. 2012; 58(12):1636-43. PMID 22730450

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January, 2025 the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/18	4/17/18	4/17/18	Joint policy established
10/1/18	10/16/18	10/16/18	Added CxBladder™ to policy.
12/11/18	12/12/18	12/12/18	Added Pigmented Lesion Assay, myPath Melanoma and DecisionDx-Melanoma to policy.
2/19/19	2/19/19		Added Apifiny, ExoDX Prostate Intelliscore, myTAI Heart, Prostate Health Index and SelectMDx to policy. Removed Thyroseq and Mammaprint.
4/16/19	4/16/19		Added cfDNA, noninvasive prenatal screening for microdeletions using cfDNA.
6/18/19	6/18/19		Added FMR2 variant testing and TERT testing to policy.
8/20/19	8/20/19		No additions/deletions.
10/15/19	10/15/19		Added: Target Selector ctDNA kit, CellMax-CRC Early Detection, CellSearch, ClearID solid tumor panel, FoundationOne Liquid, Guardant360®, Velox™, CancerIntercept® Detect, PlasmaSELECT, OncoBEAM, Theranostics and ATM.
12/17/19	12/17/19		Added Tumor Mutational Burden testing as E/I.
2/18/20	2/18/20		Added TGFBI testing (81333), Adalimumab (80145), Infliximab (80230) and Vedolilzumab testing (80280) to the policy as E/I.
4/14/20	4/14/20		Added codes 81522 and 81542 to policy as E/I.
6/16/20	6/16/20		No new codes added/deleted.
8/18/20	8/18/20		No new codes added/deleted.
10/20/20	10/20/20		No new codes added/deleted.
12/15/20	12/15/20		No new codes added/deleted.

2/16/21	2/16/21		Added SLCO1B1 testing for statin-induced myopathy, code 81328. Added Colvera (0229U) and Signatera (no specific code).
4/20/21	4/20/21		Added codes: 80204, 81529 and 0234U.
6/15/21	6/15/21		Removed codes 80145, 80230 and 80280 now established. Removed Decipher, OncotypeDX Prostate, Prolaris and ProMark, now established. Added codes 81513, 81514, 0113U, 0228U as E/I. Added Foundation One CDx (F1CDx), Foundation One CDx Heme Test to table.
8/17/21	8/17/21		No new codes added/deleted.
10/19/21	10/19/21		No new codes added/deleted.
12/14/21	12/14/21		Added SMART PGT-A testing as E/I.
2/15/22	2/15/22		Added Envisia™ (Veracyte™) code 81554, removed TMB, removed code 81455 as is now established. Veristrat is now E/I for all indications.
4/19/22	4/19/22		Removed 0005U, 0113U and 0037U as they are now established under certain circumstances.
6/1/22	6/21/22		Removed code 0239U as it is established per policy, *Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)*, EFD 9/1/22
8/16/22	8/16/22		Removed Mammostrat, BreastOncPX, NexCourse, Breast PRS tests from policy as they are no longer available.
10/18/22	10/18/22		Removed codes 81513 and 81514 for bacterial vaginosis testing as they are now covered. Added codes 0332U, 0333U, 0342U and 0351U as E/I.
12/20/22	12/20/22		No additions or deletions.
5/123	2/21/23		No additions or deletions.

7/1/23	4/18/23		Added code 0375U as E/I. Vendor managed: N/A. (ds)
9/1/23	6/13/23		No additions or deletions. (ds)
11/1/23	8/15/23		Added Guardant Reveal test as E/I. Removed several tests for prostate biomarkers using coded 81313 as they are covered tests. Vendor managed: N/A (ds)
1/1/24	10/17/23		Removed Gene trails, Illumine trusight, Memorial sloan kettering, MI profile, Pigmented lesion assay, Foundation one liquid, CHEK2, and Guardant360. Vendor managed: N/A (ds)
3/1/24	12/19/23		Title change from: "Genetic, Molecular, and Other Tests – Experimental/Investigational Status" to: "Laboratory Tests – Genetic, Molecular, and Other – Experimental/Investigational Status" Table 1 updates: removed all PLA codes; removed FDA status; removed and added multiple tests (full list noted on the cover page for this review); updated medical policy titles. Per medical policy updates, added tests: BRACAnalysis CDx, and Vistara. Background and Rationale sections updated. Post-JUMP: Additional deletions of tests not found on related JUMP policies. (ls)
5/1/24	2/20/24		Deleted tests: ImmunoGenomic Profile and ResponseDX: Colon. "Prometheus" added to Crohn's Prognostic and IBD sgi Diagnostic Galleri test added, Veracyte (Envisia Genomic Classifier) added. (ls) 2/29/24: BRACAnalysis CDx was placed on this policy Dec 23 in error. Removed from this policy. (ls)
7/1/24	4/16/24		Per JUMP policy updates: • 81265, 81266 added for the Know Error test. (ls)
9/1/24	6/11/24		Per JUMP policy updates: • SOMAmer test (0019M) added • Enhanced Liver Fibrosis (ELF) test (81517) added

			• FIBROSpect II test (81599) added • Elecsys amyloid tests (83520, 84999) deleted • Heartsbreath billing code corrected to 84999; PLAC test billing code 0423T deleted. • Extreme Drug Resistance Assay: 87230, 88104, 88305, 88313, 88358, 89050 removed from code section. (ls)
11/1/24	8/20/24		Statement added to table: “When the CPT code represents the Test Name, the code is considered E/I. Some CPT codes may be used for other testing that is considered established.” References updated. (ls)
1/1/25	10/15/24		• 81403 deleted (SensiGene Fetal RHD); policy “Genetic Testing-Noninvasive Prenatal Testing for Fetal RBC Antigen Status” updated, states this code is established. (ls)
3/1/25	12/17/24		• Tests removed from policy, as a result of JUMP policy retirement: Adenosine Triphosphate Bioluminescence Assay, ChemoFx, CorrectChemo Assay, DiSC Assay, EVA/PCD Assay, Extreme Drug Resistance Assay, Fluorometric microculture cytotoxicity assay, Histoculture Drug Resistance Assay, Microculture Kinetic Assay, Tritiated thymine incorporation; • Tests removed from policy due to new PLA codes: DCISionRT, BreastNext, OvaNext • Other tests removed: iGene Cancer Panel, ThXID-BRAF Kit, Boston Heart Cardiovascular Risk Panel • Tests added: RetnaGene AMD, RosettaGX Reveal (ls)
5/1/25	2/18/25		• No additions or deletions. (ls)

Next Review Date: Every JUMP meeting