
Medical Policy



Blue Cross
Blue Shield
Blue Care Network
of Michigan

Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Proprietary Laboratory Analyses (PLA) Codes

Description/Background

Proprietary Laboratory Analyses (PLA) codes are a part of the overall code sets developed and released by the American Medical Association – Current Procedural Terminology (AMA-CPT) Editorial Panel. They are alpha-numeric codes consisting of four numbers ending in a capital U. They are meant to represent specific laboratory tests developed by a proprietary laboratory.

The PLA Code section includes Advanced Diagnostic Laboratory Tests (ADLTs) and Clinical Diagnostic Laboratory Tests (CDLTs). These analyses may include a range of medical laboratory tests including Multianalyte Assays with Algorithmic Analyses (MAAA) and Genomic Sequencing Procedures (GSP).¹

PLA codes were established by the American Medical Association in response to laboratories and manufacturers that were seeking a way to more specifically identify their testing. The creation of these codes was also an answer to the implementation of the Protecting Access to Medicare Act of 2014 (PAMA). In the final rule for PAMA implementation, the Centers for Medicare and Medicaid Services (CMS) established the definition of advanced diagnostic laboratory tests (ADLTs) as tests created and offered by a single lab that use a unique algorithm to analyze multiple DNA, RNA, or protein markers, and which provide new clinical diagnostic information that cannot be obtained by any other test. Tests assigned to PLA codes must meet two specific criteria: the tests must be performed on human specimens; and, the PLA code must be requested by the manufacturer or clinical laboratory that offers the test.²

PLA codes describe proprietary clinical laboratory analyses and may be provided by “one, sole source” laboratory or may be licensed or marketed to multiple laboratories that have been

cleared or approved by the U.S. Food and Drug Administration, and are able to provide the analysis.

Generally, when a PLA code is released, there is limited information that clearly demonstrates that clinical validity or clinical utility have been proven or, that a definitive positive incremental impact on clinical outcomes has been established. PLA codes are updated and released quarterly by the AMA.

Regulatory Status

N/A

Medical Policy Statement

PLA codes are considered experimental/investigational until the laboratory test the code represents is formally documented as Established.

Established CPT codes may be used to represent and reimburse testing for incremental codes or multi-target codes.

Inclusionary and Exclusionary Guidelines

N/A

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:

Multiple

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

Multiple

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Proprietary panels include gene targets that have been proven to be clinically useful in the diagnosis of certain conditions. However, the tests also include gene targets of uncertain or

unproven clinical significance. While it can be argued that selected gene targets have been proven to impact clinical outcomes and contribute to clinical decision making, it is not always clear to what extent there is incremental value to the addition of genes of uncertain or unproven clinical utility in justifying the use of specific panels (with assigned PLA codes) versus identifying the proven genes related to the condition(s) of interest and billing a CPT code that references the number of targets being analyzed as opposed to a proprietary combination.

At the time PLA codes are released, there is very little clinical information available for review to ascertain the demonstrated value of the testing and to what extent “the panel itself” (not the included targets with known proven clinical value) supports clinical decision making or has demonstrated a definitive positive impact on clinical outcomes.

Table 1. PLA Codes and Coverage Status

Proprietary Laboratory Analyses (PLA) codes that have a status of experimental/investigational are excluded from coverage due to lack of literature establishing clinical efficacy, safety, or applicability to clinical practice.

Notes:

- **“Payable” in the JUMP Medical Policy Title column denotes that the code is payable in BCBSM/BCN systems, but is not associated with a JUMP medical policy.**
- **A blank field in the “JUMP Medical Policy Title” column denotes there is no associated JUMP medical policy.**

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Code Status (EI or EST)	JUMP Medical Policy Title
0001U	PreciseType® HEA Test	Immucor, Inc	EI	
0002U	PolypDX™	Atlantic Diagnostic Laboratories, LLC, Metabolomic Technologies, Inc	EI	Polymetabolite Urine Testing for Adenomatous Polyps
0003U	Overa (OVA1 Next Generation)	Aspira Labs, Inc, Vermillion, Inc	EST	Multimarker Serum Testing Related to Ovarian Cancer (e.g., OVA1, Overa, OvaWatch and ROMA testing)
0005U	ExosomeDx® Prostate (IntelliScore)	Exosome Diagnostics, Inc, Exosome Diagnostics, Inc	EST	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0007U	ToxProtect	Genotox Laboratories LTD	EST	Payable
0008U	AmHPR® H. pylori Antibiotic Resistance Panel	American Molecular Laboratories, Inc	EI	
0009U	DEPArray™ HER2	PacificDx	EI	
0010U	Bacterial Typing by Whole Genome Sequencing	Mayo Clinic	EI	

0011U	Cordant CORE™	Cordant Health Solutions	EI	
0016U	BCR-ABL1 major and minor breakpoint fusion transcripts	University of Iowa, Department of Pathology, Asuragen	EST	Genetic Testing-BCR/ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia
0017U	JAK2 Mutation	University of Iowa, Department of Pathology	EST	Genetic Testing-JAK2, MPL and CALR Testing for Myeloproliferative Neoplasms
0018U	ThyraMIR™	Interpace Diagnostics	EST	Genetic Testing-Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid
0019U	OncoTarget/OncoTreat	Columbia University Department of Pathology and Cell Biology, Darwin Health	EI	
0021U	Apifiny®	Armune BioScience, Inc	EI	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0022U	Oncomine™ Dx Target Test	Thermo Fisher Scientific, Thermo Fisher Scientific	EST	Genetic Testing-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0023U	LeukoStrat®CDx <i>FLT3</i> Mutation Assay	LabPMM LLC, an Invivoscribe Technologies, Inc Company, Invivoscribe Technologies, Inc	EST	Payable
0024U	GlycA	Laboratory Corporation of America, Laboratory Corporation of America	EI	
0025U	UrSure Tenofovir Quantification Test	Synergy Medical Laboratories, UrSure Inc	EI	
0026U	Thyroseq Genomic Classifier	CBLPath, Inc, University of Pittsburgh Medical Center	EST	Genetic Testing-Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid
0027U	JAK2 Exons 12 to 15 Sequencing	Mayo Clinic, Mayo Clinic	EST	Genetic Testing-JAK2, MPL and CALR Testing for Myeloproliferative Neoplasms
0029U	Focused Pharmacogenomics Panel	Mayo Clinic, Mayo Clinic	EI	Genetic Testing for Specified Conditions Using Testing Panels
0030U	Warfarin Response Genotype	Mayo Clinic, Mayo Clinic	EI	
0031U	Cytochrome P450 1A2 Genotype	Mayo Clinic, Mayo Clinic	EI	Genetic Testing for Specified Conditions Using Testing Panels
0032U	Catechol-O-Methyltransferase (COMT) Genotype	Mayo Clinic, Mayo Clinic	EI	Genetic Testing for Specified Conditions Using Testing Panels

0033U	Serotonin Receptor Genotype (<i>HTR2A</i> and <i>HTR 2C</i>)	Mayo Clinic, Mayo Clinic	EI	Genetic Testing for Specified Conditions Using Testing Panels
0034U	Thiopurine Methyltransferase (<i>TPMT</i>) and Nudix Hydrolase (<i>NUDT15</i>)	Mayo Clinic, Mayo Clinic	EST	Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines
0035U	Real-time quaking-induced conversion for prion detection (RT-QuIC)	National Prion Disease Pathology Surveillance Center	EI	
0036U	ExaCT-1 Whole Exome Testing	Lab of Oncology-Molecular Detection, Weill Cornell Medicine-Clinical Genomics Laboratory	EI	
0037U	FoundationOne CDx™ (F1CDx)	Foundation Medicine, Inc, Foundation Medicine, Inc	EST	<p>Genetic Testing-NGS Testing of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions</p> <p>Gene Expression Profile Analysis for Risk Stratification for Prostate Cancer Management</p> <p>Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (<i>KRAS</i>, <i>NRAS</i>, <i>BRAF</i>, <i>NTRK</i> and <i>HER2</i>)</p> <p>Genetic Testing-<i>BRAF/NTRK</i> Mutation in Selecting Melanoma Patients for Targeted Therapy Including Liquid Biopsy</p> <p>Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (<i>BRCA1</i>, <i>BRCA2</i>, Homologous Recombination Deficiency, <i>NTRK</i>)</p> <p>Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (<i>BRCA1/2</i>, Homologous Recombination Repair Gene Alterations, <i>NTRK</i> Gene Fusion)</p> <p>Genetic Testing-Somatic Biomarker Testing for Immune Checkpoint Inhibitor Therapy (<i>BRAF</i>, MSI/MMR, PD-L1, TMB)</p> <p>Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Non-Small-Cell Lung Cancer (<i>EGFR</i>, <i>ALK</i>, <i>ROS1</i>, <i>TET</i>, <i>MET</i>, <i>KRAS</i>, <i>HER2</i>, PD-L1, TMB)</p>

0038U	Sensieva™ Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay	InSource Diagnostics, InSource Diagnostics	EI	
0039U	Anti-dsDNA, High Salt/Avidity	University of Washington, Department of Laboratory Medicine, Bio-Rad	EST	Payable
0040U	MRDx BCR-ABL Test	MolecularMD, MolecularMD	EST	Genetic Testing-BCR/ABL 1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia
0041U	Lyme ImmunoBlot IgM	IgeneX Inc, ID-FISH Technology Inc (ASR) (Lyme ImmunoBlot IgM Strips Only)	EST	Payable
0042U	Lyme ImmunoBlot IgG	IgeneX Inc, ID-FISH Technology Inc (ASR) (Lyme ImmunoBlot IgG Strips Only)	EST	Payable
0043U	Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgM Test	IgeneX Inc, ID-FISH Technology Inc (Provides TBRF ImmunoBlot IgM Strips)	EST	Payable
0044U	Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgG Test	IgeneX Inc, ID-FISH Technology Inc (Provides TBRF ImmunoBlot IgG Strips)	EST	Payable
0045U	The Oncotype DX® Breast DCIS Score™ Test	Genomic Health, Inc, Genomic Health, Inc	EI	Genetic Testing-Assays of Genetic Expression in Tumor Tissue as a Technique to Help Guide Decision-Making in Patients With Breast Cancer
0046U	FLT3 ITD MRD by NGS	LabPMM LLC, an Invivoscribe Technologies, Inc Company	EST	Payable
0047U	Genomic Prostate Score® (GPS) Test	MDxHealth, Inc, MDxHealth, Inc	EST	Gene Expression Profile Analysis for Risk Stratification for Prostate Cancer Management
0048U	MSK-IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets)	Memorial Sloan Kettering Cancer Center	EI	Genetic Testing-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0049U	NPM1 MRD by NGS	LabPMM LLC, an Invivoscribe Technologies, Inc Company	EST	Payable
0050U	MyAML NGS Panel	LabPMM LLC, an Invivoscribe Technologies, Inc Company	EI	

0051U	UcompliDx	Elite Medical Laboratory Solutions, LLC, Elite Medical Laboratory Solutions, LLC (LDT)	EI	
0052U	VAP Cholesterol Test	VAP Diagnostics Laboratory, Inc, VAP Diagnostics Laboratory, Inc	EI	Nontraditional Biomarkers in Risk Assessment and Management of Cardiovascular Disease
0054U	AssuranceRx Micro Serum	Firstox Laboratories, LLC, Firstox Laboratories, LLC	EI	
0055U	myTAIHEART	TAI Diagnostics, Inc TAI Diagnostics, Inc	EI	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
0058U	Merkel SmT Oncoprotein Antibody Titer	University of Washington, Department of Laboratory Medicine	EI	
0059U	Merkel Virus VP1 Capsid Antibody	University of Washington, Department of Laboratory Medicine	EI	
0060U	Twins Zygosity PLA	Natera, Inc, Natera, Inc	EI	Genetic Testing-Noninvasive Prenatal Screening for Fetal Aneuploidies, Microdeletions, Single-Gene Disorders, and Twin Zygosity Using Cell-Free Fetal DNA
0061U	Transcutaneous multispectral measurement of tissue oxygenation and hemoglobin using spatial frequency domain Imaging (SFDI)	Modulated Imaging, Inc, Modulated Imaging, Inc	EI	
0062U	SLE-key® Rule Out	Veracis Inc, Veracis Inc	EI	
0063U	NPDX ASD ADM Panel I	Stemina Biomarker Discovery, Inc, Stemina Biomarker Discovery, Inc d/b/a NeuroPointDX	EI	
0064U	BioPlex 2200 Syphilis Total & RPR Assay	Bio-Rad Laboratories, Bio-Rad Laboratories	EST	Payable
0065U	BioPlex 2200 RPR Assay	Bio-Rad Laboratories, Bio-Rad Laboratories	EST	Payable
0067U	BBDRisk Dx™	Silbiotech, Inc, Silbiotech, Inc	EI	

0068U	MYCODART-PCR™ Dual Amplification Real Time PCR Panel for 6 Candida species	RealTime Laboratories, Inc/MyoDART, Inc, RealTime Laboratories, Inc	EST	Payable
0069U	miR-31now™	GoPath Laboratories, GoPath Laboratories	EI	
0070U	CYP2D6 Common Variants and Copy Number	Mayo Clinic, Laboratory Developed Test	EI	Genetic Testing for Specified Conditions Using Testing Panels
0071U	CYP2D6 Full Gene Sequencing	Mayo Clinic, Laboratory Developed Test	EI	Genetic Testing for Specified Conditions Using Testing Panels
0072U	CYP2D6-2D7 Hybrid Gene Targeted Sequence Analysis	Mayo Clinic, Laboratory Developed Test	EI	Genetic Testing for Specified Conditions Using Testing Panels
0073U	CYP2D7-2D6 Hybrid Gene Targeted Sequence Analysis	Mayo Clinic, Laboratory Developed Test	EI	Genetic Testing for Specified Conditions Using Testing Panels
0074U	CYP2D6 trans-duplication/multiplication non-duplicated gene targeted sequence analysis	Mayo Clinic, Laboratory Developed Test	EI	Genetic Testing for Specified Conditions Using Testing Panels
0075U	CYP2D6 5' gene duplication/multiplication targeted sequence analysis	Mayo Clinic, Laboratory Developed Test	EI	Genetic Testing for Specified Conditions Using Testing Panels
0076U	CYP2D6 3' gene duplication/multiplication targeted sequence analysis	Mayo Clinic, Laboratory Developed Test	EI	Genetic Testing for Specified Conditions Using Testing Panels
0077U	M-Protein Detection and Isotyping by MALDI-TOF Mass Spectrometry	Mayo Clinic, Laboratory Developed Test	EST	Payable
0079U	ToxLok™	InSource Diagnostics, InSource Diagnostics	EI	
0080U	BDX-XL2	Biodesix®, Inc, Biodesix®, Inc	EI	Molecular Testing in the Management of Pulmonary Nodules
0082U	NextGen Precision™ Testing	Precision Diagnostics, Precision Diagnostics LBN Precision Toxicology, LLC	EI	
0083U	Onco4D™	Animated Dynamics, Inc, Animated Dynamics, Inc	EI	
0084U	BLOODchip® ID CORE XT™	Grifols Diagnostic Solutions Inc	EI	

0086U	Accelerate PhenoTest™ BC kit	Accelerate Diagnostics, Inc	EI	
0087U	Molecular Microscope® MMDx-Heart	Kashi Clinical Laboratories	EI	
0088U	Molecular Microscope® MMDx-Kidney	Kashi Clinical Laboratories	EI	Transplant-Kidney
0089U	Pigmented Lesion Assay (PLA)	DermTech	EST	Gene Expression Profiling for Cutaneous Melanoma
0090U	myPath® Melanoma	Castle Biosciences, Inc	EI	
0091U	FirstSightCRC™	CellMax Life	EI	Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)
0092U	REVEAL Lung Nodule Characterization	MagArray, Inc	EI	Molecular Testing in the Management of Pulmonary Nodules
0093U	ComplyRX	Claro Labs	EST	Payable
0094U	RCIGM Rapid Whole Genome Sequencing	Rady Children's Institute for Genomic Medicine (RCIGM)	EST	Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0095U	Esophageal String Test™ (EST)	Children's Hospital Colorado Department of Pathology and Laboratory Medicine	EI	
0096U	HPV, High-Risk, Male Urine	Molecular Testing Labs	EI	
0101U	ColoNext®	Ambry Genetics®, Ambry Genetics®	EI	
0102U	BreastNext®	Ambry Genetics®, Ambry Genetics®	EI	Genetic Testing for Li-Fraumeni Syndrome Germline Genetic Testing for <i>BRCA1</i> , <i>BRCA2</i> , and <i>PALB2</i> for Hereditary Breast/Ovarian Cancer Syndrome and Associated High-Risk Cancers
0103U	OvaNext®	Ambry Genetics®, Ambry Genetics®	EI	Germline Genetic Testing for <i>BRCA1</i> , <i>BRCA2</i> , and <i>PALB2</i> for Hereditary Breast/Ovarian Cancer Syndrome and Associated High-Risk Cancers
0105U	KidneyIntelX™	RenalytixAI, RenalytixAI	EI	
0106U	13C-Spirulina Gastric Emptying Breath Test (GEBT)	Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC, Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC	EI	
0107U	Singulex Clarity C. diff toxins A/B assay	Singulex	EST	Payable
0108U	TissueCypher® Barrett's Esophagus Assay	Ceranostics, Ceranostics	EI	

0109U	MYCODART-PCR™ Dual Amplification Real Time PCR Panel for 4 Aspergillus species	RealTime Laboratories, Inc/MycoDART, Inc	EI	
0110U	Oral OncolyticAssuranceRX	Firstox Laboratories, LLC, Firstox Laboratories, LLC	EI	
0111U	Praxis™ Extended RAS Panel	Illumina, Illumina	EST	Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (<i>KRAS</i> , <i>NRAS</i> , <i>BRAF</i> , <i>NTRK</i> and <i>HER2</i>)
0112U	MicroGenDX qPCR & NGS For Infection	MicroGenDX, MicroGenDX	EI	
0113U	MyProstateScore	Lynx DX, Lynx DX	EST	Payable
0114U	EsoGuard™	Lucid Diagnostics, Lucid Diagnostics	EI	
0115U	ePlex Respiratory Pathogen (RP) Panel	GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	EI	Identification of Microorganisms Using Nucleic Acid Probes
0116U	Snapshot Oral Fluid Compliance	Ethos Laboratories	EI	
0117U	Foundation PI SM	Ethos Laboratories	EI	
0118U	Eurofins TRAC™ dd-cfDNA	Transplant Genomics Inc, Transplant Genomics, Inc	EI	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
0119U	MI-HEART Ceramides, Plasma	Mayo Clinic, Laboratory Developed Test	EI	
0120U	Lymph3Cx Lymphoma Molecular Subtyping Assay	Mayo Clinic, Laboratory Developed Test	EI	
0121U	Flow Adhesion of Whole Blood on VCAM-1 (FAB-V)	Functional Fluidics, Functional Fluidics	EI	
0122U	Flow Adhesion of Whole Blood to P-SELECTIN (WB-PSEL)	Functional Fluidics, Functional Fluidics	EI	
0123U	Mechanical Fragility, RBC by shear stress profiling and spectral analysis	Functional Fluidics, Functional Fluidics	EI	

0129U	BRCAplus	Ambry Genetics	EI	<p>Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (<i>BRCA1</i>, <i>BRCA2</i>, Homologous Recombination Deficiency, <i>NTRK</i>)</p> <p>Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (<i>BRCA1/2</i>, Homologous Recombination Repair Gene Alterations, <i>NTRK</i> Gene Fusion)</p> <p>Germline Genetic Testing for <i>BRCA1</i>, <i>BRCA2</i>, and <i>PALB2</i> for Hereditary Breast/Ovarian Cancer Syndrome and Associated High-Risk Cancers</p>
0130U	+RNAinsight™ for ColoNext®	Ambry Genetics	EI	
0131U	+RNAinsight™ for BreastNext®	Ambry Genetics	EI	Genetic Testing for Li-Fraumeni Syndrome
0132U	+RNAinsight™ for OvaNext®	Ambry Genetics	EI	
0133U	+RNAinsight™ for ProstateNext®	Ambry Genetics	EI	
0134U	+RNAinsight™ for CancerNext®	Ambry Genetics	EI	
0135U	+RNAinsight™ for GYNPlus®	Ambry Genetics	EI	
0136U	+RNAinsight™ for ATM	Ambry Genetics	EI	
0137U	+RNAinsight™ for <i>PALB2</i>	Ambry Genetics	EI	
0138U	+RNAinsight™ for <i>BRCA1/2</i>	Ambry Genetics	EI	
0140U	ePlex® BCID Fungal Pathogens Panel	GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	EI	
0141U	ePlex® BCID Gram-Positive Panel	GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	EI	
0142U	ePlex® BCID Gram-Negative Panel	GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	EI	
0152U	Karius® Test	Karius Inc, Karius Inc	EI	
0153U	Insight TNBCtype™	Insight Molecular Labs	EI	Genetic Testing-Assays of Genetic Expression in Tumor Tissue as a Technique to Help Guide Decision-Making in Patients With Breast Cancer

0154U	therascreen® <i>FGFR</i> RGQ RT-PCR Kit	QIAGEN QIAGEN GmbH	EI	
0155U	therascreen® <i>PIK3CA</i> RGQ RT-PCR Kit	QIAGEN QIAGEN GmbH	EST	Payable
0156U	SMASH™	New York Genome Center, Marvel Genomics™	EI	<p>Genetic Testing-Chromosomal Microarray (CMA) Analysis and Next-Generation Sequencing Panels, for the Evaluation of Children with Developmental Delay/Intellectual Disability, Autism Spectrum Disorder, and/or Congenital Anomalies</p> <p>Genetic Testing-Chromosomal Microarray Testing for the Evaluation of Early Pregnancy Loss and Intrauterine Fetal Demise</p> <p>Genetic Testing for Specified Conditions Using Testing Panels</p>
0157U	CustomNext + RNA: <i>APC</i>	Ambry Genetics®, Ambry Genetics®	EI	
0158U	CustomNext + RNA: <i>MLH1</i>	Ambry Genetics®, Ambry Genetics®	EI	
0159U	CustomNext + RNA: <i>MSH2</i>	Ambry Genetics®, Ambry Genetics®	EI	
0160U	CustomNext + RNA: <i>MSH6</i>	Ambry Genetics®, Ambry Genetics®	EI	
0161U	CustomNext + RNA: <i>PMS2</i>	Ambry Genetics®, Ambry Genetics®	EI	
0162U	CustomNext + RNA: Lynch (<i>MLH1, MSH2, MSH6, PMS2</i>)	Ambry Genetics®, Ambry Genetics®	EI	
0163U	BeScreened™-CRC	Beacon Biomedical Inc, Beacon Biomedical Inc	EI	Serologic Genetic and Molecular Screening for Colorectal Cancer
0164U	ibs-smart™	Gemelli Biotech, Gemelli Biotech	EI	
0165U	VeriMAP™ Peanut Dx – Bead-based Epitope Assay	AllerGenis™ Clinical Laboratory, AllerGenis™ LLC	EI	
0166U	LiverFAST™	Fibronostics	EI	
0169U	NT (<i>NUDT15</i> and <i>TPMT</i>) genotyping panel	RPRD Diagnostics	EI	Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines
0170U	Clarifit™	Quadrant Biosciences, Inc, Quadrant Biosciences, Inc	EI	Genetic Testing-Chromosomal Microarray (CMA) Analysis and Next-Generation Sequencing Panels, for the Evaluation of Children with Developmental Delay/Intellectual Disability, Autism Spectrum Disorder, and/or Congenital Anomalies
0171U	MyMRD® NGS Panel	Laboratory for Personalized Molecular Medicine, Laboratory for Personalized Molecular Medicine	EI	

0172U	myChoice® CDx	Myriad Genetics Laboratories, Inc, Myriad Genetics Laboratories, Inc	EST	Genetic Testing-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (<i>BRCA1</i> , <i>BRCA2</i> , Homologous Recombination Deficiency, <i>NTRK</i>) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (<i>BRCA1/2</i> , Homologous Recombination Repair Gene Alterations, <i>NTRK</i> Gene Fusion)
0173U	Psych HealthPGx Panel	RPRD Diagnostics, RPRD Diagnostics	EI	Genetic Testing for Specified Conditions Using Testing Panels
0174U	LC-MS/MS Targeted Proteomic Assay	OncoOmicDx Laboratory, LDT	EI	
0175U	Genomind® Professional PGx Express™ CORE	Genomind, Inc, Genomind, Inc	EI	Genetic Testing for Specified Conditions Using Testing Panels
0176U	IBScheck®	Commonwealth Diagnostics International, Inc, Commonwealth Diagnostics International, Inc	EI	
0177U	therascreen® <i>PIK3CA</i> RGQ PCR Kit	QIAGEN, QIAGEN GmbH	EST	Payable
0178U	VeriMAP™ Peanut Reactivity Threshold-Bead Based Epitope Assay	AllerGenis™ Clinical Laboratory, AllerGenis™ LLC	EI	
0179U	Resolution ctDx Lung™	Resolution Bioscience, Resolution Bioscience, Inc	EI	Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)
0180U	Navigator ABO Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0181U	Navigator CO Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0182U	Navigator CROM Sequencing	Grifols Immunohematology Center	EI	

0183U	Navigator DI Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0184U	Navigator DO Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0185U	Navigator FUT1 Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0186U	Navigator FUT2 Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0187U	Navigator FY Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0188U	Navigator GE Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0189U	Navigator GYPA Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0190U	Navigator GYPB Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	

0191U	Navigator IN Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0192U	Navigator JK Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0193U	Navigator JR Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0194U	Navigator KEL Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0195U	Navigator <i>KLF1</i> Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0196U	Navigator LU Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0197U	Navigator LW Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0198U	Navigator RHD/CE Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	

0199U	Navigator SC Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0200U	Navigator XK Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0201U	Navigator YT Sequencing	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0202U	BioFire® Respiratory Panel 2.1 (RP2.1)	BioFire® Diagnostics BioFire® Diagnostics, LLC	EST	Payable
0203U	PredictSURE IBD™ Test	KSL Diagnostics, PredictImmune Ltd	EI	
0205U	Vita Risk®	Arctic Medical Laboratories, Arctic Medical Laboratories	EI	Genetic Testing for Macular Degeneration
0206U	DISCERN™	NeuroDiagnostics, NeuroDiagnostics	EI	
0207U	DISCERN™	NeuroDiagnostics, NeuroDiagnostics	EI	
0209U	CNGnome™	PerkinElmer Genomics, PerkinElmer Genomics	EI	Genetic Testing-Chromosomal Microarray (CMA) Analysis and Next-Generation Sequencing Panels, for the Evaluation of Children with Developmental Delay/Intellectual Disability, Autism Spectrum Disorder, and/or Congenital Anomalies
0210U	BioPlex 2200 RPR Assay – Quantitative	Bio-Rad Laboratories, Bio-Rad Laboratories	EI	
0211U	MI Cancer Seek™ - NGS Analysis	Caris MPI d/b/a Caris Life Sciences, Caris MPI d/b/a Caris Life Sciences	EI	
0212U	Genomic Unity® Whole Genome Analysis – Proband	Variantyx Inc, Variantyx Inc	EI	Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0213U	Genomic Unity® Whole Genome Analysis – Comparator	Variantyx Inc, Variantyx Inc	EI	Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0214U	Genomic Unity® Exome Plus Analysis – Proband	Variantyx Inc, Variantyx Inc	EI	Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders

0215U	Genomic Unity® Exome Plus Analysis – Comparator	Variantyx Inc, Variantyx Inc	EI	Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0216U	Genomic Unity® Ataxia Repeat Expansion and Sequence Analysis	Variantyx Inc, Variantyx Inc	EI	
0217U	Genomic Unity® Comprehensive Ataxia Repeat Expansion and Sequence Analysis	Variantyx Inc, Variantyx Inc	EI	
0218U	Genomic Unity® DMD Analysis	Variantyx Inc, Variantyx Inc	EI	
0219U	Sentosa® SQ HIV-1 Genotyping Assay	Vela Diagnostics USA, Inc, Vela Operations Singapore Pte Ltd	EI	
0220U	PreciseDx™ Breast Cancer Test	PreciseDx, PreciseDx	EI	
0221U	Navigator ABO Blood Group NGS	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0222U	Navigator Rh Blood Group NGS	Grifols Immunohematology Center, Grifols Immunohematology Center	EI	
0223U	QIAstat-Dx Respiratory SARS CoV-2 Panel	QIAGEN Sciences, QIAGEN GmbH	EST	Payable
0224U	COVID-19 Antibody Test	Mt Sinai, Mount Sinai Laboratory	EST	Payable
0225U	ePlex® Respiratory Pathogen Panel 2	GenMark Dx, GenMark Diagnostics, Inc	EI	Identification of Microorganisms Using Nucleic Acid Probes
0226U	Tru-Immune™	Ethos Laboratories, GenScript® USA Inc	EST	Payable
0227U	Comprehensive Screen	Aspenti Health	EI	
0228U	PanGIA Prostate	Genetics Institute of America, Entopsis, LLC	EI	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0229U	Colvera®	Clinical Genomics Pathology Inc	EI	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)
0230U	Genomic Unity® AR Analysis	Variantyx Inc, Variantyx Inc	EI	

0231U	Genomic Unity® CACNA1A Analysis	Variantyx Inc, Variantyx Inc	EI	Genetic Testing for Epilepsy
0232U	Genomic Unity® CSTB Analysis	Variantyx Inc, Variantyx Inc	EI	
0233U	Genomic Unity® FXN Analysis	Variantyx Inc, Variantyx Inc	EI	
0234U	Genomic Unity® MECP2 Analysis	Variantyx Inc, Variantyx Inc	EI	Genetic Testing for Rett Syndrome
0235U	Genomic Unity® PTEN Analysis	Variantyx Inc, Variantyx Inc	EI	Genetic Testing for <i>PTEN</i> Hamartoma Tumor Syndrome
0236U	Genomic Unity® SMN1/2 Analysis	Variantyx Inc, Variantyx Inc	EI	Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing
0237U	Genomic Unity® Cardiac Ion Channelopathies Analysis	Variantyx Inc, Variantyx Inc	EI	Genetic Testing for Cardiac Ion Channelopathies
0238U	Genomic Unity® Lynch Syndrome Analysis	Variantyx Inc, Variantyx Inc	EI	Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes
0239U	FoundationOne® Liquid CDx	Foundation Medicine, Inc, Foundation Medicine, Inc	EST	Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy) Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy) Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (<i>KRAS</i> , <i>NRAS</i> , <i>BRAF</i> , <i>NTRK</i> and <i>HER2</i>) Genetic Testing- <i>BRAF/NTRK</i> Mutation in Selecting Melanoma Patients for Targeted Therapy Including Liquid Biopsy Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (<i>BRCA1</i> , <i>BRCA2</i> , Homologous Recombination Deficiency, <i>NTRK</i>) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (<i>BRCA1/2</i> , Homologous Recombination Repair Gene Alterations, <i>NTRK</i> Gene Fusion) Genetic Testing-Somatic Biomarker Testing for Immune Checkpoint Inhibitor Therapy (<i>BRAF</i> , MSI/MMR, PD-L1, TMB)

0240U	Xpert® Xpress CoV-2/Flu/RSV plus (SARS-CoV-2 and Flu targets)	Cepheid®	EST	Payable
0241U	Xpert® Xpress CoV-2/Flu/RSV plus (all targets)	Cepheid®	EST	Payable
0242U	Guardant360® CDx	Guardant Health Inc, Guardant Health Inc	EST	<p>Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)</p> <p>Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)</p> <p>Genetic Testing-<i>BRAF/NTRK</i> Mutation in Selecting Melanoma Patients for Targeted Therapy Including Liquid Biopsy</p> <p>Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (<i>KRAS</i>, <i>NRAS</i>, <i>BRAF</i>, <i>NTRK</i> and <i>HER2</i>)</p> <p>Genetic Testing-Somatic Biomarker Testing for Immune Checkpoint Inhibitor Therapy (<i>BRAF</i>, MSI/MMR, PD-L1, TMB)</p>
0243U	PIGF Preeclampsia Screen	PerkinElmer Genetics, PerkinElmer Genetics, Inc	EI	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
0244U	Oncotype MAP™ Pan-Cancer Tissue Test	Paradigm Diagnostics, Inc, Paradigm Diagnostics, Inc	EST	Genetic Testing-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0245U	ThyGeNEXT® Thyroid Oncogene Panel	Interpace Diagnostics, Interpace Diagnostics	EST	Genetic Testing-Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid
0246U	PrecisionBlood™	San Diego Blood Bank, San Diego Blood Bank	EI	
0247U	PreTRM®	Sera Prognostics, Sera Prognostics, Inc®	EI	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
0248U	3D Predict Glioma	KIYATEC®, Inc	EI	Chemosensitivity and Chemoresistance Assay, In Vitro (Retired)
0249U	Theralink® Reverse Phase Protein Array (RPPA)	Theralink® Technologies, Inc, Theralink® Technologies, Inc	EI	
0250U	PGDx elio™ tissue complete	Personal Genome Diagnostics, Inc, Personal Genome Diagnostics, Inc	EST	Genetic Testing-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions

0251U	Intrinsic Hepcidin IDx™ Test	IntrinsicDx, Intrinsic LifeSciences™ LLC	EI	
0252U	POC (Products of Conception)	Igenomix®, Igenomix® USA	EI	Genetic Testing-Chromosomal Microarray Testing for the Evaluation of Early Pregnancy Loss and Intrauterine Fetal Demise
0253U	ERA® (Endometrial Receptivity Analysis)	Igenomix®, Igenomix® USA	EI	Assisted Reproductive Techniques
0254U	SMART PGT-A (Pre-implantation Genetic Testing – Aneuploidy)	Igenomix®, Igenomix® USA	EI	Genetic Testing-Preimplantation
0255U	Cap-Score™ Test	Androvia LifeSciences, Avantor Clinical Services (previously known as Therapak)	EI	
0256U	Trimethylamine (TMA) and TMA N-Oxide	Children's Hospital Colorado Laboratory	EI	
0257U	Very-Long Chain Acyl-CoA Dehydrogenase (VLCAD) Enzyme Activity	Children's Hospital Colorado Laboratory	EI	
0258U	Mind.Px	Mindera, Mindera Corporation	EI	
0259U	GFR by NMR	Labtech™ Diagnostics	EI	
0260U	Augusta Optical Genome Mapping	Georgia Esoteric and Molecular (GEM) Laboratory, LLC, Bionano Genomics Inc	EI	
0261U	Immunoscore®	HalioDx, HalioDx	EI	
0262U	OncoSignal 7 Pathway Signal	Protean BioDiagnostics, Philips Electronics Nederland BV	EI	
0263U	NPDX ASD and Central Carbon Energy Metabolism	Stemina Biomarker Discovery, Inc, Stemina Biomarker Discovery, Inc	EI	
0264U	Praxis Optical Genome Mapping	Praxis Genomics LLC	EI	
0265U	Praxis Whole Genome Sequencing	Praxis Genomics LLC	EI	
0266U	Praxis Transcriptome	Praxis Genomics LLC	EI	
0267U	Praxis Combined Whole Genome Sequencing and Optical Genome Mapping	Praxis Genomics LLC	EI	Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0268U	Versiti™ aHUS Genetic Evaluation	Versiti™ Diagnostic Laboratories, Versiti™	EI	

0269U	Versiti™ Autosomal Dominant Thrombocytopenia Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0270U	Versiti™ Coagulation Disorder Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0271U	Versiti™ Congenital Neutropenia Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0272U	Versiti™ Comprehensive Bleeding Disorder Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0273U	Versiti™ Fibrinolytic Disorder Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0274U	Versiti™ Comprehensive Platelet Disorder Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0275U	Versiti™ Heparin-Induced Thrombocytopenia Evaluation – PEA	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0276U	Versiti™ Inherited Thrombocytopenia Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0277U	Versiti™ Platelet Function Disorder Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0278U	Versiti™ Thrombosis Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0279U	Versiti™ VWF Collagen III Binding	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0280U	Versiti™ VWF Collagen IV Binding	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0281U	Versiti™ VWF Propeptide Antigen	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0282U	Versiti™ Red Cell Genotyping Panel	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0283U	Versiti™ VWD Type 2B Evaluation	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0284U	Versiti™ VWF Type 2N Binding	Versiti™ Diagnostic Laboratories, Versiti™	EI	
0285U	RadTox™ cfDNA test	DiaCarta Clinical Lab, DiaCarta Inc	EI	

0286U	CNT (<i>CEP72</i> , <i>TPMT</i> and <i>NUDT15</i>) genotyping panel	RPRD Diagnostics	EI	
0287U	ThyroSeq® CRC	CBLPath, Inc, University of Pittsburgh Medical Center	EI	
0288U	DetermaRx™	Oncocyte Corporation	EI	
0289U	MindX Blood Test™ Memory/Alzheimer's	MindX Sciences™ Laboratory, MindX Sciences™ Inc	EI	
0290U	MindX Blood Test™ - Pain	MindX Sciences™ Laboratory, MindX Sciences™ Inc	EI	
0291U	MindX Blood Test™ - Mood	MindX Sciences™ Laboratory, MindX Sciences™ Inc	EI	
0292U	MindX Blood Test™ - Stress	MindX Sciences™ Laboratory, MindX Sciences™ Inc	EI	
0293U	MindX Blood Test™ - Suicidality	MindX Sciences™ Laboratory, MindX Sciences™ Inc	EI	
0294U	MindX Blood Test™ - Longevity	MindX Sciences™ Laboratory, MindX Sciences™ Inc	EI	
0295U	DCISIONRT®	PreludeDx™, Prelude Corporation	EI	Genetic Testing-Assays of Genetic Expression in Tumor Tissue as a Technique to Help Guide Decision-Making in Patients With Breast Cancer
0296U	mRNA CancerDetect™	Viome Life Sciences, Inc, Viome Life Sciences, Inc	EI	
0297U	Praxis Somatic Whole Genome Sequencing	Praxis Genomics LLC	EI	
0298U	Praxis Somatic Transcriptome	Praxis Genomics LLC	EI	
0299U	Praxis Somatic Optical Genome Mapping	Praxis Genomics LLC	EI	
0300U	Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping	Praxis Genomics LLC	EI	
0301U	Bartonella ddPCR	Galaxy Diagnostics, Inc	EI	
0302U	Bartonella Digital ePCR™	Galaxy Diagnostics, Inc	EI	
0303U	Hypoxic BioChip Adhesion	BioChip Labs™, BioChip Labs™	EI	
0304U	Normoxic BioChip Adhesion	BioChip Labs™, BioChip Labs™	EI	
0305U	Ektacytometry	BioChip Labs™, BioChip Labs™	EI	

0306U	Invitae PCM Tissue Profiling and MRD Baseline Assay	Invitae Corporation, Invitae Corporation	EI	
0307U	Invitae PCM MRD Monitoring	Invitae Corporation, Invitae Corporation	EI	
0308U	HART CADhs®	Atlas Genomics, Prevencio, Inc	EI	
0309U	HART CVE®	Atlas Genomics, Prevencio, Inc	EI	
0310U	HART KD®	Atlas Genomics, Prevencio, Inc	EI	
0311U	Accelerate PhenoTest® BC kit, AST configuration	Accelerate Diagnostics, Inc, Accelerate Diagnostics, Inc	EI	
0312U	Avise® Lupus	Exagen Inc, Exagen Inc	EI	
0313U	PancreaSeq® Genomic Classifier	Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center	EI	Genetic Testing-Molecular Testing for the Diagnosis and Management of Pancreatic Cysts, Barrett Esophagus, and Solid Pancreaticobiliary Lesions (e.g., PathFinderTG®, PancraGEN, BarreGEN)
0314U	DecisionDx® DiffDx™- Melanoma	Castle Biosciences, Inc, Castle Biosciences, Inc	EI	Gene Expression Profiling for Cutaneous Melanoma
0315U	DecisionDx®-SCC	Castle Biosciences, Inc, Castle Biosciences, Inc	EI	
0316U	Lyme Borrelia Nanotrap® Urine Antigen Test	Galaxy Diagnostics Inc	EI	
0317U	LungLB®	LungLife AI®, LungLife AI®	EI	
0318U	EpiSign Complete	Greenwood Genetic Center	EI	Genetic Testing-Chromosomal Microarray (CMA) Analysis and Next-Generation Sequencing Panels, for the Evaluation of Children with Developmental Delay/Intellectual Disability, Autism Spectrum Disorder, and/or Congenital Anomalies
0319U	Clarava™	Verici Dx, Verici Dx, Inc	EI	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
0320U	Tuteva™	Verici Dx, Verici Dx, Inc	EI	Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure
0321U	Bridge Urinary Tract Infection Detection and Resistance Test	Bridge Diagnostics	EI	Identification of Microorganisms Using Nucleic Acid Probes
0322U	NPDX ASD Test Panel III	Stemina Biomarker Discovery d/b/a NeuroPointDX, Stemina Biomarker Discovery d/b/a NeuroPointDX	EI	

0323U	Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease Diagnostics	Johns Hopkins Medical Microbiology Laboratory	EI	
0326U	Guardant360®	Guardant Health, Inc, Guardant Health, Inc	EST	<p>Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)</p> <p>Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)</p> <p>Genetic Testing-<i>BRAF/NTRK</i> Mutation in Selecting Melanoma Patients for Targeted Therapy Including Liquid Biopsy</p> <p>Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (<i>KRAS</i>, <i>NRAS</i>, <i>BRAF</i>, <i>NTRK</i> and <i>HER2</i>)</p> <p>Genetic Testing-Somatic Biomarker Testing for Immune Checkpoint Inhibitor Therapy (<i>BRAF</i>, <i>MSI/MMR</i>, <i>PD-L1</i>, <i>TMB</i>)</p>
0327U	Vasistera™	Natera, Inc, Natera, Inc	EST	Genetic Testing-Noninvasive Prenatal Screening for Fetal Aneuploidies, Microdeletions, Single-Gene Disorders, and Twin Zygosity Using Cell-Free Fetal DNA
0328U	CareView360	Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	EI	
0329U	Oncomap™ ExTra	Exact Sciences, Inc, Genomic Health Inc	EI	
0330U	Bridge Women's Health Infectious Disease Detection Test	Bridge Diagnostics, Thermo Fisher and Hologic Test Kit on Panther Instrument	EI	
0331U	Augusta Hematology Optical Genome Mapping	Georgia Esoteric and Molecular Labs, Augusta University, Bionano	EI	
0332U	EpiSwitch® CiRT (Checkpoint-inhibitor Response Test)	Next Bio-Research Services, LLC, Oxford BioDynamics, PLC	EI	
0333U	HelioLiver™ Test	Fulgent Genetics, LLC, Helio Health, Inc	EI	Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing

0334U	Guardant360 TissueNext™	Guardant Health, Inc, Guardant Health, Inc	EST	Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, NTRK and HER2) Genetic Testing-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions Genetic Testing-Somatic Biomarker Testing for Immune Checkpoint Inhibitor Therapy (BRAF, MSI/MMR, PD-L1, TMB)
0335U	IriSight™ Prenatal Analysis – Proband	Variantyx, Inc, Variantyx, Inc	EI	Invasive Prenatal (Fetal) Diagnostic Testing Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0336U	IriSight™ Prenatal Analysis – Comparator	Variantyx, Inc, Variantyx, Inc	EI	Invasive Prenatal (Fetal) Diagnostic Testing Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0337U	CELLSEARCH® Circulating Multiple Myeloma Cell (CMMC) Test	Menarini Silicon Biosystems, Inc, Menarini Silicon Biosystems, Inc	EI	BMT-Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma, plasma cell leukemia, plasmacytoma, and POEMS Syndrome
0338U	CELLSEARCH® HER2 Circulating Tumor Cell (CTC-HER2) Test	Menarini Silicon Biosystems, Inc, Menarini Silicon Biosystems, Inc	EI	Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)
0339U	SelectMDx® for Prostate Cancer	MDxHealth®, Inc, MDxHealth®, Inc	EST	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0340U	Signatera™	Natera, Inc, Natera, Inc	EI	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)
0341U	Single Cell Prenatal Diagnosis (SCPD) Test	Luna Genetics, Inc, Luna Genetics, Inc	EI	
0342U	IMMray® PanCan-d	Immunovia, Inc, Immunovia, Inc	EI	
0343U	miR Sentinel™ Prostate Cancer Test	miR Scientific, LLC, miR Scientific, LLC	EI	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0344U	OWLiver®	CIMA Sciences, LLC	EI	
0345U	GeneSight® Psychotropic	Assurex Health, Inc, Myriad Genetics, Inc	EI	Genetic Testing for Specified Conditions Using Testing Panels
0347U	RightMed® PGx16 Test	OneOme®, OneOme®, LLC	EI	
0348U	RightMed® Comprehensive Test Exclude F2 and F5	OneOme®, OneOme®, LLC	EI	
0349U	RightMed® Comprehensive Test	OneOme®, OneOme®, LLC	EI	

0350U	RightMed® Gene Report	OneOme®, OneOme®, LLC	EI	
0351U	MeMed BV®	MeMed Diagnostics, Ltd, MeMed Diagnostics, Ltd	EI	
0355U	Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping	Quest Diagnostics®, Quest Diagnostics®	EI	Transplant-Kidney
0356U	NavDx®	Naveris, Inc, Naveris, Inc	EI	
0358U	Lumipulse® G β-Amyloid Ratio (1-42/1-40) Test	Fujirebio Diagnostics, Inc, Fujirebio Diagnostics, Inc	EI	
0359U	IsoPSA®	Cleveland Diagnostics, Inc, Cleveland Diagnostics, Inc	EST	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0360U	Nodify CDT®	Biodesix, Inc, Biodesix, Inc	EI	Molecular Testing in the Management of Pulmonary Nodules
0361U	Neurofilament Light Chain (NfL)	Mayo Clinic, Mayo Clinic	EI	
0362U	Thyroid GuidePx®	Protean BioDiagnostics, Qualisure Diagnostics	EI	
0363U	Cxbladder™ Triage	Pacific Edge Diagnostics USA, Ltd, Pacific Edge Diagnostics USA, Ltd	EI	Urinary Biomarkers for Bladder Cancer
0364U	clonoSEQ® Assay	Adaptive Biotechnologies	EST	Genetic Testing-Next Generation Sequencing for Assessment of Measurable Residual Disease (ClonoSEQ) in Hematological Malignancies
0365U	Oncuria® Detect	DiaCarta Clinical Lab, DiaCarta, Inc	EI	
0366U	Oncuria® Monitor	DiaCarta Clinical Lab, DiaCarta, Inc	EI	
0367U	Oncuria® Predict	DiaCarta Clinical Lab, DiaCarta, Inc	EI	
0368U	ColoScape™ Colorectal Cancer Detection	DiaCarta Clinical Lab, DiaCarta, Inc	EI	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)
0369U	GI assay (Gastrointestinal Pathogen with ABR)	Lab Genomics LLC, Thermo Fisher Scientific	EI	
0370U	Lesion Infection (Wound)	Lab Genomics LLC, Thermo Fisher Scientific	EI	
0371U	Qclear UTI	Lifescan Labs of Illinois, Thermo Fisher Scientific	EI	
0372U	Qclear UTI – Reflex ABR	Lifescan Labs of Illinois, Thermo Fisher Scientific	EI	
0373U	Respiratory Pathogen with ABR (RPX)	Lab Genomics LLC, Thermo Fisher Scientific	EI	
0374U	Urogenital Pathogen with Rx Panel (UPX)	Lab Genomics LLC, Thermo Fisher Scientific	EI	

0375U	OvaWatch sm	Aspira Women's Health sm , Aspira Labs, Inc	EI	Multimarker Serum Testing Related to Ovarian Cancer (e.g., OVA1, Overa, OvaWatch and ROMA testing)
0376U	ArteraAI Prostate Test	Artera Inc [®] , Artera Inc [®]	EI	
0377U	Liposcale [®]	CIMA Sciences, LLC	EI	
0378U	UCGSL RFC1 Repeat Expansion Test	University of Chicago Genetic Services Laboratories	EI	
0379U	Solid Tumor Expanded Panel	Quest Diagnostics [®] , Quest Diagnostics [®]	EST	Genetic Testing-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0381U	Branched-Chain Amino Acids, Self-Collect, Blood Spot	Mayo Clinic, Laboratory Developed Test	EI	
0382U	Phenylalanine and Tyrosine, Self-Collect, Blood Spot	Mayo Clinic, Laboratory Developed Test	EI	
0383U	Tyrosinemia Follow-Up Panel, Self-Collect, Blood Spot	Mayo Clinic, Laboratory Developed Test	EI	
0384U	NaviDKD™ Predictive Diagnostic Screening for Kidney Health	Journey Biosciences, Inc, Journey Biosciences, Inc	EI	
0385U	PromarkerD	Sonic Reference Laboratory, Proteomics International Pty Ltd	EI	
0387U	AMBLo [®] melanoma prognostic test	Avero [®] Diagnostics	EI	
0388U	InVisionFirst [®] -Lung Liquid Biopsy	Inivata, Inc, Inivata, Inc	EI	Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Non-Small-Cell Lung Cancer (EGFR, ALK, ROS1, TET, MET, KRAS, HER2, PD-L1, TMB)
0389U	KawasakiDx	OncoOmicsDx Laboratory, mProbe	EI	
0390U	PEPredictDx	OncoOmicsDx Laboratory, mProbe	EI	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
0391U	Strata Select TM	Strata Oncology, Inc, Strata Oncology, Inc	EI	
0392U	Medication Management Neuropsychiatric Panel	RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx	EI	
0393U	SYNTap [®] Biomarker Test	Amprion Clinical Laboratory, Amprion Clinical Laboratory	EI	

0394U	PFAS Testing & PFASure™	National Medical Services, NMS Labs, Inc	EI	
0395U	OncobiotaLUNG	Micronoma™, Micronoma™	EI	
0398U	ESOPREDICT® Barrett's Esophagus Risk Classifier Assay	Capsulomics, Inc d/b/a Previse	EI	
0399U	FRAT® (Folate Receptor Antibody Test)	Religen Inc, Religen Inc	EI	
0400U	Genesys Carrier Panel	Genesys Diagnostics, Inc	EI	Genetic Testing-Carrier Screening for Genetic Diseases
0401U	CARDIO inCode-Score (CIC-SCORE)	GENinCode U.S. Inc, GENinCode U.S. Inc	EI	Cardiovascular Risk Panels
0402U	Abbott Alinity™ m STI Assay	Abbott Molecular, Inc	EI	
0403U	MyProstateScore 2.0	LynxDX, LynxDX	EST	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0404U	DiviTum®TKa	Biovica Inc, Biovica International AB	EI	
0405U	BTG Early Detection of Pancreatic Cancer	Breakthrough Genomics, Breakthrough Genomics	EI	
0406U	CyPath® Lung	Precision Pathology Services, bioAffinity Technologies, Inc	EI	
0407U	kidneyintelX.dkd™	Renalytix Inc, Renalytix Inc, NYC, NY	EI	
0408U	Omnia™ SARS-CoV-2 Antigen Test	Qorvo Biotechnologies, Qorvo Biotechnologies	EI	
0409U	LiquidHALLMARK®	Lucence Health, Inc	EI	
0410U	Avantect™ Pancreatic Cancer Test	ClearNote™ Health, ClearNote™ Health	EI	
0411U	IDgenetix®	Castle Biosciences, Inc, Castle Biosciences, Inc	EI	Genetic Testing for Specified Conditions Using Testing Panels
0412U	PrecivityAD® blood test	C2N Diagnostics LLC, C2N Diagnostics LLC	EI	
0413U	DH Optical Genome Mapping/Digital Karyotyping Assay	The Clinical Genomics and Advanced Technology (CGAT) Laboratory at Dartmouth Health, Bionano Genomics	EI	
0414U	LungOI	Imagene	EI	
0415U	SmartHealth Vascular Dx™	Morningstar Laboratories, LLC, SmartHealth DX	EI	

0417U	Genomic Unity® Comprehensive Mitochondrial Disorders Analysis	Variantyx Inc, Variantyx Inc	EI	
0418U	PreciseDx Breast Biopsy Test	PreciseDx, PreciseDx, Inc NYC,NY	EI	
0419U	Tempus nP	Tempus Labs, Inc, Tempus Labs, Inc	EI	
0420U	Cxbladder Detect+	Pacific Edge Diagnostics USA LTD, Pacific Edge Diagnostics USA LTD	EI	Urinary Biomarkers for Bladder Cancer
0421U	Colosense™	Geneoscopy, Inc, Geneoscopy, Inc	EI	
0422U	Guardant360 Response™	Guardant Health, Inc, Guardant Health, Inc	EI	
0423U	Genomind® Pharmacogenetics Report – Full	Genomind®, Inc, Genomind®, Inc	EI	Genetic Testing for Specified Conditions Using Testing Panels
0424U	miR Sentinel™ Prostate Cancer Test	miR Scientific®, LLC, miR Scientific®, LLC	EI	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0425U	RCIGM Rapid Whole Genome Sequencing, Comparator Genome	Rady Children's Institute for Genomic Medicine, Rady Children's Institute for Genomic Medicine	EST	Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0426U	RCIGM Ultra-Rapid Whole Genome Sequencing	Rady Children's Institute for Genomic Medicine, Rady Children's Institute for Genomic Medicine	EST	Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0427U	Early Sepsis Indicator	Beckman Coulter, Inc	EI	
0429U	Omnipathology Oropharyngeal HPV PCR Test	OmniPathology Solutions, Medical Corporation, OmniPathology Solutions, Medical Corporation	EI	
0430U	Malabsorption Evaluation Panel	Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories	EI	
0431U	Glycine Receptor Alpha1 IgG	Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories	EI	
0432U	Kelch-Like Protein 11 Antibody	Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo	EI	

		Clinic Laboratories		
0433U	EpiSwitch® Prostate Screening Test (PSE)	Oxford BioDynamics Inc, Oxford BioDynamics PLC	EI	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0434U	RightMed® Gene Test Exclude F2 and F5	OneOme® LLC, OneOme® LLC	EI	Genetic Testing for Specified Conditions Using Testing Panels
0435U	ChemoID®	ChemoID® Lab, Cordgenics, LLC	EI	
0436U	PROphet® NSCLC Test	OncoHost, Inc, OncoHost, Inc	EI	
0437U	MindX One™ Blood Test – Anxiety	MindX Sciences, MindX Sciences	EI	Genetic Testing for Specified Conditions Using Testing Panels
0438U	EffectiveRX™ Comprehensive Panel	RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx	EI	Genetic Testing for Specified Conditions Using Testing Panels
0439U	Epi+Gen CHD™	Cardio Diagnostics, Inc, Cardio Diagnostics, Inc	EI	
0440U	PrecisionCHD™	Cardio Diagnostics, Inc, Cardio Diagnostics, Inc	EI	
0441U	IntelliSep® Test	Cytovale	EI	
0442U	FebriDx® Bacterial/Non-Bacterial Point-of-Care Assay	Lumos Diagnostics, LLC, Lumos Diagnostics, LLC	EI	
0443U	Neurofilament Light Chain (NfL)	Neuromuscular Clinical Laboratory at Washington University in St. Louis School of Medicine, Neuromuscular Clinical Laboratory at Washington University in St. Louis School of Medicine	EI	Evaluation of Biomarkers for Alzheimer's Disease
0444U	Aventa™ FusionPlus	Aventa Genomics, LLC	EI	Genetic Testing-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0445U	Elecsys® Phospho-Tau (181P) CSF (pTau181) and β-Amyloid (1-42) CSF II (Abeta 42) Ratio	Roche Diagnostics Operations, Inc (US owner/operator)	EI	Evaluation of Biomarkers for Alzheimer's Disease
0446U	aiSLE™ DX Disease Activity Index	Progentec Diagnostics, Inc, Progentec Diagnostics, Inc	EI	
0447U	aiSLE™ DX Flare Risk Index	Progentec Diagnostics, Inc, Progentec Diagnostics, Inc	EI	

0449U	UNITY Carrier Screen™	BillionToOne Laboratory, BillionToOne, Inc	EI	Genetic Testing-Carrier Screening for Genetic Diseases
0450U	M-inSight® Patient Definition Assay	Corgenix Clinical Laboratory, Sebia	EI	
0451U	M-inSight® Patient Follow-Up Assessment	Corgenix Clinical Laboratory, Sebia	EI	
0452U	EarlyTect® Bladder Cancer Detection (EarlyTect® BCD)	Promis Diagnostics, Inc, Promis Diagnostics, Inc	EI	Urinary Biomarkers for Bladder Cancer
0453U	ColonAiQ®	Breakthrough Genomics, Singlera Genomics, Inc	EI	
0454U	Chromosome Genome Mapping	UR Medicine Labs, Bionano Genomics, Inc	EI	
0455U	Abbott Alinity™ m STI Assay	Abbott Molecular, Inc	EI	Diagnosis of Vaginitis Identification of Microorganisms Using Nucleic Acid Probes
0457U	PFAS (Forever Chemicals) 9 Panel	Quest Diagnostics®, Quest Diagnostics®	EI	
0458U	Auria®	Namida Lab, Inc, Namida Lab, Inc	EI	
0459U	Elecsys® Total Tau CSF (tTau) and β-Amyloid (1-42) CSF II (Abeta 42) Ratio	Roche Diagnostics Operations, Inc (US owner/operator)	EI	Evaluation of Biomarkers for Alzheimer's Disease
0460U	RightMed® Oncology Gene Report	OneOme® LLC, OneOme® LLC	EI	
0461U	RightMed® Oncology Medication Report	OneOme® LLC, OneOme® LLC	EI	
0462U	Salimetrics® Salivary Melatonin Profile (Circadian Phase Assessment)	Salimetrics® Clinical Laboratory, Salimetrics®, LLC	EI	
0463U	Proofer '7 HPV mRNA E6 and E7 Biomarker Test	Global Diagnostics Labs, LLC, PreTect AS, a Mel-Mont Medical, Inc, wholly owned subsidiary	EI	
0464U	Cologuard Plus™	Exact Sciences Laboratories, LLC, Exact Sciences Corporation	EI	
0465U	UriFind® Urothelial Carcinoma Assay	DiaCarta, Inc, AnchorDx	EI	Urinary Biomarkers for Bladder Cancer

0466U	CardioRisk+	Gene by Gene, Ltd, OpenDNA, Ltd	EI	Cardiovascular Risk Panels
0467U	UroAmp MRD	Convergent Genomics, Inc, Convergent Genomics, Inc	EI	
0468U	NASHnext™ (NIS4™)	Labcorp, Labcorp	EI	Noninvasive Techniques for Evaluation of Chronic Liver Disease
0469U	IriSight™ CNV Analysis	Variantyx Inc, Variantyx Inc	EI	
0470U	HPV-SEQ Test	Sysmex Inostics, Inc, Sysmex Inostics, Inc	EI	
0471U	CRCdx® RAS Mutation Detection Kit	EntroGen, Inc, EntroGen, Inc	EST	Genetic Testing-NGS Testing of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (<i>KRAS</i> , <i>NRAS</i> , <i>BRAF</i> , <i>NTRK</i> and <i>HER2</i>)
0472U	Early Sjögren's Syndrome Profile	Immco Diagnostics, Inc, Immco Diagnostics, Inc	EI	
0473U	xT CDx	Tempus AI, Inc, Tempus AI, Inc	EST	Genetic Testing-NGS Testing of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (<i>KRAS</i> , <i>NRAS</i> , <i>BRAF</i> , <i>NTRK</i> and <i>HER2</i>)
0474U	GeneticsNow® Comprehensive Germline Panel	GoPath Diagnostics, Inc, GoPath Diagnostics, Inc	EI	
0475U	ProstateNow™ Prostate Germline Panel	GoPath Diagnostics, Inc, GoPath Diagnostics, Inc	EI	Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (<i>BRCA1/2</i> , Homologous Recombination Repair Gene Alterations, <i>NTRK</i> Gene Fusion)
0476U	RightMed® Mental Health Gene Report	OneOme, LLC, OneOme, LLC	EI	
0477U	RightMed® Mental Health Medication Report	OneOme, LLC, OneOme, LLC	EI	
0478U	Lung HDPCR™	Protean BioDiagnostics, Protean BioDiagnostics	EI	Genetic Testing-NGS Testing of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0479U	ALZpath pTau217	Neurocode USA, Inc, Quanterix/ALZpath	EI	Evaluation of Biomarkers for Alzheimer's Disease

0480U	Bacteria, Viruses, Fungus, and Parasite Metagenomic Sequencing, Spinal Fluid (MSCSF)	Mayo Clinic, Laboratory Developed Test	EI	Identification of Microorganisms Using Nucleic Acid Probes
0481U	IDH1, IDH2, and TERT Mutation Analysis, Next-Generation Sequencing, Tumor (IDTRT)	Mayo Clinic, Laboratory Developed Test	EI	
0482U	Preeclampsia sFlt-1/PIGF Ratio (PERA)	Mayo Clinic, Laboratory Developed Test	EI	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
0483U	Ciprofloxacin Susceptibility of <i>Neisseria gonorrhoeae</i>	MedArbor Diagnostics, SpeeDx, Inc	EI	Identification of Microorganisms Using Nucleic Acid Probes
0484U	Macrolide Resistance of <i>Mycoplasma genitalium</i>	MedArbor Diagnostics, SpeeDx, Inc	EI	Identification of Microorganisms Using Nucleic Acid Probes
0485U	Caris Assure™	Caris MPI, Inc d/b/a Caris Life Sciences®, Caris MPI, Inc d/b/a Caris Life Sciences®	EI	Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)
0486U	Northstar Response™	BillionToOne Laboratory, BillionToOne, Inc	EI	Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)
0487U	Northstar Select™	BillionToOne Laboratory, BillionToOne, Inc	EI	Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)
0488U	UNITY Fetal Antigen™ NIPT	BillionToOne Laboratory, BillionToOne, Inc	EST	Genetic Testing-Noninvasive Prenatal Testing for Fetal RBC Antigen Status
0489U	UNITY Fetal Risk Screen™	BillionToOne Laboratory, BillionToOne, Inc	EI	Genetic Testing-Noninvasive Prenatal Screening for Fetal Aneuploidies, Microdeletions, Single-Gene Disorders, and Twin Zygosity Using Cell-Free Fetal DNA
0490U	CELLSEARCH® Circulating Melanoma Cell (CMC) Test	Menarini Silicon Biosystems Inc, Menarini Silicon Biosystems Inc	EI	
0491U	CELLSEARCH® ER Circulating Tumor Cell (CTC-ER) Test	Menarini Silicon Biosystems Inc, Menarini Silicon Biosystems Inc	EI	Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)
0492U	CELLSEARCH® PD-L1 Circulating Tumor Cell (CTC-PD-L1) Test	Menarini Silicon Biosystems Inc, Menarini Silicon Biosystems Inc	EI	Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy)
0493U	Prospera™	Natera™	EI	

0494U	Rh Test	Natera™	EST	Genetic Testing-Noninvasive Prenatal Testing for Fetal RBC Antigen Status
0495U	Stockholm3	BioAgilytix Diagnostics	EI	Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
0496U	ColoScape™ PLUS	DiaCarta, Inc, DiaCarta, Inc	EI	
0497U	OncoAssure™ Prostate	DiaCarta, Inc, DiaCarta, Inc	EI	GT-Gene Expression Profile Analysis for Risk Stratification for Prostate Cancer Management
0498U	OptiSeq™ Colorectal Cancer NGS Panel	DiaCarta, Inc, DiaCarta, Inc	EI	
0499U	OptiSeq™ Dual Cancer Panel Kit	DiaCarta, Inc, DiaCarta Inc	EI	
0500U	QClamp® Plex VEXAS UBA1 Mutation Test	DiaCarta, Inc, DiaCarta Inc	EI	
0501U	QuantiDNA™ Colorectal Cancer Triage Test	DiaCarta, Inc, DiaCarta Inc	EI	
0502U	QuantiVirus™ HPV E6/E7 mRNA Test for Cervical Cancer	DiaCarta, Inc, DiaCarta Inc	EI	
0503U	PrecivityAD2™	C2N Diagnostics, LLC, C2N Diagnostics, LLC	EI	Evaluation of Biomarkers for Alzheimer's Disease
0504U	Urinary Tract Infection Testing	NxGen MDx LLC, NxGen MDx LLC	EI	
0505U	Vaginal Infection Testing	NxGen MDx LLC, NxGen MDx LLC	EI	Identification of Microorganisms Using Nucleic Acid Probes
0506U	EndoSign® Barrett's Esophagus Test	Cyted Health Inc, Cyted Health Inc	EI	
0507U	Avantect Ovarian Cancer Test	ClearNote® Health	EI	
0508U	VitaGraft™ Kidney Baseline + 1st Plasma Test	Oncocyte Corporation, Oncocyte Corporation	EI	
0509U	VitaGraft™ Kidney Subsequent	Oncocyte Corporation, Oncocyte Corporation	EI	
0510U	PuriST™	Tempus AI, Inc, Tempus AI, Inc	EI	
0511U	PARIS	Tempus AI, Inc, Tempus AI, Inc (by its wholly owned subsidiary SEngine Precision Medicine, LLC)	EI	
0512U	Tempus p-MSI	Tempus AI, Inc, Tempus AI, Inc	EI	
0513U	Tempus p-Prostate	Tempus AI, Inc, Tempus AI, Inc	EI	
0514U	Procise ADL™	ProciseDx Inc	EI	

0515U	Procise IFX™	ProciseDx Inc	EI	
0516U	MyGenVar Pharmacogenomics Test	Geisinger Medical Laboratories, Geisinger Medical Laboratories	EI	
0517U	PrecisView® CNS	Phenomics Health™ Inc, Phenomics Health™ Inc	EI	
0518U	SyncView® Pain	Phenomics Health™ Inc, Phenomics Health™ Inc	EI	
0519U	SyncView® PainPlus	Phenomics Health™ Inc, Phenomics Health™ Inc	EI	
0520U	SyncView® Rx	Phenomics Health™ Inc, Phenomics Health™ Inc	EI	
0521U	Seronegative Rheumatoid Arthritis Panel	KSL Diagnostics- Beutner Laboratories, Inc, KSL Biomedical, Inc	EI	
0522U	Tissue Specific Markers for Early Diagnosis of Sjogren's Disease	KSL Diagnostics, Inc, KSL Diagnostics, Inc	EI	
0523U	oncoReveal™ CDx	Pillar Biosciences, Inc, Pillar Biosciences, Inc	EI	
0524U	sFlt-1/PIGF	Thermo Fisher Scientific, Thermo Fisher Scientific	EI	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
0525U	3D Predict™ Ovarian	KIYATEC®, Inc, KIYATEC®, Inc	EI	
0526U	CXCL10 Urine Test	One Lambda™, Inc, One Lambda™, Inc	EI	
0527U	Abbott Alinity™ m HSV 1 & 2 / VZV Assay	Abbott Molecular, Inc	EI	
0528U	BIOFIRE® FILMARRAY® Pneumonia (PN) Panel	bioMérieux, bioMérieux	EI	
0529U	Lifetime Genomics Risk Assessment, VTE	GenomicMD, Inc, GenomicMD, Inc	EI	Genetic Testing for Inherited Thrombophilias

0530U	LiquidHALLMARK®	Lucence Health, Inc, Lucence Health, Inc	EI	Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (<i>KRAS, NRAS, BRAF, NTRK</i> and <i>HER2</i>) Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Non-Small Cell Lung Cancer (<i>EGFR, ALK, BRAF, ROS1, RET, Met, KRAS, HER2, PD-L1, TMB</i>)
-------	-----------------	---	----	---

Government Regulations

National:

There is no national coverage determination (NCD) for Proprietary Laboratory Analyses (PLA) Codes.

Local:

A Medicare Administrative Contractor (MAC) may have Local Coverage Determinations or Local Coverage Articles that address coverage of specific PLA codes.

The Medicare Coverage Database may be found at the following:

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35490&ver=40&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=Michigan&KeyWord=category+III&KeyWordLookUp=Title&KeyWordSearchType=And&bc=qAAAACAAAAAA&>

(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 [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. American Medical Association. CPT® PLA Codes. Last updated October 11, 2024. <https://www.ama-assn.org/practice-management/cpt/cpt-pla-codes> Accessed 11/4/24.
2. Nordley, B. Making Sense of Proprietary Laboratory Analyses (PLA) Codes. January 30, 2020. Medlearn Publishing.
3. Blue Cross Blue Shield of Rhode Island. Proprietary Laboratory Codes (PLA). Medical Policy. Effective Date: 10/1/2019.
4. Blue Cross Blue Shield of Massachusetts. Medical Technology Assessment Investigational (Non-Covered) Services List. Medical Policy #400, 2023.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/22	12/14/21		Joint policy established
5/1/22	2/15/22		<ul style="list-style-type: none"> • Added the new PLA codes 02–5U – 0305U effective 1/1/22 under Other Codes (investigational, not medically necessary, etc.): • Revised codes 0022U eff 4/1/22, 0051U, 0090U • Revision to the test names for codes (0240U and 0241U) eff 4/1/22 • Deleted codes 0097U, 0151U eff 4/1/22
7/1/22	4/19/22		<ul style="list-style-type: none"> • Added the addition of the new 17 PLA codes (0306U-0322U) effective 4/1/22 under E/I. • Codes 0005U and 0113U moved from E/I to EST per Prostate Cancer Early Detection – Biomarkers Prior to Biopsy (EST) (Previous title: Genetic and Protein Biomarkers for Prostate Cancer) • Code 0037U moved from E/I to EST per Genetic Testing-NGS Testing of Multiple Genes (Panel) for Malignant Conditions (MXD) (Previous title: Genetic Test-ng – NGS Testing of Multiple Genes (Panel) to Identify Targeted Cancer Therapy). The code 0037U remains E/I on the Genetic Cancer Susceptibility Panels Using Next Generation Sequencing.
9/1/22	6/21/22		<ul style="list-style-type: none"> • No additions or deletions • Codes 0239U and 0242U moved from E/I to EST per Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)
11/1/22	8/16/22		<ul style="list-style-type: none"> • Added codes 0323U-0331U (EFD 7/1/22) to noncovered codes • Added Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing as the applicable policy for code 0236U (E/I)

1/1/23	10/18/22		<ul style="list-style-type: none"> Added 23 new PLA codes (0332U-0353U) effective 10/1/22 – all codes E/I except 0339U (EST) Deleted codes 0012U 0013U 0014U 0056U effective 10/1/22 Revision to code 0276U Addition of the word “of” between “sequencing” and “at least” in the long descriptor for code 0296U. Per discussion at post-jump moved 0172U from E/I to EST. (ky)
3/1/23	12/20/22		<p>Added the Genetic, Molecular and Other Tests- E/I Status pol to the below E/I codes based on policy update from October 18, 2022 JUMP (0332U, 0333U, 0342U, and 0351U)</p> <ul style="list-style-type: none"> Added the Somatic Biomarker Testing (including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS,BRAF, MMR/MSI, HER2, and TMB) to code 0037U EST. Added codes 0239U and 0242U as E/I under the Somatic Biomarker Testing (including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS,BRAF, MMR/MSI, HER2, and TMB) per October 18, 2022. Added the Genetic Testing- Noninvasive Prenatal Screening For Fetal Aneuploidies, Microdeletions, and Twin Zygosity Using Cell-Free Fetal DNA policy to code 0327U. Per code update – added 9 codes (0355U–0363U) as E/I effective 1/1/2023. (ky)
5/1/23	2/21/23		<ul style="list-style-type: none"> Revision of 2 codes (0022U, 0095U), deletion of 2 codes (0324U, 0325U) eff 4/1/2023. Added 23 new codes eff 4/1/2023 (0364U to 0386U) as E/I. Added the Genetic Testing- BCR/ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia to the code

			<p>0040U under EST from December 20, 2022 JUMP.</p> <ul style="list-style-type: none"> Added the Genetic Testing – NGS Testing of Multiple Genes (Panel) for Malignant Conditions to the code 0172U under EST from October 18, 2022 JUMP. (ky)
7/1/23	4/18/23		<ul style="list-style-type: none"> Added the Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid Biopsy) policy to the code 0338U under E/I from February 21, 2023 JUMP. Added the Genetic Testing and Counseling policy to the codes 0332U, 0345U, 0347U, 0348U, 0349U and 0350U under E/I from February 21, 2023 JUMP. Added the Genetic Testing- Molecular Testing for the Diagnosis and Management of Pancreatic Cysts, Barrett Esophagus, and Solid Pancreaticobiliary Lesions (e.g., PathFinderTG®, PancraGEN, BarreGEN) policy to the code 0313U under E/I from February 21, 2023 JUMP. Added the Genetic Test–ng – Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders and Invasive Prenatal (Fetal) Diagnostic Testing policies to the codes 0335U and 0336U under E/I from February 21, 2023 JUMP. Added the Genetic Testing for Cytochrome P450 Polymorphisms policy to the code 0380U under E/I from February 21, 2023 JUMP. Added the Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines policy to the code 0169U under E/I from February 21, 2023 JUMP. (ky)
9/1/23	6/13/23		<ul style="list-style-type: none"> Revision to code 0308U, revision to laboratory name for codes 0308U, 0309U, and 0310U, released to AMA 3/13/23 effective date 7/1/23. Deletion of 9 codes (0053U, 0143U- 0150U), released to AMA 3/13/23 effective date 7/1/23.

			<ul style="list-style-type: none"> • Revision to proprietary, laboratory and manufacturer name for code 0113U. • Correction to code 0095U by changing uppercase “E” in “Eotaxin-3” to lowercase “e” and adding closed parenthesis “)” after “protein]”. • Added the Multimarker Serum Testing Related to Ovarian Cancer (e.g., OVA1®, Overa™, OvaWatch and ROMA™ testing) policy to the code 0375U under E/I from April 18, 2023 JUMP. • Added the Prostate Cancer Early Detection: Biomarkers Prior to Biopsy policy to the code 0359U and moved this code from E/I to EST from June 13, 2023. The code should have been EST because it represents IsoPSA which is covered on the Prostate Biomarkers policy since 2022. This code should be EST as of 1/1/23. • Added the Diagnosis of Vaginitis (including Bacterial Vaginosis, Trichomonas and Candidiasis) using Multi-target PCR Testing policy to the code 0352U under E/I from June 13, 2023 JUMP. • Added the Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy) policy to the code 0326U under E/I from June 13, 2023 JUMP. • Per change request (FCR# 2023001151) code 0364U moved from Experimental Investigational (E/I) to payable effective April 1, 2023. (ky)
11/1/23	8/15/23		<ul style="list-style-type: none"> • Addition of 15 codes (0387U – 0401U) released to AMA 3/13/23 effective date 7/1/23. • All codes E/I except 0397U is EST – this code will also be added to the Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy) as payable.

			<ul style="list-style-type: none"> Code 0089U is moved to established from E/I per Gene Expression Profiling for Cutaneous Melanoma policy. Code 0089U to be effective 9/1/2023. <p>Post JUMP:</p> <ul style="list-style-type: none"> Added policy Genetic Testing – Next Generation Sequencing for Assessment of Measurable Residual Disease (ClonoSEQ) in Hematological Malignancies to code 0364U under EST per 8/15/23 JUMP. Added policy Genetic Test–ng – Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders to codes 0213U, 0214U, and 0215U under E/I per 8/15/23 JUMP. (ky)
1/1/24	10/17/23		<ul style="list-style-type: none"> Revision of 7 codes (0269U, 0271U, 0272U, 0274U, 0277U, 0278U, 0362U) eff 10/1/23. Deletion of 4 codes (0066U, 0357U, 0386U, 0397U) eff 10/1/23. Addition of 18 codes (0402U–0419U) accepted by the CPT Editorial Panel eff 10/1/23 under E/I. Addition and/or deletion of commas to several code descriptors (0095U, 0365U-0368U) per CPT convention eff 10/1/23. Addition of the term “quantitative” to the code descriptor for code 0389U eff 10/1/23. Replace abbreviation CAD with CHD for coronary heart disease in the code descriptor for code 0401U eff 10/1/23. Added policy Genetic Testing-NGS of Multiple Genes (Panel) for Malignant Conditions to codes 0022U – this code was already EST. Added this JUMP policy to codes 0244U, 0250U, 0334U, and 0379U. Moved these codes from E/I to under EST per Oct 17, 2023 JUMP. Added code 0239U representing FoundationOne® Liquid CDx and 0242U representing Guardant360® CDx as EST on policies: <ul style="list-style-type: none"> Circulating Tumor DNA and Circulating Tumor Cells for

			<p>Management of Solid Cancers (Liquid Biopsy)</p> <ul style="list-style-type: none"> ○ Somatic Biomarker Testing (including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, MMR/MSI, HER2, and TMB) ○ Genetic Testing—BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy ● Added policy Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management of Solid Cancers (Liquid Biopsy) to code 0326U under EST. Added policy Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management of Solid Cancers (Liquid Biopsy) to code 0091U under E/I per October 17, 2023 JUMP. ● Added policy Genetic Testing for Specified Conditions Using Testing Panels to codes 0029U, 0032U, 0033U, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U, 0156U 0173U 0175U and 0345U under E/I per Oct 17, 2023 JUMP. (ky) <p>Post JUMP</p> <ul style="list-style-type: none"> ● Added Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, MMR/MSI, HER2 and TMB) policy to code 0326U under EST per Oct 17, 2023 JUMP. ● Added Genetic Test–ng – BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy policy to codes 0326U and 0037U under EST per Oct 17, 2023 JUMP.
3/1/24	12/19/23		<ul style="list-style-type: none"> ● Revision of 2 codes (0351U, 0356U). ● Per code update added of 19 codes (0420U–0438U) under E/I. ● Added Genetic Testing – Preimplantation policy to the code 0396U under E/I.

			<ul style="list-style-type: none"> Added Urinary Biomarkers for Bladder Cancer policy to the code 0420U under E/I per 12/19/23 JUMP. Added Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (BRCA1, BRCA2, Homologous Recombination Deficiency) policy to codes 0037U, 0172U, and 0239U under EST and to code 0129U under E/I per 12/19/23 JUMP. Added Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (BRCA1/2, Homologous Recombination Repair Gene Alterations) to codes 0037U, 0172U, and 0239U under EST and to code 0129U under E/I per 12/19/23 JUMP. Added Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes policy to codes 0243U, 0247U, and 0390U under E/I per 12/19/23 JUMP. (ky)
5/1/24	2/20/24		<p>Updates:</p> <ul style="list-style-type: none"> Covered / Noncovered tables deleted, one table with code status of EST or EI created PLA codes that referenced JUMP policy Genetic, Molecular and Other Tests-Experimental/Investigational Status, the policy reference is removed, as PLA codes have been removed from that policy. Government Regulations section updated Policy Germline Genetic Testing for BRCA1, BRCA2, and PALB2 for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers added to EI codes: 0102U, 0103U, 0129U (Dec JUMP) Policy Genetic Testing-Somatic Biomarker Testing for Immune Checkpoint Inhibitor Therapy (BRAF, MSI/MMR, PD-L1, TMB) added to EST codes: 0037U, 0239U, 0242U, 0326U, 0334U (Dec JUMP) 0245U: from EI to EST. This test went from EI to EST 1/11/23 on the JUMP policy Genetic Testing-Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid. Review of all codes and associated policies: additions of related JUMP policy names February JUMP changes:

			<ul style="list-style-type: none"> ○ Policy Genetic Testing and Counseling: PLA codes were removed, removed policy title from codes 0001U, 0003U, 0005U, 0246U, 0332U, 0345U, 0347U, 0348U, 0349U, 0350U. ○ 0400U (EI): Policy GT-Carrier Screening for Genetic Diseases added to the code ○ Code update: <ul style="list-style-type: none"> ✓ 0439U, 0440U, 0441U, 0442U, 0443U, 0444U, 0445U, 0446U, 0447U, 0449U added as EI, codes are effective 4/1/2024. ✓ 0448U added as EST, code is effective as of 4/1/2024 ✓ 0354U and 0416U are deleted from CPT as of 3/31/2024 ✓ 0407U – revision to test name Post-JUMP: Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders policy title added to 0212U and 0267U. (ls)
7/1/24	4/16/24		<p>April JUMP policy changes:</p> <ul style="list-style-type: none"> • 0205U (EI) added to policy Genetic Testing for Macular Degeneration. • 0048U, 0444U (EI) added to policy GT-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions. • 0363U (EI) added to policy Urinary Biomarkers for Bladder Cancer. • 0327U (status from EI to EST) and 0449U (EI) added to policy Genetic Testing-Noninvasive Prenatal Screening for Fetal Aneuploidies, Microdeletions, Single-Gene Disorders, and Twin Zygosity Using Cell-Free Fetal DNA. • 0231U (EI) added to policy Genetic Testing for Epilepsy. • 0403U (EI to EST), 0424U (EI), 0433U (EI) added to policy Prostate Cancer Early Detection, Biomarkers Prior to Biopsy. 0113U (EST): code is removed from the JUMP policy; JUMP policy title is no longer a reference on this policy. • 0388U, 0447U, 0448U added as EI to policy Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Non-Small-Cell Lung Cancer. (ls)
9/1/24	6/11/24		<p>June code update changes eff 7/1/24:</p> <ul style="list-style-type: none"> • Deletions: 0204U, 0353U • Additions: 0450U to 0475U (0471U, 0473U are EST, all other codes are EI) • Revision to 0047U <p>(Continued below)</p>

			<p>June JUMP policy changes:</p> <ul style="list-style-type: none"> • 0401U (EI), 0466U (EI) added to policy Cardiovascular Risk Panels • 0352U (EI to EST), 0455U (EI) added to policy Diagnosis of Vaginitis • 0468U (EI) added to policy Noninvasive Tech for Evaluation of Chronic Liver Disease • 0443U, 0445U, 0459U (EI) added to policy Evaluation of Biomarkers for Alzheimer's Disease • 0353U (EI to EST) per internal meeting and MPI process; however, code is being deleted per code update • 0326U (EI to EST) per policy Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Is)
11/1/24	8/20/24		<p>August code update changes eff 10/1/24:</p> <ul style="list-style-type: none"> • Deletions: 0078U, 0167U, 0396U • Additions: 0476U to 0520U (all EI) • Revisions: 0118U, 0248U, 0403U, 0463U, 0465U, 0472U <p>August JUMP policy changes:</p> <ul style="list-style-type: none"> • 0452U, 0465U (EI) added to policy Urinary Biomarkers for Bladder Cancer • 0475U (EI) added to policy Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (BRCA1/2, Homologous Recombination Repair Gene Alterations) • 0092U, 0360U (EI) added to Molecular Testing in the Management of Pulmonary Nodules • 0037U, 0048U, 0244U, 0334U (EI) deleted from policy Genetic Cancer Susceptibility Panels Using Next Generation Sequencing • 0295U (EI) added to GT-Assays of Genetic Expression in Tumor Tissue as a Technique to Help Guide Decision-Making in Patients With Breast Cancer <p>Corrections:</p> <ul style="list-style-type: none"> • 0447U, policy reference Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Non-Small-Cell Lung Cancer removed • 0156U, 0252U; policy reference Genetic Testing-Chromosomal Microarray Testing for the Evaluation of Early Pregnancy Loss and Intrauterine Fetal Demise added • 0346U, policy reference Genetic Testing for Alzheimer's Disease added • Policy "Kidney Transplantation" corrected to "Transplant-Kidney" <p>References updated. (Is)</p>

1/1/25	10/15/24		<p>October JUMP policy changes:</p> <ul style="list-style-type: none"> • 0495U (EI) added to Prostate Cancer Early Detection: Biomarkers Prior to Biopsy • 0471U, 0473U (EST); and 0478U (EI) added to GT-NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions • 0449U (EI) added to GT-Carrier Screening for Genetic Diseases • 0489U (EI) added to Genetic Testing- Noninvasive Prenatal Screening for Fetal Aneuploidies, Microdeletions, Single-Gene Disorders, and Twin Zygosity Using Cell-Free Fetal DNA • 0449U (EI) deleted from Genetic Testing- Noninvasive Prenatal Screening for Fetal Aneuploidies, Microdeletions, Single-Gene Disorders, and Twin Zygosity Using Cell-Free Fetal DNA • 0485U, 0486U, 0487U, 0491U, 0492U (EI) added to Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy) • 0479U and 0503U (EI) added to Evaluation of Biomarkers for Alzheimer's Disease • 0455U, 0480U, 0483U, 0484U, 0505U (EI) added to Identification of Microorganisms Using Nucleic Acid Probes • 0411U, 0423U, 0434U, 0437U, 0438U (EI) added to Genetic Testing for Specified Conditions Using Testing Panels • 0471U and 0473U (EST) added to Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, MMR/MSI, HER2, AND TMB) • 0488U and 0494U (EST) added to Genetic Testing-Fetal RHD. Code status for both codes changed from EI to EST. (Is)
3/1/25	12/17/24		<p>December code update changes, eff 1/1/25:</p> <ul style="list-style-type: none"> • Revised 0095U, 0365U, 0440U • Deleted 0346U, 0352U, 0380U, 0428U, 0448U, 0456U • Added 0521U to 0530U (all EI) (continued below)

3/1/25			<p>December JUMP changes:</p> <ul style="list-style-type: none"> • 0529U (EI) added to Genetic Testing for Inherited Thrombophilias • 0027U (EST) added to Genetic Testing- JAK2, MPL, and CALR Testing for Myeloproliferative Neoplasms • 0482U and 0524U (EI) added to Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes • 0530U (EI) added to Genetic Testing- Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, NTRK and HER2) AND Genetic Testing-Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Non-Small Cell Lung Cancer (EGFR, ALK, BRAF, ROS1, RET, Met, KRAS, HER2, PD-L1, TMB) • Policy Chemosensitivity and Chemoresistance Assay, In Vitro was retired October 2024 JUMP; policy title updated to indicate retired status • 0497U (EI) added to GT-Gene Expression Profile Analysis for Risk Stratification for Prostate Cancer Management (Is)
--------	--	--	---

Next Review Date: Every JUMP meeting