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## Medical Policy



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.**

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**\*Current Policy Effective Date: 3/1/24**  
(See policy history boxes for previous effective dates)

### **Title: Proprietary Laboratory Analyses (PLA) Codes**

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#### **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. These 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 lab. The PLA code set includes:

- Advanced Diagnostic Laboratory Tests (ADLTs)
- Clinical Diagnostic Laboratory Tests (CDLTs)
- Multianalyte Assays with Algorithmic Analyses (MAAA)
- Genomic Sequencing Procedures.

PLA codes describe proprietary analyses and may be provided by “one, sole source” laboratory or may be licensed to multiple labs that may provide the analysis. Proprietary labs apply for assignment of PLA codes for their products. In order for the AMA-CPT Editorial Board to issue a specific code, the Proprietary Lab test must be performed on human specimens and the PLA CODE must be formally requested by the Lab through completion of an AMA-CPT Code Request application.

When the PLA code is released, it generally is not released with information clearly demonstrating 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 quarterly.

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## Regulatory Status

N/A

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## 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.

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## Inclusionary and Exclusionary Guidelines

N/A

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**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.*

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## 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, if any clinical information to review to ascertain the actual 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.

The following PLA Laboratory Analyses (PLA) codes are covered.

**Table 1. PLA Codes That are Covered**

<b>Code</b>	<b>Brand Name</b>	<b>Laboratory and Headquarters Location</b>	<b>Policy (If Applicable)</b>
0003U	Overa (OVA1 Next Generation)	Aspira Labs, Inc Texas	1.)Genetic testing and Counseling) ( 0001U-0005U )  2.)Multimarker Serum Testing Related to Ovarian Cancer (e.g., OVA1®, Overa™ and ROMA™ testing)
0005U	ExosomeDx® Prostate (IntelliScore)	Exosome Diagnostics, Inc. Massachusetts	1.) Prostate Cancer Early Detection – Biomarkers Prior to Biopsy (Previous title: Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer)
0007U	ToxProtect	Genotox Laboratories LTD Texas	
0016U	BCR-ABL1 major and minor breakpoint fusion transcripts	Asuragen Texas	Genetic testing - BCR-ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia
0017U	JAK2 Mutation	University of Iowa, Department of Pathology Iowa	Genetic Testing - JAK2, MPL and CALR Testing for Myeloproliferative Neoplasms
0018U	ThyraMir	Interpace Diagnostics New Jersey	Genetic Testing- Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid
0022U revision eff 4/1/22	Oncomine™ Dx Target Test, Thermo Fisher Scientific	Thermo Fisher Scientific Massachusetts	Genetic Testing – NGS of Multiple Genes (Panel) for

			Solid and Hematolymphoid Malignant Conditions
0023U	LeukoStrat® CDx FLT3 Mutation Assay	LabPMM LLC California	
0026U	Thyroseq Genomic Classifier	CBLPath, Inc New York	Genetic Testing- Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid
0027U	JAK2 Exons 12 to 15 Sequencing	Mayo Clinic Minnesota	
0034U	Thiopurine Methyltransferase (TPMT) and Nudix Hydrolase (NUDT15) Genotyping	Mayo Clinic Minnesota	Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines
0037U	FoundationOne CDx™ (F1CDx)	Foundation Medicine, Inc Massachusetts	<p>1.) Genetic Testing – NGS Testing of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions</p> <p>2.) Somatic Biomarker Testing (including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, MMR/MSI, HER2, and TMB)</p> <p>3.) Genetic Testing - BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy</p> <p>4.) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (BRCA1, BRCA2, Homologous</p>

			Recombination Deficiency)  5.) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (BRCA1/2, Homologous Recombination Repair Gene Alterations)
0039U	Anti-dsDNA, High Salt/Avidity	University of Washington, Department of Laboratory Medicine Washington	
0040U	MRDx BCR-ABL Test	MolecularMD Oregon	Genetic Testing-BCR/ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia
0041U	Lyme ImmunoBlot IgM	IGeneX Inc California	
0042U	Lyme ImmunoBlot IgG	IGeneX Inc California	
0043U	Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgM Test	IGeneX Inc California	
0044U	Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgG Test	IGeneX Inc California	
0046U	FLT3 ITD MRD by NGS	LabPMM LLC California	
0047U	Oncotype DX Genomic Prostate Score	Genomic Health, Inc California	Gene Expression Profile Analysis for Risk Stratification
0049U	NPM1 MRD by NGS	LabPMM LLC California	
0064U	BioPlex 2200 Syphilis Total & RPR Assay	Bio-Rad Laboratories California	
0065U	BioPlex 2200 RPR Assay	Bio-Rad Laboratories California	

0068U	MYCODART Dual Amplification Real Time PCR Panel for 6 Candida species	RealTime Laboratories, Inc/MycoDART, Inc Texas	
0077U	M-Protein Detection and Isotyping by MALDI-TOF Mass Spectrometry	Mayo Clinic Minnesota	
0089U effective 9/1/2023	Pigmented Lesion Assay (PLA)	DermTech California	Gene Expression Profiling for Cutaneous Melanoma
0093U	ComplyRX	Claro Labs Colorado	
0094U	RCIGM Rapid Whole Genome Sequencing	Rady Children's Institute for Genomic Medicine (RCIGM) California	Genetic Testing - Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0107U	Singulex Clarity C.diff toxins A/B assay	Singulex California	
0111U	Praxis(TM) Extended RAS Panel	Illumina California	KRAS, NRAS AND BRAF VARIANT ANALYSIS IN METASTATIC COLORECTAL CANCER (INCLUDING LIQUID BIOPSY)
0113U	MyProstate Score, Lynx DX	Lynx Dx Michigan	Prostate Cancer Early Detection – Biomarkers Prior to Biopsy (Previous title: Genetic and Protein Biomarkers for Prostate Cancer)
0155U	therascreen® PIK3CA	QIAGEN Sciences Maryland	
0172U	myChoice® CDx	Myriad Genetic Laboratories Utah	1.) Genetic Testing – NGS Testing of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions  2.) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for

			<p>Targeted Treatment in Ovarian Cancer (BRCA1, BRCA2, Homologous Recombination Deficiency)</p> <p>3.) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (BRCA1/2, Homologous Recombination Repair Gene Alterations)</p>
0177U	therascreen® PIK3CA RGQ PCR Kit	QIAGEN Sciences Maryland	
0202U	BioFire® Respiratory 2.1 (RP2.1) Panel with SARS-CoV-2	BioFire® Diagnostics Utah	COVID CR 6/11/20
0223U	QIAstat-Dx Respiratory SARS CoV-2 Panel	QIAGEN Sciences Maryland	
0224U	COVID-19 Antibody Test	Mount Sinai Laboratory New York	
0226U	Tru-Immune™	Ethos Laboratories Kentucky	
0239U	FoundationOne® Liquid CDx	Foundation Medicine Massachusetts	<p>1.) Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)</p> <p>2.) Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management of Solid Cancers (Liquid Biopsy)</p> <p>3.) Somatic Biomarker Testing (including Liquid</p>

			<p>Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, MMR/MSI, HER2, and TMB)</p> <p>4.) Genetic Testing— BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy</p> <p>5.) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (BRCA1, BRCA2, Homologous Recombination Deficiency)</p> <p>6.) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (BRCA1/2, Homologous Recombination Repair Gene Alterations)</p>
0240U revision to name eff 4/1/22	Xpert® Xpress CoV-2/Flu/RSV plus (all targets), Cepheid®	Cepheid California	
0241U revision to name eff 4/1/22	Xpert® Xpress CoV-2/Flu/RSV plus (all targets), Cepheid®	Cepheid California	
0242U	Guardant360® CDx	Guardant Health California	1.) Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)



			<p>2.) Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management of Solid Cancers (Liquid Biopsy)</p> <p>3.) Somatic Biomarker Testing (including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, MMR/MSI, HER2, and TMB)</p> <p>4.) Genetic Testing— BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy</p>
0244U	Oncotype MAP™ PanCancer Tissue Test	Paradigm Diagnostics, Inc Arizona	Genetic Testing – NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0250U	PGDx elio™ tissue complete	Personal Genome Diagnostics, Inc Maryland	Genetic Testing – NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0326U	Guardant360®	Guardant Health, Inc California	<p>1.) Circulating Tumor DNA and Circulating Tumor Cells for Management of Solid Cancers (Liquid Biopsy)</p> <p>2.) Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and</p>

			Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, MMR/MSI, HER2 and TMB)  3.) Genetic Testing - BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy
0334U	Guardant360 TissueNext™	Guardant Health, Inc California	Genetic Testing – NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions
0359U EST eff as of 1/1/23.	IsoPSA®	Cleveland Diagnostics, Inc, Cleveland, OH	Prostate Cancer Early Detection – Biomarkers Prior to Biopsy
0364U	clonoSEQ® Assay	Adaptive Biotechnologies, Seattle, WA	Genetic Testing – Next Generation Sequencing for Assessment of Measurable Residual Disease (ClonoSEQ) in Hematological Malignancies
0379U	Solid Tumor Expanded Panel, Quest Diagnostics®	Quest Diagnostics®	Genetic Testing – NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions

The following PLA Laboratory Analyses (PLA) codes are excluded from coverage and considered experimental/investigational due to lack of literature establishing clinical efficacy, safety, or the applicability to clinical practice.

**Table 2. PLA Codes That are Noncovered Due to Experimental/Investigational Status**

Code	Brand Name	Laboratory and Headquarters Location	Policy (If Applicable)
0001U	Precise Type ® HEA test	Immucor, Inc. Georgia	Genetic Testing and counseling Policy
0002U	PolypDX™	Atlantic Diagnostic Laboratories Pennsylvania	1.) Genetic Testing and counseling Policy

			2.) Polymetabolite Urine Testing – Adenomatous Polyps
0008U	AmHPR Helicobacter pylori Antibiotic Resistance Next Generation Sequencing Panel	American Molecular Laboratories, Inc. Illinois	
0009U	DEPArray™ HER2	PacificDx California	
0010U	Bacterial Typing by Whole Genome Sequencing	Mayo Clinic Minnesota	
0011U	Cordant CORE™	Cordant Health Solutions Colorado	Drug testing of Urine, Oral Fluids and Hair Policy-EST 5/1/19 U codes removed 6/20/19. Policy renamed Drug testing in Pain Management and Substance Use Disorder (no U codes included) Effective 3/1/2020)
0019U	OncoTarget/OncoTreat	Columbia University Department of Pathology and Cell Biology New York	
0021U	Apify®	Armune BioScience, Inc. Wisconsin	1.) Genetic Tests - Experimental  2.) Prostate Cancer Early Detection – Biomarkers Prior to Biopsy (Previous title: Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer
0024U	GlycA	Laboratory Corporation of America North Carolina	
0025U	UrSure Tenofovir Quantification Test	Synergy Medical Laboratories New Jersey	
0029U	Focused Pharmacogenomics Panel	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0030U	Warfarin Response Genotype	Mayo Clinic Minnesota	

0031U	Cytochrome P450 1A2 Genotype	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0032U	Catechol-Omethyltransferase (COMT) Genotype	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0033U	Serotonin Receptor Genotype (HTR2A and HTR2C)	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0035U	Real-time quaking-induced conversion for prion detection (RT-QuIC)	National Prion Disease Pathology Surveillance Center Ohio	
0036U	EXaCT-1 Whole Exome Testing	Weill Cornell Medicine- Clinical Genomics Laboratory New York	Whole Exome /Whole Genome Sequencing for Diagnosis of Genetic Disorders PCR E/I effective 3/1/21
0037U	FoundationOne CDx™ (F1CDx)	Foundation Medicine, Inc Massachusetts	1.)Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
0038U	Sensieva™ Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay	InSource Diagnostics California	
0045U	The Oncotype DX® Breast DCIS Score™ Test	Genomic Health, Inc California	Genetic Testing-Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis in Patients with Breast Cancer
0048U	MSK-IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets)	Memorial Sloan Kettering Cancer Center New York	Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
0050U	MyAML NGS Panel	LabPMM LLC California	
0051U	UcomplIDx	Elite Medical Laboratory Solutions, LLC Texas	
0052U	VAP Cholesterol Test	VAP Diagnostics Laboratory, Inc Alabama	Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease
0054U	AssuranceRx Micro Serum	Firstox Laboratories, LLC Texas	Drug testing of Urine, Oral Fluids and Hair Policy-EST 5/1/19 U codes removed 6/20/19. Policy renamed Drug testing in Pain Management and Substance Use Disorder

			(no U codes included) Effective 3/1/2020)
0055U	myTAIHEART	TAI Diagnostics, Inc. Wisconsin	1.)Genetic Test-Experimental  2.)Laboratory Tests Post Transplant (Kidney and Heart) and for Heart Failure (Combination of 2 policies: Content and codes from Molecular Testing for CHF and Heart transplant merged into this policy )Effective date 9/1/2021
0058U	Merkel SmT Oncoprotein Antibody Titer	University of Washington, Department of Laboratory Medicine Washington	
0059U	Merkel Virus VP1 Capsid Antibody	University of Washington, Department of Laboratory Medicine Washington	
0060U	Twins Zygosity PLA	Natera, Inc. California	Genetic Testing -Noninvasive Prenatal Screening for Fetal Aneuploidies, Microdeletions 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 California	
0062U	SLE-key® Rule Out	Veracis Inc Virginia	
0063U	NPDX ASD ADM Panel I	Stemina Biomarker Discovery, Inc Wisconsin	
0067U	BBDRisk Dx™	Silbiotech, Inc Maryland	
0069U	miR-31now™	GoPath Laboratories Illinois	
0070U	CYP2D6 Common Variants and Copy Number	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels

0071U	CYP2D6 Full Gene Sequencing	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0072U	CYP2D6-2D7 Hybrid Gene Targeted Sequence Analysis	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0073U	CYP2D7-2D6 Hybrid Gene Targeted Sequence Analysis	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0074U	CYP2D6 trans-duplication/multiplication non-duplicated gene targeted sequence analysis	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0075U	CYP2D6 5' gene duplication/multiplication targeted sequence analysis	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0076U	CYP2D6 3' gene duplication/multiplication targeted sequence analysis	Mayo Clinic Minnesota	Genetic Testing for Specified Conditions Using Testing Panels
0078U	INFINITI® Neural Response Panel	PersonalizeDx Labs California	
0079U	ToxLok™	InSource Diagnostics California	
0080U	BDX-XL2	Biodesix®, Inc Colorado	Molecular Testing in the Management of Pulmonary Nodules
0082U	NextGen Precision™ Testing	Precision Diagnostics Massachusetts	
0083U	Onco4D™	Animated Dynamics, Inc Indiana	
0084U	BLOODchip® ID CORE XT™	Grifols Diagnostic Solutions Inc California	
0086U	Accelerate PhenoTest™ BC kit	Accelerate Diagnostics, Inc Arizona	
0087U	Molecular Microscope® MMDx—Heart	Kashi Clinical Laboratories Oregon	
0088U	Molecular Microscope® MMDx—Kidney	Kashi Clinical Laboratories Oregon	Kidney Transplantation

0090U Revision eff 1/1/22	myPath® Melanoma	Castle Biosciences, Inc Texas	
0091U	FirstSightCRC	CellMax Life California	1.) Genetic, Molecular and Other Tests- Experimental/Investigational Status  2.) Circulating Tumor DNA and Circulating Tumor Cells for Management of Solid Cancers (Liquid Biopsy)
0092U	REVEAL Lung Nodule Characterization	MagArray, Inc California	
0095U	Esophageal String Test™ (EST)	Children's Hospital Colorado Department of Pathology and Laboratory Medicine	
0096U	HPV, High-Risk, Male Urine	Molecular Testing Labs Washington	
0101U	ColoNext®	Ambry Genetics California	
0102U	BreastNext®	Ambry Genetics California	Genetic Testing for Li- Fraumeni Syndrome
0103U	OvaNext®	Ambry Genetics California	
0105U	KidneyIntelXTM	RenalytixAI New York	
0106U	13C-Spirulina Gastric Emptying Breath Test (GEBT)	Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC Iowa	
0108U	TissueCypher® Barrett's Esophagus Assay	Cernostics Pennsylvania	
0109U	MYCODART Dual Amplification Real Time PCR Panel for 4 Aspergillus species	RealTime Laboratories, Inc/MycoDART, Inc Texas	
0110U	Oral OncolyticAssuranceRX	Firstox Laboratories, LLC Texas	
0112U	MicroGenDX qPCR & NGS For Infection	MicroGenDX Texas	
0114U	EsoGuard™	Lucid Diagnostics New York	

0115U	ePlex Respiratory Pathogen (RP) Panel	GenMark Diagnostics, Inc California	
0116U	Snapshot Oral Fluid Compliance	Ethos Laboratories Kentucky	
0117U	Foundation PISM	Ethos Laboratories Kentucky	
0118U	Viracor TRACTM; dd-cfDNA	Viracor Eurofins Missouri	1.) Genetic, Molecular and Other Tests Experimental/Investigational Status 2.) Laboratory Tests Post Transplant (Kidney and Heart) and for Heart Failure (Combination of 2 policies: Content and codes from Molecular Testing for CHF and Heart transplant merged into this policy (effective date 9/1/2021))
0119U	MI-HEART Ceramides, Plasma	Mayo Clinic Minnesota	
0120U	Lymph3Cx Lymphoma Molecular Subtyping Assay	Mayo Clinic Minnesota	
0121U	Flow Adhesion of Whole Blood on VCAM-1 (FAB-V)	Functional Fluidics Michigan	
0122U	Flow Adhesion of Whole Blood to P-SELECTIN(WB-PSEL)	Functional Fluidics Michigan	
0123U	Mechanical Fragility, RBC by shear stress profiling and spectral analysis	Functional Fluidics Michigan	
0129U	BRCaPlus	Ambry Genetics California	1.) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (BRCA1, BRCA2, Homologous Recombination Deficiency)  2.) Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (BRCA1/2, Homologous Recombination Repair Gene Alterations)



0130U	RNAinsight™ for ColoNext®	Ambry Genetics California	
0131U	RNAinsight™ for BreastNext®	Ambry Genetics California	Genetic Testing for Li-Fraumeni Syndrome (effective date 1/1/22)
0132U	RNAinsight™ for OvaNext®	Ambry Genetics California	
0133U	RNAinsight™ for ProstateNext®	Ambry Genetics California	
0134U	RNAinsight™ for CancerNext®	Ambry Genetics California	
0135U	RNAinsight™ for GYNPlus®	Ambry Genetics California	
0136U	RNAinsight™ for ATM	Ambry Genetics California	
0137U	RNAinsight™ for PALB2	Ambry Genetics California	
0138U	RNAinsight™ for BRCA1/2	Ambry Genetics California	
0140U	ePlex BCID Fungal Pathogens Panel	GenMark Diagnostics, Inc California	
0141U	ePlex BCID Gram-Positive Panel	GenMark Diagnostics, Inc California	
0142U	ePlex BCID Gram-Negative Panel	GenMark Diagnostics, Inc California	
0152U	Karius Test	Karius Inc California	
0153U	Insight TNBCtype	Insight Molecular Labs Tennessee	Genetic Testing Assays of Genetic Expression in Tumor Tissue A Technique to Determine Prognosis In patients With Breast Cancer
0154U	Therascreen FGFR3	QIAGEN Sciences Maryland	
0156U	SMASH	New York Genome Center New York	1.) 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  2.) Genetic Testing for Specified Conditions Using Testing Panels

0157U	CustomNext + RNA: APC	Ambry Genetics California	
0158U	CustomNext + RNA: MLH1	Ambry Genetics California	
0159U	CustomNext + RNA: MSH2	Ambry Genetics California	
0160U	CustomNext + RNA: MSH6	Ambry Genetics California	
0161U	CustomNext + RNA: PMS2	Ambry Genetics California	
0162U	CustomNext + RNA: Lynch (MLH1, MSH2, MSH6, PMS2)	Ambry Genetics California	
0163U	BeScreened™-CRC	Beacon Biomedical Inc Arizona	
0164U	ibs-smart™	Gemelli Biotech California	
0165U	VeriMAP Peanut Dx – Bead-based Epitope Assay	AllerGenis™ LLC Pennsylvania	
0166U	LiverFASt™	Fibronostics Florida	
0167U	ADEXUSDx hCG Test	NOWDiagnostics Arkansas	
0169U	NT (NUDT15 and TPMT) genotyping panel	RPRD Diagnostics Wisconsin	Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines
0170U	Clarifi™	Quadrant Biosciences, Inc New York	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 California	
0173U	Psych HealthPGx Panel	RPRD Diagnostics Wisconsin	Genetic Testing for Specified Conditions Using Testing Panels
0174U	LC-MS/MS Targeted Proteomic Assay	OncoOmicDx Laboratory, LDT Maryland	

0175U	Genomind® Professional PGx Express™ CORE	Genomind, Inc Pennsylvania	Genetic Testing for Specified Conditions Using Testing Panels
0176U	IBSchek®	Commonwealth Diagnostics International, Inc Massachusetts	
0178U	VeriMAP™ Peanut Reactivity Threshold – Bead Based Epitope Assay	AllerGenis™ LLC Pennsylvania	
0179U	Resolution ctDx Lung™	Resolution Bioscience, Inc Washington	Circulating Tumor DNA for management of NSC Lung CA (Liquid Biopsy)
0180U	Navigator ABO Sequencing	Grifols Immunohematology Center California	
0181U	Navigator CO Sequencing	Grifols Immunohematology Center California	
0182U	Navigator CROM Sequencing	Grifols Immunohematology Center California	
0183U	Navigator DI Sequencing	Grifols Immunohematology Center California	
0184U	Navigator DO Sequencing	Grifols Immunohematology Center California	
0185U	Navigator FUT1 Sequencing	Grifols Immunohematology Center California	
0186U	Navigator FUT2 Sequencing	Grifols Immunohematology Center California	
0187U	Navigator FY Sequencing	Grifols Immunohematology Center California	
0188U	Navigator GE Sequencing	Grifols Immunohematology Center California	

0189U	Navigator GYPA Sequencing	Grifols Immunoematology Center California	
0190U	Navigator GYPB Sequencing	Grifols Immunoematology Center California	
0191U	Navigator IN Sequencing	Grifols Immunoematology Center California	
0192U	Navigator JK Sequencing	Grifols Immunoematology Center California	
0193U	Navigator JR Sequencing	Grifols Immunoematology Center California	
0194U	Navigator KEL Sequencing	Grifols Immunoematology Center California	
0195U	Navigator KLF1 Sequencing	Grifols Immunoematology Center California	
0196U	Navigator LU Sequencing	Grifols Immunoematology Center California	
0197U	Navigator LW Sequencing	Grifols Immunoematology Center California	
0198U	Navigator RHD/CE Sequencing	Grifols Immunoematology Center California	
0199U	Navigator SC Sequencing	Grifols Immunoematology Center California	
0200U	Navigator XK Sequencing	Grifols Immunoematology Center California	

0201U	Navigator YT Sequencing	Grifols Immunoematology Center California	
0203U	PredictSURE IBD™ Test	KSL Diagnostics New York	
0204U	Afirma Xpression Atlas	Veracyte, Inc California	
0205U	Vita Risk	Arctic Medical Laboratories Michigan	
0206U	DISCERN™	NeuroDiagnostics Maryland	
0207U	DISCERN™	NeuroDiagnostics Maryland	
0209U	CNGnome	PerkinElmer Genomics Pennsylvania	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	Bio-Rad Laboratories California	
0211U	MI Cancer Seek™ NGS Analysis	Caris MPI d/b/a Caris Life Sciences Texas	
0212U	Genomic Unity® Whole Genome Analysis	Varietyx Inc Massachusetts	
0213U	Genomic Unity® Whole Genome Analysis – Comparator	Varietyx Inc Massachusetts	Genetic Testing - Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0214U	Genomic Unity® Exome Plus Analysis – Proband	Varietyx Inc Massachusetts	Genetic Testing - Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0215U	Genomic Unity® Exome Plus Analysis – Comparator	Varietyx Inc Massachusetts	Genetic Testing - Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders
0216U	Genomic Unity® Ataxia Repeat Expansion and Sequence Analysis	Varietyx Inc Massachusetts	
0217U	Genomic Unity® Comprehensive Ataxia	Varietyx Inc Massachusetts	

	Repeat Expansion and Sequence Analysis		
0218U	Genomic Unity® DMD Analysis	Variantyx Inc Massachusetts	
0219U	Sentosa® SQ HIV-1 Genotyping Assay	Vela Diagnostics USA, Inc New Jersey	
0220U	PreciseDx™ Breast Cancer Test	PreciseDx New York	
0221U	Navigator ABO Blood Group NGS	Grifols Immunoematology Center California	
0222U	Navigator Rh Blood Group NGS	Grifols Immunoematology Center California	
0225U	ePlex® Respiratory Pathogen Panel 2,	GenMark Diagnostics, Inc California	
0227U	Comprehensive Screen	Aspenti Health Massachusetts	
0228U	PanGIA Prostate	Genetics Institute of America Florida	1.)Genetic Tests - Experimental  2.)Genetic and Protein Biomarkers for the DX and Cancer Risk Assessment of Prostate Cancer
0229U	Colvera	Clinical Genomics Pathology Inc New Jersey	1.)Genetic tests - Experimental  2.)Gene Expression Profile Testing and circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer
0230U	Genomic Unity® AR Analysis	Variantyx Inc Massachusetts	
0231U	Genomic Unity® CACNA1A Analysis	Variantyx Inc Massachusetts	
0232U	Genomic Unity® CSTB Analysis	Variantyx Inc Massachusetts	
0233U	Genomic Unity® FXN Analysis	Variantyx Inc Massachusetts	
0234U	Genomic Unity® MECP2 Analysis	Variantyx Inc Massachusetts	1.)Genetic tests - Experimental  2.)Genetic Testing for Rett Syndrome

0235U	Genomic Unity® PTEN Analysis	Varietyx Inc Massachusetts	Genetic Testing for PTEN Hamartoma Tumor Syndrome-
0236U	Genomic Unity® SMN1/2 Analysis	Varietyx Inc Massachusetts	Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing
0237U	Genomic Unity® Cardiac Ion Channelopathies Analysis	Varietyx Inc Massachusetts	Genetic Testing for Cardiac Ion Channelopathies
0238U	Genomic Unity® Lynch Syndrome Analysis	Varietyx Inc Massachusetts	1.)Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes  2.)Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
0243U	PIGF Preeclampsia Screen	PerkinElmer Genomics Pennsylvania	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
0244U	Oncotype MAP™ PanCancer Tissue Test	Paradigm Diagnostics, Inc Arizona	Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
0245U	ThyGeNEXT® Thyroid Oncogene Panel	Interpace Diagnostics New Jersey	Genetic Testing-Molecular Markers in Fine Needle Aspirates of the Thyroid
0246U	PrecisionBlood™	San Diego Blood Bank California	
0247U	PreTRM®	Sera Prognostics Utah	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
0248U	3D Predict Glioma	KIYATEC® South Carolina	Chemosensitivity and Chemoresistance Assay in Vitro (effective date 1/1/22)
0249U	Theralink® Reverse Phase Protein Array (RPPA)	Theralink® Technologies, Inc Colorado	
0251U	Intrinsic Hecpidin Idx™ Test	Intrinsic LifeSciences LLC California	
0252U	POC (Products of Conception)	Igenomix Florida	
0253U	ERA® (Endometrial Receptivity Analysis)	Igenomix Florida	Reproductive Techniques (effective date 1/1/22)

0254U	SMART PGT-A (Pre implantation Genetic Testing – Aneuploidy)	Igenomix Florida	Genetic Testing-Preimplantation (effective date 3/1/22)
0255U	Cap-Score™ Test	Androvia LifeSciences, Avantor Clinical Services New Jersey	
0256U	Trimethylamine (TMA) and TMA N-Oxide	Children’s Hospital Colorado Laboratory Colorado	
0257U	Very-Long Chain AcylCoA Dehydrogenase (VLCAD) Enzyme Activity	Children’s Hospital Colorado Laboratory Colorado	
0258U	Mind.Px	Mindera Corporation California	
0259U	GFR by NMR	Labtech™ Diagnostics South Carolina	
0260U	Augusta Optical Genome Mapping	Bionano Genomics Inc California	
0261U	Immunoscore	HalioDx Virginia	
0262U	OncoSignal 7 Pathway Signal	Protean BioDiagnostics Florida	
0263U	NPDX ASD and Central Carbon Energy Metabolism	Stemina Biomarker Discovery, Inc Wisconsin	
0264U	Praxis Optical Genome Mapping	Praxis Genomics LLC Georgia	
0265U	Praxis Whole Genome Sequencing	Praxis Genomics LLC Georgia	
0266U	Praxis Transcriptome	Praxis Genomics LLC Georgia	
0267U	Praxis Combined Whole Genome Sequencing and Optical Genome Mapping	Praxis Genomics LLC Georgia	
0268U	Versiti™ aHUS Genetic Evaluation	Versiti™ Diagnostic Laboratories Wisconsin	



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

0285U	RadTox™ cfDNA	DiaCarta Clinical Lab California	
0286U	CNT (CEP72, TPMT and NUDT15) genotyping panel	RPRD Diagnostics Wisconsin	
0287U	ThyroSeq® CRC	CBLPath, Inc. New York	
0288U	DetermaRx™	Oncocyte Corporation California	
0289U	MindX Blood Test™ - Memory/Alzheimer's	MindX Sciences™ Inc. Indiana	
0290U	MindX Blood Test™ - Pain	MindX Sciences™ Inc. Indiana	
0291U	MindX Blood Test™ - Mood	MindX Sciences™ Inc. Indiana	
0292U	MindX Blood Test™ - Stress	MindX Sciences™ Inc. Indiana	
0293U	MindX Blood Test™ - Suicidality	MindX Sciences™ Inc. Indiana	
0294U	MindX Blood Test™ - Longevity	MindX Sciences™ Inc. Indiana	
0295U	DCISionRT®	Prelude Corporation California	
0296U	mRNA CancerDetect™	Viome Life Sciences, Inc. Washington	
0297U	Praxis Somatic Whole Genome Sequencing	Praxis Genomics, LLC. Georgia	
0298U	Praxis Somatic Transcriptome	Praxis Genomics, LLC. Georgia	
0299U	Praxis Somatic Optical Genome Mapping	Praxis Genomics, LLC. Georgia	
0300U	Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping	Praxis Genomics, LLC. Georgia	

0301U	Bartonella ddPCR	Galaxy Diagnostics, Inc. North Carolina	
0302U	Bartonella Digital ePCR™	Galaxy Diagnostics, Inc. North Carolina	
0303U	Hypoxic BioChip Adhesion	BioChip Labs™ Ohio	
0304U	Normoxic BioChip Adhesion	BioChip Labs™ Ohio	
0305U	Ektacytometry	BioChip Labs™ Ohio	
0306U	Invitae PCM Tissue Profiling and MRD Baseline Assay	Invitae Corporation California	
0307U	Invitae PCM MRD Monitoring	Invitae Corporation California	
0308U	HART CADhs®	Atlas Genomics, Washington	
0309U	HART CVE®	Atlas Genomics, Washington	
0310U	HART KD®	Atlas Genomics, Washington	
0311U	Accelerate PhenoTest® BC kit, AST configuration	Accelerate diagnostics, Inc, Arizona	
0312U	Avise® Lupus	Exagen Inc, California	
0313U	PancreaSeq® Genomic Classifier, Molecular and Genomic	Pathology Laboratory, University of Pittsburgh Medical Center, Pennsylvania	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, Texas	
0315U	DecisionDx®-SCC	Castle Biosciences, Inc, Texas	
0316U	Lyme Borrelia Nanotrap® Urine Antigen Test	Galaxy Diagnostics Inc, North Carolina	
0317U	LungLB®, LungLife AI®, LungLife AI®	LungLife AI, California	

0318U	EpiSign Complete	Greenwood Genetic Center, South Carolina	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, Inc Tennessee	
0320U	Tuteva™	Verici Dx, Inc Tennessee	
0321U	Bridge Urinary Tract Infection Detection and Resistance Test	Bridge Diagnostics, Colorado	
0322U	NPDX ASD Test Panel III	Stemina Biomarker Discovery d/b/a NeuroPointDX, Wisconsin	
0323U	Johns Hopkins Metagenomic NextGeneration Sequencing Assay for Infectious Disease Diagnostics	Johns Hopkins Medical Microbiology Laboratory, Baltimore, MD	
0326U	Guardant360®	Guardant Health, Inc, Redwood City, CA	Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)
0327U	Vasistera™	Natera, Inc, Carlos, CA	Genetic Testing-Noninvasive Prenatal Screening For Fetal Aneuploidies, Microdeletions, and Twin Zygosity Using Cell-Free Fetal DNA
0328U	CareView360	Newstar Medical Laboratories, LLC, Kennesaw, GA	
0329U	Oncomap™ ExTra	Exact Sciences, Inc, Madison, WI Genomic Health Inc, Redwood City, CA	
0330U	Bridge Women's Health Infectious Disease Detection Test	Bridge Diagnostics, Irvine CA	
0331U	Augusta Hematology Optical Genome Mapping	Georgia Esoteric and Molecular Labs, Augusta	

		University, Bionano Genomics Inc California	
0332U	EpiSwitch® CiRT (Checkpoint-inhibitor Response Test)	Bio-Research Services, LLC, Oxford BioDynamics, PLC Oxford, UK	1.) Genetic, Molecular and Other Tests- Experimental/Investigational Status  2.) Genetic Testing and Counseling
0333U	HelioLiver™ Test	Fulgent Genetics, LLC, Helio Health, Inc	Genetic, Molecular and Other Tests- Experimental/Investigational Status
0335U	IriSight™ Prenatal Analysis – Proband	Variantix, Inc Massachusetts	Genetic Testing – Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders, Invasive Prenatal (Fetal) Diagnostic Testing
0336U	IriSight™ Prenatal Analysis – Comparator	Variantix, Inc Massachusetts	Genetic Testing – Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders, Invasive Prenatal (Fetal) Diagnostic Testing
0337U	CELLSEARCH® Circulating Multiple Myeloma Cell (CMMC) Test	Menarini Silicon Biosystems, Inc Pennsylvania	BMT – Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome
0338U	CELLSEARCH® HER2 Circulating Tumor Cell (CTC-HER2) Test	Menarini Silicon Biosystems, Inc Pennsylvania	Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid Biopsy)
0340U	Signatera™	Natera, Inc Carlos, CA	Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer (e.g., Coloprint, Colon PRS, GeneFx, OncoDefender, Oncotype Dx® Colon Cancer Test)
0341U	Single Cell Prenatal Diagnosis (SCPD) Test	Luna Genetics, Inc Houston, TX	
0342U	IMMray® PanCan-d	Immunovia, Inc Marlborough, MA	Genetic, Molecular and Other Tests- Experimental/Investigational Status

0343U	miR Sentinel™ Prostate Cancer Test	miR Scientific, LLC New York, NY	Prostate Cancer Early Detection – Biomarkers Prior to Biopsy
0344U	OWLiver®	CIMA Sciences, LLC San Antonio, TX	
0345U	GeneSight® Psychotropic	Assurex Health, Inc, Myriad Genetics, Inc	Genetic Testing and Counseling  Genetic Testing for Specified Conditions Using Testing Panels
0346U	QUEST AD-Detect™, Beta-Amyloid 42/40 Ratio, Plasma	Quest Diagnostics	
0347U	RightMed® PGx16 Test	OneOme®, LLC Minneapolis, MN	Genetic Testing and Counseling
0348U	RightMed® Comprehensive Test Exclude F2 and F5	OneOme®, LLC Minneapolis, MN	Genetic Testing and Counseling
0349U	RightMed® Comprehensive Test	OneOme®, LLC Minneapolis, MN	Genetic Testing and Counseling
0350U	RightMed® Gene Report	OneOme®, LLC Minneapolis, MN	Genetic Testing and Counseling
0351U	MeMed BV®	MeMed Diagnostics, Ltd Israel	Genetic, Molecular and Other Tests- Experimental/Investigational Status
0352U	Xpert® Xpress MVP	Cepheid® Sunnyvale, CA	Diagnosis of Vaginitis (including Bacterial Vaginosis, Trichomonas and Candidiasis) using Multi-target PCR Testing
0353U	Xpert® CT/NG	Cepheid® Sunnyvale, CA	
0354U	PreTect HPV-Proofer® 7	GenePace Laboratories, LLC, PreTech	
0355U	Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping	Quest Diagnostics®,	
0356U	NavDx®	Naveris, Inc Natick, MA	
0358U	Lumipulse® G β-Amyloid Ratio (1-42/1-40) Test	Fujirebio Diagnostics, Inc, Malvern, PA	
0360U	Nodify CDT®	Biodesix, Inc, Boulder, CO	
0361U	Neurofilament Light Chain (NfL)	Mayo Clinic,	

0362U	Thyroid GuidePx®	Protean BioDiagnostics, Orlando, FL	
0363U	Cxbladder™ Triage, Pacific Edge	Pacific Edge Diagnostics USA, Ltd, Hershey, PA	
0365U	Oncuria® Detect, DiaCarta Clinical Lab	DiaCarta, Inc Pleasanton, CA	
0366U	Oncuria® Monitor, DiaCarta Clinical Lab	DiaCarta, Inc Pleasanton, CA	
0367U	Oncuria® Predict, DiaCarta Clinical Lab	DiaCarta, Inc Pleasanton, CA	
0368U	ColoScape™ Colorectal Cancer Detection, DiaCarta Clinical Lab,	DiaCarta, Inc Pleasanton, CA	
0369U	GI assay (Gastrointestinal Pathogen with ABR), Lab Genomics LLC,	Thermo Fisher Scientific, Waltham, MA	
0370U	Lesion Infection (Wound), Lab Genomics LLC,	Thermo Fisher Scientific, Waltham, MA	
0371U	Qlear UTI, Lifescan Labs of Illinois,	Thermo Fisher Scientific, Waltham, MA	
0372U	Qlear UTI – Reflex ABR, Lifescan Labs of Illinois,	Thermo Fisher Scientific, Waltham, MA	
0373U	Respiratory Pathogen with ABR (RPX), Lab Genomics LLC	Thermo Fisher Scientific, Waltham, MA	
0374U	Urogenital Pathogen with Rx Panel (UPX), Lab Genomics LLC,	Thermo Fisher Scientific, Waltham, MA	
0375U	OvaWatch <sup>SM</sup> , Aspira Women's Health <sup>SM</sup>	Aspira Labs, Inc Austin, TX	Multimarker Serum Testing Related to Ovarian Cancer (e.g., OVA1®, Overa™, OvaWatch and ROMA™ testing)
0376U	ArteraAI Prostate Test, Artera Inc ©	Artera Inc © Atlanta, GA	
0377U	Liposcale®	CIMA Sciences, LLC San Antonio, TX	
0378U	UCGSL RFC1 Repeat Expansion Test	University of Chicago Genetic	

		Services Laboratories Chicago, IL	
0380U	PersonalisedRX, Lab Genomics LLC	Agena Bioscience, Inc	Genetic Testing for Cytochrome P450 Polymorphisms
0381U	Branched-Chain Amino Acids, Self- Collect, Blood Spot	Mayo Clinic, Laboratory Developed Test	
0382U	Phenylalanine and Tyrosine, Self- Collect, Blood Spot	Mayo Clinic, Laboratory Developed Test	
0383U	Tyrosinemia Follow- Up Panel, Self- Collect, Blood Spot	Mayo Clinic, Laboratory Developed Test	
0384U	NaviDKDTM Predictive Diagnostic Screening for Kidney Health	Journey Biosciences, Inc Lebanon, NH	
0385U	PromarkerD, Sonic Reference Laboratory	Proteomics International Pty Ltd	
0387U	AMBLor® melanoma prognostic test	Avero® Diagnostics Irving, TX	
0388U	InVisionFirst®-Lung Liquid Biopsy	Inivata, Inc, Durham, NC	
0389U	KawasakiDx, OncoOmicsDx Laboratory	mProbe Rockville, MD	
0390U	PEPredictDx, OncoOmicsDx Laboratory	mProbe Rockville, MD	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
0391U	Strata Select™	Strata Oncology, Inc, Ann Arbor, MI	
0392U	Medication Management Neuropsychiatric Panel	RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx Glen Allen, VA	
0393U	SYNTap® Biomarker Test	Amprion Clinical Laboratory San Diego, CA	
0394U	PFAS Testing & PFASure™	National Medical Services, NMS Labs, Inc Grand Prairie, TX	
0395U	OncobiotaLUNG, Micronoma™	Micronoma™ San Diego, CA	



0396U	Spectrum PGT-M	Natera, Inc, San Carlos, CA	Genetic Testing - Preimplantation
0398U	ESOPREDICT® Barrett's Esophagus Risk Classifier Assay	Capsulomics, Inc d/b/a Previsé Baltimore, MD	
0399U	FRAT® (Folate Receptor Antibody Test),	Religen Inc, Plymouth Meeting, PA	
0400U	Genesys Carrier Panel	Genesys Diagnostics, Inc Oakdale, CT	
0401U	CARDIO inCode- Score (CICSCORE)	GENinCode U.S. Inc, Irvine, CA	
0402U	Abbott Alinity™ m STI Assay	Abbott Molecular, Inc, Des Plaines, IL	
0403U	MyProstateScore 2.0	LynxDX Ann Arbor, MI	
0404U	DiviTum®TKa, Biovica Inc	Biovica International AB Uppsala, Sweden	
0405U	BTG Early Detection of Pancreatic Cancer	Breakthrough Genomics Irvine, California	
0406U	CyPath® Lung, Precision Pathology Services	BioAffinity Technologies, Inc San Antonio, Texas	
0407U	IntelxDKD™, Renalytix Inc,	Renalytix Inc, NYC, NY	
0408U	Omnia™ SARSCoV- 2 Antigen Test	Qorvo Biotechnologies Plymouth, MN	
0409U	LiquidHALLMARK®	Lucence Health, Inc Palo Alto, CA	
0410U	Avantect™ Pancreatic Cancer Test	ClearNote™ Health San Mateo, CA	
0411U	IDgenetix®	Castle Biosciences, Inc Friendswood, TX	
0412U	PrecivityAD® blood test	C2N Diagnostics LLC St. Louis, MO	
0413U	DH Optical Genome Mapping/Digital Karyotyping Assay	Bionano Genomics San Diego, CA	
0414U	LungOI	Imagene	

0415U	SmartHealth Vascular Dx™	Morningstar Laboratories, LLC Irvine, CA	
0416U	GENETWORx UTI with ABR, RCA	Laboratory Services LLC d/b/a GENETWORx Allen, VA	
0417U	Genomic Unity® Comprehensive Mitochondrial Disorders Analysis	Varietyx Inc Framingham, MA	
0418U	PreciseDx Breast Biopsy Test	PreciseDx, Inc NYC, NY	
0419U	Tempus nP	Tempus Labs, Inc Chicago, IL	
0420U	Cxbladder Detect+	Pacific Edge Diagnostics USA LTD, Hummelstown, PA	Urinary Biomarkers for Bladder Cancer
0421U	Colosense™	Geneoscopy, Inc St. Louis, MO	
0422U	Guardant360 Response™	Guardant Health, Inc Redwood City, CA	
0423U	Genomind® Pharmacogenetics Report	Genomind®, Inc King of Prussia, PA	
0424U	miR Sentinel™ Prostate Cancer Test	miR Scientific® LLC	
0425U	RCIGM Rapid Whole Genome Sequencing, Comparator Genome	Rady Children's Institute for Genomic Medicine San Diego, CA	
0426U	RCIGM Ultra-Rapid Whole Genome Sequencing	Rady Children's Institute for Genomic Medicine San Diego, CA	
0427U	Early Sepsis Indicator	Beckman Coulter, Inc Pasadena, CA	
0428U	Epic Sciences ctDNA Metastatic Breast Cancer Panel	Epic Sciences, Inc San Diego, CA	
0429U	Omnipathology Oropharyngeal HPV	OmniPathology Solutions, Medical	

	PCR Test	Corporation Pasadena, CA	
0430U	Malabsorption Evaluation Panel	Mayo Clinic/Mayo Clinic Laboratories	
0431U	Glycine Receptor Alpha1 IgG	Mayo Clinic/Mayo Clinic Laboratories	
0432U	Kelch-Like Protein 11 Antibody	Mayo Clinic/Mayo Clinic Laboratories	
0433U	EpiSwitch® Prostate Screening Test (PSE)	Oxford BioDynamics PLC United Kingdom	
0434U	RightMed® Gene Test Exclude F2 and F5	OneOme® LLC Minneapolis, MN	
0435U	ChemID®	Cordgenics, LLC Huntington, WV	
0436U	PROphet® NSCLC Test	OncoHost, Inc Binyamina-Giv'at Ada, Israel	
0437U	MindX One™ Blood Test	MindX Sciences Indianapolis, IN	
0438U	EffectiveRX™ Comprehensive Panel	RCA Laboratory Services LLC d/b/a GENETWORx Glen Allen, VA	

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## Government Regulations

### National:

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

### Local:

Local Coverage Determination (L37764), MoIDX: MULTIPLEX NUCLEIC ACID AMPLIFIED TESTS FOR RESPIRATORY VIRAL PANELS, **Original Effective Date:** For services performed on or after 12/17/2018; **Revision Effective Date:** For services performed on or after 10/29/2020; **Revision Ending Date:** 04/16/2022, **Retirement Date:** 04/16/2022

Article (A57579) Billing and Coding: MoIDX: “Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels” Original Effective Date: 11/28/2019, Revision Effective Date: 02/03/2022, **Revision Ending Date:** 04/16/2022, **Retirement Date:** 04/16/2022

To report a multiplex PCR respiratory viral panel service, please submit the following claim information:

- If the panel being used does not have its own proprietary CPT® Code, use CPT® code 87631, 87632 or 87633.
- If the test does have a PLA code then submit the appropriate code.

Per the MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels L37764 LCD, tests that include more than 5 viral pathogens are non-covered. Included in this are 87632, 87633, and additional PLA CODES 0115U, 0151U, 0202U, 0223U, 0225U. Code 0151U will be deleted effective 4/1/22

- Enter 1 unit of service (UOS)
  - Select the appropriate ICD-10-CM code
- Additional Medicare Guidelines and pre-requirements available (A57579)

[Article - Billing and Coding: MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels \(A57579\) \(cms.gov\)](#)

*(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.)*

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## Related Policies

N/A

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## References

1. American Medical Association. CPT® PLA Codes. Last updated September 29, 2023.
2. Blue Cross Blue Shield of Rhode Island. Proprietary Laboratory Codes (PLA). Medical Policy. Effective Date: 10/1/2019, last updated DRAFT 11/7/2023 for 1/1/24.
3. Blue Cross Blue Shield of Massachusetts. Medical Technology Assessment Investigational (Non-Covered) Services List. Medical Policy #400, 2023.
4. Centers for Medicare and Medicaid Services. Local Coverage Determination (A57579): Billing and Coding: MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels – Effective for services performed on or after 11/28/2019; Revised 4/16/22; **Retired 4/16/22**

*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 9, 2023, 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"> <li>Added the new PLA codes 0285U - 0305U effective 1/1/22 under Other Codes (investigational, not medically necessary, etc.):</li> <li>Revised codes 0022U eff 4/1/22, 0051U, 0090U</li> <li>Revision to the test names for codes (0240U and 0241U) eff 4/1/22</li> <li>Deleted codes 0097U, 0151U eff 4/1/22</li> </ul>
7/1/22	4/19/22		<ul style="list-style-type: none"> <li>Added the addition of the new 17 PLA codes (0306U-0322U) effective 4/1/22 under E/I.</li> <li>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)</li> <li>Code 0037U moved from E/I to EST per Genetic Testing – NGS Testing of Multiple Genes (Panel) for Malignant Conditions (MXD) (Previous title: Genetic Testing - 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.</li> </ul>
9/1/22	6/21/22		<ul style="list-style-type: none"> <li>No additions or deletions</li> <li>Codes 0239U and 0242U moved from E/I to EST per Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)</li> </ul>

11/1/22	8/16/22		<ul style="list-style-type: none"> <li>• Added codes 0323U-0331U (EFD 7/1/22) to noncovered codes</li> <li>• Added Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing as the applicable policy for code 0236U (E/I)</li> </ul>
1/1/23	10/18/22		<ul style="list-style-type: none"> <li>• Added 23 new PLA codes (0332U-0353U) effective 10/1/22 – all codes E/I except 0339U (EST)</li> <li>• Deleted codes 0012U 0013U 0014U 0056U effective 10/1/22</li> <li>• Revision to code 0276U</li> <li>• Addition of the word “of” between “sequencing” and “at least” in the long descriptor for code 0296U.</li> <li>• Per discussion at post-jump moved 0172U from E/I to EST. (ky)</li> </ul>
3/1/23	12/20/22		<ul style="list-style-type: none"> <li>• Added the Genetic, Molecular and Other Tests- E/I Status policy to the below E/I codes based on policy update from October 18, 2022 JUMP (0332U, 0333U, 0342U, and 0351U)</li> <li>• 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.</li> <li>• 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.</li> <li>• Added the Genetic Testing- Noninvasive Prenatal Screening For Fetal Aneuploidies, Microdeletions, and Twin Zygosity Using Cell-Free Fetal DNA policy to code 0327U.</li> </ul>

			<ul style="list-style-type: none"> <li>Per code update – added 9 codes (0355U–0363U) as E/I effective 1/1/2023. (ky)</li> </ul>
5/1/23	2/21/23		<ul style="list-style-type: none"> <li>Revision of 2 codes (0022U, 0095U), deletion of 2 codes (0324U, 0325U) eff 4/1/2023.</li> <li>Added 23 new codes eff 4/1/2023 (0364U to 0386U) as E/I.</li> <li>Added the Genetic Testing- BCR/ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia to the code 0040U under EST from December 20, 2022 JUMP.</li> <li>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)</li> </ul>
7/1/23	4/18/23		<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> <li>Added the Genetic Testing - 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</li> </ul>

			<p>E/I from February 21, 2023 JUMP.</p> <ul style="list-style-type: none"> <li>• Added the Genetic Testing for Cytochrome P450 Polymorphisms policy to the code 0380U under E/I from February 21, 2023 JUMP.</li> <li>• 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)</li> </ul>
9/1/23	6/13/23		<ul style="list-style-type: none"> <li>• 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.</li> <li>• Deletion of 9 codes (0053U, 0143U-0150U), released to AMA 3/13/23 effective date 7/1/23.</li> <li>• Revision to proprietary, laboratory and manufacturer name for code 0113U.</li> <li>• Correction to code 0095U by changing uppercase “E” in “Eotaxin-3” to lowercase “e” and adding closed parenthesis “)” after “protein}}”.</li> <li>• 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.</li> <li>• 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.</li> <li>• Added the Diagnosis of Vaginitis (including Bacterial Vaginosis,</li> </ul>



			<p>Trichomonas and Candidiasis) using Multi-target PCR Testing policy to the code 0352U under E/I from June 13, 2023 JUMP.</p> <ul style="list-style-type: none"> <li>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.</li> <li>Per change request (FCR# 2023001151) code 0364U moved from Experimental Investigational (E/I) to payable effective April 1, 2023. (ky)</li> </ul>
11/1/23	8/15/23		<ul style="list-style-type: none"> <li>Addition of 15 codes (0387U – 0401U) released to AMA 3/13/23 effective date 7/1/23.</li> <li>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.</li> <li>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.</li> </ul> <p>Post JUMP:</p> <ul style="list-style-type: none"> <li>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.</li> <li>Added policy Genetic Testing - 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)</li> </ul>
1/1/24	10/17/23		<ul style="list-style-type: none"> <li>Revision of 7 codes (0269U, 0271U, 0272U, 0274U,</li> </ul>

			<p>0277U, 0278U, 0362U) eff 10/1/23.</p> <ul style="list-style-type: none"> <li>• Deletion of 4 codes (0066U, 0357U, 0386U, 0397U) eff 10/1/23.</li> <li>• Addition of 18 codes (0402U–0419U) accepted by the CPT Editorial Panel eff 10/1/23 under E/I.</li> <li>• Addition and/or deletion of commas to several code descriptors (0095U, 0365U–0368U) per CPT convention eff 10/1/23.</li> <li>• Addition of the term “quantitative” to the code descriptor for code 0389U eff 10/1/23.</li> <li>• Replace abbreviation CAD with CHD for coronary heart disease in the code descriptor for code 0401U eff 10/1/23.</li> <li>• 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.</li> <li>• Added code 0239U representing FoundationOne® Liquid CDx and 0242U representing Guardant360® CDx as EST on policies: <ul style="list-style-type: none"> <li>○ Circulating Tumor DNA and Circulating Tumor Cells for Management of Solid Cancers (Liquid Biopsy)</li> <li>○ Somatic Biomarker Testing (including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF,</li> </ul> </li> </ul>
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			<p>MMR/MSI, HER2, and TMB)</p> <ul style="list-style-type: none"> <li>○ Genetic Testing— BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy</li> <li>● 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.</li> <li>● 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)</li> </ul> <p><b>Post JUMP</b></p> <ul style="list-style-type: none"> <li>● 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.</li> <li>● Added Genetic Testing - BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy policy to codes 0326U and 0037U under EST per Oct 17, 2023 JUMP.</li> </ul>
3/1/24	12/19/23		<ul style="list-style-type: none"> <li>● Revision of 2 codes (0351U, 0356U).</li> </ul>

			<ul style="list-style-type: none"> <li>• Per code update added of 19 codes (0420U–0438U) under E/I.</li> <li>• Added Genetic Testing – Preimplantation policy to the code 0396U under E/I.</li> <li>• Added Urinary Biomarkers for Bladder Cancer policy to the code 0420U under E/I per 12/19/23 JUMP.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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)</li> </ul>
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Next Review Date: Every JUMP meeting

### Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

**BLUE CARE NETWORK BENEFIT COVERAGE**  
**POLICY: Proprietary Laboratory Analyses (PLA) Codes.**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	PLA codes are considered experimental/ investigational until the laboratory test the code represents is formally documented as Established in an Interim Medical Policy or Joint Uniform Medical Policy document.
<b>BCNA (Medicare Advantage)</b>	Refer to the Medicare information under the Government Regulations section of this policy.
<b>BCN65 (Medicare Complementary)</b>	Coinsurance covered if primary Medicare covers the service.

**II. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- *Duplicate (back-up) equipment is not a covered benefit.*