

Medicare Advantage Medical Policy



Proprietary Laboratory Analyses (PLA) Codes – Medicare Advantage

Medicare Advantage Plan

- ☒ Medicare Plus BlueSM
- ☒ BCN AdvantageSM

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Description

Proprietary Laboratory Analyses (PLA) codes describe proprietary clinical laboratory analyses and can be provided either by a single ("sole source") laboratory or licensed or marketed to multiple providing laboratories (e.g., cleared or approved by the Food and Drug Administration [FDA]). 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.

In accordance with Title XVIII of the Social Security Act, Section 1862(a)(1)(A), Medicare covers only items and services that are reasonable and necessary for the diagnosis or treatment of a specific illness or injury. Consequently, Proprietary Laboratory Analysis (PLA) tests utilized solely for pre-symptomatic screening, disease risk prediction, or population health assessment—rather than the diagnosis or active management of an existing medical condition—are considered screening services and do not constitute a covered Medicare benefit.

Consistent with CFR, Title 42, Section 414.502, advanced diagnostic laboratory tests must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

Policy Guidelines

Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network of Michigan (BCN) adhere to guidance from the Centers for Medicare and Medicaid Services (CMS), including when performing organization determinations for Medicare Advantage plan members. CMS Medicare statutes, regulations, manuals, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and other sub-regulatory guidance provide the clinical guidelines for coverage determinations, payment integrity functions, and all other uses by CMS regulations. When CMS Medicare guidance is silent, incomplete, or insufficient, CMS permits BCBSM/BCN to utilize "internal coverage criteria",

such as independent criteria, health plan policy research, LCD/LCAs outside the services area or research from independent medical research repositories (i.e., Hayes) for coverage policies consistent with 42 CFR § 422.101. BCBSM/BCN internal medical coverage policies are developed and based on current evidence in widely accepted treatment guidelines or clinical literature; in addition, they address how clinical benefits may or may not outweigh member harm.

Clinical review follows guidance provided in the BCBSM Medicare Advantage Coverage Determination Hierarchy policy, which may be found at <https://www.bcbsm.com/providers/mpradmin/> by entering the policy name.

Coverage Guidance

To ensure consistency with coverage guidance, the Medicare statutes, regulations, coverage manuals, NCD, LCD, and LCA should be reviewed and applied first. BCBSM/BCN internal coverage criteria should only be applied when CMS guidance is silent, incomplete, or insufficient for a code.

Coverage Criteria:

Under Title XVIII §1862(a)(1)(A), CMS strictly covers tests that are used for the direct diagnosis and treatment of a symptomatic illness or injury. A PLA test may be considered medically necessary only when ALL the following criteria are met:

1. Symptomatic Presentation: The beneficiary exhibits specific clinical signs, symptoms, or a documented personal history of the disease, indicating a high suspicion of the condition the test is designed to detect.
2. Diagnostic Intent & Actionability: The test is ordered to confirm/rule out a suspected diagnosis or guide treatment (e.g., pharmacogenomics, oncology markers) for an established diagnosis. Medical records must confirm that results are essential for clinical management and will directly alter the clinician's subsequent therapeutic choices.
3. Uniqueness of Service: No other standard Category I CPT laboratory test is available that provides the same clinical information with equal or greater accuracy.
4. Evidence-Based Validity: The test must have established Analytical Validity (reliability of the measurement), Clinical Validity (relationship to the clinical condition), and Clinical Utility (positive impact on health outcomes), supported by peer-reviewed literature or a formal Technical Assessment (e.g., MoIDX).
5. Provider Oversight: The test is ordered by the physician or qualified practitioner actively treating the beneficiary for the specific medical problem addressed by the test.
6. Regulatory Compliance: The test must be performed in a CLIA-certified laboratory.

Documentation in the medical record must support the criteria above. If the test is performed for a patient who is asymptomatic or if the results are used purely for risk prediction or health status monitoring without a specific diagnostic intent, the service will be denied as a statutory exclusion under Title XVIII §1862(a)(1)(A).

Nationally Non-Covered Indications

Proprietary Laboratory Analyses (PLA) tests are nationally non-covered when performed in the absence of signs, symptoms, or a personal history of illness, or when the results do not directly guide active clinical management. Such services do not meet Medicare criteria for a defined benefit category and are denied as a statutory exclusion under Title XVIII §1862(a)(1)(A) of the Social Security Act.

Based on the Medicare Benefit requirements, the following test types are examples of services that may not be considered a benefit (statutory excluded) and therefore would be denied as Medicare Excluded tests:

1. Asymptomatic, Pre-symptomatic, Predictive Testing: Genetic tests and services designed to identify an undiagnosed disease, disease predisposition, or potential future illness in a healthy, asymptomatic individual. This includes tests marketed or utilized as predictive screening tools in the absence of signs, symptoms, or a personal history of associated illness.
2. Risk Prediction & Stratification: Services performed purely to estimate the statistical probability of developing a future condition, including tests that yield general "risk scores," "probability percentages," or "susceptibility mapping" without an active diagnostic intent.
3. Redundant or Confirmatory Testing: Tests performed to confirm a previously established clinical diagnosis or to duplicate known genetic information without a documented clinical need for re-testing.
4. Lack of Clinical Actionability: Testing where the results are not expected to directly alter or change the patient's current medical management, treatment plan, surgical choices, or medication selection (e.g., when the patient is already on a definitive or terminal treatment path).
5. Carrier Screening: Testing utilized primarily to identify genetic variants for reproductive planning, preconception screening, or general family risk assessment, rather than diagnosing or treating the patient's own active medical condition.
6. Population Health/Wellness: Routine or generalized testing protocols administered to the general population or corporate wellness programs, which are not tailored to the patient's specific, documented clinical presentation.
7. Experimental, Investigational, or Unproven Services: Tests where the peer-reviewed medical literature lacks sufficient high-quality evidence to establish analytical validity, clinical validity, and clinical utility, or fail to demonstrate a positive impact on net health outcomes.

Apart from durable medical equipment (DME), Medicare Administrative Contractor (MAC) jurisdiction for the purpose of clinical determination is based upon place of service. The place of service for laboratory testing is defined as the geographic location of the reference laboratory. Non-jurisdictional LCD/LCAs may not be utilized for a determination unless they have been specifically identified as internal coverage criteria by the policy. Alternatively, jurisdiction for DME MAC is determined by the member place of residence. Please see CMS Medicare Administrative Contractors (MAC) table for state MAC assignments below.

Please refer to all applicable policies and/or coverage articles in effect for the lab's jurisdiction

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0001U	PRECISETYPE® HEA TEST	Immucor, Inc. (Specialized Regional Labs located in CA, GA, PA, NY)	NCD: None NGS: None Noridian: L38331, A57124 - MolDX: Blood Product Molecular Antigen Testing* L35160, A57526 – MolDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 – MoldDX: Repeat Germline Testing* Novitas: L35062, A56541 – Biomarkers Overview A58917 – Molecular Pathology and Genetic Testing Palmetto: L38240, A58308 - MolDX: Blood Product Molecular Antigen Testing* L35025, A56853 – MolDX: Molecular Diagnostic Tests (MDT)* L38274, A58017 – MolDX: Repeat Germline Testing*
0002U	POLYPDX™	Atlantic Diagnostic Laboratories, LLC, Metabolomic Technologies, Inc (Laboratory in PA)	NCD: 210.3 Colorectal Cancer Screening Tests
0003U	OVERA (OVA1 NEXT GENERATION)	Aspira Labs, Inc, Vermillion, Inc (Laboratory in TX)	NCD: None Novitas: None BCBSM/BCNA Guidance: Multimarker Serum-Based Testing Related to Ovarian Cancer (e.g., Ova1®, Overa™, OvaWatch and ROMA™ Testing) – Medicare Advantage
0005U	EXODX® PROSTATE INTELLISCORE (EPI)	Mdxhealth (Formerly Exosome Diagnostics, Inc) (Laboratory in MA, CA, TX)	NCD: None NGS: A56609 - Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis Noridian: L35160, A57526 - MolDX: Molecular Diagnostic Testing* Novitas: A58917 - Billing and Coding: Molecular Pathology and Genetic Testing. BCBSM/BCNA Guidance: Prostate Cancer Early Detection-Biomarkers Prior to Biopsy – Medicare Advantage
0007U	TOXPROTECT™	Genotox Laboratories LTD (Laboratory in TX)	NCD 130.5 – Treatment of Alcohol and Drug Abuse in a Freestanding Clinic 130.6 – Treatment of Drug Abuse (Chemical Dependency) 130.7 – Withdrawal Treatments for Narcotic Addictions Novitas: L35006, A56645 – Controlled Substance Monitoring and Drugs of Abuse Testing
0009U	DEPARRAY™ HER2	PacificDx (Laboratory in CA)	NCD: None Noridian L35160, A57526 – MolDX: Molecular Diagnostic Tests (MDT) – Technical Assessment (TA) for coverage determination has not been completed*
0011U	CORDANT CORE™	Cordant Health Solutions (Laboratories in AZ, CO, IN, MA, NY, WA)	NCD 130.5 – Treatment of Alcohol and Drug Abuse in a Freestanding Clinic 130.6 – Treatment of Drug Abuse (Chemical Dependency) 130.7 – Withdrawal Treatments for Narcotic Addictions WPS: None NGS: None Noridian: None

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
			Novitas L35006, A56645 – Controlled Substance Monitoring and Drugs of Abuse Testing
0012M	CXBLADDER DETECT, ONCOLOGY (UROTHELIAL), MRNA	Pacific Edge Diagnostics USA, Ltd (Laboratories in PA)	NCD: None Novitas: L39365, A59125 – Genetic Testing in Oncology: Specific Tests – not covered
0016U	BCR/ABL1 (t(9;22)) RNA QUANTITATION WITH INTERPRETATION	Auragen (Laboratory in TX)	NCD: None Novitas L39365, A59125 - Genetic Testing for Oncology L35062, A56541 - Biomarkers Overview A58917 - Billing and Coding: Molecular Pathology and Genetic Testing.
0017U	JAK2 MUTATION	University of Iowa, Department of Pathology	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Tests (MDT)* BCBSM/BCNA Guidance Genetic Testing-JAK2, MPL and CALR Testing for Myeloproliferative Neoplasms
0018U	THYRAMIR™	Interpace Diagnostics (Laboratory in NJ)	NCD: None Novitas: L35396, A52986 – Biomarkers for Oncology
0021U	APIFINY®	Armune BioScience, Inc (Laboratory in WI)	NCD: None NGS: None BCBSM/BCNA Guidance Prostate Cancer Early Detection-Biomarkers Prior to Biopsy – Medicare Advantage
0022U	ONCOMINE™ DX TARGET TEST	Thermo Fisher Scientific, (Oncomine Dx Target Tests are processed at specialized, certified laboratory partners across the US, rather than just one central Thermo Fisher lab. States include but are not limited to AZ, CA, FL, ID, IL, MI, NC, NJ, NY, OR, TN, TX, UT, WA)	NCD 90.2 – Next Generation Sequencing (NGS) WPS: L36807, A57772 – MolDX: Molecular Diagnostic Tests (MDT)* CGS: L36021, A56973 – MolDx; Molecular Diagnostic Tests (MDT)* First Coast: A58918 – Molecular Pathology and Genetic Testing NGS: None Noridian: L35160, A57526 – MolDx; Molecular Diagnostic Tests (MDT)* Novitas A58917 – Molecular Pathology and Genetic Testing L35396, A52986 – Biomarkers for Oncology Palmetto: L35160, A57526 – MolDx; Molecular Diagnostic Tests (MDT)*
0023U	LEUKOSTRAT®CDX FLT3 MUTATION ASSAY	LabPMM LLC, an Invivoscribe Technologies, Inc Company (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MolDx; Molecular Diagnostic Tests (MDT)*
0024U	GLYCA	Laboratory Corporation of America, (Laboratory in NC)	NCD: None Palmetto: L35160, A57526 – MolDx; Molecular Diagnostic Tests (MDT)*
0026U	THYROSEQ GENOMIC CLASSIFIER	CBLPath, Inc, (Laboratory in NY)	NCD: 90.2 – Next Generation Sequencing (NGS) NGS: L38968, A58656 – Thyroid Nodule Molecular Testing
0027U	JAK2 EXONS 12 TO 15 Sequencing	Mayo Clinic, (Laboratory in MN)	NCD: None NGS: L35000, A56199 – Molecular Pathology Procedures
0031U	CYTOCHROME P450 1A2 GENOTYPE	Mayo Clinic, (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing
0032U	CATECHOL-O-METHYLTRANSFERASE (COMT) GENOTYPE	Mayo Clinic, (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0034U	THIOPURINE METHYLTRANSFERASE (TPMT) AND NUDIX HYDROLASE (NUDT15)	Mayo Clinic, (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing BCBSM/BCNA Guidance: Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines
0036U	EXACT-1 WHOLE EXOME TESTING	Weill Cornell Medicine-Clinical Genomics Laboratory (Laboratory in NY)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing - Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0037U	FOUNDATIONONE CDX™ (F1CDX)	Foundation Medicine, Inc, (Laboratory in MA)	NCD: 90.2 – Next Generation Sequencing (NGS)
0040U	MRDx BCR-ABL TEST	MolecularMD, (Laboratory in OR)	NCD: None Noridian L38814, A58996 – MoIDX: Minimal Residual Disease Testing for Hematologic Cancers* L39923, A59835 - MoIDX: Non-Next Generation Sequencing Tests for The Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms* A55595 - Billing and Coding: MoIDX: BCR-ABL*
0045U	ONCOTYPE DX® BREAST DCIS SCORE™ TEST	Exact Science, Inc., Genomic Health, Inc - California (Laboratory in CA)	NCD: None Noridian: L36941, A57619 - MoIDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™)*
0046U	FLT3 ITD MRD ASSAY	Laboratory for Personalized Molecular Medicine (LabPMM) LLC (Laboratory in CA)	NCD: 90.2 – Next Generation Sequencing (NGS) Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0047U	GENOMIC PROSTATE SCORE® (GPS) TEST (FORMERLY KNOWN AS ONCOTYPE DX® GPS)	MDxHealth SA, Inc (Laboratory in CA)	NCD: None Noridian: L38339, A57372 – MoIDX: Prostate Cancer Genomic Classifier Assay for men with Localized Disease
0048U	MSK-IMPACT (INTEGRATED MUTATION PROFILING OF ACTIONABLE CANCER TARGETS)	Memorial Sloan Kettering Cancer Center (Laboratory in CA)	NCD: 90.2 – Next Generation Sequencing (NGS) Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0049U	NPM1 MRD ASSAY	Laboratory for Personalized Molecular Medicine (LabPMM) LLC (Laboratory in CA)	NCD: 90.2 – Next Generation Sequencing (NGS) Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0050U	MYAML 194 GENE NGS PANEL	Laboratory for Personalized Molecular Medicine (LabPMM) LLC (Laboratory in CA)	NCD: 90.2 – Next Generation Sequencing (NGS) Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)
0051U	UCOMPLIDX	Elite Medical Laboratory Solutions, LLC (Laboratory in TX)	NCD 130.5 – Treatment of Alcohol and Drug Abuse in a Freestanding Clinic 130.6 – Treatment of Drug Abuse (Chemical Dependency) 130.7 – Withdrawal Treatments for Narcotic Addictions Novitas: L35006, A56645 – Controlled Substance Monitoring and Drugs of Abuse Testing
0052U	VAP CHOLESTEROL TEST	VAP Diagnostics Laboratory, Inc (Laboratory in AL)	NCD: None Palmetto: None BCBSM/BCNA Guidance: Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease – Medicare Advantage

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0054U	ASSURANCERX MICRO SERUM	Firstox Laboratories, LLC (Laboratory in TX)	NCD 130.5 – Treatment of Alcohol and Drug Abuse in a Freestanding Clinic 130.6 – Treatment of Drug Abuse (Chemical Dependency) 130.7 – Withdrawal Treatments for Narcotic Addictions Novitas: L35006, A56645 – Controlled Substance Monitoring and Drugs of Abuse Testing
0055U	MYTAIHEART	TAI Diagnostics, Inc (Laboratory in WI)	NCD: None NGS: None BCBSM/BCNA Guidance: Laboratory Tests Post Transplant (Kidney and Heart) and for Heart Failure – Medicare Advantage
0058U	MERKEL SMT ONCOPROTEIN ANTIBODY TITER	University of Washington, Department of Laboratory Medicine (Laboratory in WA)	National Regulatory Guidance: This genetic test is for determining the likelihood of developing skin cancer (Merkel cell carcinoma). Medicare generally does not cover routine screening tests, as they are statutorily excluded under §1862(a)(7). This includes pre-symptomatic genetic tests or risk assessment tests that do not directly affect the immediate management of the patient.
0060U	TWIN ZYGOSITY PLA	Natera, Inc, (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0067U	BBDRISK DX™	Silbiotech, Inc (Laboratory in MD)	National Regulatory Guidance: This genetic test is proposed to predict the likelihood of breast cancer development. Medicare generally does not cover routine screening tests, as they are statutorily excluded under §1862(a)(7). This includes pre-symptomatic genetic tests or risk assessment tests that do not directly affect the immediate management of the patient. NCD: None Novitas: None BCBSM/BCNA Guidance: None
0068U	MYCODART-PCR™ DUAL AMPLIFICATION REAL TIME PCR PANEL FOR 6 CANDIDA SPECIES	RealTime Laboratories (Laboratory in TX)	NCD: None Novitas: A58917 – Molecular Pathology and Genetic Testing BCBSM/BCNA Guidance: None
0069U	MIR-31/NOW™	GoPath Laboratories, LLC (Laboratory in AZ and IL)	National Regulatory Guidance: This genetic test is for determining the likelihood of developing prostate cancer. Medicare generally does not cover routine screening tests, as they are statutorily excluded under §1862(a)(7). This includes pre-symptomatic genetic tests or risk assessment tests that do not directly affect the immediate management of the patient. See NCD 210.3 for types of colorectal cancer screening tests that are covered NCD: 210.3 Colorectal Cancer Screening Tests NGS: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)* BCBSM/BCNA Guidance: None
0070U	CYP2D6 COMMON VARIANTS AND COPY NUMBER	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing
0071U	CYP2D6 FULL GENE SEQUENCING	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing
0072U	CYP2D6-2D7 HYBRID GENE	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
	TARGETED SEQUENCE ANALYSIS		
0073U	CYP2D7-2D6 HYBRID GENE TARGETED SEQUENCE ANALYSIS	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing
0074U	CYP2D6 TRANS-DUPLICATION/MULTIPLICATION NON-DUPLICATED GENE TARGETED SEQUENCE ANALYSIS	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing
0075U	CYP2D6 5' GENE DUPLICATION/MULTIPLICATION TARGETED SEQUENCE ANALYSIS	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing
0076U	CYP2D6 3' GENE DUPLICATION/MULTIPLICATION TARGETED SEQUENCE ANALYSIS	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing
0077U	M-PROTEIN DETECTION AND ISOTYPING BY MALDI-TOF MASS SPECTROMETRY	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L39189, A58921 – Mass Spectrometry (MS) testing in Monoclonal Gammopathy (MG)
0079U	TOXLOK™	InSource Diagnostics (Laboratory in CA)	NCD 130.5 – Treatment of Alcohol and Drug Abuse in a Freestanding Clinic 130.6 – Treatment of Drug Abuse (Chemical Dependency) 130.7 – Withdrawal Treatments for Narcotic Addictions Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)* L38351, A57331 – MoIDX: Repeat Germline Testing*
0080U	BDX-XL2	Biodesix®, Inc (Laboratory in CO)	NCD: None Novitas: None BCBSM/BCNA Guidance: Molecular Testing in the Management of Pulmonary Nodules – Medicare Advantage
0082U	NEXTGEN PRECISION™ TESTING	Precision Diagnostics, Precision Diagnostics LBN Precision Toxicology, LLC (Laboratory in MA)	NCD 130.5 – Treatment of Alcohol and Drug Abuse in a Freestanding Clinic 130.6 – Treatment of Drug Abuse (Chemical Dependency) 130.7 – Withdrawal Treatments for Narcotic Addictions NGS: None BCBSM/BCNA Guidance: None
0087U	MOLECULAR MICROSCOPE® MMDX-HEART	Kashi Clinical Laboratories (Laboratory in OR)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0088U	MOLECULAR MICROSCOPE® MMDX-KIDNEY	Kashi Clinical Laboratories (Laboratory in OR)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0089U	PIGMENTED LESION ASSAY (DERMTECH MELANOMA TEST)	DermTech (Laboratory in CA)	NCD: None Noridian: L38151, A58052 – MoIDX: Pigmented Lesion Assay*
0090U	MYPATH® MELANOMA	Castle Biosciences, Inc (Laboratory in AZ and PA)	NCD: None Noridian: L39373, A59179 – MoIDX: Molecular

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
			Assays for the Diagnosis of Cutaneous Melanoma* Novitas: A58917 – Molecular Pathology and Genetic Testing
0091U	FIRSTSIGHTCRC™	CellMax Life (Laboratory in CA)	National Regulatory Guidance: Preventive services are non-covered by Medicare unless specifically covered in NCDs, statutes, or regulations NCD: 210.3 Colorectal Cancer Screening Tests Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0092U	REVEAL LUNG NODULE CHARACTERIZATION	MagArray, Inc (Laboratory in CA)	National Regulatory Guidance: This genetic test is for determining the likelihood of lung cancer. Medicare generally does not cover routine screening tests, as they are statutorily excluded under §1862(a)(7). This includes pre-symptomatic genetic tests or risk assessment tests that do not directly affect the immediate management of the patient. Preventive services are non-covered by Medicare unless specifically covered in NCDs, statutes, or regulations. NCD: 210.14 Lung Cancer Screening Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0093U	COMPLYRX	Claro Labs (Laboratory in CO)	NCD 130.5 – Treatment of Alcohol and Drug Abuse in a Freestanding Clinic 130.6 – Treatment of Drug Abuse (Chemical Dependency) 130.7 – Withdrawal Treatments for Narcotic Addictions Novitas: None BCBSM/BCNA Guidance: None
0094U	RCIGM RAPID WHOLE GENOME SEQUENCING	Rady Children's Institute for Genomic Medicine (RCIGM) (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 – MoIDX: Repeat Germline Testing* BCBSM/BCNA Guidance: Genetic Testing - Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0096U	HPV, HIGH-RISK, MALE URINE	Molecular Testing Labs (Laboratory in WA)	NCD: 210.10 – Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIs Noridian: L39001, A58720 – MoIDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing*
0101U	COLONEXT®	Ambry Genetics® (Laboratory in CA)	NCD: 90.2 – Next Generation Sequencing (NGS) Noridian: L38972, A58679 – MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer*
0105U	KIDNEYINTELX™	Renalytix AI, Inc. (Laboratory in NY and UT)	NCD: None NGS: L39726, A59595 – KidneyIntelX and KidneyIntelX.dks Testing Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0108U	TISSUECYPHER® BARRETT'S ESOPHAGUS ASSAY	Ceranostics (Laboratory in PA)	NCD: None Novitas: None BCBSM/BCNA Guidance: Adjunctive Techniques for Screening, Surveillance, and Risk Classification of Barrett Esophagus and Esophageal Dysplasia (e.g., WATS3D, TissueCypher, EsoCheck, EsoGuard, EsoPredict) – Medicare Advantage

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0109U	MYCODART-PCR™ DUAL AMPLIFICATION REAL TIME PCR PANEL FOR 4 ASPERGILLUS SPECIES	RealTime Laboratories (Laboratory in TX)	NCD: None Novitas: A58917 – Molecular Pathology and Genetic Testing
0111U	PRAXIS™ EXTENDED RAS PANEL	Illumina, Inc. (Laboratory in CA)	NCD: 90.2 – Next Generation Sequencing (NGS) Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)
0112U	MICROGENDX QPCR & NGS FOR INFECTION	MicroGenDX, (Laboratory in TX)	NCD: None Novitas: A58917 – Molecular Pathology and Genetic Testing
0113U	MYPROSTATESCORE	Lynx DX, Inc. (Laboratory in MI)	NCD: None WPS: L36807, A57772 – MoDX: Molecular Diagnostic Tests (MDT)*
0114U	ESOGUARD™	Lucid Diagnostics (Laboratory in CA)	NCD: None Noridian: L39262, A59032 – MoIDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia*
0115U	EPLEX RESPIRATORY PATHOGEN (RP) PANEL	GenMark Diagnostics, Inc. (Laboratory in CA)	NCD: None Noridian: L39001, A58720 – MoIDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing*
0117U	FOUNDATION PI SM	Ethos Laboratories (Laboratory in KY)	NCD: None CGS: L39616, A59423 – Urinary Biomarkers for Chronic Pain Management
0118U	EUROFINS TRAC™ DD-CFDNA	Transplant Genomics Inc (Dedicated Laboratory in CA to process Eurfins TRAC tests)	NCD: None Noridian: L38629, A58168 – MoIDX: Molecular Testing for Solid Organ Allograft Rejection*
0119U	MI-HEART CERAMIDES, PLASMA	Mayo Clinic (Laboratory in MN)	NCD: None NGS: L35000, A56199 – Molecular Pathology Procedures
0129U	BRCAPLUS	Ambry Genetics® (Laboratory in CA)	NCD: None Noridian: L38972, A59130 - MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer*
0130U	COLONEXT +RNAinsight™	Ambry Genetics® (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0133U	+RNAinsight™ FOR PROSTATENEXT®	Ambry Genetics® (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0134U	+RNAinsight™ FOR CANCERNEXT®	Ambry Genetics® (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0136U	+RNAinsight™ FOR ATM	Ambry Genetics® (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0137U	+RNAinsight™ FOR PALB2	Ambry Genetics® (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0138U	BRCA1/2 +RNAinsight™	Ambry Genetics® (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0140U	EPLEX® BCID FUNGAL PATHOGENS PANEL	GenMark Diagnostics, Inc. (Laboratory in CA)	NCD: None Noridian: L39044, A58761 – MoIDX: Molecular Syndromic Panels for Infections Disease Pathogen Identification Testing*
0141U	EPLEX® BCID GRAM-POSITIVE PANEL	GenMark Diagnostics, Inc. (Laboratory in CA)	NCD: None Noridian: L39044, A58761 – MoIDX: Molecular Syndromic Panels for Infections Disease Pathogen Identification Testing*
0142U	EPLEX® BCID GRAM-NEGATIVE PANEL	GenMark Diagnostics, Inc. (Laboratory in CA)	NCD: None Noridian: L39044, A58761 – MoIDX: Molecular Syndromic Panels for Infections Disease Pathogen Identification Testing*
0152U	KARIUS® TEST	Karius, Inc. (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0153U	INSIGHT TNBCTYPE™	Insight Molecular Labs (Laboratory in TN)	NCD: None Palmetto: L35025, A56853 – MoIDX: Molecular Diagnostic Tests (MDT)*
0154U	THERASCREEN® FGFR RGQ RT-PCR KIT	QIAGEN Sciences (Laboratory in MD)	NCD: None Novitas: A58917 – Molecular Pathology and Genetic Testing
0155U	THERASCREEN® PIK3CA RGQ RT-PCR KIT	QIAGEN Sciences (Laboratory in MD)	NCD: None Novitas: A58917 – Molecular Pathology and Genetic Testing
0156U	SMASH™	New York Genome Center (Laboratory in NY)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing for Specified Conditions Using Testing Panels – Medicare Advantage Genetic Testing - Chromosomal Microarray Analysis (CMA) and Next-Generation Sequencing Panels, for the Evaluation of Children with Developmental Delay/Intellectual Disability, Autism Spectrum Disorder, and/or Congenital Anomalies – Medicare Advantage
0157U	CUSTOMNEXT +RNAinsight: APC	Ambry Genetics® (Laboratory in CA)	NCD: 210.3 - Colorectal Cancer Screening Tests NCD: 90.2 - Next Generation Sequencing (NGS) Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0158U	CUSTOMNEXT +RNAinsight: MLH1	Ambry Genetics® (Laboratory in CA)	NCD: 210.3 - Colorectal Cancer Screening Tests NCD: 90.2 - Next Generation Sequencing (NGS) Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0159U	CUSTOMNEXT +RNAinsight: MSH2	Ambry Genetics® (Laboratory in CA)	NCD: 210.3 - Colorectal Cancer Screening Tests NCD: 90.2 - Next Generation Sequencing (NGS) Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0160U	CUSTOMNEXT +RNAinsight: MSH6	Ambry Genetics® (Laboratory in CA)	NCD: 210.3 - Colorectal Cancer Screening Tests NCD: 90.2 - Next Generation Sequencing (NGS) Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0161U	CUSTOMNEXT +RNAinsight: PMS2	Ambry Genetics® (Laboratory in CA)	NCD: 210.3 - Colorectal Cancer Screening Tests NCD: 90.2 - Next Generation Sequencing (NGS) Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0162U	LYNCH GENES (MLH1, MSH2, MSH6, PMS2) +RNAinsight	Ambry Genetics® (Laboratory in CA)	NCD: 210.3 - Colorectal Cancer Screening Tests NCD: 90.2 - Next Generation Sequencing (NGS) Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)* L38351, A57331 - MoIDX: Repeat Germline Testing*
0163U	BeScreened™-CRC	Beacon Biomedical, Inc. (Laboratory in AZ)	NCD: 210.3 Colorectal Cancer Screening Tests – Blood based biomarker screening tests must have Food and Drug Administration (FDA) market authorization with an indication for colorectal cancer. BeScreened™ is not FDA approved. Noridian: None
0165U	VERIMAP™ PEANUT DX – BEAD-BASED EPITOPE ASSAY	AllerGenis™ Clinical Laboratory (Laboratory in PA)	NCD: None Novitas: L36421, A56558 – Allergy Testing
0169U	NT (<i>NUDT15</i> AND <i>TPMT</i>) GENOTYPING PANEL	RPRD Diagnostics, LLC (Laboratory in WI)	NCD: None NGS: None BCBSM/BCNA Guidance: Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines – Medicare Advantage
0170U	CLARIFI™	Quadrant Biosciences, Inc. (Laboratory in NY)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing - Chromosomal Microarray Analysis (CMA) and Next-Generation Sequencing Panels, for the Evaluation of Children with Developmental Delay/Intellectual Disability, Autism Spectrum Disorder, and/or Congenital Anomalies – Medicare Advantage
0171U	MYMRD® NGHERS PANEL	Laboratory for Personalized Molecular Medicine (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0172U	MYCHOICE® CDX	Myriad Genetics Laboratories, Inc. (Laboratory in UT)	NCD: 90.2 – Next Generation Sequencing (NGS)
0173U	PSYCH HEALTHPGX PANEL	RPRD Diagnostics, LLC (Laboratory in WI)	NCD: None NGS: None BCSM/BCNA Guidance: Genetic Testing for Specified Conditions Using Testing Panels – Medicare Advantage
0175U	GENOMIND® PROFESSIONAL PGX EXPRESS™ CORE	Genomind, Inc. (Laboratory in PA)	NCD: None Novitas: L39063, A58801 – Pharmacogenomics Testing A56541 – Biomarkers Overview
0177U	THERASCREEN® PIK3CA RGQ PCR KIT	QIAGEN Science (Laboratory in MD)	NCD: None Novitas: A58917 – Molecular Pathology and Genetic Testing

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0178U	VERIMAP™ PEANUT REACTIVITY THRESHOLD-BEAD BASED EPITOPE ASSAY	AllerGenis™ Clinical Laboratory (Laboratory in PA)	NCD: None Novitas: L36421, A56558 – Allergy Testing
0179U	RESOLUTION CTDx LUNG™	Exact Science, Inc., Resolution Bioscience, Inc. (Laboratory in WA)	NCD: None Noridian: L39230, A58973 – MolDX: Plasma-Based Genomic Profiling in Solid Tumors*
0193U	NAVIGATOR JR SEQUENCING	Grifols Immunohematology Center (Laboratory in TX)	NCD: None Novitas: L39063, A58801 – Pharmacogenomics Testing
0202U	BIOFIRE® RESPIRATORY PANEL 2.1 (RP2.1)	BioFire® Diagnostics, LLC (Laboratory in UT)	NCD: None Noridian: L39001, A58720 - Moldx: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing*
0205U	VITA RISK®	Arctic Medical Laboratories (Laboratory in MI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Tests (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing*
0209U	CNGNOME™	PerkinElmer Genomics (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: 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 (Laboratory in CA)	NCD: 210.10 Screening for Sexually Transmitted Infections and High-Intensity Behavioral counseling Noridian: None BCBSM/BCNA Guidance: None
0211U	MI CANCER SEEK™ - NGS ANALYSIS	Caris Life Sciences (Laboratory in TX)	NCD: 90.2 – Next Generation Sequencing (NGS) Novitas: A58917 – Molecular Pathology and Genetic Testing
0212U	GENOMIC UNITY® WHOLE GENOME ANALYSIS – PROBAND	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0213U	GENOMIC UNITY® WHOLE GENOME ANALYSIS – COMPARATOR	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0214U	GENOMIC UNITY® EXOME PLUS ANALYSIS – PROBAND	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0215U	GENOMIC UNITY® EXOME PLUS ANALYSIS – COMPARATOR	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0219U	SENTOSA® SQ HIV- 1 GENOTYPING ASSAY	Vela Diagnostics USA, Inc. (Laboratory in NJ)	NCD: None Novitas: A58917 – Molecular Pathology and Genetic Testing
0223U	QIASTAT-DX RESPIRATORY SARS COV-2 PANEL	QIAGEN Sciences (Laboratory in MD)	NCD: None Novitas: L38916, A58575 – Respiratory Pathogen Panel Testing

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0225U	EPLEX® RESPIRATORY PATHOGEN PANEL 2	GenMark Diagnostics, Inc (Laboratory in CA)	NCD: None Noridian: L39001, A58720 – MoIDX: Molecular Syndromic Panels for Infections Disease Pathogen Identification Testing*
0228U	PANGIA PROSTATE	Genetics Institute of America, Entopsis, LLC (Laboratory in FL)	NCD: None First Coast: None BCBSM/BCNA Guidance: Prostate Cancer Early Detection – Biomarkers Prior to Biopsy – Medicare Advantage
0229U	COLVERA®	Clinical Genomics Pathology, Inc. (Laboratory in NJ)	NCD: None Novitas: L39365, A59125 – Genetic Testing in Oncology: Specific Tests
0231U	GENOMIC UNITY® CACNA1A ANALYSIS	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing for Epilepsy – Medicare Advantage
0234U	GENOMIC UNITY® MECP2 ANALYSIS	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing for Rett Syndrome – Medicare Advantage
0235U	GENOMIC UNITY® PTEN ANALYSIS	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing for <i>PTEN</i> Hamartoma Tumor Syndrome – Medicare Advantage
0236U	GENOMIC UNITY® SMN1/2 ANALYSIS	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Cancer Susceptibility Panels Using Next- Generation Sequencing – Medicare Advantage
0237U	GENOMIC UNITY® CARDIAC ION CHANNELOPATHIES ANALYSIS	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing for Cardiac Ion Channelopathies – Medicare Advantage
0238U	Genomic Unity® Lynch Syndrome Analysis	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes – Medicare Advantage and Genetic Cancer Susceptibility Panels Using Next- Generation Sequencing – Medicare Advantage
0239U	FOUNDATIONONE® LIQUID CDX	Foundation Medicine, Inc, (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: - Somatic Biomarker Testing (Including Liquid Biopsy) For Targeted Treatment in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, NTRK, RET and HER2) – Medicare Advantage - 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) – Medicare Advantage - GT-Somatic Biomarker Testing for Immune Checkpoint Inhibitor Therapy (BRAF, MSI/MMR, PF-L1, TMB) – Medicare Advantage - Circulating Tumor DNA and Circulating Tumor Cells for Selecting Targeted Therapy for Advanced Solid Cancers (Liquid Biopsy) – Medicare Advantage - Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy) – Medicare

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
			Advantage - Genetic Testing-BRAF Mutation in Selecting Melanoma Patients for Targeted Therapy Including Liquid Biopsy – Medicare Advantage - Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (BRCA1, BRCA2, Homologous Recombination Deficiency) – Medicare Advantage
0242U	GUARDANT360® CDX	Guardant Health, Inc. (Laboratory in CA)	NCD: 210.3 - Colorectal Cancer Screening Tests – Blood based biomarker screening tests must have Food and Drug Administration market authorization with an indication for colorectal cancer. Guardant360® CDx is FDA approved. 90.2 - Next Generation Sequencing (NGS)
0243U	PLGF PREECLAMPSIA SCREEN	PerkinElmer Genetics, Inc. (Laboratory in PA)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1
0244U	ONCOTYPE MAP™ PAN-CANCER TISSUE TEST	Exact Science, Inc., Genomic Health, Inc. – Arizona (Formerly known as Paradigm Diagnostics, Inc.) (Laboratory in AZ)	NCD: 90.2 - Next Generation Sequencing (NGS) Noridian: L38119, A57901 – MolDX: Next-Generation Sequencing for Solid Tumors* A55624 – MolDX: Targeting and Comprehensive Genomic Profile Testing in Cancer*
0245U	THYGENEXT® THYROID ONCOGENE PANEL	Interpace Diagnostics (Laboratory in NJ)	NCD: None Novitas: L35396, A52986 – Biomarkers for Oncology
0246U	PRECISIONBLOOD™	San Diego Blood Bank (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MolDX: Molecular Diagnostic Tests (MDT)* L38351, A57331 – MolDX: Repeat Germline Testing*
0247U	PRETRM®	Sera Prognostics, Inc. (Laboratory in UT)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 Noridian: L35160, A57526 – MolDX: Molecular Diagnostic Tests (MDT)*
0248U	3D PREDICT GLIOMA	Kiyatec®, Inc. (Laboratory in SC)	NCD: None Palmetto: L34554, A56871 – MolDX: In Vitro Chemosensitivity & Chemoresistance Assays*
0250U	PGDX ELIO™ TISSUE COMPLETE	Personal Genome Diagnostics, Inc. (Laboratory in MD)	NCD: None Novitas: None BCBSM/BCNA Guidance: Genetic Testing–NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions – Medicare Advantage
0252U	POC (PRODUCTS OF CONCEPTION)	Igenomix® USA (Laboratories in CA and FL)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 First Coast: L34519 – Molecular Pathology Procedures Noridian: L35160, A57526 – Molecular Diagnostic

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
			Tests (MDT)*
0253U	ERA® (ENDOMETRIAL RECEPTIVITY ANALYSIS)	Igenomix® USA (Laboratories in CA and FL)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 First Coast: None Noridian: L35160, A57526 – MolDx: Molecular Diagnostic Tests (MDT)*
0254U	SMART PGT-A (PRE-IMPLANTATION GENETIC TESTING – ANEUPLOIDY)	Igenomix® USA (Laboratories in CA and FL)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 First Coast: None Noridian: L35160, A57526 – MolDx: Molecular Diagnostic Tests (MDT)*
0258U	MIND.PX	Mindera Corporation (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MolDx: Molecular Diagnostic Tests (MDT)* L38351, A57331 – MolDx: Repeat Germline Testing*
0259U	GFR BY NMR	Labtech™ Diagnostics (Laboratory in SC)	NCD: None Palmetto: L35025, A56853 – MolDx: Molecular Diagnostic Tests (MDT)* A59636 – MolDx: Proteomics Testing*
0260U	AUGUSTA OPTICAL GENOME MAPPING	Bionano Genomics, Inc. (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MolDx: Molecular Diagnostic Tests (MDT)* L38351, A57331 – MolDx: Repeat Germline Testing*
0264U	PRAXIS OPTICAL GENOME MAPPING	Praxis Genomics LLC (Laboratory in GA)	NCD: None Palmetto: L35025, A56853 – MolDx: Molecular Diagnostic Tests (MDT)* L38274, A58017 – MolDx: Repeat Germline Testing*
0265U	PRAXIS WHOLE GENOME SEQUENCING	Praxis Genomics LLC (Laboratory in GA)	NCD: None Palmetto: L35025, A56853 – MolDx: Molecular Diagnostic Tests (MDT)* L38274, A58017 – MolDx: Repeat Germline Testing*
0266U	PRAXIS TRANSCRIPTOME	Praxis Genomics LLC (Laboratory in GA)	NCD: None Palmetto: L35025, A56853 – MolDx: Molecular Diagnostic Tests (MDT)* L38274, A58017 – MolDx: Repeat Germline Testing*
0267U	PRAXIS COMBINED WHOLE GENOME SEQUENCING AND OPTICAL GENOME MAPPING	Praxis Genomics LLC (Laboratory in GA)	NCD: None Palmetto: L35025, A56853 – MolDx: Molecular Diagnostic Tests (MDT)* L38274, A58017 – MolDx: Repeat Germline Testing*
0268U	VERSITI™ AHUS GENETIC EVALUATION	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDx: Molecular Diagnostic Testing (MDT)*

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
			L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0269U	VERSITI™ AUTOSOMAL DOMINANT THROMBOCYTOPENIA PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0270U	VERSITI™ COAGULATION DISORDER PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0271U	VERSITI™ CONGENITAL NEUTROPENIA PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0272U	VERSITI™ COMPREHENSIVE BLEEDING DISORDER PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0273U	VERSITI™ FIBRINOLYTIC DISORDER PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0274U	VERSITI™ COMPREHENSIVE PLATELET DISORDER PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0276U	VERSITI™ INHERITED THROMBOCYTOPENIA PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0277U	VERSITI™ PLATELET FUNCTION DISORDER PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0278U	VERSITI™ THROMBOSIS PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MolDX: Repeat Germline Testing* CGS: L36021, A56973 – MolDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MolDX: Repeat Germline Testing* NGS: None

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
			Novitas: None BCBSM/BCBNA Guidance: None
0282U	VERSITI™ RED CELL GENOTYPING PANEL	Versiti™ Diagnostic Laboratories (Laboratory in IL, IN, MI, OH, TX, WI)	NCD: None WPS: L36807, A57772 – MoIDX: Molecular Diagnostic Testing (MDT)* L38429, A57100 – MoIDX: Repeat Germline Testing* CGS: L36021, A56973 – MoIDX: Molecular Diagnostic Testing (MDT)* L38288, A57141 – MoIDX: Repeat Germline Testing* NGS: None Novitas: None BCBSM/BCBNA Guidance: None
0285U	RADTOX™ cfDNA TEST	DiaCarta Clinical Lab, (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)*
0286U	CNT (CEP72, TPMT and NUDT15) GENOTYPING PANEL	RPRD Diagnostics (Laboratory in WI)	NCD: None NGS: L39995, A59915 – Pharmacogenomic Testing
0288U	RISKREVEAL™	Razor Genomics (Laboratory in TN)	NCD: None Palmetto: L38238, A58031 – MoIDX: Predictive Classifiers for Early-Stage Non-Small Cell Lung Cancer*
0289U	MINDX BLOOD TEST™ MEMORY/ALZHEIMER'S	MindX Sciences™, Inc. (Laboratory in IN)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services." WPS: L36807, L57772 – MoIDX: Molecular Diagnostic Tests (MDT)* L38429, A57100 – MoIDX: Repeat Germline Testing*
0290U	MINDX BLOOD TEST™ - PAIN	MindX Sciences™, Inc. (Laboratory in IN)	NCD: None WPS: L36807, L57772 – MoIDX: Molecular Diagnostic Tests (MDT)* L38429, A57100 – MoIDX: Repeat Germline Testing*
0291U	MINDX BLOOD TEST™ - MOOD	MindX Sciences™ Inc. (Laboratory in IN)	NCD: None WPS: L36807, L57772 – MoIDX: Molecular Diagnostic Tests (MDT)* L38429, A57100 – MoIDX: Repeat Germline Testing*
0292U	MINDX BLOOD TEST™ - STRESS	MindX Sciences™, Inc. (Laboratory in IN)	NCD: None WPS: L36807, L57772 – MoIDX: Molecular Diagnostic Tests (MDT)* L38429, A57100 – MoIDX: Repeat Germline Testing*
0293U	MINDX BLOOD TEST™ - SUICIDALITY	MindX Sciences™, Inc. (Laboratory in IN)	NCD: None WPS: L36807, L57772 – MoIDX: Molecular Diagnostic Tests (MDT)* L38429, A57100 – MoIDX: Repeat Germline Testing*

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0294U	MINDX BLOOD TEST™ - LONGEVITY	MindX Sciences™, Inc. (Laboratory in IN)	NCD: None WPS: L36807, L57772 – MoIDX: Molecular Diagnostic Tests (MDT)* L38429, A57100 – MoIDX: Repeat Germline Testing*
0295U	DCISIONRT®	Prelude Corporation (Laboratory in CA)	National Regulatory Guidance: This genetic test is for determining the likelihood of breast cancer recurrence as reported in a recurrence risk score. Medicare generally does not cover routine screening tests, as they are statutorily excluded under §1862(a)(7). This includes pre-symptomatic genetic tests or risk assessment tests that do not directly affect the immediate management of the patient. Preventive services are non-covered by Medicare unless specifically covered in NCDs, statutes, or regulations. Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)* L38351, A57331 – MoIDX: Repeat Germline Testing*
0296U	MRNA CANCERDETECT™	Viome Life Sciences, Inc. (Laboratory in WA)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Testing (MDT)*
0297U	PRAXIS SOMATIC WHOLE GENOME SEQUENCING	Praxis Genomics LLC (Laboratory in GA)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 Palmetto: L35025, A56853 – MoIDX: Molecular Diagnostic Testing (MDT)*
0298U	PRAXIS SOMATIC TRANSCRIPTOME	Praxis Genomics LLC (Laboratory in GA)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 Palmetto: L35025, A56853 – MoIDX: Molecular Diagnostic Testing (MDT)*
0299U	PRAXIS SOMATIC OPTICAL GENOME MAPPING	Praxis Genomics LLC (Laboratory in GA)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 Palmetto: L35025, A56853 – MoIDX: Molecular Diagnostic Testing (MDT)*
0300U	PRAXIS SOMATIC COMBINED WHOLE GENOME SEQUENCING AND OPTICAL GENOME MAPPING	Praxis Genomics LLC (Laboratory in GA)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 Palmetto: L35025, A56853 – MoIDX: Molecular Diagnostic Testing (MDT)*

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0301U	BARTONELLA DDPCR	Galaxy Diagnostics Inc (Laboratory in NC)	NCD: None Palmetto: L38988, A58710 – MoIDX: Molecular Syndromic Panels for infectious Disease Pathogen Identification Testing*
0302U	BARTONELLA DIGITAL EPCR™	Galaxy Diagnostics Inc (Laboratory in NC)	NCD: None Palmetto: L38988, A58710 – MoIDX: Molecular Syndromic Panels for infectious Disease Pathogen Identification Testing*
0306U	INVITAE PCM TISSUE PROFILING AND MRD BASELINE ASSAY	Invitae Corporation (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Tests (MDT)*
0307U	INVITAE PCM MRD MONITORING	Invitae Corporation (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Tests (MDT)*
0308U	HART CADHS®	Complete Omics, Inc. (Laboratory in MD)	NCD: None Novitas: A58917 – Billing and Coding: Molecular Pathology and Genetic Testing
0309U	HART CVE®	Complete Omics, Inc. (Laboratory in MD)	NCD: None Novitas: A58917 – Billing and Coding: Molecular Pathology and Genetic Testing
0310U	HART KD®	Complete Omics, Inc. (Laboratory in MD)	NCD: None Novitas: A58917 – Billing and Coding: Molecular Pathology and Genetic Testing
0312U	AVISE® LUPUS	Exagen, Inc. (Laboratory in CA)	NCD: None Noridian: L35160 – MoIDX: Molecular Diagnostic Tests (MDT)*; A59641 – MoIDX: Proteomics Testing*
0313U	PANCREASEQ® GENOMIC CLASSIFIER	Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center (Laboratory in PA)	NCD: None Novitas: L39365, A59125 – Genetic Testing in Oncology: Specific Tests
0314U	DECISIONDX® DIFFDX™- MELANOMA	Castle Biosciences, Inc. (Laboratory in AZ)	NCD: None Noridian: L39373, A59179 - MoIDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma*
0315U	DECISIONDX®-SCC	Castle Biosciences, Inc. (Laboratory in AZ)	NCD: None Noridian: L39589, A59386 - MoIDX: Molecular Biomarker Testing for Risk Stratification of Cutaneous Squamous Cell Carcinoma*
0317U	LungLB®	LungLife AI® (Laboratory in CA)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1 Noridian: None BCBSM/BCNA Guidance: None
0318U	EPISIGN COMPLETE	Greenwood Genetic Center (Laboratory in SC)	NCD: None Palmetto: L35025, A56853 – MoIDX: Molecular Diagnostic Tests (MDT)* L38274, A58017 – Repeat Germline Testing
0319U	PRETRANSPLANT RISK ASSESSMENT (PTRA)	Verici Dx, Inc. (Laboratory in TN)	NCD: None Palmetto: L35025, A56853 – MoIDX: Molecular Diagnostic Tests (MDT)
0320U	TUTIVIA™	Verici Dx, Inc. (Laboratory in TN)	NCD: None Palmetto: L38568, A58019 – MoIDX: Molecular Testing for Solid Organ Allograft Rejection*
0321U	BRIDGE URINARY TRACT INFECTION DETECTION AND	Bridge Diagnostics (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
	RESISTANCE (Listed as UTI ID with ABR and AST Detection Assay in the DEX® Registry)		
0326U*	GUARDANT360®	Guardant Health, Inc. (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MolDX: Molecular Diagnostic Tests (MDT)*; A58973 – MolDX: Plasma-Based Genomic Profiling in Solid Tumors*
0327U	VASISTERA™	Natera, Inc. (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MolDX: Molecular Diagnostic Tests (MDT)*
0328U	CAREVIEW360	Newstar Medical Laboratories LLC (Laboratory in GA)	NCD 130.5 – Treatment of Alcohol and Drug Abuse in a Freestanding Clinic 130.6 – Treatment of Drug Abuse (Chemical Dependency) 130.7 – Withdrawal Treatments for Narcotic Addictions
0329U	ONCOEXTRA™ (FORMERLY KNOWN AS ONCOMAP™ EXTRA AND GEM EXTRA)	Exact Sciences, Inc., Genomic Health, Inc. - Arizona. (May be performed by Ashion Analytics on behalf of Exact Science/Genomic health in AZ) (Laboratory in AZ)	NCD: 90.2 - Next Generation Sequencing (NGS) Noridian: L38119, A57901 – MolDX: Next-Generation Sequencing for Solid Tumors*
0330U	BRIDGE WOMEN'S HEALTH INFECTIOUS DISEASE DETECTION TEST	Bridge Diagnostics (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MolDX: Molecular Diagnostic Tests (MDT)*
0331U	AUGUSTA HEMATOLOGY OPTICAL GENOME MAPPING	Georgia Esoteric and Molecular Labs, (Laboratory in GA)	NCD: None Palmetto: L35025, A56853 - MolDX: Molecular Diagnostic Testing (MDT)* L38274, A58017 – Repeat Germline Testing*
0332U	EPISWITCH® CiRT (Checkpoint- inhibitor Response Test)	Next Bio-Research Services, LLC, and Oxford BioDynamics, PLC (Laboratory in VA)	NCD: None Palmetto: L35025, A56853 - MolDX: Molecular Diagnostic Testing (MDT)*
0333U	HELIOLIVER™ TEST	Fulgent Genetics and Helio Genomics (Laboratory in IN)	NCD: None WPS: L36807, A57772 – MolDX: Molecular Diagnostic Tests (MDT)*
0334U	GUARDANT360 TISSUE™ (formerly called Guardant360 TissueNext)	Guardant Health, Inc. (Laboratory in CA)	NCD: None Noridian: L38119, A57901 – MolDX: Next-Generation Sequencing for Solid Tumors*
0335U	IRISIGHT™ PRENATAL ANALYSIS – PROBAND	Variantyx, Inc. (Laboratories in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing - Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0336U	IRISIGHT™ PRENATAL ANALYSIS – COMPARATOR	Variantyx, Inc. (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing - Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0337U	CELLSEARCH® CIRCULATING MULTIPLE MYELOMA CELL (CMMC) TEST	Menarini Silicon Biosystems, Inc. (Laboratory in CA)	NCD: None LCD: None BCBSM/BCNA Guidance: BMT - Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma, Plasma Cell Leukemia,

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
			Plasmacytoma, and POEMS Syndrome – Medicare Advantage
0338U	CELLSEARCH® HER2 CIRCULATING TUMOR CELL (CTC-HER2) TEST	Menarini Silicon Biosystems, Inc. (Laboratory in CA)	NCD: None Noridian: L35160, A57526 MoIDX: Molecular Diagnostic Tests (MDT)*
0339U	SELECTMDX® FOR PROSTATE CANCER	MDxHealth, Inc. (Formerly Exosome Diagnostics, Inc) (Laboratory in CA)	NCD: 210.1 Prostate Cancer Screening Tests Noridian: L39005, A58718 – MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer*
0340U	SIGNATERA™ SINGLE PLAMA TEST	Natera, Inc. (Laboratory in CA)	NCD: None Noridian: L38814, A58454 - MoIDX: Minimal Residual Testing for Cancer*
0341U	SINGLE CELL PRENATAL DIAGNOSIS (SCPD) TEST	Luna Genetics, Inc. (Laboratory in TX)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1
0342U	IMMRAY® PANCAN-D	Immunovia, Inc. (Laboratory in NC)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1
0343U	MIR SENTINEL™ PROSTATE CANCER TEST	miR Scientific, LLC (Laboratory in NY)	NCD: None NGS: None BCBSM/BCNA Guidance: Prostate Cancer Early Detection – Biomarkers Prior to Biopsy
0345U	GENESIGHT® PSYCHOTROPIC	Myriad Genetics, Inc. (Laboratory in OH)	NCD: None CGS: L36021, A56973 - MoIDX: Molecular Diagnostic Tests (MDT)* L38288, A57141 - MoIDX: Repeat Germline Testing* L38394, A58324 - MoIDX: Pharmacogenomics Testing*
0347U	RIGHTMED® PGX16 TEST	OneOme®, LLC (Laboratory in MN)	NCD: None NGS: L39995, A59515 – Pharmacogenomic Testing
0348U	RIGHTMED® COMPREHENSIVE TEST EXCLUDE F2 AND F5	OneOme®, LLC (Laboratory in MN)	NCD: None NGS: L39995, A59515 – Pharmacogenomic Testing
0349U	RIGHTMED® COMPREHENSIVE TEST	OneOme®, LLC (Laboratory in MN)	NCD: None NGS: L39995, A59515 – Pharmacogenomic Testing
0350U	RIGHTMED® GENE REPORT	OneOme®, LLC (Laboratory in MN)	NCD: None NGS: L39995, A59515 – Pharmacogenomic Testing
0355U	APOLIPOPROTEIN L1 (APOL1) RENAL RISK VARIANT GENOTYPING	Quest Diagnostics® (Laboratories in multiple markets)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1
0359U	ISOPSA®	Cleveland Diagnostics, Inc. (Laboratory in OH)	NCD: None CGS: L39284, A59066 – Prostate Cancer Detection with IsoPSA®

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0363U	CXBLADDER™ TRIAGE	Pacific Edge Diagnostics USA Ltd. (Laboratory in PA)	NCD: None Novitas: L39365, A 59125 – Genetic Testing in Oncology: Specific Tests
0398U	ESOPREDICT® BARRETT'S ESOPHAGUS RISK CLASSIFIER ASSAY	Capsulomics, Inc d/b/a Previsio (Laboratory in MD)	NCD: None Novitas: A58917 – Molecular Pathology and Genetic Testing
0407U	KIDNEYINTELX.DKD™	Renalytix AI, Inc. (Laboratory in NY and UT)	NCD: None NGS: L39726, A59595 – KidneyIntelX and KidneyIntelX.dks Testing Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0412U	PRECIVITYAD® BLOOD TEST	C2N Diagnostics LLC (Laboratory in MO)	NCD: None WPS: L36807, A57772 - MoIDX: Molecular Diagnostic Tests (MDT)*
0429U	OMNIPATHOLOGY OROPHARYNGEAL HPV PCR TEST	OmniPathology Solutions, Medical Corporation (Laboratory in CA)	NCD: None Noridian: L39001, A58720 - MoIDX: Molecular Syndromic Panels for Infectious Disease Pathogen
0452U	EARLYTECT® BLADDER CANCER DETECTION (BCD)	Promis Diagnostics, Inc. (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Tests (MDT)*
0465U	URIFIND® UROTHELIAL CARCINOMA ASSAY	DiaCarta, Inc. (Laboratory in CA)	NCD: None Noridian: L35160, A57526 - MoIDX: Molecular Diagnostic Tests (MDT)*
0498U	OPTISEQ™ COLORECTAL CANCER NGS PANEL	DiaCarta, Inc. (Laboratory in CA)	NCD: 210.3 – Colorectal Cancer Screening Tests Noridian: L39367, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0499U	OPTISEQ™ DUAL CANCER PANEL KIT (COLORECTAL AND LUNG)	DiaCarta, Inc. (Laboratory in CA)	NCD: 210.3 – Colorectal Cancer Screening Tests Noridian: L39367, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0501U	QUANTIDNA™ COLORECTAL CANCER TRIAGE TEST	DiaCarta, Inc. (Laboratory in CA)	NCD: 210.3 – Colorectal Cancer Screening Tests Noridian: L39367, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0502U	QUANTIVIRUSTM HPV E6/E7 MRNA TEST FOR CERVICAL CANCER	DiaCarta, Inc. (Laboratory in CA)	NCD: None Noridian: L39001, A58720 - MoIDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing*
0503U	PRECIVITYAD2™	C2N Diagnostics, LLC (Laboratory in CA)	NCD: None Noridian: L39367, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0504U	Urinary Tract Infection Testing	NxGen MDx LLC (Laboratory in MI)	NCD: None WPS: L36807, A57772 – MoIDX: Molecular Diagnostic Tests (MDT)*
0505U	Vaginal Infection Testing	NxGen MDx LLC (Laboratory in MI)	NCD: None WPS: L36807, A57772 – MoIDX: Molecular Diagnostic Tests (MDT)*
0506U	EndoSign® Barrett's Esophagus Test	Cyted Health Inc. (Laboratory in GA)	NCD: None Palmetto: L35025, A56853 - MoIDX: Molecular Diagnostic Testing (MDT)*
0524U	PreClara™ Ratio (sFit- 1/PIGF)	Thermo Fisher Scientific (Laboratory in MI)	National Regulatory Guidance Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded by law. Section 1862(a) (1) (A) of the Social Security Act Medicare Claims Processing Manual: Chapter 16, §120.1

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0537U	SHIELD™	Guardant Health, Inc. (Laboratory in CA)	NCD: 210.3 - Colorectal Cancer Screening Tests Noridian: L39367, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0548U	GLIAL FIBRILLARY ACIDIC PROTEIN BLOOD TEST	Neurocode USA, Inc (Laboratory in WA)	NCD: None Noridian: None BCBSM/BCNA Guidance: Evaluation of Biomarkers for Alzheimer's Disease – Medicare Advantage
0549U	BLADDER CARE™	Pangea Laboratory LLC (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)* A technical assessment (TA) is required to determine Medicare coverage. This test has not yet undergone the required TA review by the MoIDX Contractor and therefore does not meet requirements for coverage.
0567U	GENOMIC UNITY® 2.0	Variantix, Inc (Laboratory in MA)	NCD: None NGS: None BCBSM/BCNA Guidance: Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders – Medicare Advantage
0572U	PROSTAV®	Life Length S.L. (Test was originally developed by Life Length in Spain but are available in US through partnership with Laboratories in FL, PA, TX)	National Regulatory Guidance: This genetic test is for determining the likelihood of developing prostate cancer. Medicare generally does not cover routine screening tests, as they are statutorily excluded under §1862(a)(7). This includes pre-symptomatic genetic tests or risk assessment tests that do not directly affect the immediate management of the patient. See NCD 210.1 for types of prostate cancer screening tests that are covered. NCD: 210.1 – Prostate Cancer Screening Tests First Coast: None Novitas: None BCBSM/BCNA Guidance: Prostate Cancer Early Detection: Biomarkers Prior to Biopsy – Medicare Advantage
0573U	AMPLIFIED SCIENCES PANCYSTPRO™	Amplified Sciences, Inc (Laboratory in CA)	NCD: None Noridian: L35160 – MoIDX: Molecular Diagnostic Tests (MDT)* A59641 – MoIDX: Proteomics Testing* A technical assessment (TA) is required to determine Medicare coverage. This test has not yet undergone the required TA review by the MoIDX Contractor and therefore does not meet requirements for coverage.
0576U	OmniGraf® Liver	Eurofins Transplant Genomics (Laboratory in KS)	NCD: None WPS:
0591U	MICHECK® PROSTATE	Minomic®, Inc (Laboratory in MD)	National Regulatory Guidance: This genetic test is for determining the likelihood of developing prostate cancer. Medicare generally does not cover routine screening tests, as they are statutorily excluded under §1862(a)(7). This includes pre-symptomatic genetic tests or risk assessment tests that do not directly affect the immediate management of the patient. See NCD 210.1 for types of prostate cancer screening tests that are covered. NCD: 210.1 – Prostate Cancer Screening Tests Novitas: None BCBSM/BCNA Guidance: Prostate Cancer Early Detection: Biomarkers Prior to Biopsy – Medicare Advantage

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0599U	PANCREASURE™	Immunovia, Inc (Laboratory is in NC)	NCD: None Palmetto: L35025, A56853 – MoIDX: Molecular Diagnostic Tests (MDT)*
0600U	FIDALAB WOUND INFECTION TEST	FidaLab LLC (Laboratory in WA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT) *
0603U	SLL COMPREHENSIVE DRUG ANALYSIS	Soft Landing Labs (Laboratory in IL)	NCD: None NGS: None BCBSM/BCNA Guidance: Drug Testing in Pain Management and Substance Use Disorder Treatment – Medicare Advantage
0611U	HELIOHCC™ STRAT	Helio Genomics® (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
06112U	HELIOHCC™ TRACE	Helio Genomics® (Laboratory in CA)	NCD: None Noridian: L35160, A57526 – MoIDX: Molecular Diagnostic Tests (MDT)*
0616U	TRUD MDS ALZHEIMER'S & MCI	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.
0618U	TRUD MDS BIPOLAR	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.
0619U	TRUD MDS COPD	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.
0621U	TRUD MDS LYME DISEASE	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
			the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.
0622U	TRUD MDS MAJOR DEPRESSIVE DISORDER	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.
0623U	TRUD MDS MULTIPLE SCLEROSIS	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.
0624U	TRUD MDS NASH	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.
0625U	TRUD MDS OSTEOPOROSIS	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.
0626U	TRUD MDS PARKINSON'S	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.

CPT Code	Test Name	Clinical Laboratory or Manufacturer	Guidance
0627U	TRUD MDS SCHIZOPHRENIA	TruDiagnostic™, Inc (Laboratory in KY)	National Regulatory Guidance: Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (See also Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, §20 - Services Not Reasonable and Necessary). The purpose of these tests is to predict the risk of developing a disease or condition. They are not diagnostic tests. Therefore, they are considered excluded tests services.

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* CMS MoIDX Program

The MoIDX Program, administered by Palmetto GBA, is a Medicare Molecular Diagnostic Program that aims to identify and establish coverage and reimbursement for molecular diagnostic tests. This program is implemented by several Medicare Administrative Contractors (MACs), including **WPS, CGS, Noridian, and Palmetto**.

The MoIDX Program evaluates genetic and proteomic tests to determine their analytical and clinical validity (AV/CV) and clinical utility (CU), ensuring that each test meets Medicare criteria.

The program's coverage determinations are maintained in the DEX™ Diagnostic Exchange registry. Dex Diagnostic Exchange Registry Coverage Determinations:

1. Not Covered: Not covered tests in the Dex Registry have undergone a review of their clinical utility and analytical validity and have been determined to not meet the requirements for medical necessity under Section 1862(a)(1)(A) of the Social Security Act. As a result, they are not considered medically reasonable or necessary for Medicare coverage.
2. No Determinations: Tests that have not completed the required technical assessment (TA) review are, by default, also considered not medically reasonable or necessary for Medicare under Section 1862(a)(1)(A) until the review is completed. The MoIDX Program does not provide coverage for tests provided with dates of services prior to the effective date of approval.
3. Covered: Covered Tests in Dex Registry have completed the required TA review and have been determined to be medically reasonable and necessary for Medicare under Section 1862(a)(1)(A). However, coverage is not automatic and is subject to the following conditions:
 - a. The test must meet the applicable criteria outlined in NCDs, LCDs, and LCAs; and
 - b. The patient must exhibit signs or symptoms of a relevant disease or condition, making the test medically necessary for their care.

For specific coding and billing information on covered and excluded tests, please refer to the MoIDX website at <https://www.palmettogba.com/MoIDX>. This website provides up-to-date information on the program's coverage determinations and guidelines.

NOTE: Per § 2.3.3. of the Molecular Diagnostic Program [MoIDX®] Manual, the MoIDX Program does not provide coverage for tests that have not been reviewed and approved through the MoIDX process or for tests provided with dates of services prior to the effective date of approval. For additional information regarding what tests will fall into a Medicare benefit

category or which tests are statutory excluded (e.g., predictive, prenatal, and carrier testing and tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law) please refer to <https://www.palmettogba.com/palmetto/moldxv2.nsf/DID/DPR5GEM991>

The above information is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document.

Please refer to the Medicare Coverage Database website at <https://www.cms.gov/medicare-coverage-database/search.aspx> for the most current applicable NCD, LCD, LCA, and CMS Online Manual System Transmittals.

CMS Medicare Administrative Contractors (MAC) Jurisdictions Guidance

Part A and Part B MAC Jurisdictions	
Wisconsin Physicians Service Insurance Corporation (WPS)	IA, IN, KS, MI, MO, NE
CGS Administrators, LLC	KY, OH
First Coast Service Options, Inc	FL, PR, US VI
Noridian Healthcare Solutions, LLC, Jurisdiction JE	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
Noridian Healthcare Solutions, LLC, Jurisdiction JF	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
Novitas Solutions, Inc	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX,
Palmetto GBA	AL, GA, TN NC, SC, VA, WV
Wellpoint Federal - Previously known as: National Government Services, Inc (NGS)	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI,
DME MAC Jurisdictions	
CGS Administrators, LLC, Jurisdictions JB and JC	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NM, NC, OH, OK, Puerto Rico, SC, TN, TX, VA, Virgin Island, WI, WV
Noridian Healthcare Solutions, LLC, Jurisdictions JA and JD	AK, American Soamoa, AZ, CA, CT, DE, DC, Guam, HI, ID, IA, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY, Northern Mariana Islands, OR, PA, RI, SD, UT, VT, WA, WY

Important Reminder

BCBSM and BCN follow CMS Medicare coverage guidance to limit coverage to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Medicare Advantage Medical Policies list the criteria BCBSM and BCN use to decide which medical services are considered “reasonable and necessary” when Medicare coverage rules are not fully developed, or as otherwise may permitted by CMS Medicare regulations. Individual member benefit plan documents, such as the Evidence of Coverage and Annual Notice of Change, as well as applicable laws govern benefit coverage, including any inclusion, exclusion, and/or other restrictions.

Medicare Advantage Medical policies are created when permitted by CMS Medicare regulations, reviewed regularly, and may be revised periodically. BCBSM/BCN Medical Policies are proprietary and should not be copied or disseminated without the express, prior written approval of BCBSM. All providers are required to review applicable BCBSM reimbursement

policies prior to claim submission and bill for covered services in accordance with those policies. Additionally, providers contracted with BCBSM or BCN's Medicare Advantage network(s) should review the provider manual for any additional claim submission requirements. Providers not contracted with BCBSM or BCN's Medicare Advantage network may be required to submit documentation to BCBSM, BCN, or its delegated entity supporting billed claims, including but not limited to applicable medical records.

Note: U.S. Food and Drug Administration (FDA) approval for a specific indication or the issuance of a CPT code is not sufficient for a procedure to be considered medically reasonable and necessary. Similarly, the presence of a procedure/device code or payment amount for the service in the Medicare fee schedule does not necessarily indicate coverage. If a service is deemed not reasonable and necessary, to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), the procedure is considered not covered.

Disclaimer: This medical policy is not an authorization, certification, explanation of benefits, or a contract for the services, devices, or drugs that is referenced in the medical policy. Medical policies do not constitute medical advice and do not guarantee any results or outcomes or guarantee payment. The medical policy is not intended to replace independent medical judgment for the treatment of individuals. Treating physicians and health care providers are solely responsible for determining what care to provide to their patients. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another.

Pursuant to Section 1557 and Section 504, Blue Cross does not discriminate on the basis of race, color, national origin, age, disability, or sex (including sex characteristics, intersex traits; pregnancy or related conditions; sexual orientation; gender identity, and sex stereotypes). This includes our rules, benefit designs and medical policies.

References

1. Medicare Claims Processing Manual, Chapter 16 – Laboratory Services and Chapter 23, Section 40 Clinical Diagnostic Laboratory Fee Schedule
2. Medicare Benefit Processing Manual, Chapter 15, Section 80.1 – Clinical Laboratory Services

BCBSM/BCN Medicare Advantage Policy History

Policy Effective Date	UM Committee Approval Date	Comments
06/20/2026	05/20/2026	Medicare Advantage policy established