Experimental, Investigational, or Unproven Laboratory Testing

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Introduction

Experimental, investigational, or unproven (E/I/U) molecular and genomic testing is addressed by this guideline.

Procedures addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

Procedures address by this guideline	Procedure codes
9p21 Genotype	81479
AlloSure Heart	81479
AlloSure Lung	81479
AmHPR Helicobacter pylori Antibiotic Resistance Next Generation Sequencing Panel	0008U
Apolipoprotein E Genotype (APOE)	81401
Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping	0355U
ARISk Autism Risk Assessment Test	81479
AssureMDx	81479
Augusta Hematology Optical Genome Mapping	0331U
Augusta Optical Genome Mapping	0260U
Avantect Ovarian Cancer Test	0507U
Avantect Pancreatic Cancer Test	0410U
BarreGEN	81599
BBDRisk Dx	0067U
Bladder EpiCheck	81599
BluePrint Molecular Subtyping Profile	81479
BTG Early Detection of Pancreatic Cancer	0405U

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Procedures address by this guideline	Procedure codes
CARDIO inCode Score (CIC SCORE)	0401U
CardioRisk+	0466U
CELLSEARCH CTC Test	86152, 86153
ChemoFX	81535 81536
Chromosome Genome Mapping	0454U
Clarava	0319U
Clarifi ASD	0170U
CNGnome	0209U
Cologuard Plus	0464U
ColonAiQ	0453U
ColonSentry	81479
ColoScape Colorectal Cancer Detection	0368U
ColoScape PLUS	0496U
Colvera	0229U
CyPath Lung	0406U
Cytogenomic (genome-wide) analysis, hematologic malignancy, structural variants and copy number variants, optical genome mapping (OGM)	81195
Decipher Bladder TURBT	0016M
DecisionDx Cutaneous Melanoma	81529
DecisionDx DiffDx - Melanoma	0314U
DecisionDx - SCC	0315U
DEPArray	0009U
DetermaRx	0288U
DH Optical Genome Mapping/Digital Karyotyping Assay	0413U
Digitization of pathology slides	0760T, 0761T, 0762T, 0763T, 0848T, 0849T, 0850T, 0851T, 0852T, 0853T
EarlyTect Bladder Cancer Detection (EarlyTect BCD)	0452U
EndoSign Barrett's Esophagus Test	0506U

E/I/U

Procedures address by this guideline	Procedure codes
Envisia Genomic Classifier	81554
Epi+Gen CHD	0439U
Epignostix CNS Tumor Methylation Classifier	0020M
EpiSign Complete	0318U
EpiSwitch CiRT	0332U
EpiSwitch Prostate Screening Test	0433U
ERA (Endometrial Receptivity Analysis)	0253U
EsoGuard	0114U
ESOPREDICT Barrett's Esophagus Risk Classifier Assay	0398U
Eurofins TRAC dd-cfDNA	0118U
ExoDx Prostate (IntelliScore)	0005U
FM/a fibromyalgia	81599
GPS Cancer	81479
Guardant Reveal	81479
HelioLiver Test	0333U
Hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis	81451
HPV-SEQ Test	0470U
Insight TNBCtype	0153U
Invitae PCM MRD Monitoring	0307U
Invitae PCM Tissue Profiling and MRD Baseline Assay	0306U
IriSight CNV Analysis	0469U
IriSight Prenatal Analysis – Proband	0335U
IriSight Prenatal Analysis – Comparator	0336U
KawasakiDx	0389U
KIF6 Genotype	81479

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Procedures address by this guideline	Procedure codes
Know error	81479, 81265, 81266
LactoTYPE	81400
Lifetime Genomics Risk Assessment, VTE	0529U
LPA-Aspirin Genotype	81479
LPA-Intron 25 Genotype	81479
LungLB	0317U
LungOI	0414U
Lymph2Cx Lymphoma Molecular Subtyping Assay	0017M
Lymph3Cx Lymphoma Molecular Subtyping Assay	0120U
Macula Risk	81401, 81479
Mammostrat Breast Cancer Recurrence Assay	S3854
Mind.Px	0258U
MindX Blood Test - Longevity	0294U
MindX Blood Test - Memory/Alzheimer's	0289U
MindX Blood Test - Mood	0291U
MindX Blood Test - Pain	0290U
MindX Blood Test - Stress	0292U
MindX Blood Test - Suicidality	0293U
MindX One Blood Test – Anxiety	0437U
miR-31now	0069U
miR Sentinel Prostate Cancer Test	0343U
miR Sentinel Prostate Cancer Test	0424U
Molecular Microscope MMDx—Heart	0087U
Molecular Microscope MMDx—Kidney	0088U
mRNA CancerDetect	0296U
myPath Melanoma	0090U
MyProstateScore	81599 or 0113U
MyProstateScore 2.0	0403U
myPRS Myeloma Prognostic Risk Signature	81479

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Procedures address by this guideline	Procedure codes
myTAIHEART	0055U
NavDx	0356U
Northstar Response	0486U
OncoAssure Prostate	0497U
OncobiotaLUNG	0395U
Oncomap ExTra	0329U
OncoSignal 7 Pathway Signal	0262U
OncoTarget/OncoTreat	0019U
OncotypeDx AR-V7 Nucleus Detect	81479
OptiSeq Colorectal Cancer NGS Panel	0498U
PAI-1 Testing for Cardiovascular Disease Risk Assessment	81400, 85415
PancreaSeq Genomic Classifier	0313U
PanGIA Prostate	0228U
Pathway Fit	81291, 81401, 81479
PCR Fungal Screen for Onychomycosis	87481, 87798
Percepta Genomic Sequencing Classifier	81479
Pharmaco-oncologic Algorithmic Treatment Ranking	0794T
POC (Products of Conception)	0252U
Praxis Optical Genome Mapping	0264U
Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping	0300U
Praxis Somatic Optical Genome Mapping	0299U
Praxis Somatic Transcriptome	0298U
Praxis Somatic Whole Genome Sequencing	0297U
Praxis Transcriptome	0266U
PreciseDx Breast Biopsy Test	0418U
PreciseDx Breast Cancer Test	0220U
PrecisionCHD	0440U
ProMark Proteomic Prognostic Test	81479

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Procedures address by this guideline	Procedure codes
Prospera	0493U
PurIST	0510U
QuantiDNA Colorectal Cancer Triage Test	0501U
RadTox cfDNA test	0285U
RetnaGene AMD	81401, 81405, 81408, 81479, 81599
ROMA Risk of Ovarian Malignancy Algorithm	81500
Signatera	0340U
Single Cell Prenatal Diagnosis (SCPD) Test	0341U
SMART PGT-A (Pre-implantation Genetic Testing - Aneuploidy)	0254U
SMASH	0156U
Solid organ neoplasm, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis	81449
Solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes, genomic sequence analysis panel, interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis	81456
Statin Induced Myopathy Genotype (SLCO1B1)	81328
Strata Select	0391U
Stockholm3	0495U
Thyroid GuidePx	0362U
ToxLok	0079U
TruGraf Kidney	81558
Tuteva	0320U
Twin Zygosity, cell free fetal DNA	0060U
UriFind Urothelial Carcinoma Assay	0465U
UroAmp MRD	0467U

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Procedures address by this guideline	Procedure codes
Vectra	81490
VitaGraft Kidney Baseline + 1st Plasma Test	0508U
VitaGraft Kidney Subsequent	0509U
Vita Risk	0205U
Investigational and experimental tests that make use of molecular and genomic technologies	81479, 84999, 81599, and others

What is E/I/U molecular and genomic testing?

Definition

An experimental, investigational, or unproven (E/I/U) procedure is the use of a service, supply, drug, or device that is not recognized as standard medical care for the condition, disease, illness, or injury. Treatment is determined by the health plan based on an independent, peer review of literature and scientific data. E/I/U molecular and genomic tests refer to assays involving chromosomes, DNA, RNA, or gene products that have insufficient data to determine the net health impact.

Experimental, investigational, or unproven determinations

Molecular and genomic tests are routinely released to market that make use of novel technologies or have a novel clinical application. These tests are often available on a clinical basis long before the required evidence to support clinical validity and clinical utility are established. Typically, there is insufficient data to support that the test

- accurately assesses the outcome of interest, analytical and clinical validity
- significantly improves health outcomes, clinical utility, and
- performs better than an existing standard of care medical management option.

Because these tests are often proprietary, there may be no independent test evaluation data available in the early stages to support the laboratory's claims regarding test performance and utility.

As new molecular and genomic tests become commercially available, the evidence base is reviewed. Tests determined to be E/I/U by the Health Plan are addressed by this guideline or a test-specific guideline and are not eligible for reimbursement.

Food and Drug Administration (FDA) clearance

In the case of laboratory testing, FDA clearance is not a suitable standard given that the clearance assessment does not require evidence to support clinical utility. In

E/I/U

addition, while the FDA has stated that it has the discretion to regulate laboratory developed tests (LDTs), it is currently only selectively exercising that discretion to take action against egregious practices.

Note This benefit/harm statement only applies to those jurisdictions that do not have Medicare guidance. Based upon the clinical policy, following EviCore's Experimental, Investigational, or Unproven Laboratory Testing criteria will ensure that members will not receive testing for which there is not a body of evidence demonstrating analytical validity, clinical validity, and/or clinical utility. Use of a test that does not have evidence to support analytical validity, clinical validity, and/or clinical utility can lead to negative consequences. These include but are not limited to physical implications, psychological implications, treatment burden, social implications, and dissatisfaction with healthcare.* However, it is possible that there will be a delay in care while providers search for an appropriate test with sufficient evidence (analytical validity, clinical validity, and clinical utility).[*Korenstein D, Chimonas S, Barrow B, et al. Development of a conceptual map of negative consequences for patients of overuse of medical tests and treatments. JAMA Inter Med. 2018;178(10):1401-1407.]

Criteria

Introduction

This section catalogues some, but not all, molecular and genomic tests that have been determined to be experimental, investigational, or unproven (E/I/U). E/I/U tests may also be addressed in test-specific guidelines and the reader is referred to those documents for additional information. New E/I/U tests may not yet be specifically listed in this guideline, but such decisions will be made using the following criteria.

Criteria: general coverage guidance

Molecular and genomic tests are only eligible for reimbursement when ALL of the following conditions are met:

- Technical and clinical validity: The test must be accurate, sensitive and specific, based on sufficient, quality scientific evidence to support the claims of the test.
- Clinical utility: Healthcare providers can use the test results to provide significantly better medical care for the individual.
- Reasonable use: The usefulness of the test is not significantly offset by negative factors, such as expense, clinical risk, or social or ethical challenges.

Experimental, investigational, or unproven molecular and genomic tests

The following tests do not meet the above criteria and are not eligible for reimbursement.

E/I/U

- 9p21 Genotype Test (rs10757278 and rs1333049 alleles) CPT: 81479
- AlloSure Heart [Proprietary non-invasive assay to screen for organ injury and rejection in heart transplant recipients through measurement of donor-derived cell-free DNA in recipient blood sample from CareDx] CPT: 81479
- AlloSure Lung [Proprietary non-invasive assay to screen for organ injury and rejection in lung transplant recipients through measurement of donor-derived cell-free DNA in recipient blood sample from CareDx] CPT: 81479
- AmHPR Helicobacter pylori Antibiotic Resistance Next Generation Sequencing Panel [Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin from American Molecular Laboratories, Inc.] CPT: 0008U
- Apolipoprotein E Genotype (APOE) CPT: 81401
- Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping [APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2) from Quest Diagnostics] CPT: 0355U
- ARISk Autism Risk Assessment Test [Proprietary test from IntegraGen] CPT: 81479
- AssureMDx [Proprietary non-invasive assay that analyzes tumor markers in the urine of individuals with hematuria to identify those at low risk and high risk for bladder cancer by MDx Health] CPT: 81479
- Augusta Optical Genome Mapping [Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping from Bionano Genomics, Inc] CPT: 0260U
- Augusta Hematology Optical Genome Mapping [Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alternations from Georgia Esoteric and Molecular Labs] CPT: 0331U
- Avantect Ovarian Cancer Test [Oncology (ovarian), DNA, whole-genome sequencing with 5-hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as cancer detected or not detected from ClearNote Health] CPT: 0507U
- Avantect Pancreatic Cancer Test[Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected from ClearNote Health] CPT: 0410U
- BarreGEN [Oncology (esophageal) risk assessment, quantification of mutational load by multiplex amplification and next-generation sequencing of tumor suppressor genes associated with progression from Barrett's esophagus to high-grade dysplasia and esophageal cancer, algorithm reported as risk score by Interpace Diagnostics] CPT: 81599

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- BBDRisk Dx [Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score from Silbiotech, Inc] CPT: 0067U
- Bladder EpiCheck [Proprietary non-invasive assay that analyzes methylation biomarkers in the urine of individuals with hematuria to identify those at low risk and high risk for bladder cancer or to monitor tumor recurrence from Nucleix Ltd] CPT: 81599
- BluePrint Molecular Subtyping Profile [Proprietary 80-gene expression signature to classify Basal-type, Luminal-type and ERBB2-type breast cancers from Agendia] CPT: 81479
- BTG Early Detection of Pancreatic Cancer [Oncology (pancreatic), 59 methylation haplotype block markers, next generation sequencing, plasma, reported as cancer signal detected or not detected from Breakthrough Genomics] CPT: 0405U
- CARDIO inCode Score (CIC SCORE) [Cardiology (coronary heart disease [CHD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event from GENinCode U.S. Inc] CPT: 0401U
- CardioRisk+ [Cardiology (coronary artery disease [CAD]), DNA, genome-wide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease from Gene by Gene, Ltd] CPT: 0466U
- CELLSEARCH CTC Test [Immunologic selection of circulating tumor cells in individuals with metastatic breast, prostate, or colorectal cancer for purposes of assessing prognosis from Menarini Silicon Biosystems] CPT: 86152, 86153
- ChemoFX [Proprietary test from Helomics to assess chemosensitivity] CPT: 81535, 81536
- Chromosome Genome Mapping [Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping from Bionano Genomics, Inc] CPT: 0454U
- Clarava [Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood from Verici Dx, Inc] CPT: 0319U
- Clarifi ASD [Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis from Quadrant Biosciences] CPT: 0170U
- CNGnome [Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities from PerkinElmer Genomics] CPT: 0209U

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- Cologuard Plus [Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result from Exact Sciences Laboratories, LLC] CPT: 0464U
- ColonAiQ [Oncology (colorectal cancer), cell-free DNA (cfDNA), methylation-based quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA) from Breakthrough Genomics/ Singlera Genomics, Inc] CPT: 0453U
- ColonSentry [Proprietary 7-gene signature to detect colorectal cancer from StageZero Life Sciences] CPT: 81479
- ColoScape Colorectal Cancer Detection [Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132, and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer from DiaCarta Clinical Lab] CPT: 0368U
- ColoScape PLUS [Oncology (colorectal), cell-free DNA, 8 genes for mutations, 7 genes for methylation by real-time RT-PCR, and 4 proteins by enzyme-linked immunosorbent assay, blood, reported positive or negative for colorectal cancer or advanced adenoma risk from DiaCarta, Inc] CPT: 0496U
- Colvera [BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis from Colvera] CPT: 0229U
- CyPath Lung [Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer from Precision Pathology Services, bioAffinity Technologies, Inc] CPT: 0406U
- Cytogenomic (genome-wide) analysis, hematologic malignancy, structural variants and copy number variants, optical genome mapping (OGM) CPT: 81195
- Decipher Bladder TURBT [Oncology (bladder), mRNA, microarray gene expression profiling of 219 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)] CPT: 0016M
- DecisionDx - Cutaneous Melanoma assay [Proprietary 31-gene signature to assess melanoma metastatic risk from Castle Biosciences] CPT: 81529
- DecisionDx DiffDx - Melanoma [Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant) from Castle Biosciences, Inc] CPT: 0314U

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- DecisionDx - SCC [Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B) from Castle Biosciences, Inc] CPT: 0315U
- DEPArray [Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin fixed paraffin embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified from PacificDx] CPT: 0009U
- DetermaRx [Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score from Oncocyte Corporation] CPT: 0288U
- DH Optical Genome Mapping/Digital Karyotyping Assay [Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations from The Clinical Genomics and Advanced Technology (CGAT) Laboratory at Dartmouth Health] CPT: 0413U
- Digitization of pathology slides CPT: 0760T, 0761T, 0762T, 0763T, 0848T, 0849T, 0850T, 0851T, 0852T, 0853T
- EarlyTect Bladder Cancer Detection (EarlyTect BCD) [Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer from Promis Diagnostics, Inc] CPT: 0452U
- EndoSign Barrett's Esophagus Test [Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus from Cyted Health Inc] CPT: 0506U
- Envisia Genomic Classifier [Proprietary gene expression assay designed to aid in the diagnosis of idiopathic pulmonary fibrosis from Veracyte] CPT: 81554
- Epi+Gen CHD [Cardiology (coronary heart disease [CHD]), DNA, analysis of 5 single-nucleotide polymorphisms (SNPs) (rs11716050 [LOC105376934], rs6560711 [WDR37], rs3735222 [SCIN/LOC107986769], rs6820447 intergenic], and rs9638144 [ESYT2]) and 3 DNA methylation markers (cg00300879 [transcription start site {TSS200} of CNKSR1], cg09552548 [intergenic], and cg14789911 [body of SPATC1L]), qPCR and digital PCR, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic CHD from Cardio Diagnostics, Inc] CPT: 0439U
- Epignostix CNS Tumor Methylation Classifier [Oncology (central nervous system), analysis of 30000 DNA methylation loci by methylation array, utilizing DNA extracted from tumor tissue, diagnostic algorithm reported as probability of matching a reference tumor subclass from Heidelberg Epignostix] CPT: 0020M

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- EpiSign Complete [Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood from Greenwood Genetic Center] CPT: 0318U
- EpiSwitch CiRT (Checkpoint-inhibitor Response Test) [Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint–inhibitor therapy from Next Bio-Research Services, LLC] CPT: 0332U
- EpiSwitch Prostate Screening Test [Oncology (prostate), 5 DNA regulatory markers by quantitative PCR, whole blood, algorithm, including prostate-specific antigen, reported as likelihood of cancer from Oxford BioDynamics, Inc] CPT: 0433U
- ERA (Endometrial Receptivity Analysis) [Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive) from Igenomix] CPT: 0253U
- EsoGuard [Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus from Lucid Diagnostics] CPT: 0114U
- ESOPREDICT Barrett's Esophagus Risk Classifier Assay [Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer from Capsulomics, Inc d/b/a Previse] CPT: 0398U
- Eurofins TRAC dd-cfDNA [Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA from Transplant Genomics, Inc] CPT: 0118U
- ExoDx Prostate (IntelliScore) [Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score from Exosome Diagnostics, Inc.] CPT: 0005U
- FM/a fibromyalgia [interleukin-6, interleukin-8, macrophage inflammatory protein-1 alpha and macrophage inflammatory protein-beta (IL-6, IL-8, MIP-1a and MIP-1b, supernatant of stimulated cell culture, immunoassay, multianalyte assay with algorithmic analysis, reported as a score from EpicGenetics, Inc] CPT: 81599
- GPS Cancer [Proprietary test using a tissue block sample of the highest carcinoma grade of a tumor and a sample of blood to compare an individual's normal DNA to the tumor DNA to be used as part of a precision medicine approach for individuals with cancer from NantHealth] CPT: 81479
- Guardant Reveal [Oncology minimal residual disease (MRD) detection in colorectal, breast, and lung cancers, circulating tumor DNA (ctDNA) analysis by next-generation sequencing, algorithm reported as positive or negative result, to complement current surveillance methods by Guardant Health] CPT: 81479

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- HelioLiver Test [Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in high-risk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gamma-carboxy prothrombin (DCP), algorithm reported as normal or abnormal result from Fulgent Genetics] CPT: 0333U
- Hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis CPT: 81451
- HPV-SEQ Test [Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma from Sysmex Inostics, Inc] CPT: 0470U
- Insight TNBCtype [Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement from Insight Molecular Labs] CPT: 0153U
- Invitae PCM MRD Monitoring [Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD from Invitae Corporation] CPT: 0307U
- Invitae PCM Tissue Profiling and MRD Baseline Assay [Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient specific panel for future comparisons to evaluate for MRD from Invitae Corporation] CPT: 0306U
- IriSight CNV Analysis [Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception), identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if performed, as comparators and/or maternal cell contamination from Variantyx Inc] CPT: 0469U
- IriSight Prenatal Analysis – Proband [Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, fetal sample, identification and categorization of genetic variants from Variantyx, Inc] CPT: 0335U
- IriSight Prenatal Analysis – Comparator [Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions,

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uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent) from Variantyx, Inc] CPT: 0336U

- KawasakiDx [Pediatric febrile illness (Kawasaki disease [KD]), interferon alpha-inducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using quantitative reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD from OncoOmicsDx Laboratory, mProbe] CPT: 0389U
- KIF6 Genotype Test CPT: 81479
- Know error [Proprietary test for DNA based specimen provenance confirmation from Strand Diagnostics] CPT: 81479, 81265, 81266
- LactoTYPE [Proprietary test from Prometheus that assesses the hypolactasia C/T genetic variant] CPT: 81400
- Lifetime Genomics Risk Assessment, VTE [Hematology (venous thromboembolism [VTE]), genome-wide single-nucleotide polymorphism variants, including F2 and F5 gene analysis, and Leiden variant, by microarray analysis, saliva, report as risk score for VTE from GenomicMD, Inc] CPT: 0529U
- LPA-Aspirin Genotype Test (4399Met allele) CPT: 81479
- LPA-Intron 25 Genotype Test CPT: 81479
- LungLB [Oncology (lung cancer), four-probe FISH (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm generated evaluation reported as decreased or increased risk for lung cancer from LungLife AI] CPT: 0317U
- LungOI [Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalinfixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker from Imagene] CPT: 0414U
- Lymph2Cx Lymphoma Molecular Subtyping Assay, [Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin embedded tissue, algorithm reported as cell of origin from Mayo Clinic] CPT: 0017M
- Lymph3Cx Lymphoma Molecular Subtyping Assay, [Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter from Mayo Clinic] CPT: 0120U
- Macula Risk [SNP-based assay to assist in the selection of eye supplement formulations for individuals diagnosed with intermediate dry age-related macular degeneration from ArcticDx, Inc] CPT: 81401, 81479

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- Mammostrat Breast Cancer Recurrence Assay [Proprietary immunohistochemical (IHC) assay of 5 proteins in individuals with early stage breast cancer to assess recurrence risk from Clarient, Inc.] CPT: S3854
- MethylDetox Profile [The MethylDetox Profile test is a testing panel that assesses genes in the methylation pathway to provide "more actionable information than MTHFR testing alone" and provides "suggestions for specific nutrient needs" based on test findings from Cell Science Systems] CPT: none; no insurance billing
- Mind.Px [Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics from Mindera Corporation] CPT: 0258U
- MindX Blood Test - Longevity [Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score from MindX Sciences Inc] CPT: 0294U
- MindX Blood Test - Memory/Alzheimer's [Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score from MindX Sciences Inc] CPT: 0289U
- MindX Blood Test - Mood [Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144 genes, whole blood, algorithm reported as predictive risk score from MindX Sciences Inc] CPT: 0291U
- MindX Blood Test - Pain [Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as predictive risk score from MindX Sciences Inc] CPT: 0290U
- MindX Blood Test - Stress [Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score from MindX Sciences Inc] CPT: 0292U
- MindX Blood Test - Suicidality [Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score from MindX Sciences Inc] CPT: 0293U
- MindX One Blood Test – Anxiety [Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score from MindX Sciences] CPT: 0437U
- miR-31now [Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin fixed paraffin-embedded tissue, algorithm reported as an expression score from GoPath Laboratories] CPT: 0069U
- miR Sentinel Prostate Cancer Test [Oncology (prostate), exosome-based analysis of 442 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chainreaction (RT-qPCR), urine, reported as molecular evidence of no-, low-, intermediate- or high-risk of prostate cancer from miR Scientific, LLC] CPT: 0343U
- miR Sentinel Prostate Cancer Test [Oncology (prostate), exosome-based analysis of 53 small noncoding RNAs (sncRNAs) by quantitative reverse transcription

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polymerase chain reaction (RT-qPCR), urine, reported as no molecular evidence, low-, moderate- or elevated-risk of prostate cance from miR Scientific, LLC] CPT: 0424U

- Mitomic Prostate Test [Proprietary test using mitochondrial DNA to detect prostate cancer not identified by standard biopsy pathology from MDNA Life Sciences] CPT: none; research use only
- Molecular Microscope MMDx—Heart [Transplantation medicine (heart allograft rejection), microarray gene expression profiling of 1283 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection from Kashi Clinical Laboratories] CPT: 0087U
- Molecular Microscope MMDx—Kidney [Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection from Kashi Clinical Laboratories] CPT: 0088U
- mRNA CancerDetect [Oncology (oral and/or oropharyngeal cancer), gene expression profiling by RNA sequencing at least 20 molecular features (eg, human and/or microbial mRNA), saliva, algorithm reported as positive or negative for signature associated with malignancy from Viome Life Sciences, Inc] CPT: 0296U
- Myeloma Prognostic Risk Signature (myPRS) [Proprietary gene expression assay that is designed to predict an individual's risk of early relapse of multiple myeloma from Quest Diagnostics] CPT: 81479
- myPath Melanoma [Proprietary 23-gene expression assay to assess the risk of malignant melanoma when a result cannot be obtained by clinical assessment and/or histopathology alone from Castle Biosciences, Inc] CPT: 0090U
- MyProstateScore [urine analysis of TMPRSS2:ERG and PCA3 genes combined with blood PSA levels for early detection of prostate cancer from Lynx Dx] CPT: 81599 or 0113U
- MyProstateScore 2.0, [Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch urine, algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer from LynxDX] CPT: 0403U
- myTAIHEART CPT: 0055U
- NavDx [Oncology (oropharyngeal or anal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence from Naveris] CPT: 0356U
- Northstar Response [Oncology (pan-solid tumor), next-generation sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of methylation as a correlate of tumor fraction from BillionToOne Laboratory] CPT: 0486U
- OncoAssure Prostate [Oncology (prostate), mRNA gene-expression profiling by real-time RT-PCR of 6 genes (FOXM1, MCM3, MTUS1, TTC21B, ALAS1, and PPP2CA), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer from DiaCarta, Inc] CPT: 0497U

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- OncobiotaLUNG [Oncology (lung), multi-omics (microbial DNA by shotgun next-generation sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease from Micronoma] CPT: 0395U
- Oncomap ExTra [Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations from Exact Sciences] CPT: 0329U
- OncoSignal 7 Pathway Signal [Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalin-fixed paraffin-embedded (FFPE), algorithm reported as gene pathway activity score from Protean BioDiagnostics] CPT: 0262U
- OncoTarget/OncoTreat [Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents from Columbia University Department of Pathology and Cell Biology, Darwin Health] CPT: 0019U
- OncotypeDx AR-V7 Nucleus Detect [Proprietary test designed to detect AR-V7 proteins in the nucleus of CTCs to determine response to AR-targeted therapies from Genomic Health] CPT: 81479
- OptiSeq Colorectal Cancer NGS Panel [Oncology (colorectal), next-generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation from DiaCarta, Inc] CPT: 0498U
- PAI-1 Testing for Cardiovascular Disease Risk Assessment CPT: 81400, 85415
- PancreaSeq Genomic Classifier [Oncology (pancreas), DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (ie, negative, low probability of neoplasia or positive, high probability of neoplasia) from Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center] CPT: 0313U
- PanGIA Prostate [Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer from Genetics Institute of America] CPT: 0228U
- Pathway Fit [Proprietary test from Pathway Genomics that focuses on metabolism, diet, and exercise traits] CPT: 81291, 81401, 81479
- PAULA [Proprietary panel of four proteins designed to detect lung cancer in asymptomatic individuals at high risk from Genesys Biolabs] CPT: none; no insurance billing

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- PCR Fungal Screen for Onychomycosis [Molecular tests for onychomycosis (e.g. Bako Diagnostics Onychodystrophy DNA Test)] CPT: 87481, 87798
- Percepta Genomic Sequencing Classifier [Proprietary gene expression assay designed to assess the risk of malignancy of lung nodules from Veracyte] CPT: 81479
- Pharmaco-oncologic Algorithmic Treatment Ranking [Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately from CureMatch] CPT: 0794T
- POC (Products of Conception) [Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy from Igenomix] CPT: 0252U
- Praxis Optical Genome Mapping [Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping from Praxis Genomics, LLC] CPT: 0264U
- Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping [Oncology (pan tumor), whole genome sequencing and optical genome mapping of paired malignant and normal DNA specimens, fresh tissue, blood, or bone marrow, comparative sequence analyses and variant identification from Praxis Genomics LLC] CPT: 0300U
- Praxis Somatic Optical Genome Mapping [Oncology (pan tumor), whole genome optical genome mapping of paired malignant and normal DNA specimens, fresh frozen tissue, blood, or bone marrow, comparative structural variant identification from Praxis Genomics LLC] CPT: 0299U
- Praxis Somatic Transcriptome [Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal RNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and expression level and chimeric transcript identification from Praxis Genomics LLC] CPT: 0298U
- Praxis Somatic Whole Genome Sequencing [Oncology (pan tumor), whole genome sequencing of paired malignant and normal DNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and variant identification from Praxis Genomics LLC] CPT: 0297U
- Praxis Transcriptome [Unexplained constitutional or other heritable disorders or syndromes, tissue-specific gene expression by whole-transcriptome and next-generation sequencing, blood, formalin-fixed paraffin-embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of splicing or expression changes from Praxis Genomics, LLC] CPT: 0266U

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- PreciseDx Breast Biopsy Test [Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score from PreciseDx, Inc] CPT: 0418U
- PreciseDx Breast Cancer Test [Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score from PreciseDx] CPT: 0220U
- PrecisionCHD [Cardiology (coronary heart disease [CHD]), DNA, analysis of 10 single-nucleotide polymorphisms (SNPs) rs710987 [LINC010019], rs1333048 [CDKN2B-AS1], rs12129789 [KCND3], rs942317 [KTN1-AS1], rs1441433 [PPP3CA], rs2869675 [PREX1], rs4639796 [ZBTB41], rs4376434 [LINC00972], rs12714414 [TMEM18], and rs7585056 [TMEM18]) and 6 DNA methylation markers (cg03725309 [SARS1], cg12586707 [CXCL1], cg04988978 [MPO], cg17901584 [DHCR24-DT], cg21161138 [AHRR], and cg12655112 [EHD4]), qPCR and digital PCR, whole blood, algorithm reported as detected or not detected for CHD from Cardio Diagnostics, Inc] CPT: 0440U
- ProMark Proteomic Prognostic Test [Proprietary proteomic assay designed to assess the risk of aggressive prostate cancer from Metamark] CPT: 81479
- Prospera [Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA from Natera] CPT: 0493U
- PurIST [Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole-transcriptome data, reported as probability of predicted molecular subtype from Tempus AI, Inc] CPT: 0510U
- QuantiDNA Colorectal Cancer Triage Test [Oncology (colorectal), blood, quantitative measurement of cell-free DNA (cfDNA) from DiaCarta, Inc] CPT: 0501U
- RadTox cfDNA test [Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported as a radiation toxicity score from DiaCarta Inc] CPT: 0285U
- RetnaGene AMD [Proprietary test from Sequenom CMM to predict risk of wet AMD progression] CPT: 81401, 81405, 81408, 81479, 81599
- ROMA Risk of Ovarian Malignancy Algorithm [Proprietary test using the combination of CA125 + HE4 antigens to assess the likelihood of malignancy before surgery; test kit from Fujirebio Diagnostics, Inc. and offered by several reference laboratories] CPT: 81500
- Signatera [Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate from Natera, Inc] CPT: 0340U
- Single Cell Prenatal Diagnosis (SCPD) Test [Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal

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(euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid from Luna Genetics, Inc] CPT: 0341U

- SMART PGT-A (Pre-implantation Genetic Testing - Aneuploidy) [Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy, per embryo tested from Igenomix] CPT: 0254U
- SMASH [Copy number (eg, intellectual disability, dysmorphology), sequence analysis from Marvel Genomics] CPT: 0156U
- Solid organ neoplasm, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis CPT: 81449
- Solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes, genomic sequence analysis panel, interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis CPT: 81456
- Statin Induced Myopathy Genotype (SLCO1B1) CPT: 81328
- Stockholm3 [Oncology (prostate), analysis of circulating plasma proteins (tPSA, fPSA, KLK2, PSP94, and GDF15), germline polygenic risk score (60 variants), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer from BioAgilytix Diagnostics] CPT: 0495U
- Strata Select [Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice-site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score from Strata Oncology, Inc] CPT: 0391U
- Thyroid GuidePx [Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture-enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, fine needle aspirate or formalin-fixed paraffin embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes from Protean BioDiagnostics] CPT: 0362U
- ToxLok [Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (SNPs), urine and buccal DNA, for specimen identity verification from InSource Diagnostics] CPT: 0079U
- TruGraf Kidney [Transplantation medicine (allograft rejection, kidney), mRNA, gene expression profiling by quantitative polymerase chain reaction (qPCR) of 139 genes, utilizing whole blood, algorithm reported as a binary categorization as transplant excellence, which indicates immune quiescence, or not transplant excellence, indicating subclinical rejection from Eurofins Transplant Genomics, Inc] CPT: 81558

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- Tuteva [Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection from Verici Dx, Inc] CPT: 0320U
- Twin zygosity [genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood from Natera] CPT: 0060U
- UriFind Urothelial Carcinoma Assay [Oncology (urothelial carcinoma), DNA, quantitative methylation-specific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative from DiaCarta, Inc, AnchorDx] CPT: 0465U
- UroAmp MRD [Oncology (bladder), DNA, next-generation sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden from Convergent Genomics, Inc] CPT: 0467U
- Vectra [Proprietary panel of 12 biomarkers that yields a rheumatoid arthritis disease activity score from LabCorp] CPT: 81490
- VitaGraft Kidney Baseline + 1st Plasma Test [Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single-nucleotide polymorphisms (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell-free DNA with risk for active rejection from Oncocyte Corporation] CPT: 0508U
- VitaGraft Kidney Subsequent [Transplantation medicine, quantification of donor-derived cell-free DNA using up to 12 single-nucleotide polymorphisms (SNPs) previously identified, plasma, reported as percentage of donor-derived cell-free DNA with risk for active rejection from Oncocyte Corporation] CPT: 0509U
- Vita Risk [Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements from Arctic Medical Laboratories] CPT: 0205U

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