**Medical Policy Manual** Laboratory, Policy No. 77

# *Investigational Gene Expression, Biomarker, and Multianalyte Testing*

**Effective**: July 1, 2026

**Next Review:** November 2026
**Last Review:** June 2026

## IMPORTANT REMINDER

## DESCRIPTION

Gene expression, biomarker, and multianalyte tests have been proposed to aid in the risk-assessment, diagnosis, and prognosis of many disorders.

## MEDICAL POLICY CRITERIA

**Notes:** See Cross References section for policies related to gene expression and multianalyte testing for specific indications.

The following tests are considered **investigational,** because the current scientific evidence is not yet sufficient to establish the impact of these tests on health outcomes:

| Test Name | Laboratory |
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| AdvanceAD-Tx | Castle Biosciences, Inc. |
| aiSLE™ DX Disease Activity Index and aiSLE™ DX Flare Risk Index | Progentec Diagnostics |
| Auria® | Namida Lab |
| Avise® Lupus | Exagen, Inc. |

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| Clarifi™ (ASD) | Quadrant Biosciences |
| DecisionDx®-SCC | Castle Biosciences, Inc. |
| DiviTum® TKa | Biovica, Inc. |
| EndoSign® Barrett's Esophagus Test | Cyted Health |
| EpiSwitch® Checkpoint-inhibitor Response Test (CiRT) | Next Bio Research Services |
| ESOPREDICT® Barrett's Esophagus Risk Classifier Assay | Previse |
| FebriDx® | Lumos Diagnostics |
| FRAT® (Folate Receptor Antibody Test) | Religen, Inc. |
| HART CADhs® | Prevencio, Inc. |
| HART CVE® | Prevencio, Inc. |
| HART KD® | Prevencio, Inc. |
| HeproDx™ | GoPath Laboratories |
| IGoCheck™ | Milagen, Inc. |
| IMMray® PanCan-d | Immunovia |
| IntelliSep | Cytovale |
| KawasakiDx™ | mProbe |
| KidneyIntelX.dkd™ | Renalytix Inc. |
| Liposcale® | CIMA Sciences |
| LungOI | Imagene AI |
| MammoCheck™ | Milagen, Inc. |
| MeMed BV® | MeMed Diagnostics |
| Mind.Px™ | Mindera Health™ |
| MindX™ Blood Tests:<br>Anxiety<br>Longevity<br>Memory/Alzheimer's<br>Mood<br>Pain<br>Stress<br>Suicidality | MindX Sciences™ Laboratory |
| M-inSight® | Corgenix/Sebia |
| mRNA CancerDetect™ | Viome® Life Sciences, Inc. |
| myOLARIS™-KTdx | Olaris, Inc. |
| NaviDKD™ | Journey Biosciences |
| NETest™ | Wren Laboratories |

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| NPDX ASD Test Panel I, II, and III | NeuroPointDX |
| OWLiver® | CIMA Sciences |
| PancreaSeq® Genomic Classifier | University of Pittsburgh Medical Center |
| PancreaSure® | Immunovia |
| PreciseDx Breast Biopsy Test | PreciseDx |
| PrismRA® | Scipher Medicine® |
| Promarker®D | Proteomics International/Sonic Reference Laboratory |
| PurIST$^{SM}$ | Tempus AI |
| RiskReveal™ (previously DetermaRx™) | Razor Genomics |
| Salimetrics® Salivary Melatonin Profile | Salimetrics® Clinical Laboratory |
| SmartVascular DX | SmartHealth DX |
| SOMAmer® | SomaLogic |
| SAAmplify™-aSYN | Amprion Clinical Laboratory |
| Tempus p-MSI | Tempus AI |
| Tempus p-Prostate | Tempus AI |
| Thyroid GuidePx® | Protean Biodiagnostics |
| TissueCypher® Barrett's Esophagus Assay | Castle Biosciences, Inc. |
| TruD MDS Tests:<br>Alzheimer's & MCI<br>ASCVD<br>Bipolar<br>COPD<br>Hepatocellular Carcinoma<br>Lyme Disease<br>Major Depressive Disorder<br>Multiple Sclerosis<br>NASH<br>Osteoporosis<br>Parkinson’s<br>Schizophrenia | TruDiagnostic™ |

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## CROSS REFERENCES

1. Gene Expression-Based Assays for Cancers of Unknown Primary, Genetic Testing, Policy No. 15
2. Gene-Based Tests for Screening, Detection, and Management of Prostate or Bladder Cancer, Genetic Testing, Policy No. 17
3. Genetic and Molecular Diagnostic Testing, Genetic Testing, Policy No. 20
4. Gene Expression Profiling for Melanoma, Genetic Testing, Policy No. 29

5. Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis in Patients with Breast Cancer, Genetic Testing, Policy No. 42
6. Genetic Testing for Diagnosis and Management of Behavioral Health Conditions, Genetic Testing, Policy No. 53
7. Microarray-Based Gene Expression Profile Testing for Multiple Myeloma Risk Stratification, Genetic Testing, Policy No. 70
8. Analysis of Proteomic and Metabolomic Patterns for Cancer Detection, Risk, Prognosis, or Treatment Selection, Laboratory, Policy No. 41
9. Multianalyte Assays with Algorithmic Analysis for the Evaluation and Monitoring of Patients with Chronic Liver Disease, Laboratory, Policy No. 47
10. Multimarker and Proteomics-based Serum Testing Related Ovarian Cancer, Laboratory, Policy No. 60
11. Protein Biomarkers for Screening, Detection, and/or Management of Prostate Cancer, Laboratory, Policy No. 69
12. Urinary Biomarkers for Cancer Screening, Diagnosis, and Surveillance, Laboratory, Policy No. 72
13. Molecular Testing in the Management of Pulmonary Nodules, Laboratory, Policy No. 73
14. Multianalyte and Gene Expression Assays for Predicting Recurrence in Colon Cancer, Laboratory, Policy No. 76

## BACKGROUND

### GENE EXPRESSION TESTING

Gene expression tests are used to measure the relative levels of gene transcription for select genes. This provides information on how much a gene is expressed, or active, in a particular tissue. Because changes in gene expression may be associated with the presence or prognosis of many disorders, such tests have been developed and studied for various purposes: primarily cancer diagnosis and prognosis, but also for other disorders, including behavioral health conditions.

Gene expression testing can be performed with a variety of methods, including polymerase chain reaction (PCR), microarray, immunohistochemistry, and RNA sequencing. Results are usually expressed as a score, risk percentage, and/or a classification (e.g., “positive” or “high-risk”).

### MULTIANALYTE ASSAYS

Similar to gene expression tests, multi-analyte assays measure a pattern of biomarkers that may differentiate between healthy tissue and disease. These tests measure multiple biochemical and molecular analytes, and may include metabolites, peptides, proteins, and/or genetic biomarkers. These biomarkers are often measured by mass spectrometry or immunoassays.

Multianalyte assays with algorithmic analyses (MAAAs) are tests that include the processing of the analyte measurements with an algorithm to generate a classification or score result. Often, such algorithms incorporate clinical or demographic information, such as age, sex, or cancer stage in addition to the analyte measures. MAAA algorithms may be proprietary or nonproprietary. MAAAs have been developed for many indications, including cancers, sepsis, acute kidney injury, and preeclampsia.

### REGULATORY STATUS

Many of the tests listed above have not been submitted to the U.S. Food and Drug Administration (FDA) for marketing clearance but, if available, are offered as laboratory-developed tests by Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories.

## EVIDENCE SUMMARY

Gene expression tests and multianalyte tests have been developed for many indications, including cancer detection and prognosis, behavioral health disorders, dermatologic conditions, and neurodegenerative diseases. While studies using these tests may generate information that may help elucidate the biologic mechanisms of disease and eventually help design treatments, the tests listed in this policy are currently in a developmental phase, with limited evidence of clinical utility for diagnosis, prognosis, or risk assessment.

## SUMMARY

There is not enough research to show that the tests listed in this policy can improve health outcomes for patients. Therefore, these tests are considered investigational.

## CODES

| Codes | Number | Description |
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| CPT | 0006M | Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier |
| | 0007M | Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index |
| | 0019M | Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations |
| | 0063U | Neurology (autism), 32 amines by LCMS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder |
| | 0108U | Gastroenterology (Barrett’s esophagus), whole slide-digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer |
| | 0170U | Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis |
| | 0258U | 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 |
| | 0263U | Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, αketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD) |
| | 0288U | Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, |

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| | WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score |
| 0289U | Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score |
| 0290U | Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as predictive risk score |
| 0291U | Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144 genes, whole blood, algorithm reported as predictive risk score |
| 0292U | Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score |
| 0293U | Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score |
| 0294U | Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score |
| 0296U | 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 |
| 0308U | Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]) with 3 clinical parameters (age, sex, history of cardiac intervention), plasma, algorithm reported as a risk score for obstructive CAD |
| 0309U | Cardiology (cardiovascular disease), analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for major adverse cardiac event |
| 0310U | Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NTproBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for KD |
| 0312U | Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment |
| 0313U | 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) |
| 0315U | 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) |
| 0322U | Neurology (autism spectrum disorder [ASD]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma, results reported as negative or positive for risk of metabolic subtypes associated with ASD |

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| 0332U | 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 |
| 0342U | Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline |
| 0344U | Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH |
| 0351U | Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis inducing ligand (TRAIL), interferon gamma-inducedprotein-10 (IP-10), and C-reactive protein, serum, or venous whole blood, algorithm reported as likelihood of bacterial infection |
| 0362U | 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 |
| 0377U | Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables) |
| 0384U | Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LCMS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease |
| 0385U | Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease |
| 0389U | Pediatric febrile illness (Kawasaki disease [KD]), interferon alphainducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD |
| 0393U | Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative |
| 0398U | 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 |
| 0399U | Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgG binding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected |
| 0404U | Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression |
| 0407U | Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis |

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| | factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function |
| 0414U | 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, formalin-fixed paraffin embedded (FFPE) tissue, reported as positive or negative for each biomarker |
| 0415U | Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLig and, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS |
| 0418U | Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score |
| 0437U | Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score |
| 0441U | Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability B5 cytometry), whole blood, with algorithmic analysis and result reported as an index |
| 0442U | Infectious disease (respiratory infection), Myxovirus resistance protein A (MxA) and C-reactive protein (CRP), fingerstick whole blood specimen, each biomarker reported as present or absent |
| 0446U | Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity |
| 0447U | Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare |
| ~~0450U~~ | ~~Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides~~ (Deleted 10/01/2025) |
| ~~0451U~~ | ~~Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance~~ (Deleted 10/01/2025) |
| 0458U | Oncology (breast cancer), S100A8 and S100A9, by enzyme linked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score |
| 0462U | Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary |
| 0506U | 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 |
| 0510U | Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA wholetranscriptome data, reported as probability of predicted molecular subtype |
| 0512U | Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffinembedded (FFPE) tissue, reported as increased or decreased probability of MSI-high (MSI-H) |

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| 0513U | Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) and homologous recombination deficiency (HRD) status, formalinfixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker |
| 0542U | Nephrology (renal transplant), urine, nuclear magnetic resonance (NMR) spectroscopy measurement of 84 urinary metabolites, combined with patient data, quantification of BK virus (human polyomavirus 1) using real-time PCR and serum creatinine, algorithm reported as a probability score for allograft injury status |
| 0558U | Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression |
| 0559U | Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression |
| 0579U | Nephrology (diabetic chronic kidney disease), enzyme linked immunosorbent assay (ELISA) of apolipoprotein A4 (APOA4), CD5 antigen-like (CD5L) combined with estimated glomerular filtration rate (GFR), age, plasma, algorithm reported as a risk score for kidney function decline |
| 0599U | Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19-9, serum, diagnostic algorithm reported as positive or negative |
| 0616U | Neurology (dementia), DNA methylation analysis of more than 30,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0617U | Cardiovascular (atherosclerotic cardiovascular disease), [ASCVD]]), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0618U | Psychiatry (bipolar disorder), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0619U | Pulmonary (chronic obstructive pulmonary disease [COPD]), DNA methylation analysis of more than 18,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0620U | Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0621U | Infectious disease (Lyme borreliosis), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0622U | Psychiatry (major depressive disorder), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0623U | Autoimmune (multiple sclerosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0624U | Hepatology (nonalcoholic steatohepatitis [NASH]), DNA methylation analysis of 5,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0625U | Endocrinology (osteoporosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0626U | Neurology (Parkinson disease), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk |
| 0627U | Psychiatry (schizophrenia), DNA methylation analysis of more than 15,000 sites, whole blood, algorithm reported as positive or negative risk |

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| | 0635U | Autoimmune (atopic dermatitis), mRNA, nextgeneration sequencing (NGS), gene expression profiling of 487 genes, noninvasive skinsurface scraping, algorithm reported as likelihood of response to therapy |
| | 81479 | Unlisted molecular pathology procedure |
| | 81599 | Unlisted multianalyte assay with algorithmic analysis |
| HCPCS | None | |

***Date of Origin:*** *November 2021*