

## Experimental or Investigational (Unproven) Services, Products, Drugs, and Biologicals

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

The services, products, drugs, and biologicals referenced in this Clinical Guideline are considered experimental or investigational and are therefore not covered by the Plan. This Clinical Guideline may not encompass all services, products, drugs, and biologicals; specific benefit plan documents (e.g., Evidence of Coverage, Schedule of Benefits) and federal or state mandated health benefits and laws supersede this Clinical Guideline. The member's benefit plan documents specify the services that are covered, excluded, or subject to limitations.

A service, product, drug, or biological is considered experimental or investigational when its safety and efficacy have not been established. These interventions may yield outcomes that are inferior to standard medical treatments with proven long-term clinical utility. To determine whether a service, device, treatment, or procedure has proven safety and efficacy, a thorough review of the available reliable evidence is conducted. This evidence may include, but is not limited to, the following sources (listed in order of decreasing reliability):

1. Published technology assessments and/or high-quality meta-analyses
2. Randomized, controlled trials (RCTs)
3. Other controlled studies, such as non-randomized controlled trials, and cohort studies
4. Case reports or case series

## 5. Reports of expert opinion and consensus statements from professional organizations

### Definitions

"Experimental, Investigational, and Unproven Services" include any drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply used in or directly related to the diagnosis, evaluation, or treatment of a disease, injury, illness, or other health condition for which one or more of the following criteria apply when the service is rendered with respect to the use for which benefits are sought:

- The drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply cannot be legally marketed in the United States without the final approval of the Food and Drug Administration ("FDA"), or other licensing or regulatory agency, and such final approval has not been granted;
- The FDA has determined the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply to be contraindicated for the specific use;
- The drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply is provided as part of a clinical research protocol or clinical trial or is provided in any other manner that is intended to evaluate the safety, toxicity, or efficacy of the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply;
- The drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply is subject to review and approval of an Institutional Review Board ("IRB") or other body serving a similar function;
- The drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply is provided pursuant to informed consent documents that describe the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply as Experimental/Investigational, or otherwise indicate that the safety, toxicity, or efficacy of the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply is under evaluation.

"Off-Label Use" refers to the use of an FDA-approved drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply for a purpose, condition, or patient population other than those for which it has received FDA approval. Off-label use may be considered experimental or investigational, depending on the available evidence supporting its safety and efficacy for the specific use in question.

"Peer Review" refers to the evaluation process in which experts in a relevant field critically assess the quality, validity, and reliability of a research study or publication. Peer review helps ensure that only scientifically sound and credible evidence is considered in the development of clinical policies and guidelines.

“Standard Medical Treatment” refers to any healthcare service, treatment, procedure, facility, equipment, drug, device, or supply that is in general use in the medical community in the United States, and:

- Has been demonstrated through reliable evidence in peer-reviewed medical literature to have scientifically established medical value for diagnosing, curing or alleviating the condition being treated; *and*
- Is appropriate for the hospital or other facility provider in which it is performed; *and*
- The performing physician or other professional provider has had the appropriate training and experience to provide the service, treatment or procedure.

“Reliable Evidence” means reports and articles with scientifically valid data published in authoritative, peer-reviewed medical and scientific literature. Reports, articles, or statements by providers or groups of providers that only contain abstracts, anecdotal evidence or personal professional opinions are not considered reliable evidence.

### Coverage Exclusions

The following services are considered experimental, investigational, or unproven and are therefore NOT covered:

<i>Code</i>	<i>Description</i>	<i>Date Added</i>	<i>Last Review Date</i>
0002M	Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and alcoholic steatohepatitis (ASH) [ASH FibroSURE; FibroMAX]	10/11/2017	5/2/2023
0003M	Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and nonalcoholic steatohepatitis (NASH) [NASH FibroSURE; FIBROSpect II]	10/11/2017	5/2/2023
0004M	Scoliosis, DNA analysis of 53 single nucleotide polymorphisms (SNPs), using saliva, prognostic algorithm reported as a risk score [ScoliScore]	10/11/2017	5/2/2023
0015M	Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy	5/2/2023	5/2/2023
0016M	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,	5/2/2023	5/2/2023

	neuroendocrine-like)		
0017M	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	5/2/2023	5/2/2023
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	7/21/2020	5/2/2023
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	7/21/2020	5/2/2023
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	7/21/2020	5/2/2023
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	7/21/2020	5/2/2023
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed	7/21/2020	5/2/2023
0002U	Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps	1/18/2018	5/2/2023
0003U	Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score	1/18/2018	5/2/2023
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score	1/18/2018	5/2/2023
0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service	1/18/2018	5/2/2023
0008U	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 or fecal sample, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline, and rifabutin	5/2/2023	5/2/2023
0009U	Oncology (breast cancer), ERBB2 (HER2) copy number by FISH,	5/2/2023	5/2/2023

	tumor cells from formalin fixed paraffin embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified		
0010U	Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate	5/2/2023	5/2/2023
0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites	1/18/2018	5/2/2023
0019U	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	5/2/2023	5/2/2023
0053U	Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade	5/2/2023	5/2/2023
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma	5/2/2023	5/2/2023
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood	5/2/2023	5/2/2023
0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis	5/2/2023	5/2/2023
0067U	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	5/2/2023	5/2/2023
0069U	Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score	5/2/2023	5/2/2023
0079U	Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (SNPs), urine and buccal DNA, for specimen identity	5/2/2023	5/2/2023

	verification		
0086U	Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility	5/2/2023	5/2/2023
0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score	5/2/2023	5/2/2023
0088U	Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection	5/2/2023	5/2/2023
0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)	5/2/2023	5/2/2023
0090U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)	5/2/2023	5/2/2023
0094U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis	5/2/2023	5/2/2023
0109U	Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species	5/2/2023	5/2/2023
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene	5/2/2023	5/2/2023
0113U	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score	5/2/2023	5/2/2023
0118U	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	5/2/2023	5/2/2023

0120U	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	5/2/2023	5/2/2023
0149U	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	5/2/2023	5/2/2023
0150U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	5/2/2023	5/2/2023
0152U	Infectious disease (bacteria, fungi, parasites, and DNA viruses), microbial cell-free DNA, plasma, untargeted next-generation sequencing, report for significant positive pathogens	5/2/2023	5/2/2023
0153U	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	5/2/2023	5/2/2023
0156U	Copy number (eg, intellectual disability, dysmorphology), sequence analysis	5/2/2023	5/2/2023
0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis	5/2/2023	5/2/2023
0203U	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness	5/2/2023	5/2/2023
0205U	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	5/2/2023	5/2/2023

0206U	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease	5/2/2023	5/2/2023
0207U	Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)	5/2/2023	5/2/2023
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities	5/2/2023	5/2/2023
0213U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent, sibling)	5/2/2023	5/2/2023
0214U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband	5/2/2023	5/2/2023
0215U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator exome (eg, parent, sibling)	5/2/2023	5/2/2023
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score	5/2/2023	5/2/2023
0228U	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first	5/2/2023	5/2/2023



	morning voided urine, algorithm reported as likelihood of prostate cancer		
0229U	BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis	5/2/2023	5/2/2023
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	5/2/2023	5/2/2023
0247U	Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth	5/2/2023	5/2/2023
0252U	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	5/2/2023	5/2/2023
0253U	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)	5/2/2023	5/2/2023
0254U	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	5/2/2023	5/2/2023
0255U	Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score	5/2/2023	5/2/2023
0256U	Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, tandem mass spectrometry (MS/MS), urine, with algorithmic analysis and interpretive report	5/2/2023	5/2/2023
0258U	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface	5/2/2023	5/2/2023

	collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics		
0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	5/2/2023	5/2/2023
0262U	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	5/2/2023	5/2/2023
0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	5/2/2023	5/2/2023
0266U	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	5/2/2023	5/2/2023
0279U	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen III binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen III binding	5/2/2023	5/2/2023
0280U	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen IV binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen IV binding	5/2/2023	5/2/2023
0281U	Hematology (von Willebrand disease [VWD]), von Willebrand propeptide, enzyme-linked immunosorbent assays (ELISA), plasma, diagnostic report of von Willebrand factor (VWF) propeptide antigen level	5/2/2023	5/2/2023
0285U	Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported as a radiation toxicity score	4/25/2022	5/2/2023
0288U	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	4/25/2022	5/2/2023
0289U	Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score	4/25/2022	5/2/2023
0290U	Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as	4/25/2022	5/2/2023

	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	4/25/2022	5/2/2023
0292U	Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score	4/25/2022	5/2/2023
0293U	Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score	4/25/2022	5/2/2023
0294U	Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score	4/25/2022	5/2/2023
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	4/25/2022	5/2/2023
0297U	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	4/25/2022	5/2/2023
0298U	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	4/25/2022	5/2/2023
0299U	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	4/25/2022	5/2/2023
0300U	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	4/25/2022	5/2/2023
0301U	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR)	5/2/2023	5/2/2023
0302U	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital	5/2/2023	5/2/2023

	PCR (ddPCR); following liquid enhancement		
0303U	Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; hypoxic	5/2/2023	5/2/2023
0304U	Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; normoxic	5/2/2023	5/2/2023
0305U	Hematology, red blood cell (RBC) functionality and deformity as a function of shear stress, whole blood, reported as a maximum elongation index	5/2/2023	5/2/2023
0306U	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	4/25/2022	5/2/2023
0307U	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	4/25/2022	5/2/2023
0308U	Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for obstructive CAD	5/2/2023	5/2/2023
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	5/2/2023	5/2/2023
0310U	Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NT-proBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for KD	5/2/2023	5/2/2023
0311U	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility for each organisms identified	4/25/2022	5/2/2023
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	5/2/2023	5/2/2023

	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)	4/25/2022	5/2/2023
0314U	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)	4/25/2022	5/2/2023
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)	4/25/2022	5/2/2023
0316U	<i>Borrelia burgdorferi</i> (Lyme disease), OspA protein evaluation, urine	5/2/2023	5/2/2023
0317U	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	4/25/2022	5/2/2023
0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood	4/25/2022	5/2/2023
0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection	4/25/2022	5/2/2023
0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection	4/25/2022	5/2/2023
0321U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique	4/25/2022	5/2/2023
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	5/2/2023	5/2/2023
0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing,	4/25/2022	5/2/2023

	cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi		
0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service	5/2/2023	5/2/2023
0329U	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	4/25/2022	5/2/2023
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab	4/25/2022	5/2/2023
0331U	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	4/25/2022	5/2/2023
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	5/2/2023	5/2/2023
0333U	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	5/2/2023	5/2/2023
0335U	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	5/2/2023	5/2/2023
0336U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element	5/2/2023	5/2/2023

	insertions, 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)		
0340U	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	5/2/2023	5/2/2023
0341U	Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid	5/2/2023	5/2/2023
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	5/2/2023	5/2/2023
0343U	Oncology (prostate), exosome-based analysis of 442 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RT-qPCR), urine, reported as molecular evidence of no-, low-, intermediate- or high-risk of prostate cancer	5/2/2023	5/2/2023
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	5/2/2023	5/2/2023
0346U	Beta amyloid, AB40 and AB42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma	5/2/2023	5/2/2023
0347U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 16 gene report, with variant analysis and reported phenotypes	5/2/2023	5/2/2023
0348U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes	5/2/2023	5/2/2023
0349U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with	5/2/2023	5/2/2023

	variant analysis, including reported phenotypes and impacted gene-drug interactions		
0350U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes	5/2/2023	5/2/2023
0351U	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP-10), and C-reactive protein, serum, algorithm reported as likelihood of bacterial infection	5/2/2023	5/2/2023
0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, Atopobium vaginae, and Megasphaera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected	5/2/2023	5/2/2023
0353U	Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected	5/2/2023	5/2/2023
0354U	Human papilloma virus (HPV), high-risk types (ie, 16, 18, 31, 33, 45, 52 and 58) qualitative mRNA expression of E6/E7 by quantitative polymerase chain reaction (qPCR)	5/2/2023	5/2/2023
0355U	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)	5/2/2023	5/2/2023
0362U	Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture-enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, formalin-fixed paraffin embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes	5/2/2023	5/2/2023
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma	1/18/2018	5/2/2023
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)	4/27/2020	5/2/2023
20561	Needle insertion(s) without injection(s); 3 or more muscles	4/27/2020	5/2/2023



22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	1/18/2018	5/2/2023
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)	1/18/2018	5/2/2023
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level	1/18/2018	5/2/2023
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)	1/18/2018	5/2/2023
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	1/18/2018	5/2/2023
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	1/18/2018	5/2/2023
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed	4/27/2020	5/2/2023
41512	Tongue base suspension, permanent suture technique	4/11/2017	5/2/2023
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session	4/11/2017	5/2/2023
43206	Esophagoscopy, flexible, transoral; with optical endomicroscopy	1/18/2018	5/2/2023
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed	1/18/2018	5/2/2023
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy	4/11/2017	5/2/2023
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed	1/18/2018	5/2/2023
43285	Removal of esophageal sphincter augmentation device	1/18/2018	5/2/2023

43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease	4/11/2017	5/2/2023
46707	Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])	4/11/2017	5/2/2023
53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance	5/2/2023	5/2/2023
53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance	5/2/2023	5/2/2023
53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon	5/2/2023	5/2/2023
53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	5/2/2023	5/2/2023
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence	1/18/2018	5/2/2023
61630	Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous	4/11/2017	5/2/2023
62263	Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days	1/18/2018	5/2/2023
62264	Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day	1/18/2018	5/2/2023
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar	1/18/2018	5/2/2023
62291	Injection procedure for discography, each level; cervical or thoracic	1/18/2018	5/2/2023
62292	Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar	1/18/2018	5/2/2023
64630	Destruction by neurolytic agent; pudendal nerve	1/18/2018	5/2/2023
72285	Discography, cervical or thoracic, radiological supervision and interpretation	1/18/2018	5/2/2023

76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method	4/11/2017	5/2/2023
77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment	4/11/2017	5/2/2023
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)	4/11/2017	5/2/2023
77605	Hyperthermia, externally generated; deep (ie, heating to depths greater than 4 cm)	1/18/2018	5/2/2023
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators	1/18/2018	5/2/2023
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators	1/18/2018	5/2/2023
78350	Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry	1/18/2018	5/2/2023
78351	Bone density (bone mineral content) study, 1 or more sites; dual photon absorptiometry, 1 or more sites	1/18/2018	5/2/2023
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)	4/11/2017	5/2/2023
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C) [Healthy Weight DNA Insight; PGxOne Plus (Admera Health)]	4/11/2017	5/2/2023
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)	1/18/2018	5/2/2023
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c.173+1000C>T) [Healthy Weight DNA Insight]	10/11/2017	5/2/2023
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	10/11/2017	5/2/2023
81426	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)	10/11/2017	5/2/2023
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)	10/11/2017	5/2/2023

81440	Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including BCS1L, C10orf2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, and TYMP	10/11/2017	5/2/2023
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed [CancerIntercept; Myeloid Molecular Profile]	4/11/2017	5/2/2023
81460	Whole mitochondrial genome (eg, Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON]), genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection	10/11/2017	5/2/2023
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed	10/11/2017	5/2/2023
81470	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2 [Autism NGS Panel (Fulgent Diagnostics); Comprehensive Non-Specific Intellectual Disability Panel; Intellectual Disability NGS Panel (Fulgent); MNG Laboratories Comprehensive Intellectual Disability NextGen DNA Screening Panel (362 Genes)]	10/11/2017	5/2/2023
81471	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2 [Intellectual Disability NGS Panel (Fulgent)]	10/11/2017	5/2/2023
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score [Vectra DA Score]	10/11/2017	5/2/2023
81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score	4/11/2017	5/2/2023

81500	Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score	10/11/2017	5/2/2023
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores [Tissue of Origin Test (ResponseDX)]	10/11/2017	5/2/2023
81506	Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score	1/18/2018	5/2/2023
81525	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score	10/11/2017	5/2/2023
81529	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis	5/2/2023	5/2/2023
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination	10/11/2017	5/2/2023
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)	10/11/2017	5/2/2023
81540	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype	10/11/2017	5/2/2023
81596	Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver	7/21/2020	5/2/2023
82107	Alpha-fetoprotein (AFP); AFP-L3 fraction isoform and total AFP (including ratio) [AFP-L3 (Alpha-Fetoprotein L3)]	10/11/2017	5/2/2023
82387	Cathepsin-D [Cathepsin-D, Cathepsin-L]	10/11/2017	5/2/2023
82777	Galectin-3	4/11/2017	5/2/2023

83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)	4/11/2017	5/2/2023
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)	4/11/2017	5/2/2023
83700	Lipoprotein, blood; electrophoretic separation and quantitation	4/11/2017	5/2/2023
83701	Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (eg, electrophoresis, ultracentrifugation)	4/11/2017	5/2/2023
83704	Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed	4/11/2017	5/2/2023
83719	Lipoprotein, direct measurement; VLDL cholesterol	1/18/2018	5/2/2023
83951	Oncoprotein; des-gamma-carboxy-prothrombin (DCP) [Des-gamma-carboxy prothrombin (DCP) (also known as "prothrombin produced by vitamin K absence or antagonism II" [PIVKA II]) for diagnosing and monitoring hepatocellular carcinoma (HCC) and other indications]	10/11/2017	5/2/2023
83987	pH; exhaled breath condensate	1/18/2018	5/2/2023
84112	Evaluation of cervicovaginal fluid for specific amniotic fluid protein(s) (eg, placental alpha microglobulin-1 [PAMG-1], placental protein 12 [PP12], alpha-fetoprotein), qualitative, each specimen	4/11/2017	5/2/2023
84431	Thromboxane metabolite(s), including thromboxane if performed, urine	1/18/2018	5/2/2023
85547	Mechanical fragility, RBC	1/18/2018	5/2/2023
86001	Allergen specific IgG quantitative or semiquantitative, each allergen	4/11/2017	5/2/2023
86152	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)	4/11/2017	5/2/2023
86153	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required	4/11/2017	5/2/2023
86305	Human epididymis protein 4 (HE4)	4/11/2017	5/2/2023
86343	Leukocyte histamine release test (LHR)	4/11/2017	5/2/2023
86677	Antibody; Helicobacter pylori	4/11/2017	5/2/2023
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique [GynecoloGene BV]	10/11/2017	5/2/2023
87482	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification	10/11/2017	5/2/2023

87512	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, quantification	10/11/2017	5/2/2023
87623	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44)	4/11/2017	5/2/2023
91020	Gastric motility (manometric) studies	1/18/2018	5/2/2023
91022	Duodenal motility (manometric) study	1/18/2018	5/2/2023
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	4/11/2017	5/2/2023
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report	05/02/2023	5/2/2023
91117	Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, eg, meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report	1/18/2018	5/2/2023
91132	Electrogastrography, diagnostic, transcutaneous	1/18/2018	5/2/2023
91133	Electrogastrography, diagnostic, transcutaneous; with provocative testing	4/27/2020	5/2/2023
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	4/11/2017	5/2/2023
92548	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report;	4/11/2017	5/2/2023
93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive	1/18/2018	5/2/2023
93278	Signal-averaged electrocardiography (SAECG), with or without ECG	4/11/2017	5/2/2023
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve	1/18/2018	5/2/2023
93740	Temperature gradient studies	4/15/2019	5/2/2023
95056	Photo tests	1/18/2018	5/2/2023
95065	Direct nasal mucous membrane test	1/18/2018	5/2/2023

95905	Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report	4/11/2017	5/2/2023
96000	Comprehensive computer-based motion analysis by video-taping and 3D kinematics	1/18/2018	5/2/2023
96001	Comprehensive computer-based motion analysis by video-taping and 3D kinematics; with dynamic plantar pressure measurements during walking	1/18/2018	5/2/2023
96002	Dynamic surface electromyography, during walking or other functional activities, 1-12 muscles	1/18/2018	5/2/2023
96003	Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle	1/18/2018	5/2/2023
96004	Review and interpretation by physician or other qualified health care professional of comprehensive computer-based motion analysis, dynamic plantar pressure measurements, dynamic surface electromyography during walking or other functional activities, and dynamic fine wire electromyography, with written report	1/18/2018	5/2/2023
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes	4/11/2017	5/2/2023
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	1/18/2018	5/2/2023
A4639	Replacement pad for infrared heating pad system, each	1/18/2018	5/2/2023
A6000	Noncontact wound-warming wound cover for use with the noncontact wound-warming device and warming card	1/18/2018	5/2/2023
A9291	Prescription digital cognitive and/or behavioral therapy, fda cleared, per course of treatment	5/2/2023	5/2/2023
C1821	Interspinous process distraction device (implantable)	4/11/2017	5/2/2023
C2614	Probe, percutaneous lumbar discectomy	1/18/2018	5/2/2023
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components	1/18/2018	5/2/2023
C9359	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc	1/18/2018	5/2/2023



C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length	1/18/2018	5/2/2023
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	1/18/2018	5/2/2023
C9716	Creations of thermal anal lesions by radiofrequency energy	1/18/2018	5/2/2023
C9727	Insertion of implants into the soft palate; minimum of three implants	4/11/2017	5/2/2023
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	1/18/2018	5/2/2023
E0218	Fluid circulating cold pad with pump, any type	4/11/2017	5/2/2023
E0221	Infrared heating pad system	1/18/2018	5/2/2023
E0231	Noncontact wound-warming device (temperature control unit, AC adapter and power cord) for use with warming card and wound cover	1/18/2018	5/2/2023
E0232	Warming card for use with the noncontact wound-warming device and noncontact wound-warming wound cover	1/18/2018	5/2/2023
E0744	Neuromuscular stimulator for scoliosis	1/18/2018	5/2/2023
E0755	Electronic salivary reflex stimulator (intraoral/noninvasive)	1/18/2018	5/2/2023
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting	1/18/2018	5/2/2023
E0849	Traction equipment, cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible	4/11/2017	5/2/2023
E0850	Traction stand, free-standing, cervical traction	4/11/2017	5/2/2023
E0935	Continuous passive motion exercise device for use on knee only	1/18/2018	5/2/2023
E0936	Continuous passive motion exercise device for use other than knee	1/18/2018	5/2/2023
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material	4/11/2017	5/2/2023
E1801	Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories	1/18/2018	5/2/2023
E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface material	1/18/2018	5/2/2023
E1805	Dynamic adjustable wrist extension/flexion device, includes soft interface material	1/18/2018	5/2/2023

E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories	1/18/2018	5/2/2023
E1810	Dynamic adjustable knee extension/flexion device, includes soft interface material	4/11/2017	5/2/2023
E1811	Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories	1/18/2018	5/2/2023
E1812	Dynamic knee, extension/flexion device with active resistance control	1/18/2018	5/2/2023
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material	1/18/2018	5/2/2023
E1816	Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories	1/18/2018	5/2/2023
E1818	Static progressive stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories	1/18/2018	5/2/2023
E1820	Replacement soft interface material, dynamic adjustable extension/flexion device	4/27/2020	5/2/2023
E1821	Replacement soft interface material/cuffs for bi-directional static progressive stretch device	1/18/2018	5/2/2023
E1830	Dynamic adjustable toe extension/flexion device, includes soft interface material	4/11/2017	5/2/2023
E1831	Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories	1/18/2018	5/2/2023
E1840	Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material	1/18/2018	5/2/2023
E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories	1/18/2018	5/2/2023
E2120	Pulse generator system for tympanic treatment of inner ear endolymphatic fluid	1/18/2018	5/2/2023
G0130	Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)	4/11/2017	5/2/2023

G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)	4/11/2017	5/2/2023
G0255	Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve	1/18/2018	5/2/2023
G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses	1/18/2018	5/2/2023
G0327	Colorectal cancer screening; blood-based biomarker	4/25/2022	5/2/2023
G0329	Electromagnetic therapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care	1/18/2018	5/2/2023
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	1/18/2018	5/2/2023
G9147	Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration	1/18/2018	5/2/2023
J0172	Injection, aducanumab-awwa, 2 mg	5/2/2023	5/2/2023
J1726	Injection, hydroxyprogesterone caproate, (Makena), 10 mg	5/2/2023	5/2/2023
J1729	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg	5/2/2023	5/2/2023
No specific code available, miscellaneous codes C9399 or J3590	Injection, lecanemab-irmb	5/2/2023	5/2/2023
K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application	5/2/2023	5/2/2023
K1029	Oral device/appliance for neuromuscular electrical stimulation	5/2/2023	5/2/2023

	of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply		
L1005	Tension based scoliosis orthotic and accessory pads, includes fitting and adjustment	1/18/2018	5/2/2023
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source	4/11/2017	5/2/2023
L5990	Addition to lower extremity prosthesis, user adjustable heel height	1/18/2018	5/2/2023
L6026	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)	1/18/2018	5/2/2023
L6895	Addition to upper extremity prosthesis, glove for terminal device, any material, custom fabricated	1/18/2018	5/2/2023
P2033	Thymol turbidity, blood	1/18/2018	5/2/2023
P2038	Mucoprotein, blood (seromucoid) (medical necessity procedure)	1/18/2018	5/2/2023
S0596	Phakic intraocular lens for correction of refractive error	1/18/2018	5/2/2023
S2080	Laser-assisted uvulopalatoplasty (LAUP)	4/11/2017	5/2/2023
S2103	Adrenal tissue transplant to brain	1/18/2018	5/2/2023
S2117	Arthroereisis, subtalar	1/18/2018	5/2/2023
S2300	Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy	1/18/2018	5/2/2023
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar	1/18/2018	5/2/2023
S3652	Saliva test, hormone level; to assess preterm labor risk	1/18/2018	5/2/2023
S3852	DNA analysis for APOE epsilon 4 allele for susceptibility to Alzheimer's disease	1/18/2018	5/2/2023
S3865	Comprehensive gene sequence analysis for hypertrophic cardiomyopathy	1/18/2018	5/2/2023
S3900	Surface electromyography (EMG)	1/18/2018	5/2/2023
S3902	Ballistocardiogram	1/18/2018	5/2/2023
S9056	Coma stimulation per diem	1/18/2018	5/2/2023

S9986	Not medically necessary service (patient is aware that service not medically necessary)	4/27/2020	5/2/2023
S9992	Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion	1/18/2018	5/2/2023
S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion	1/18/2018	5/2/2023
S9996	Meals for clinical trial participant and one caregiver/companion	1/18/2018	5/2/2023
V2787	Astigmatism correcting function of intraocular lens	4/11/2017	5/2/2023
V2788	Presbyopia correcting function of intraocular lens	4/11/2017	5/2/2023

#### Clinical Guideline Revision / History Information

Original Date: 4/11/2017

Reviewed/Revised: 10/11/2017, 1/18/2018, 4/15/2019, 5/5/2020, 7/21/2020, 04/21/2021, 12/01/2021, 04/25/2022, 05/2/2023