

Non-Covered Experimental, Investigational, and Unproven Services

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Oscar only covers services, procedures, and treatments that have been proven to be safe and effective when compared to other established options. Oscar defines experimental, investigational, and unproven as the use of any treatment, procedure, facility, equipment, drug, device, or supply not accepted as standard medical treatment of the condition being treated or any of such items requiring Federal or other governmental agency approval not granted at the time services were provided. Any health care service, testing, procedure, treatment, device or prescription drug for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven, and is therefore not covered by Oscar.

Genetic tests are used to screen for, diagnose, and guide treatment of a variety of different diseases and healthy processes. Most genetic tests are performed using blood samples or tissue samples, and some may be part of more involved procedures or surgeries. Oscar only covers genetic tests that have been proven to be safe and effective when compared to other established options. Any genetic test for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven, and is therefore not covered by Oscar.

To determine whether a service, device, treatment or procedure has proven safety and efficacy, the available reliable evidence is reviewed, which may include but is not limited to (listed in order of decreasing reliability):

1. Published technology assessments and/or high quality meta analyses
2. Randomized, controlled trials
3. Other controlled studies or cohort studies

4. Case reports or case series
5. Reports of expert opinion

The services referenced in this Clinical Guideline are considered to be experimental, investigational, or unproven as they have either not demonstrated long-term benefit, have not demonstrated clinical utility, have unnecessary risks, or have demonstrated inferior outcomes to safer, more appropriate techniques. The services referenced in this Clinical Guideline may not be all-inclusive. Specific benefit plan documents (e.g., Certificate of Coverage, Schedule of Benefits) and federal or state mandated health benefits and laws take precedence over this Clinical Guideline.

Definitions

“Experimental, Investigational, and Unproven Services” include any health care service, treatment, procedure, facility, equipment, drug, device, or supply that:

- Is not accepted as standard medical treatment of the condition; *or*
- Has not been approved by the U.S. Food and Drug Administration (FDA) to be lawfully used; *or*
- Has not been identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; *or*
- Requires review and approval by any institutional review board (IRB) for the proposed use or are subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trials set forth in the FDA regulations; *or*
- Requires any Federal or other governmental agency approval not listed above that has not been and will not be granted at the time services will be provided.

“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.

Clinical Indications and Coverage

Oscar may consider coverage of an experimental, investigational, or unproven health care service, treatment, procedure, facility, equipment, drug, device, or supply only if ALL of the following criteria are met:

1. The member's condition is life-threatening or disabling; *and*
2. The member's condition has not improved with standard medical treatment; *and*
3. No other standard medical treatment is available for the member's condition; *and*
4. The treating, licensed provider submits a letter of medical necessity, supporting medical records, and clinical evidence supporting the treatment modality.

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>
0001M	Infectious disease, HCV, 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 [HCV FibroSure, FibroTest, ActiTest]	4/11/2017	10/11/2017
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	10/11/2017
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	10/11/2017
0004M	Scoliosis, DNA analysis of 53 single nucleotide polymorphisms (SNPs), using saliva, prognostic algorithm reported as a risk score [ScoliScore]	10/11/2017	10/11/2017
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	1/18/2018
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	1/18/2018
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3	1/18/2018	1/18/2018

	genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score		
0006U	Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service	1/18/2018	1/18/2018
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	1/18/2018
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	1/18/2018
0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)	1/18/2018	1/18/2018
0013U	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)	1/18/2018	1/18/2018
0014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)	1/18/2018	1/18/2018
0015U	Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support	1/18/2018	1/18/2018
00640	Anesthesia for manipulation of the spine or for closed procedures on the cervical, thoracic or lumbar spine	1/18/2018	1/18/2018
0624	FDA investigational devices	1/18/2018	1/18/2018
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma	1/18/2018	1/18/2018
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure)	4/11/2017	4/11/2017
22505	Manipulation of spine requiring anesthesia, any region	1/18/2018	1/18/2018
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	1/18/2018

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	1/18/2018
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	1/18/2018
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	1/18/2018
26340	Manipulation, finger joint, under anesthesia, each joint	4/11/2017	4/11/2017
27275	Manipulation, hip joint, requiring general anesthesia	4/11/2017	4/11/2017
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia	4/11/2017	4/11/2017
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple	4/11/2017	4/11/2017
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	1/18/2018	1/18/2018
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	1/18/2018	1/18/2018
33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure), without cardiopulmonary bypass	4/11/2017	4/11/2017
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	1/18/2018	1/18/2018
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)	1/18/2018	1/18/2018
41512	Tongue base suspension, permanent suture technique	4/11/2017	4/11/2017
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session	4/11/2017	4/11/2017
43206	Esophagoscopy, flexible, transoral; with optical endomicroscopy	1/18/2018	1/18/2018

43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed	1/18/2018	1/18/2018
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy	4/11/2017	4/11/2017
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed	1/18/2018	1/18/2018
43285	Removal of esophageal sphincter augmentation device	1/18/2018	1/18/2018
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	4/11/2017
46707	Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])	4/11/2017	4/11/2017
46762	Sphincteroplasty, anal, for incontinence, adult; implantation artificial sphincter	1/18/2018	1/18/2018
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement	4/11/2017	4/11/2017
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence	1/18/2018	1/18/2018
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency	1/18/2018	1/18/2018
61630	Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous	4/11/2017	4/11/2017
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	1/18/2018
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	1/18/2018
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	1/18/2018	1/18/2018

	indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar		
62291	Injection procedure for discography, each level; cervical or thoracic	1/18/2018	1/18/2018
62292	Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar	1/18/2018	1/18/2018
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed)	1/18/2018	1/18/2018
64462	Paravertebral block (PVB) (paraspinous block), thoracic; second and any additional injection site(s) (includes imaging guidance, when performed) (List separately in addition to code for primary procedure)	1/18/2018	1/18/2018
64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)	1/18/2018	1/18/2018
64630	Destruction by neurolytic agent; pudendal nerve	1/18/2018	1/18/2018
64999	Unlisted procedure, nervous system	4/11/2017	4/11/2017
72285	Discography, cervical or thoracic, radiological supervision and interpretation	1/18/2018	1/18/2018
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium	4/13/2018	4/13/2018
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method	4/11/2017	4/11/2017
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	4/11/2017
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)	4/11/2017	4/11/2017
77605	Hyperthermia, externally generated; deep (ie, heating to depths greater than 4 cm)	1/18/2018	1/18/2018
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators	1/18/2018	1/18/2018
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators	1/18/2018	1/18/2018
78350	Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry	1/18/2018	1/18/2018
78351	Bone density (bone mineral content) study, 1 or more sites; dual photon absorptiometry, 1 or more sites	1/18/2018	1/18/2018

81222	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants [Family Prep Screen (Counsyl Inc.)]	10/11/2017	10/11/2017
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	4/11/2017
81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6) [GeneSight Psychotropic (Assurex Health Inc.); Healthy Weight DNA Insight; PGxOne Plus (Admera Health)]	4/11/2017	10/11/2017
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	10/11/2017
81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis [ColoVantage, Epi proColon]	10/11/2017	10/11/2017
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)	1/18/2018	1/18/2018
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	10/11/2017
81410	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, and MYLK	4/11/2017	10/11/2017
81411	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); duplication/deletion analysis panel, must include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1	10/11/2017	10/11/2017
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	10/11/2017	10/11/2017
81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (List separately in addition to code for primary procedure)	10/11/2017	10/11/2017
81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)	10/11/2017	10/11/2017
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg,	10/11/2017	10/11/2017

	DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood		
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	10/11/2017	10/11/2017
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	10/11/2017
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	10/11/2017
81430	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel, must include sequencing of at least 60 genes, including CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A, and WFS1	10/11/2017	10/11/2017
81431	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); duplication/deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes	10/11/2017	10/11/2017
81432	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53	10/11/2017	10/11/2017
81433	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11	10/11/2017	10/11/2017
81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11	10/11/2017	10/11/2017
81436	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11	10/11/2017	10/11/2017
81438	Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL	10/11/2017	10/11/2017
81440	Nuclear encoded mitochondrial genes (eg, neurologic or myopathic	10/11/2017	10/11/2017

	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		
81442	Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1	10/11/2017	10/11/2017
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed	4/11/2017	4/11/2017
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	10/11/2017
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed [FoundationOne (Foundation Medicine Inc.)]	10/11/2017	10/11/2017
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	10/11/2017
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed	10/11/2017	10/11/2017
81470	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include	10/11/2017	10/11/2017

	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)]		
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	10/11/2017
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	10/11/2017
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	4/11/2017
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	10/11/2017
81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score	10/11/2017	10/11/2017
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	10/11/2017
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	1/18/2018
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	10/11/2017
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	10/11/2017
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm	10/11/2017	10/11/2017

	reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)		
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	10/11/2017
82107	Alpha-fetoprotein (AFP); AFP-L3 fraction isoform and total AFP (including ratio) [AFP-L3 (Alpha-Fetoprotien L3)]	10/11/2017	10/11/2017
82172	Apolipoprotein, each	4/11/2017	4/11/2017
82387	Cathepsin-D [Cathepsin-D, Cathepsin-L]	10/11/2017	10/11/2017
82777	Galectin-3	4/11/2017	4/11/2017
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)	4/11/2017	4/11/2017
83695	Lipoprotein (a)	4/11/2017	4/11/2017
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)	4/11/2017	4/11/2017
83700	Lipoprotein, blood; electrophoretic separation and quantitation	4/11/2017	4/11/2017
83701	Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (eg, electrophoresis, ultracentrifugation)	4/11/2017	4/11/2017
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	4/11/2017
83719	Lipoprotein, direct measurement; VLDL cholesterol	1/18/2018	1/18/2018
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	10/11/2017
83987	pH; exhaled breath condensate	1/18/2018	1/18/2018
83993	Calprotectin, fecal	4/11/2017	4/11/2017
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	4/11/2017
84431	Thromboxane metabolite(s), including thromboxane if performed, urine	1/18/2018	1/18/2018

85547	Mechanical fragility, RBC	1/18/2018	1/18/2018
86001	Allergen specific IgG quantitative or semiquantitative, each allergen	4/11/2017	4/11/2017
86152	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)	4/11/2017	4/11/2017
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	4/11/2017
86305	Human epididymis protein 4 (HE4)	4/11/2017	4/11/2017
86343	Leukocyte histamine release test (LHR)	4/11/2017	4/11/2017
86357	Natural killer (NK) cells, total count	4/11/2017	4/11/2017
86677	Antibody; Helicobacter pylori	4/11/2017	4/11/2017
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique [GynecoloGene BV]	10/11/2017	10/11/2017
87482	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification	10/11/2017	10/11/2017
87506	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets	4/11/2017	4/11/2017
87507	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets	4/11/2017	4/11/2017
87511	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, amplified probe technique [GynecoloGene BV]	10/11/2017	10/11/2017
87512	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, quantification	10/11/2017	10/11/2017
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	4/11/2017
91020	Gastric motility (manometric) studies	1/18/2018	1/18/2018
91022	Duodenal motility (manometric) study	1/18/2018	1/18/2018
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report	1/18/2018	1/18/2018

91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	4/11/2017	4/11/2017
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	1/18/2018
91132	Electrogastrography, diagnostic, transcutaneous	1/18/2018	1/18/2018
92132	Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral	4/11/2017	4/11/2017
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	4/11/2017	4/11/2017
92548	Computerized dynamic posturography	4/11/2017	4/11/2017
93025	Microvolt T-wave alternans for assessment of ventricular arrhythmias	4/11/2017	4/11/2017
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	1/18/2018
93278	Signal-averaged electrocardiography (SAECG), with or without ECG	4/11/2017	4/11/2017
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve	1/18/2018	1/18/2018
93701	Bioimpedance-derived physiologic cardiovascular analysis	4/11/2017	4/11/2017
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)	4/11/2017	4/11/2017
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral	4/11/2017	4/11/2017
95012	Nitric oxide expired gas determination	4/11/2017	4/11/2017
95056	Photo tests	1/18/2018	1/18/2018
95065	Direct nasal mucous membrane test	1/18/2018	1/18/2018
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)	4/11/2017	4/11/2017
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	4/11/2017

96000	Comprehensive computer-based motion analysis by video-taping and 3D kinematics	1/18/2018	1/18/2018
96001	Comprehensive computer-based motion analysis by video-taping and 3D kinematics; with dynamic plantar pressure measurements during walking	1/18/2018	1/18/2018
96002	Dynamic surface electromyography, during walking or other functional activities, 1-12 muscles	1/18/2018	1/18/2018
96003	Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle	1/18/2018	1/18/2018
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	1/18/2018
96904	Whole body integumentary photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma	4/11/2017	4/11/2017
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	4/11/2017
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters	4/11/2017	4/11/2017
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters	1/18/2018	1/18/2018
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	1/18/2018
A4639	Replacement pad for infrared heating pad system, each	1/18/2018	1/18/2018

A6000	Noncontact wound-warming wound cover for use with the noncontact wound-warming device and warming card	1/18/2018	1/18/2018
C1821	Interspinous process distraction device (implantable)	4/11/2017	4/11/2017
C2614	Probe, percutaneous lumbar discectomy	1/18/2018	1/18/2018
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components	1/18/2018	1/18/2018
C9352	Microporous collagen implantable tube (NeuraGen Nerve Guide), per cm length	4/11/2017	4/11/2017
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	1/18/2018
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length	1/18/2018	1/18/2018
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	1/18/2018	1/18/2018
C9716	Creations of thermal anal lesions by radiofrequency energy	1/18/2018	1/18/2018
C9727	Insertion of implants into the soft palate; minimum of 3 implants	4/11/2017	4/11/2017
C9741	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report	1/18/2018	1/18/2018
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	1/18/2018	1/18/2018
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed	1/18/2018	1/18/2018
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	1/18/2018	1/18/2018
E0218	Water circulating cold pad with pump	4/11/2017	4/11/2017
E0221	Infrared heating pad system	1/18/2018	1/18/2018
E0231	Noncontact wound-warming device (temperature control unit, AC adapter and power cord) for use with warming card and wound cover	1/18/2018	1/18/2018
E0232	Warming card for use with the noncontact wound-warming device and noncontact wound-warming wound cover	1/18/2018	1/18/2018
E0744	Neuromuscular stimulator for scoliosis	1/18/2018	1/18/2018
E0755	Electronic salivary reflex stimulator (intraoral/noninvasive)	1/18/2018	1/18/2018

E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting	1/18/2018	1/18/2018
E0849	Traction equipment, cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible	4/11/2017	4/11/2017
E0850	Traction stand, free-standing, cervical traction	4/11/2017	4/11/2017
E0935	Continuous passive motion exercise device for use on knee only	1/18/2018	1/18/2018
E0936	Continuous passive motion exercise device for use other than knee	1/18/2018	1/18/2018
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material	4/11/2017	4/11/2017
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	1/18/2018
E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface material	1/18/2018	1/18/2018
E1805	Dynamic adjustable wrist extension/flexion device, includes soft interface material	1/18/2018	1/18/2018
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	1/18/2018
E1810	Dynamic adjustable knee extension/flexion device, includes soft interface material	4/11/2017	4/11/2017
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	1/18/2018
E1812	Dynamic knee, extension/flexion device with active resistance control	1/18/2018	1/18/2018
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material	1/18/2018	1/18/2018
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	1/18/2018
E1818	Static progressive stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories	1/18/2018	1/18/2018
E1821	Replacement soft interface material/cuffs for bi-directional static progressive stretch device	1/18/2018	1/18/2018

E1830	Dynamic adjustable toe extension/flexion device, includes soft interface material	4/11/2017	4/11/2017
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	1/18/2018
E1840	Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material	1/18/2018	1/18/2018
E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories	1/18/2018	1/18/2018
E2120	Pulse generator system for tympanic treatment of inner ear endolymphatic fluid	1/18/2018	1/18/2018
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	4/11/2017
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	4/11/2017
G0255	Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve	1/18/2018	1/18/2018
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial	1/18/2018	1/18/2018
G0281	Electrical stimulation, (unattended), 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	1/18/2018
G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281	4/11/2017	4/11/2017
G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses	1/18/2018	1/18/2018
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	1/18/2018
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion	1/18/2018	1/18/2018

G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion	1/18/2018	1/18/2018
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion	1/18/2018	1/18/2018
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	1/18/2018
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	1/18/2018
L1005	Tension based scoliosis orthotic and accessory pads, includes fitting and adjustment	1/18/2018	1/18/2018
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source	4/11/2017	4/11/2017
L5990	Addition to lower extremity prosthesis, user adjustable heel height	1/18/2018	1/18/2018
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	1/18/2018
L6895	Addition to upper extremity prosthesis, glove for terminal device, any material, custom fabricated	1/18/2018	1/18/2018
P2033	Thymol turbidity, blood	1/18/2018	1/18/2018
P2038	Mucoprotein, blood (seromuroid) (medical necessity procedure)	1/18/2018	1/18/2018
S0596	Phakic intraocular lens for correction of refractive error	1/18/2018	1/18/2018
S1090	Mometasone furoate sinus implant, 370 micrograms	4/11/2017	4/11/2017
S2080	Laser-assisted uvulopalatoplasty (LAUP)	4/11/2017	4/11/2017
S2103	Adrenal tissue transplant to brain	1/18/2018	1/18/2018
S2117	Arthroereisis, subtalar	1/18/2018	1/18/2018
S2300	Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy	1/18/2018	1/18/2018
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar	1/18/2018	1/18/2018

S3645	HIV-1 antibody testing of oral mucosal transudate	1/18/2018	1/18/2018
S3652	Saliva test, hormone level; to assess preterm labor risk	1/18/2018	1/18/2018
S3800	Genetic testing for amyotrophic lateral sclerosis (ALS)	1/18/2018	1/18/2018
S3852	DNA analysis for APOE epsilon 4 allele for susceptibility to Alzheimer's disease	1/18/2018	1/18/2018
S3861	Genetic testing, sodium channel, voltage-gated, type V, alpha subunit (SCN5A) and variants for suspected Brugada Syndrome	1/18/2018	1/18/2018
S3865	Comprehensive gene sequence analysis for hypertrophic cardiomyopathy	1/18/2018	1/18/2018
S3900	Surface electromyography (EMG)	1/18/2018	1/18/2018
S3902	Ballistocardiogram	1/18/2018	1/18/2018
S9355	Home infusion therapy, chelation therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	1/18/2018	1/18/2018
S9056	Coma stimulation per diem	1/18/2018	1/18/2018
S9090	Services provided as part of a Phase II clinical trial	1/18/2018	1/18/2018
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	1/18/2018
S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion	1/18/2018	1/18/2018
S9996	Meals for clinical trial participant and one caregiver/companion	1/18/2018	1/18/2018
V2787	Astigmatism correcting function of intraocular lens	4/11/2017	4/11/2017
V2788	Presbyopia correcting function of intraocular lens	4/11/2017	4/11/2017

Clinical Guideline Revision / History Information

Original: Review/Revise Dates	Approval Signature/ Title
Original Date:	4/11/2017
Reviewed/Revised:	10/11/2017, 1/18/2018, 4/13/2018
Signed:	Sean Martin, MD, Medical Director