

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 28-29, 2021. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.

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Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Total Votes Received
0226U: Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum	Crosswalk: 86769	12	Gapfill		Abstain						12
86413: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative	Crosswalk: 86769 x 1.25	3	86794 x 3.125		86769 x 2	8	Gapfill		Abstain	1	12
863X4: Mitochondrial antibody (eg, M2), each	86146	12	Gapfill		Abstain						12
865X0: Voltage-gated calcium channel antibody, each	84586	12	Gapfill		Abstain						12
86XX0: Actin (smooth muscle) antibody (ASMA), each	86146	2	83516	10	Gapfill		Abstain				12
86X00: Antineutrophil cytoplasmic antibody (ANCA); screen, each antibody	86146	2	86255	10	Gapfill		Abstain				12
86X01: Antineutrophil cytoplasmic antibody (ANCA); titer, each antibody	86146		86256	12	Gapfill		Abstain				12
0X65U: Hematology (heparin-induced thrombocytopenia) platelet antibody reactivity by flow cytometry, serum	Gapfill	12	Abstain								12
0X66U: 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	83520	11	Gapfill		Abstain	1					12
0X67U: Hematology (von Willebrand disease [VWD]), von Willebrand propeptide, enzyme-linked immunosorbent assays (ELISA), plasma, diagnostic report of von Willebrand factor (VWF) propeptide antigen level	83520	6	Gapfill		Abstain	1	Crosswalk: 85246	5			12
0X68U: von Willebrand factor (VWF), type 2B, platelet-binding evaluation, radioimmunoassay, plasma	83519	11	Gapfill		Abstain	1					12
0X69U: von Willebrand factor (VWF), type 2N, factor VIII and VWF binding evaluation, enzyme-linked immunosorbent assays (ELISA), plasma	83520	1	Gapfill		Abstain	1	Crosswalk: 85246 x 1.5	4	Crosswalk: 85246 x 2.0	6	12
860XX: Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)	86146	11	Gapfill		Abstain	1					12
860X1: Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each	86341	11	Gapfill		Abstain	1					12
860X2: Aquaporin-4 (neuromyelitis optica [NMO]) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each	86367	11	Gapfill		Abstain	1					12
863X2: Myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody; cell-based immunofluorescence assay (CBA), each	86357	11	Gapfill		Abstain	1					12

863X3: Myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each	86367	11	Gapfill		Abstain	1				12
862X0: Endomysial antibody (EMA), each immunoglobulin (Ig) class	86038	5	86038 x 2	6	Gapfill		Abstain	1		12
862XX: Gliadin (deamidated) (DGP) antibody, each immunoglobulin (Ig) class	86147	11	Gapfill		Abstain	1				12
862X1: Tissue transglutaminase, each immunoglobulin (Ig) class	86147	11	Gapfill		Abstain	1				12
0X85U: 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	83520	4	85246	7	Gapfill		Abstain	1		12
86408: Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen	86769	1	86794 x 2.5		Gapfill	11	Abstain			12
86409: Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer	86769 x 3		86352		Gapfill	12	Abstain			12
87426: Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])	87430 x 2.5	1	87430 x 2	11	Gapfill		Abstain			12
0223U: Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	87633	12	Gapfill		Abstain					12
0224U: Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed	86769	11	Gapfill		Abstain	1				12
0240U: Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected	87631	11	Gapfill		Abstain	1				12
0241U: Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected	87631	11	Gapfill		Abstain	1				12
87636: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique	87631	11	Gapfill		Abstain	1				12

87637: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique	87631	11	Gapfill		Abstain	1				12
87811: Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group B severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	87804 x 2.5	1	87804 x 2	11	Gapfill		Abstain			12
8715X: Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets	87632		87506	11	Gapfill	1	Abstain			12
87428: Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B	87430 x2.5 + 87400 x 2	2	87430 x 2 + 87400 x 2	10	Gapfill		Abstain			12
0227U: Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation	80307	12	Gapfill		Abstain					12
81338: MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)	81120	12	81402		Gapfill		Abstain			12
81339: MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10	81310	12	81403		Gapfill		Abstain			12
801XX: Hydroxychloroquine	80204	12	Gapfill		Abstain					12
0248U: Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug	Gapfill	12	Abstain							12
80151: Amiodarone	80155	12	80299		Gapfill		Abstain			12
80161: Carbamazepine; 10,11-epoxide	80155	12	80299		Gapfill		Abstain			12
80167: Felbamate	80199	12	80299		Gapfill		Abstain			12
80181: Flecainide	80193	2	80155	10	80299		Gapfill		Abstain	12
81279: JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)	81272 - last year's xwalk	11	81403	1	Gapfill		Abstain			12

0225U: Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	87633	12	Gapfill		Abstain						12
0228U: Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer	Gapfill	11	Abstain								11
815X0: Transplantation medicine (allograft rejection, pediatric liver and small bowel), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score	Gapfill	11	Abstain								11
815X1: Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis	81521	11	Gapfill		Abstain						11
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	0120U	11	Gapfill		Abstain						11
0243U: Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	82731	11	Gapfill		Abstain						11
002XM: Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score	Gapfill	11	Abstain								11
0X56U: 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	Gapfill	11	Abstain								11
0X59U: Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics	0019U	6	Gapfill	5	Abstain						11
0245U: Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage	81455	9	Gapfill	2	Abstain						11

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	0080U X 0.2	10	Gapfill	1	Abstain					11
0252U: Fetal aneuploidy short tandem-repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy	0168U		Gapfill	11	Abstain					11
0249U: Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	0037U	2	Gapfill	9	Abstain					11
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)	Gapfill	11	Abstain							11
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/duplications, mosaicism, and segmental aneuploidy, per embryo tested	Gapfill	11	Abstain							11
0X71U: 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	0011M	8	Gapfill	3	Abstain					11
0X70U: Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score	0108U	3	0108U x 1.2	4	Gapfill	3	Abstain	1		11
826X0: Elastase, pancreatic (EL-1), fecal; quantitative	82715	10	Gapfill		Abstain					10
0X57U: Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, tandem mass spectrometry (MS/MS), urine, with algorithmic analysis and interpretive report	Gapfill	11	Abstain							11
0X58U: Very long chain acyl-coenzyme A (CoA) dehydrogenase (VLCAD), leukocyte enzyme activity, whole blood	Gapfill	11	Abstain							11

OX60U: Nephrology (chronic kidney disease), nuclear magnetic resonance spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to determine estimated glomerular filtration rate (GFR), serum, quantitative	(83704 x2) + (82610)	2	83704 + 82610	6	Gapfill	1	Abstain					9
O251U: Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	83520	11	Gapfill		Abstain							11
835X1: Interleukin-6 (IL-6)	83006	10	Gapfill		Abstain	1						11
8352X: Immunoglobulin light chains (ie, kappa, lambda), free, each	83520	11	Gapfill		Abstain							11
OX77U: Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, ?-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	0063U	10	Gapfill		Abstain							10
O229U: BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis	81327 x 2	9	Gapfill		Abstain							9
O230U: AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	81173 + 81204	9	Gapfill		Abstain							9
O231U: CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions	81184 + 81185	9	Gapfill		Abstain							9
O232U: CSTB (cystatin B) (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	81188 + 81189	9	Gapfill		Abstain							9
O233U: FXN (frataxin) (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	81285 + 81286	9	Gapfill		Abstain							9

0234U: MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	81302 + 81304	9	Gapfill		Abstain						9
0235U: PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	81321 + 81323	9	Gapfill		Abstain						9
0236U: SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions	81329 + 81337	9	Gapfill		Abstain						9
0237U: Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	81413 + 81414	9	Gapfill		Abstain						9
0238U: Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	81435 + 81436	9	Gapfill		Abstain						9
0239U: Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations	81455	5	Gapfill	6	Abstain						11
0X62U: Rare constitutional and other heritable disorders, whole- genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin-embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants	81425+81460	5	Gapfill	4	Abstain						9
0250U: Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden	81455	11	Gapfill		Abstain						11

OX63U: 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	81425	1	Gapfill	1	Abstain		81415	6			8
OX64U: Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole-genome sequencing	81425 + 81229	7	Gapfill	1	Abstain						8
OX73U: Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid	81432	5	Gapfill		Abstain		81443	5			10
OX74U: Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid	81432 + 81433	2	81432		Gapfill		Abstain		81443	8	10
OX75U: Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid	81432 + 81433		81432	2	Gapfill		Abstain		81443	8	10
OX76U: Hematology (genetic bleeding disorders), genomic sequence analysis of 51 genes, blood, buccal swab, or amniotic fluid, comprehensive	81443		Gapfill		Abstain		81430	10			10
OX78U: Hematology (genetic platelet disorders), genomic sequence analysis of 43 genes, blood, buccal swab, or amniotic fluid	81443	2	Gapfill		Abstain		81430	7			9
OX79U: Hematology (congenital neutropenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	81443	8	Gapfill	1	Abstain						9
OX80U: Hematology (genetic hyperfibrinolysis, delayed bleeding), genomic sequence analysis of 8 genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2, PLAU) blood, buccal swab, or amniotic fluid	81443	4	Gapfill		Abstain		81432	6			10
OX81U: Hematology (inherited thrombocytopenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	81443	9	Gapfill	1	Abstain						10
OX82U: Hematology (genetic platelet function disorder), genomic sequence analysis of 31 genes, blood, buccal swab, or amniotic fluid	81443	3	Gapfill		Abstain		81430	7			10
OX83U: Hematology (genetic thrombosis), genomic sequence analysis of 12 genes, blood, buccal swab, or amniotic fluid	81443	9	Gapfill	1	Abstain						10
OX84U: Red blood cell antigen typing, DNA, genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes	0001U	10	Gapfill		Abstain						10
OX61U: Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	Gapfill	1	Abstain	1	81229	9					11

