

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
002XM/0014M: Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years	Crosswalk: 0003M*0.35	11	Gapfill	1	Abstain					
003XM: 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	Crosswalk 0003U*2	2	Gapfill	10	Abstain					
004XM: Oncology (bladder), mRNA, microarray gene expression profiling of 209 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)	Gapfill	12	Abstain							
0071U: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, full gene sequence	Crosswalk: 81238	11	Gapfill	1	Abstain					
0101U: Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])	Gapfill	12	Abstain							
0102U: Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication])	Gapfill	12	Abstain							
0103U: Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])	Gapfill	12	Abstain							
0129U: Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)	Gapfill	12	Abstain							

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

<u>Code: Long Descriptor</u>	<u>Option</u>	<u>Votes</u>	<u>Option</u>	<u>Votes</u>	<u>Option</u>	<u>Votes</u>	<u>Option</u>	<u>Votes</u>	<u>Option</u>	<u>Votes</u>
0139U: Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, ?-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	Gapfill	12	Abstain							
0140U: Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected	Crosswalk: 87633		Gapfill	12	Abstain					
0141U: Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected	Gapfill	12	Abstain							
0142U: Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected	Gapfill	12	Abstain							
0143U: 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	Crosswalk: 0082U*1.3	2	Crosswalk: 0082U	1	Gapfill	9	Abstain			
0144U: Drug assay, definitive, 160 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	Crosswalk: 0082U*1.8	2	Crosswalk: 0082U		Gapfill	10	Abstain			
0145U: Drug assay, definitive, 65 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	Crosswalk: 0082U*0.7	1	Crosswalk: 0082U	2	Gapfill	9	Abstain			
0146U: Drug assay, definitive, 80 or more drugs or metabolites, urine, by 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	Crosswalk: 0082U*0.9	1	Crosswalk: 0082U	2	Gapfill	9	Abstain			

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
 Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
 Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
0147U: Drug assay, definitive, 85 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	Crosswalk: 0082U*0.9	2	Crosswalk: 0082U	2	Gapfill	8	Abstain			
0148U: Drug assay, definitive, 100 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	Crosswalk: 0082U*1.1	2	Crosswalk: 0082U	2	Gapfill	8	Abstain			
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	Crosswalk: 0082U*0.7	1	Crosswalk: 0082U	2	Gapfill	8	Abstain			
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	Crosswalk: 0082U*1.3	2	Crosswalk: 0082U	1	Gapfill	9	Abstain			
0151U: Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 33 targets, real-time semi-quantitative PCR, bronchoalveolar lavage, sputum, or endotracheal aspirate, detection of 33 organismal and antibiotic resistance genes with limited semi-quantitative results	Gapfill	12	Abstain							
0152U: Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens	Gapfill	12	Abstain							
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	Gapfill	12	Abstain							
0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3) utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status	Crosswalk: 81309 * 2.0	1	Crosswalk 81309+81315	8	Gapfill	3	Abstain			

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
0155U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y), utilizing formalin-fixed paraffin-embedded breast tumor tissue, reported as PIK3CA gene mutation status	Crosswalk: 81309 * 1.5	5	Crosswalk 81309	7	Gapfill		Abstain			
0156U: Copy number (eg, intellectual disability, dysmorphology), sequence analysis	Crosswalk: 81229 * 1.5		Gapfill	12	Abstain					
0157U: APC (APC regulator of WNT signaling pathway) (eg, familial adenomatous polyposis [FAP]) mRNA sequence analysis (List separately in addition to code for primary procedure)	Crosswalk: 81201	6	Gapfill	6	Abstain					
0158U: MLH1 (mutL homolog 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	Crosswalk: 81292	5	Gapfill	7	Abstain					
0159U: MSH2 (mutS homolog 2) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	Crosswalk: 81295	5	Gapfill	7	Abstain					
0160U: MSH6 (mutS homolog 6) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	Crosswalk: 81298	5	Gapfill	7	Abstain					
0161U: PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	Crosswalk: 81317	6	Gapfill	6	Abstain					
0162U: Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure)	Crosswalk: 81435	5	Gapfill	7	Abstain					
0163U: Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas	Gapfill	12	Abstain							
0164U: Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	Crosswalk: 0085U	7	Gapfill	5	Abstain					
0165U: Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy	Gapfill	12	Abstain							

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
 Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
 Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
0166U: Liver disease, 10 biochemical assays (?2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	Crosswalk: 0003M	11	Gapfill	1	Abstain					
0167U: Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood	Crosswalk: 84702	1	Crosswalk: 84703	11	Gapfill		Abstain			
0168U: Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	Crosswalk: 81420	8	Gapfill	4	Abstain					
0169U: NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	Crosswalk: 0034U	10	Crosswalk: 81335	1	Gapfill		1 Abstain			
0170U: Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis	Crosswalk: 0090U	11	Gapfill	1	Abstain	vote 2	Crosswalk 0090U	7	Gapfill	5
0171U: Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	Gapfill	10	Crosswalk 81450	2	Abstain					
0173U: Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	Gapfill	11	Abstain	1						
0174U: Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents	Crosswalk: 81538		Gapfill	12	Abstain					
0175U: Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	Crosswalk: 81443		0078U	8	Gapfill		4 Abstain			
0176U: Cytotoxic distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	Crosswalk to 86828	11	Gapfill		Abstain					
0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status	Crosswalk 81309	8	Gapfill		Abstain		Crosswalk 81309 * 1.5	4		
0178U: Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction	Gapfill	12	Abstain							

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
 Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.

Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
0179U: Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)	Gapfill	12	Abstain							
0180U: Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons	Crosswalk: 81405	3	Crosswalk: 81302	8	Gapfill	1	Abstain			
0181U: Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1	Crosswalk: 81403	2	Crosswalk: 81215	8	Gapfill		Abstain	2		
0182U: Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10	Crosswalk: 81405	5	Crosswalk: 81298	7	Gapfill		Abstain			
0183U: Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19	Crosswalk: 81403	3	Crosswalk: 81215	8	Gapfill		Abstain	1		
0184U: Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2	Crosswalk: 81403	3	Crosswalk: 81215	9	Gapfill		Abstain			
0185U: Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4	Crosswalk: 81403	3	Crosswalk: 81215	9	Gapfill		Abstain			
0186U: Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2	Crosswalk: 81403	2	Crosswalk: 81215	10	Gapfill		Abstain			
0187U: Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2	Crosswalk: 81404	2	Crosswalk: 81252	10	Gapfill		Abstain			
0188U: Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4	Crosswalk: 81404	3	Crosswalk: 81302	9	Gapfill		Abstain			
0189U: Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2	Crosswalk: 81404	3	Crosswalk: 81364	9	Gapfill		Abstain			
0190U: Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3	Crosswalk: 81404	3	Crosswalk: 81364	9	Gapfill		Abstain			
0191U: Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6	Crosswalk: 81404	3	Crosswalk: 81364	9	Gapfill		Abstain			
0192U: Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9	Crosswalk: 81404	1	Crosswalk: 81252	11	Gapfill		Abstain			
0193U: Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26	Crosswalk: 81406	2	Corrected: 81223	10	Gapfill		Abstain			

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
 Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
 Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
0194U: Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8	Crosswalk: 81403	2	Crosswalk: 81215	10	Gapfill		Abstain			
0195U: KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)	Crosswalk: 81403	5	Crosswalk: 81215	7	Gapfill		Abstain			
0196U: Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3	Crosswalk: 81403	2	Crosswalk: 81215	10	Gapfill		Abstain			
0197U: Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1	Crosswalk: 81403	2	Crosswalk: 81215	10	Gapfill		Abstain			
0198U: Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5	Crosswalk: 81406	5	Crosswalk: 81298	7	Gapfill		Abstain			
0199U: Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAD (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12	Crosswalk: 81404	2	Crosswalk: 81252	10	Gapfill		Abstain			
0200U: Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3	Crosswalk: 81404	3	Crosswalk: 81364	9	Gapfill		Abstain			
0201U: Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2	Crosswalk: 81403	2	Crosswalk: 81215	10	Gapfill		Abstain			
0202U: 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	Crosswalk: [(87631) + (87798*4) + (87502)]	1	Crosswalk: 87633	11	Gapfill		Abstain			
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	Crosswalk: 0011M	10	Gapfill	2	Abstain					
0204U: Oncology (thyroid), mRNA, gene expression analysis of 593 genes for sequence variants and rearrangements, including BRAF, RAS, RET, PAX8 and NTRK, utilizing fine needle aspirate, reported as detected/not detected	Crosswalk: 81455	8	Gapfill	4	Abstain					
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	Crosswalk: 81330	10	Gapfill	2	Abstain					

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
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	Gapfill	11	Abstain							
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)	Gapfill	11	Abstain							
0208U: Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma	Gapfill	12	Abstain							
0209U: Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities	Gapfill	12	Abstain							
0210U: Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)	Crosswalk: [0065U + (0065U * 0.03)]	12	Gapfill		Abstain					
0211U: Oncology (pan-tumor), DNA and RNA by next generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association	Crosswalk: 0019U + 0036U	6	Gapfill	3	Abstain	2				
0212U: 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, proband	Gapfill	11	Abstain							
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)	Gapfill	11	Abstain							
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	Gapfill	11	Abstain							

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
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)	Gapfill	11	Abstain							
0216U: Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes 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	Gapfill	11	Abstain							
0217U: Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes 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	Gapfill	11	Abstain							
0218U: Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants	Crosswalk to 81408 + 81161	8	Crosswalk to 81408		Crosswalk to 81161		Gapfill	3	Abstain	
0219U: Infectious agent (human immunodeficiency virus), targeted viral next generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility	Crosswalk: 0008U	1	Gapfill	10	Abstain	1				
0220U: Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score	Gapfill	12	Abstain							
0221U: Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene	Gapfill	12	Abstain							
0222U: Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3	Gapfill	12	Abstain							
802XX: Rufinamide	Crosswalk: 80199	12	Gapfill		Abstain					
80XX1: Salicylate	Crosswalk: 80299	12	Gapfill		Abstain					
80XX2: Amiodarone	Crosswalk: 80155	2	Crosswalk: 80299	10	Gapfill		Abstain			
80XX3: Carbamazepine; 10,11-epoxide	Crosswalk: 80155	7	Crosswalk: 80299	5	Gapfill		Abstain			

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
80XX4: Felbamate	Crosswalk: 80199	6	Crosswalk: 80299	6	Gapfill		Abstain			
80XX5: Flecainide	Crosswalk: 80155	4	Crosswalk: 80299	8	Gapfill		Abstain			
80XX6: Itraconazole	Crosswalk: 80187	12	Gapfill		Abstain					
80XX7: Leflunomide	Crosswalk: 80230	12	Gapfill		Abstain					
80XX8: Methotrexate	Crosswalk: 80230	12	Gapfill		Abstain					
80XXX: Acetaminophen	Crosswalk: 80299	12	Gapfill		Abstain					
81307: PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence	Crosswalk: 81317	10	Gapfill	2	Abstain					
815X3: Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera Type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported	Crosswalk: 87506	12	Gapfill		Abstain					
81XX1: Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])	Gapfill	12	Abstain							
81XX2: Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	Crosswalk: 81545	12	Gapfill		Abstain					
81XX3: Alcohol (ethanol); any specimen except urine and breath, immunoassay (eg, IA, EIA, ELISA, RIA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)	Crosswalk: 83520	12	Gapfill		Abstain					
81XX4: Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis	Crosswalk: 87631	12	Gapfill		Abstain					
81XX6: Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXB1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2	Crosswalk: 81443	10	Crosswalk: 81413 * 2	1	Gapfill	1	Abstain			
82XX1: Estradiol; free, direct measurement (eg, equilibrium dialysis)	Crosswalk to 82670	12	Gapfill		Abstain					

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
86328: Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	Crosswalk: 86794*2.5	3	Crosswalk: 86318*2.5	4	Gapfill	4	Abstain	1		
86769: Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	Crosswalk: 86794*2.5	3	Crosswalk: 86318*2.5	5	Crosswalk: 86710		Gapfill	3	Abstain	1
87635: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	Crosswalk: U0003		Crosswalk: 87502		Crosswalk: 87501	9	Gapfill	2	Abstain	1
8X000: NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis	Crosswalk: 81315	12	Gapfill		Abstain					
8X001: NTRK2 (neurotrophic receptor tyrosine kinase 2) (eg, solid tumors) translocation analysis	Crosswalk: 81315	12	Gapfill		Abstain					
8X002: NTRK3 (neurotrophic receptor tyrosine kinase 3) (eg, solid tumors) translocation analysis	Crosswalk: 81315	12	Gapfill		Abstain					
8X003: TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence	Crosswalk: 81298	11	Gapfill	1	Abstain					
8X004: TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (eg, 4 oncology)	Crosswalk: 81334	12	Gapfill		Abstain					
8X005: TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; known familial variant	Crosswalk: 81299	12	Gapfill		Abstain					
8X006: MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)	Crosswalk: 81120	12	Gapfill		Abstain					
8X007: MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10	Crosswalk: 81310	12	Gapfill		Abstain					
8X008: JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)	Crosswalk: 81272	12	Gapfill		Abstain					
8X009: IGH@/BCL2(t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative	Crosswalk: 81315	11	Gapfill		Abstain					
8X010: CCND1/IGH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed	Crosswalk: 81315	10	Gapfill		Abstain	1				
8X020: NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation analysis	Crosswalk: 81315*2.5	12	Gapfill		Abstain					
8XX00: SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)	Crosswalk: 81120	12	Gapfill		Abstain					
8XX01: SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)	Crosswalk: 81233	12	Gapfill		Abstain					

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting- July 29-30, 2020
Voting Results (v.1- August 7, 2020)

The document reflects voting results from the Medicare Advisory Panel on Clinical Laboratory Test Meeting that occurred on July 29-30, 2020. For more information on the CDLT Panel, please refer to the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests>.
Error/Edit/Correction: Results for code 0145U are corrected.

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Code: Long Descriptor	Option	Votes	Option	Votes	Option	Votes	Option	Votes	Option	Votes
8XX02: U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)	Crosswalk: 81120	12	Gapfill		Abstain					
8XX03: ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)	Crosswalk: 81120	12	Gapfill		Abstain					
U0001: CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	Gapfill	12	Abstain							
U0002: 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	Crosswalk: U0003	1	Crosswalk: 87502	4	Gapfill	7	Abstain			
U0003: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R	Crosswalk: U0003	3	Crosswalk: 87502	2	Crosswalk: 87662*2		Gapfill	7	Abstain	
U0004: 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	Crosswalk: U0004	3	Crosswalk: 87502	2	Gapfill	7	Abstain			