Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT)

Centers for Medicare & Medicaid Services (CMS)
Voting Results and Recommendations
July 31–August 1, 2017*

* Nine voting members attended the meeting on July 31, 2017; ten voting members attended on August 1, 2017.

CPT/HCPCS code	Code Description	Panel Crosswalk/Gapfill Recommendation
New Codes: Molecular Pathology		
81X04	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia) gene analysis; full gene sequence	1: Gapfill 8: 81317
81X05	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia) gene analysis; targeted sequence analysis (eg, exon 12)	0: Gapfill 9: 81218
81X30	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *22)	0: Gapfill 3: 81227 6: 81374 x 2
81X31	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism) gene analysis, common variants (eg, *2, *3, *4, *5 *6, *7)	0: Gapfill 7: 81225 2: 81227
81X32	DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism) gene analysis, common variant(s) (eg, *2A, *4, *5, *6)	0: Gapfill 8: 81227 1: 81321
81X25	F9 (coagulation factor IX) (eg, hemophilia B) full gene sequence	0: Gapfill 6: 81321 3: 81374 x 2
81X37	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; common variant(s) (eg, A, A-)	0: Gapfill 3: 81227 3: 81374 x 2 3: 81215

81X38	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; known familial variant(s)	0: Gapfill 9: 81215
81X40	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; full gene sequence	0: Gapfill 3: 81161 6: 81321
81X58	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant	0: Gapfill 8: 81215 x 2 1: 81235
81X59	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence	1: Gapfill 1: 81235 7: 81321
81X69	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants	0: Gapfill 6: 81294 3: 81376
81X15	Human Platelet Antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-1a/b (L33P)	0: Gapfill 9: 81376
81X16	Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein Ib [platelet], alpha polypeptide [GPIba]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-2a/b (T145M)	0: Gapfill 9: 81376
81X17	Human Platelet Antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex], antigen CD41 [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-3a/b (I843S)	0: Gapfill 9: 81376
81X18	Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-4a/b (R143Q)	0: Gapfill 9: 81376

81X19	Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant (eg, HPA-5a/b (K505E))	0: Gapfill 9: 81376
81X20	Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61] [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-6a/b (R489Q)	0: Gapfill 9: 81376
81X21	Human Platelet Antigen 9 genotyping (HPA-9w), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex, antigen CD41] [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-9a/b (V837M)	0: Gapfill 9: 81376
81X22	Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-15a/b (S682Y)	0: Gapfill 9: 81376
81X23	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)	0: Gapfill 9: 81275
81X24	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)	0: Gapfill 9: 81311
81X33	IFNL3 (interferon, lambda 3) (eg, drug response) gene analysis, rs12979860 variant	0: Gapfill 1: 81374 x 2 8: 81241
813XX	RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy) gene analysis, targeted sequence analysis (eg, exons 3-8)	1: Gapfill 1: 81235 7: 81235 x 2
81X34	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction) gene analysis, common variant(s) (eg, *5)	0: Gapfill 2: 81381 7: 81376

81X35	TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants (eg, *2, *3)	0: Gapfill 5: 81374 x 2 4: 81227
81X36	TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism) gene analysis, common variant(s) (eg, tandem repeat variant)	0: Gapfill 9: 81245
813X1	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)	0: Gapfill 9: 81227
813X2	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)	0: Gapfill 8: 81215 x 2 1: 81275
813X3	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)	0: Gapfill 9: 81294
813X4	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence	1: Gapfill 8: 81235
New Codes; Genomic Sequencing Procedures and Other Molecular Multianalyte Assays		
814X5	Hereditary peripheral neuropathies panel (eg, Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (eg, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, and SPTLC1)	4: Gapfill 4: 81439 1: Either gapfill or 81439
Multianalyte Assays with Algorithmic Analyses		
815XX	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score	1: Gapfill 6: 0008M 1: 87501 1: Recusal

815X2	Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis	2: Gapfill 6: 81519 1: Recusal
81X41	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a disease-specific mortality risk score	5: Gapfill 4: 81519
815X1	Oncology (prostate), promoter methylation profiling by real-time PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a likelihood of prostate cancer detection on repeat biopsy	8: Gapfill 1: 81241
New Codes: Immunology		
8600X	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each	5: Gapfill 1: 86003 x 4 1: 86003 x 5 1: 86157 1: Recusal
86X7X	Zika virus, IgM	0: Gapfill 7: 86788 3: 86356
New Codes: Microbiology		
876XX	Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique	0: Gapfill 2: 87798 8: 87801
87X6X	Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique	0: Gapfill 1: 87798 6: 87501 3: 87502
New Codes: Proprietary Laboratory Analysis		
0001U	Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported	7: Gapfill 3: 81403

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	10: Gapfill
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	8: Gapfill 1: 81539 x 1.25 1: 81539
0004U	Infectious disease (bacterial), DNA, 27 resistance genes, PCR amplification and probe hybridization in microarray format (molecular detection and identification of AmpC, carbapenemase and ESBL coding genes), bacterial culture colonies, report of genes detected or not detected, per isolate	4: Gapfill 2: 87633 2: 87507 2: 87150 x 10
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score	6: Gapfill 4: 81539
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	7: Gapfill 3: G0483
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	6: Gapfill 3: G0480 1: 81265
0008U	Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin	10: Gapfill
0009U	Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin fixed paraffin embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified	9: Gapfill 1: Crosswalk to code for ERBB2 FISH

0010U	Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate	7: Gapfill 1: 87153 + 87900 1: (87153 x 3) + 87900 1: 87153
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	7: Gapfill 3: G0480
0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)	7: Gapfill 1: 81316 2: (81316 x 2) + 81450
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)	8: Gapfill 1: (81316 x 2) +81445 1: 81316
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)	8: Gapfill 1: (81316 x 2) + 81450 1: 81316
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	5: Gapfill 5: 81432
0016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation	1: Gapfill 4: 81206 5: 81206 + (81207 x 0.5)
0017U	Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected	1: Gapfill 7: 81275 2: 81275 + 81276
Other New Codes		
02X1T	Infectious agent detection by nucleic acid (DNA or RNA), Human Papillomavirus (HPV) for five or more separately reported high-risk HPV types (eg, 16,18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (ie, genotyping)	**Withdrawn from consideration**

G0499	Hepatitis B screening in non-pregnant, high risk individual includes hepatitis B surface antigen (HBsAg) followed by a neutralizing confirmatory test for initially reactive results, and antibodies to HBsAg (anti-HBs) and hepatitis B core antigen (anti-HBc)	1: Gapfill 6: 87340; if positive, follow up with 87341 + 86706 + 86704 2: 87340 + 87341 + 86706 + 86704 1: 87340
Reconsidered Codes		
81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis	0: Gapfill 8: 81288 1: 81287 1: Recusal