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
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)
81X30	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *22)
81X31	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism) gene analysis, common variants (eg, *2, *3, *4, *5 *6, *7)
81X32	DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism) gene analysis, common variant(s) (eg, *2A, *4, *5, *6)
81X25	F9 (coagulation factor IX) (eg, hemophilia B) full gene sequence
81X37	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; common variant(s) (eg, A, A-)
81X38	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; known familial variant(s)
81X40	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; full gene sequence
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
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
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

Molecular Pathology (continued)

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)

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)

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)

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)

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))

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)

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)

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)

Molecular Pathology (continued)

81X23 IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)

81X24 IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)

81X33 IFNL3 (interferon, lambda 3) (eg, drug response) gene analysis, rs12979860 variant

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)

81X34 SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction) gene analysis, common variant(s) (eg, *5)

81X35 TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants (eg, *2, *3)

81X36 TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism) gene analysis, common variant(s) (eg, tandem repeat variant)

813X1 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)

813X2 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)

813X3 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)

813X4 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence

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)

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
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
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
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

Immunology

8600X	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
86X7X	Zika virus, IgM

Microbiology

876XX	Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique
87X6X	Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique

Proprietary Laboratory Analyses

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
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

Proprietary Laboratory Analyses (continued)

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
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
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 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
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
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
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
0010U	Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate
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

Proprietary Laboratory Analyses (continued)

0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)
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)
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)
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
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
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

Other

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)
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)

Reconsidered Codes

81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis

Codes That Were New for CY 2017 and with No Private Payor Data

We propose that each of the following laboratory test codes, which were new for calendar year 2017 and, therefore, had no private payor data during the January 1, 2016 through June 30, 2016 data collection period, be priced in accordance with the crosswalk adopted and finalized for the code in 2016. Although we received no private payor data for these codes, we have private payor data for the codes to which these codes were crosswalked. In addition, we received no reconsideration requests for these codes. Therefore, we are proposing to price these codes based on the same crosswalks adopted and finalized in 2016 and the CY2018 CLFS payment rates determined for the codes in the crosswalks.

In addition, CMS has determined that the definitive drug test codes, which we initially thought to be under the reconsideration determination, have actually already been through the reconsideration process, and therefore are not eligible for further reconsideration. However, the presumptive drug tests are included in this category of *Codes That Were New for CY 2017 and with No Private Payor Data*, and have been added to this list of codes to be discussed at the public meeting.

2017 Code	Code Descriptor	Crosswalk Code	Code Descriptor
80305	Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service	G0477	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures, (eg, immunoassay) read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service	G0478	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LCMS/MS, LDTD, MALDI, TOF)	G0479	Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service

2017 Code	Code Descriptor	Crosswalk Code	Code Descriptor
	includes sample validation when performed, per date of service		
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes	80307	Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LCMS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
81413	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A	81435	Hereditary colon cancer disorders (eg, Lynch syndrome PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis 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
81414	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1	81436	Hereditary colon cancer disorders (eg, Lynch syndrome PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood	81436	Hereditary colon cancer disorders (eg, Lynch syndrome PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11

2017 Code	Code Descriptor	Crosswalk Code	Code Descriptor
81439	Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN	81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis 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
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score	0010M	Onc prostate prob score
84410	Testosterone; bioavailable, direct measurement (eg, differential precipitation)	84402 + 84403	Testosterone; free + Testosterone; total
87483	Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes simplex virus type 1 and 2, human herpes virus 6, cytomegalovirus, varicella zoster virus, Cryptococcus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets	87633	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 12-25 targets
G0475	HIV antigen/antibody, combination assay, screening	87389	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result
G0476	Infectious agent detection by nucleic acid (DNA or RNA); human papillomavirus (hpv), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) for cervical cancer screening, must be performed in addition to pap test	87624	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)