Appendix B: Voting Results

Advisory Panel on Clinical Diagnostic Laboratory Tests
Centers for Medicare & Medicaid Services
Wednesday, August 26, 2015

Results of Panelist Voting*

RECOMMENDATION(S)	VOTES	COMMENTS
New Code Crosswalks		
G0464, Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (eg, KRAS, NDRG4 and BMP3)		
Crosswalk to HCPCS codes: 81315, *PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative*; plus 81275, *KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13*; plus 82274, *Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations*	11 (1 abstention)	Maintain 2015 pricing.
80081, Obstetric panel. This panel must include the following: Blood count, complete (CBC), and automated differential WBC count (85025 or 85027 and 85004) OR Blood count, complete (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009) Hepatitis B surface antigen (HBsAg) (87340)HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result (87389)Antibody, rubella (86762) Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART) (86592) Antibody screen, RBC, each serum technique (86850) Blood typing, ABO (86900) AND Blood typing, Rh (D) (86901). (When syphilis screening is performed using a treponemal antibody approach [86780], do not use 800XA. Use the individual codes for the tests performed in the Obstetric panel)		
Crosswalk to HCPCS codes: 85025, *Blood count; complete (CBC), automated (HgB, HCT, RBC, WBC and platelet count) and automated differential WBC count*; plus 87340, *Infectious agent antigen detection by enzyme immunoassay technique, qualitative or*	6	

*Abbreviations: AACC, American Association for Clinical Chemistry; AMP, Association for Molecular Pathology; CAP, College of American Pathologists; CLFS, Clinical Laboratory Fee Schedule; PFS, Physician Fee Schedule

RECOMMENDATION(S)	VOTES	COMMENTS
semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg); plus 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*; plus 86762, *Antibody; rubella*; plus 86592, *Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART)*; plus 86900 (x 2), *Blood typing, serologic; ABO*; plus 86901, *Blood typing, serologic; Rh (D*)		
Crosswalk to HCPCS codes: 85025, *Blood count; complete (CBC), automated (HgB, HCT, RBC, WBC and platelet count) and automated differential WBC count*; plus 87340, *Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg)*; plus 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*; plus 86762, *Antibody; rubella*; plus 86592, *Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART)*; plus 86900, *Blood typing, serologic; ABO*; plus 86901, *Blood typing, serologic; Rh (D*)	3	AACC recommendation
Crosswalk to HCPCS codes: 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*; plus 80055, *Obstetric panel this panel must include the following: blood count, complete (CBC), automated and automated differential WBC count (85025 or 85027 and 85004) or blood count, complete (CBC), automated*	1	
Crosswalk to HCPCS codes 86900 (x 2), *Blood typing, serologic; ABO*; plus 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*; plus	1	

RECOMMENDATION(S)	VOTES	COMMENTS
80055, *Obstetric panel this panel must include the following: blood count, complete (CBC), automated and automated differential WBC count (85025 or 85027 and 85004) or blood count, complete (CBC), automated*		
Gapfill	1	
G0472, Hepatitis C antibody screening, for individual at high risk and other covered indication(s)		
Crosswalk to HCPCS code 86803, *Hepatitis C antibody*	12	As recommended at the annual public meeting
81162, BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis		
Crosswalk to HCPCS codes: 81211, *BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon*; plus 81213, *BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants*	7	
Gapfill	3	Change in technology from 81211, move interpretation to PFS, variants maintain bioinformatics component for sequence algorithm, etc. Delete/inactivate 81211 and 81213 after gapfill and change to PFS.
Crosswalk to HCPCS codes: 81213, *BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants*; plus 81292, *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*; plus 87901, *Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions*	1	Use AMP/ CAP approach used in proposal for 81433 based on gene sizes.

RECOMMENDATION(S)	VOTES	COMMENTS
Crosswalk to HCPCS code: 81292, *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*; plus PFS interpretation code	1	CLFS does not cover physician decision-making.
81170, ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain		
Crosswalk to HCPCS code: 81235, *EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)*	12	
81218, CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence		
Crosswalk to HCPCS code: 81235, *EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)*	12	
81219, CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9		
Crosswalk to HCPCS code: 81245, *FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)*	12	
81272, KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18)		
Crosswalk to HCPCS code: 81235, *EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)*	12	
81273, KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s)		
Crosswalk to HCPCS code: 81210, *BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene*	12	

RECOMMENDATION(S)	VOTES	COMMENTS
analysis, v600e variant		
81276, KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)		
Crosswalk to HCPCS code: 81275, *KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13*	12	
81311, NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)		
Crosswalk to HCPCS code: 81275 (x 1.5), *KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13*	12	
81314, PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18)		
Crosswalk to HCPCS code: 81235, *EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)*	12	
81412, Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1		
Gapfill	6	
Crosswalk to HCPCS codes: 81292 (x 2.2), *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*; plus 87901 (x 2.2), *Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions*	5	
Crosswalk to HCPCS codes: 81200, *APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence*; plus 81209, *BLM (bloom syndrome, recq helicase-like) (eg, bloom syndrome) gene analysis,*	1	Individual components of test

RECOMMENDATION(S)	VOTES	COMMENTS
2281del6ins7 variant; plus 81220, *CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, acmg/acog guidelines)*; plus 81242, *FANCC (Fanconi anemia, complementation group C) (eg, Fanconi anemia, type C) gene analysis, common variant (eg, ivs4+4a>t)*; plus 81255, *Hexa (hexosaminidase A [alpha polypeptide]) (eg, Tay-Sachs disease) gene analysis, common variants (eg, 1278instatc, 1421+1g>c, g269s)*; plus 81260, *IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein) (eg, familial dysautonomia) gene analysis, common variants (eg, 2507+6t>c, r696p)*; plus 81290, *MCOLN1 (mucolipin 1) (eg, mucolipidosis, type iv) gene analysis, common variants (eg, ivs3-2a>g, del6.4kb)*; plus 81330, *SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, type A) gene analysis, common variants (eg, r496l, l302p, fsp330)*		
81432, Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53		
Crosswalk to HCPCS codes: 81292 (x 2.6), *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*; plus 87901 (x 2.6), *Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions*	7	AMP recommendation
Gapfill	5	
81433, Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11		
Gapfill	6	
Crosswalk to HCPCS codes: 81292 (x 1.6), *MLH1 (mutl homolog 1, colon*	6	AMP recommendation

RECOMMENDATION(S)	VOTES	COMMENTS
cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis; plus 87901 (x 1.6), *Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions*		
81434, Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A		
Gapfill	6	
Crosswalk to HCPCS codes: 81292 (x 2.7), *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*; plus 87901 (x 2.7), *Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions*	6	AMP recommendation
81437, Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma; genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL		
Gapfill	6	
Crosswalk to HCPCS codes: 81292 (x 1.8), *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*; plus 87901 (x 1.8), *Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions*	6	AMP recommendation
81438, Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma; duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL		
Gapfill	6	
Crosswalk to HCPCS codes: 81292 (x 1.4), *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*; plus 87901 (x 1.4), *Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions*	6	AMP recommendation

RECOMMENDATION(S)	VOTES	COMMENTS
81442, Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1		
Gapfill	6	
Crosswalk to HCPCS codes: 81292 (x 2.5), *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*; plus 87901 (x 2.5), *Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions*	6	AMP recommendation
81490, Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score		
Gapfill	9	2 votes for specific contractor price
Crosswalk to HCPCS code: 83520 (x 12), *Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified*	3	
81493, Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score		
Gapfill	12	
81525, Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score		
Gapfill	11	1 vote for specific contractor price
Crosswalk to HCPCS codes: 81292, *MLH1 (mutl homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis*	1	
81528, Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result		
Crosswalk to HCPCS code: G0464, *Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS,*	11	

RECOMMENDATION(S)	VOTES	COMMENTS
NDRG4 AND BMP3)		
Gapfill	1	
81535, Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination		
Gapfill	11 (1 absten-tion)	
81536, Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)		
Gapfill	11 (1 absten-tion)	
81538, Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival		
Gapfill	11	
Crosswalk to HCPCS code: 83789, *Mass spectrometry and tandem mass spectrometry (MS, MS/MS), analyte not elsewhere specified; quantitative, each specimen*	1	
81540, Oncology (tumor of unknown origin), mRNA, gene expression profiling by real- time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype		
Gapfill	12	
81545, Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)		
Gapfill	12	
81595, Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score		
Gapfill	12	
0009M Fetal aneuploidy (trisomy 21, and 18) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy		
Gapfill	12	
0010M, Oncology (High-Grade Prostate Cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA and human kallikrein 2 [hK2]) plus patient age, digital rectal examination status, and no history of positive prostate biopsy, utilizing plasma, prognostic algorithm reported as a probability score		

RECOMMENDATION(S)	VOTES	COMMENTS
Gapfill	10	
Crosswalk to HCPCS codes: 84153 (x 2) 84154 83520	1	
Crosswalk to HCPCS codes: 84153 84154 (x 2) 83520	1	
Drug Testing Structure		
CMS: Single Code for Presumptive Testing		
Assign two codes for presumptive testing.	12	
Descriptors for Codes for Presumptive Testing		
GXXX1: *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 including instrumented-assisted when performed (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service* GXXX2: *Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service*	12	
Pricing for Presumptive Testing Codes		
GXXX1: Crosswalk to HCPCS code G0434, *Drug screen, other than chromatographic; any number of drug classes, by clia waived test or moderate complexity test, per patient encounter* GXXX2: Crosswalk to HCPCS code G0431, *Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter*	12	
Structure and Pricing for Definitive Testing		

RECOMMENDATION(S)	VOTES	COMMENTS
Adopt AMA CPT codes; pay by tier using CMS software for tiering: Tier 1: 1–7 tests: Crosswalk to HCPCS code 82542, pay for each test separately Tier 2: 8–15 tests: Crosswalk to HCPCS code 82542 x 8 Tier 3: 16–34 tests: Crosswalk to HCPCS code 82542 x 10 Tier 4: 35+ tests: Crosswalk to HCPCS code 82542 x 12	8	
Adopt AMA CPT codes; pay by tier using CMS software for tiering: Tier 1: 1–7 tests: Crosswalk to HCPCS code G6058, pay for each test separately Tier 2: 8–15 tests: Crosswalk to HCPCS code G6058 x 8 Tier 3: 16–34 tests: Crosswalk to HCPCS code G6058 x 10 Tier 4: 35+ tests: Crosswalk to HCPCS code G6058 x 12	1	
Use tiered approach based on drug classes: Tier 1: 1–2 tests: Crosswalk to HCPCS code 82542, pay for each test separately Tier 2: 3–7 tests: Crosswalk to HCPCS code 82542 x 5 Tier 3: 8–15 tests: Crosswalk to HCPCS code 82542 x 11.5 Tier 4: 16–34 tests: Crosswalk to HCPCS code 82542 and adjust for economy of scale Tier 5: 35+ tests: Adjust for economy of scale	1	
Abstention	2	Consider class-based gap-filled grouping of parent and metabolites.
Temporary Structure and Pricing for Definitive Testing (if CMS Cannot Implement New Structure by January 1, 2016).		
Use current coding system.	N/A	Discussion without vote.
Create G codes that match the permanent tiers using the same crosswalks.	N/A	Discussion without vote.