ADVISORY PANEL ON CLINICAL DIAGNOSTIC LABORATORY TESTS (CDLT)
Voting Results and Recommendations as recorded from written ballots
October 19, 2015

Session 1 Panel Recommendations: Codes

1. The Panel recommends that CMS maintain the three-code structure for presumptive testing. (Unanimous approval)
2. The Panel recommends that the descriptors for the three presumptive drug testing codes be modified to add the word "qualitative" plus a semi-colon after the phrase "any number of drug classes." (Unanimous approval)
3. The Panel recommends that the descriptor for GXXX3 be modified to add a parenthesis and the abbreviation "eg" after the word "analyzers." (Unanimous approval)
4. The Panel recommends that CMS maintain the proposed four-level structure for definitive drug testing and revise the number of tests in the descriptors as follows:
   HCPCS code GYYY1: 1–7 (same as proposed)
   HCPCS code GYYY2: 8–14 (same as proposed)
   HCPCS code GYYY3: 15–21
   HCPCS code GYYY4: 22 or more
   (Unanimous approval)
5. The Panel recommends that CMS develop formal guidance to clarify the definition of drug classes based on the AMA CPT Manual's drug class table. (Unanimous approval)

*In the table below, Panel Recommendations are represented by the number of votes followed by the vote itself. For example, 10: 3X 82305 would indicate 10 voters recommended a crosswalk of 3 times CPT code 82305. Text in bold indicates the Panel recommendation was consistent to that of CMS' Preliminary Recommendation.

Code	Code Description	CMS Preliminary Recommendation	*Panel Crosswalk/Gapfill Recommendation
Drug 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 only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.	0.5 x G0434	10: 0.75 x G0434 1: 1 x G0434 1: need to re-evaluate both .5 and .75 as modifier

GXXX2	Drug tests(s), presumptive, any number of drug classes; 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.	G0434	**12: G0434**
GXXX3	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.	3 x G0434	7: 5 x G0434 2: 4 x G0434 **1: 3 x G0434** 1: Abstain 1: Disagree but no specific recommendation
GYYY1	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 and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.	2 x 82542 + 5 x 82542 x 0.10	1: 2 x 82542 + 5 x 82542 x 0.3 1: 5 x 82542 1: 2.5 x 82542 3: 4 x 82542 1: 2 x 82542+5 x 82542 x 0.25 4: 4 x 82542 + 3 x (0.25 x 82542) 1: 3 x 82542 + 4x (0.1 x 82542)
GYYY2	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 and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.	2 x 82542 + 12 x 82542 x 0.10	8: 8 x 82542 1: 6.5 x 82542 1: 2 x 82542 + 12 x 82542 x 0.25 1: 82542 x 7.25 1: 2 x 82542 + 12 x 82542 x 0.3
GYYY3	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 and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 15-34 drug class(es), including metabolite(s) if performed.	2 x 82542 + 32 x 82542 x 0.10	8: 82542 x 10 1: 2 x 82542 + (X)82542 x 0.25 1: 2 x 82542 + 16 x 82542 x 0.25 1: 82542 x 7.5 1: 82542 x 9

GYYY4	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 and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 35 or more drug class(es), including metabolite(s) if performed.	2 x 82542 + 48 x 82542 x 0.10	9: 82542 x 8 + 82542 x 16 x 0.25 1: 2 x 82542 + (X)82542 x 0.25 1: 2 x 82542 + 24 x 82542 x 0.25 1: 82542 x 9

Code	Code Description	CMS Preliminary Recommendation	Panel Crosswalk/Gapfill Recommendation
Other Codes			
G0464	Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3)	Delete code	**12: Delete code**
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.)	85025 + 87340 + 87389 + 86762 + 86592 + 86850 + 86900	1: 85025+87340+86762+86592+86900+86901+86902 11: 85025+87340+86762+86592+86900+86901

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 (85027) and appropriate manual differential WBC count (85007 or 85009) Hepatitis B surface antigen (HBsAg) (87340) 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 80055. Use the individual codes for the tests performed in the Obstetric panel	80055 – 87389	9: 85025 + 87340 + 86762 + 86592 + 86850 + 86900 +86901 1: 85025 + 87340 + 87389 + 86762 + 86592 + 86850 + 86900 +86901. 1: 85025 + (85007 or 85009) + 86762+ 86592 + 86850 + 86900 +86901 1: 85025 + 87340 + 86762 + 86592 + 86900 +86901 +86902.
86850	Antibody screen, RBC, each serum technique	86902	**11: 86902** 1: Abstain
G0472	Hepatitis c antibody screening, for individual at high risk and other covered indication(s)	86803	**12: 86803**
81162	BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis	0.9*81211 + 0.9*81213	**10: 0.9*81211 + 0.9*81213** 2: 81211 + 81213
81170	ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain	81235	**12: 81235**
81218	CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence	81235	**12: 81235**
81219	CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9	81245	**12: 81245**

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)	81235	**12: 81235**
81273	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s)	81270	11: 81210 **1:81270**
81276	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)	81275	**12: 81275**
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)	1.5 x 81275	**12: 1.5 x 81275**
81314	PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18)	81245	12: 81235
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	**12: Gapfill**
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	Gapfill	**10: Gapfill** 2: 2.6 x 81292 + 2.6 x 87901
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	**10: Gapfill** 2: 1.6 x 81292 + 1.6 x 87901

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	**10: Gapfill** 2: 2.7 x 81292 + 2.7 x 87901
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	**10: Gapfill** 2: 1.8 x 81292 + 1.8 x 87901
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	**10: Gapfill** 2: 1.4 x 81292 + 1.4 x 87901
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	**10: Gapfill** 2: 2.5 x 81292 + 2.5 x 87901
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score	12 x 83520	**2: 12 x 83520** 10: Gapfill
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	81292	**1: 81292** 11: Gapfill
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	81292	12: Gapfill

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	81315 + 81275 + 82274	**12: 81315 + 81275 + 82274**
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	87903	6: Gapfill 1: Abstain **5: 87903**
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)	87904	6: Gapfill 1: Abstain **5: 87904**
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival	8 x 83789	**3: 8 x 83789** 9: Gapfill
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	81214	12: Gapfill
81545	Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	1.5 x 81214	12: Gapfill
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	81292	12: Gapfill
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: Gapfill**

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	Gapfill	**9: Gapfill** 1: Crosswalk to immunoassay CPT codes (non-specified) 2: 84153 x 2 + 84154 + 83520

Session 2 Panel Recommendations: Advanced Diagnostic Laboratory Tests (ADLTs)

1. The Panel recommends that CMS revise its definition of ADLTs so that it does not require RNA or DNA biomarkers at a minimum. The definition should reflect the statutory language indicating that "a test is an analysis of multiple biomarkers of DNA, RNA, or proteins..."

2. The Panel recommends that CMS revise its definition of a "unique algorithm" under criterion A to reflect the statutory language and modify the numbering to be consistent with the changes. (Unanimous approval)

    NRPM:
    (1) The test—
    (i) Must be a molecular pathology analysis of multiple biomarkers of deoxyribonucleic acid (DNA), or ribonucleic acid (RNA);
    (ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies);
    (iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
    (iv) May include other assays.

    Panel Recommendation
    (1) The test—
    (i) Must be a molecular pathology analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;
    (ii) combined with a unique algorithm to yield a single patient-specific result; and
    (iii) May include other assays**.**