

Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Final Determinations

A. Drug Testing

Current coding for testing for drugs of abuse relies on a structure of “screening” (known as “presumptive” testing) followed by “confirmation” to confirm the results of the screening tests and quantitative or “definitive” testing that identifies the specific drug and quantity in the patient. In the 2015 CLFS final determinations file, we decided to not pay for new Current Procedural Terminology (CPT) codes for drugs of abuse testing. We stated our concern about the potential for overpayment when billing for each individual drug test rather than a single code that pays the same amount regardless of the number of drugs that are being tested. Therefore, we delayed pricing for these codes to allow additional time to study the issue. However, we agreed with commenters that this policy would leave insufficient codes available to bill for drugs of abuse testing. For that reason, we maintained the 2014 status quo for 2015 by creating alphanumeric G codes to replace the 2014 CPT codes that were deleted for 2015. For 2015, providers are using these G codes in the same manner in which they used the corresponding CPT codes for 2014.

In addition, for some of the drugs of abuse testing codes, the American Medical Association (AMA) CPT did not delete the 2014 code numbers, but revised the instructions or code descriptors in the 2015 CPT Manual. Following these instructions would have left providers without billing options. Thus, we also instructed the public to use these G codes exactly as they used them for 2014, regardless of the 2015 instruction or code descriptor changes.

In July 2015, we proposed to delete all current drug testing G codes, continue to not recognize the new AMA CPT codes, and create a single G code for presumptive testing and a single G code for definitive testing. We received written public comments in response to our proposal as well as comment and discussion at the Annual Laboratory Public Meeting and the Advisory Panel on Clinical Diagnostic Laboratory Tests (the CDLT Advisory Panel).

In September 2015, we released the 2016 CLFS Preliminary Determinations file and again proposed to delete all current drug testing G codes and continue to not recognize the new AMA CPT codes for drug testing. We modified our original recommendations and proposed to create three G codes for presumptive testing and four G codes for definitive testing. After further consideration of public comments on this issue, we are implementing the following changes for drug testing for Calendar Year (CY) 2016:

1. Delete the following G-codes:
 - a. G0431, G0434
 - b. HCPCS codes G6030 through G6058
2. Continue to not recognize the AMA CPT codes 80300 – 80377
3. For presumptive testing, create three G codes. Only one of the three presumptive G codes

may be billed per day.

4. For definitive testing, create four G codes. Only one of the four definitive G codes may be billed per day.
5. For definitive testing, the unit used to determine the appropriate definitive G code to bill is “drug class.”
6. Each drug class may only be used once per day in determining the appropriate definitive G code to bill.
7. Drug classes are listed below and are consistent with their usage in the AMA CPT Manual. The AMA CPT Manual may be consulted for examples of individual drugs within each class

- Alcohol(s)
- Alcohol Biomarkers
- Alkaloids, not otherwise Specified
- Amphetamines
- Anabolic steroids
- Analgesics, non-opioid
- Antidepressants, serotonergic class
- Antidepressants, Tricyclic and other cyclicals
- Antidepressants, not otherwise specified
- Antiepileptics, not otherwise specified
- Antipsychotics, not otherwise specified
- Barbiturates
- Benzodiazepines
- Buprenorphine
- Cannabinoids, natural
- Cannabinoids, synthetic
- Cocaine
- Fentanyls
- Gabapentin, non-blood
- Heroin metabolite
- Ketamine and Norketamine
- Methadone
- Methylenedioxyamphetamines
- Methylphenidate
- Opiates
- Opioids and opiate analogs
- Oxycodone
- Phencyclidine
- Pregabalin
- Propoxyphene
- Sedative Hypnotics (nonbenzodiazepines)
- Skeletal muscle relaxants
- Stereoisomer (enantiomer) analysis
- Stimulants, synthetic
- Tapentadol
- Tramadol
- Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified;

Presumptive Drug Testing

Code: G0477 *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.*

Commenter Recommendations: Public recommendations were divided with the majority favoring 3 presumptive codes rather than the CDLT Advisory Panel's first recommendation of 2 codes. For those recommending 3 codes, the comments were split between pricing at 1 TIMES G0434 and 0.75 TIMES G0434.

Panel Recommendation: The majority of the CDLT Advisory Panel recommended 0.75 TIMES G0434.

CMS Decision: Crosswalk to 0.75 TIMES G0434

Rationale: CMS agrees with the majority of the CDLT Advisory Panel that 0.75 TIMES G0434 is an appropriate crosswalk to G0477.

Code: G0478 *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.*

Commenter Recommendations: Crosswalk to G0434

Panel Recommendation: Crosswalk to G0434

CMS Decision: Crosswalk to G0434.

Rationale: CMS agrees with the commenters and the unanimous vote by the CDLT Advisory Panel recommending the crosswalk to code G0434, based on similarities in function of this test with the components of the new test.

Code: G0479 *Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers (eg, immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service.*

Commenter Recommendations: The public commenters were split between pricing this code at 7 TIMES G0434 to 4 TIMES G0434.

Panel Recommendation: The panel did not have a consensus and had recommendation with multiples from 3 to 5

CMS Decision: Crosswalk to 4 TIMES G0434.

Rationale: G0434 is typically used to test for 10-15 drugs. The more sophisticated machines that would be used to do drug testing under G0479 can perform 2-4 TIMES that number of tests. We believe crosswalking to 4 TIMES the current code appropriately recognizes the resources involved in the typical testing done using G0479. CMS agrees with recommendations by some CDLT Advisory Panel members and one coalition of laboratories that performs drug and other laboratory testing which recommended 4 TIMES code G0434 as the appropriate crosswalk for this test.

Definitive Drug Testing

Code: G0480 *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, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.*

Commenter Recommendations: We received public comment recommending that we use the CPT codes for definitive testing. Many public commenters continued to recommend that CMS allow billing of the first seven tests individually with 82452 as the crosswalk. A coalition of drug testing laboratories recommended crosswalking to 7 TIMES 82542. Another coalition of laboratories that does drug and other laboratory testing recommended 7 TIMES 82542 or, as an alternative, 4.5 TIMES 82542.

Panel Recommendation: Seven differing crosswalks were recommended by the panelists ranging from 2 to 5 TIMES 82542. Several used formulas similar to the one used in the CLFS Preliminary Determinations but changed the marginal increase for each additional drug class tested from 10% increase to 25%.

CMS Decision: 2 TIMES 82542 PLUS (5 TIMES 82542 TIMES 0.25) or 3.25 TIMES 82542.

Rationale: Most commenters arrived at their recommended prices for the definitive codes by proposing a formula using a specified number of base codes plus 25% of a specified additional number of tests—either one or two more than the base number of tests in that code. We continue to agree with the formulaic recommendation but with a differing number of base codes at full price plus the maximum number of tests within that code at 25%. Therefore, CMS will use the formula we proposed in our preliminary determinations and substitute 25% for 10%. As previously, for G0480, G0481, & G0482, the multiplier will be the maximum number of tests in

the code descriptor. Two will be at 100% and the remainder at the 25% increment. Thus, we will crosswalk G0480 to 2 TIMES 82542 PLUS 5 TIMES 82542 TIMES 25%.

Code: G0481 *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, includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.*

Commenter Recommendations: Crosswalk to 82542 TIMES 8 or 82542 TIMES 9.

Panel Recommendation: The majority of panel members recommended a crosswalk to 82542 TIMES 8 while others recommended 82542 TIME between 5 and 7.25.

CMS Decision: 2 TIMES 82542 PLUS (82542 TIMES 12 TIMES 0.25) or 5 TIMES 82542.

Rationale: We will use the formula we proposed in our preliminary determinations and substitute 25% for 10%. We will crosswalk G0481 to 2 TIMES 82542 PLUS 12 TIMES 82542 TIMES 25% which effectively result in G0481 being crosswalked to 5 TIMES 82542 consistent with the recommendation of one panelist.

Code: G0482 *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, includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed.)*

Commenter Recommendations: Crosswalk to 82542 TIMES 8 PLUS 82542 TIMES 8 TIMES 0.25 or 82542 TIMES 10. Another commenter recommended a crosswalk to 82542 TIMES 11.

Panel Recommendation: The majority of panel members recommended a crosswalk to 82542 TIMES 8 PLUS 82542 TIMES 8 TIMES 0.25 or 12 TIMES 82542. Other panel members recommended crosswalks to either 8 or 9 TIMES 82542.

CMS Decision: 2 TIMES 82542 PLUS (82542 TIMES 19 TIMES 0.25) or 6.75 TIMES 82542.

Rationale: We will use the formula we proposed in our preliminary determinations and substitute 25% for 10%. The change in the minimum number of tests in this code requires us to select a different multiplier. We will again choose the maximum number of tests in this code, 21, as the multiplier. We will crosswalk G0482 to 2 TIMES 82542 PLUS 19 TIMES 82542 TIMES 25% or 6.75 TIMES 82542.

Code: G0483 *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, includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed.*

Commenter Recommendations: Crosswalk to 82542 TIMES 8 PLUS (82542 TIMES 16 TIMES 0.25) or 82542 TIMES 12. Others recommended 82542 TIMES 13.

Panel Recommendation: The majority of panel members recommended a crosswalk to 82542 TIMES 8 PLUS (82542 TIMES 16 TIMES 0.25) or 12 TIMES 82542. Other panelists recommended 8 or 9 TIMES 82542.

CMS Decision: 2 TIMES 82542 PLUS (82542 TIMES 27 TIMES 0.25) or 8.75 TIMES 82542.

Rationale: We will use the formula we proposed in our preliminary determinations and substitute 25% for 10%. The change in the minimum number of tests in this code requires us to select a different multiplier. Since there will potentially be a maximum number of drug classes of 36, we are selecting a multiplier midway between 22 & 36 = 29. We will crosswalk G0483 to 2 TIMES 82542 PLUS 27 TIMES 82542 TIMES 25% or 8.75 TIMES 82542.

B. Other New and Reconsidered Test Codes

Reconsidered Code: G0464 (*Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3)*)

Commenter Recommendations: Delete this code.

Panel Recommendation: Delete this code.

CMS Decision: Delete this code.

Rationale: This code has been replaced with code 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.

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 80081. Use the individual codes for the tests performed in the Obstetric panel)*)

Commenter Recommendations: Crosswalk to codes 85025: Blood count, complete (CBC), and automated differential WBC count, PLUS 87340: Hepatitis B surface antigen (HBsAg), PLUS 87389: 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, PLUS 86850: Antibody screen, RBC, each serum technique, PLUS 86900: Blood typing, ABO, PLUS 86901: Blood typing, Rh (D); OR

Crosswalk to codes 80055, PLUS 87389: HIV code HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result

NOTE: These recommendations reflect earlier recommendations. We did not receive new comments.

Panel Recommendation: Crosswalk to codes 85025: Blood count, complete (CBC), and automated differential WBC count, PLUS 87340: Hepatitis B surface antigen (HBsAg), PLUS PLUS 86762: Antibody, rubella, PLUS 86592: Syphilis test, non-treponemal antibody; qualitative, PLUS 86900: Blood typing, ABO, PLUS 86901: Blood typing, Rh (D) (majority)

CMS Decision: Crosswalk to codes 85025 PLUS 87340 PLUS 87389 PLUS 86762 PLUS 86592 PLUS 86850 PLUS 86900 PLUS 86901.

Rationale: CPT code 80081 includes a test, 86850 that is not priced on the CLFS and has one recommended crosswalk to 80055 that is also not priced on the CLFS. We are adopting the Panel's recommendation for 80081.

Code: 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)*)

Commenter Recommendations: Not discussed at Clinical Diagnostic Laboratory Tests Panel Meeting

Panel Recommendation: 85025 PLUS 87340 PLUS 86762 PLUS 86592 PLUS 86850 PLUS 86900 PLUS 86901 (majority)

CMS Decision: 85025 PLUS 87340 PLUS 86762 PLUS 86592 PLUS 86850 PLUS 86900 PLUS 86901

Rationale: CMS agrees with the majority recommendations by the Clinical Diagnostic Laboratory Tests Panel.

Code: 86850 (*Antibody screen, RBC, each serum technique*)

Commenter Recommendations: Not discussed CDLT Advisory Panel Meeting

Panel Recommendation: Crosswalk to 86902 (unanimous with one abstention).

CMS Decision: Crosswalk to 86902: Blood typing, serologic; antigen testing of donor blood using reagent serum, each antigen test.

Rationale: CMS agrees with the unanimous recommendation by the CDLT Advisory Panel.

Code: G0472 (*Hepatitis c antibody screening, for individual at high risk and other covered indication(s)*)

Commenter Recommendations: Crosswalk to code 86803: Hepatitis C antibody

Panel Recommendation: Crosswalk to code 86803: Hepatitis C antibody (unanimous)

CMS Decision: Crosswalk to code 86803.

Rationale: CMS agrees with the commenters and the CDLT Advisory Panel recommending the crosswalk to code 86803, based on similarities in function of this test with the components of the new test.

Code: 81162 (*BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis*)

Commenter Recommendations: Crosswalk to 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 (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb), PLUS 81213: BRCA1, BRCA2; uncommon duplication/deletion variants; OR

Gapfill

Panel Recommendation: Crosswalk to 0.90 TIMES code 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 (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb), PLUS 0.90 TIMES 81213: BRCA1, BRCA2; uncommon duplication/deletion variants (majority). Two panelists recommended crosswalk to the 82111 PLUS 81213.

CMS Decision: Crosswalk to code 81211 TIMES 0.90 PLUS 0.90 TIMES 81213.

Rationale: CMS agrees with the commenters and the majority of the CDLT Advisory Panel recommending the crosswalk to codes 0.90 TIMES 81211 PLUS 0.90 TIMES 81213, based on similarities in function of this test with the components of the new test.

Code: 81170 (*ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain*)

Commenter Recommendations: Crosswalk to 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)

NOTE: This reflects earlier comments received. No new comments received.

Panel Recommendation: Crosswalk to 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) (unanimous).

CMS Decision: Crosswalk to code 81235.

Rationale: CMS agrees with the commenters and the unanimous vote by the CDLT Advisory Panel recommending the crosswalk to code 81235, based on similarities in function of this test with the components of the new test.

Code: 81218 (*CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence*)

Commenter Recommendations: Crosswalk to 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)

NOTE: This reflects earlier comments received. No new comments received.

Panel Recommendation: Crosswalk to 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) (unanimous).

CMS Decision: Crosswalk to code 81235.

Rationale: CMS agrees with the commenters and the unanimous vote by the CDLT Advisory Panel recommending the crosswalk to code 81235, based on similarities in function of this test with the components of the new test.

Code: 81219 (*CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9*)

Commenter Recommendations: Crosswalk to code 81245: FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis, internal tandem duplication (ITD) variants (ie, exons 14, 15)

NOTE: This reflects earlier comments received. No new comments received.

Panel Recommendation: Crosswalk to code 81245: FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis, internal tandem duplication (ITD) variants (i.e., exons 14, 15) (unanimous)

CMS Decision: Crosswalk to code 81245.

Rationale: CMS agrees with the commenters and the unanimous vote by CDLT Advisory Panel recommending the crosswalk to code 81245, based on similarities in function of this test with the components of the new test.

Code: 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)*)

Commenter Recommendations: Crosswalk to 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)

Panel Recommendation: Crosswalk to 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) (unanimous)

CMS Decision: Crosswalk to code 81235.

Rationale: CMS agrees with the commenters and the unanimous vote by the CDLT Advisory Panel recommending the crosswalk to code 81235, based on similarities in function of this test with the components of the new test.

Code: 81273 (*KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog)* (eg, mastocytosis), gene analysis, D816 variant(s))

Commenter Recommendations: Crosswalk to code 81210: BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant; OR

Crosswalk to code 81270: Jak2 gene

NOTE: This reflects earlier comments received.

Panel Recommendation: Crosswalk to code 81210: BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant (majority). One panel recommended a crosswalk to 81270.

CMS Decision: Crosswalk to code 81270.

Rationale: CMS agrees with the minority recommendation of crosswalking to code 81270, based on similarities in function of this test with the components of the new test.

Code: 81276 (*KRAS (Kirsten rat sarcoma viral oncogene homolog)* (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146))

Commenter Recommendations: Crosswalk to code 81275: KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis; variants in codons 12 and 13

NOTE: This reflects earlier comments received. No new comments received.

Panel Recommendation: Crosswalk to code 81275: KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis; variants in codons 12 and 13 (unanimous)

CMS Decision: Crosswalk to code 81275.

Rationale: CMS agrees with the commenters and the unanimous vote by the CDLT Advisory Panel recommending the crosswalk to code 81275, based on similarities in function of this test

with the components of the new test.

Code: 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)*)

Commenter Recommendations: Crosswalk to 1.50 TIMES code 81275: KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis; variants in codons 12 and 13;
OR

Crosswalk to 2 TIMES code 81275: KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis; variants in codons 12 and 13

NOTE: This reflects earlier comments received. No new comments received.

Panel Recommendation: Crosswalk to 1.50 TIMES code 81275: KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis; variants in codons 12 and 13 (unanimous)

CMS Decision: Crosswalk to 1.50 TIMES code 81275.

Rationale: CMS agrees with the majority of commenters and the unanimous vote by the CDLT Advisory Panel recommending the crosswalk to code 81275 TIMES 1.50, based on similarities in function of this test with the components of the new test.

Code: 81314 (*PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18)*)

Commenter Recommendations: Crosswalk to 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)

Panel Recommendation: Crosswalk to 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) (unanimous)

CMS Decision: Crosswalk to 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)

Rationale: CMS agrees with the majority of commenters and the unanimous vote by the CDLT Advisory Panel recommending the crosswalk to code 81235, based on similarities in function of this test with the components of the new test.

Code: 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*)

Commenter Recommendations: Gapfill; OR

Crosswalk to 2.20 TIMES 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 2.20 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

Panel Recommendation: Gapfill (unanimous)

CMS Decision: Gapfill.

Rationale: CMS agrees with the unanimous gapfill recommendation by the CDLT Advisory Panel, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: Gapfill; OR

Two members recommended a crosswalk to 2.60 TIMES 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 2.60 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

Panel Recommendation: Gapfill (Majority); OR

Two members recommended a crosswalk to 2.60 TIMES 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 2.60 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and

protease regions

CMS Decision: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 81432, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: Gapfill; OR

Crosswalk to 1.60 TIMES 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 1.60 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

Panel Recommendation: Gapfill (Majority); OR

Two members recommended a crosswalk to 1.60 TIMES 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 1.60 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

CMS Decision: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 81433, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: Gapfill; OR

Crosswalk to 2.70 TIMES 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 2.70 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

Panel Recommendation: Gapfill (Majority); OR

Two members recommended crosswalk to 2.70 TIMES 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 2.70 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

CMS Decision: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 81434, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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)*)

Commenter Recommendations: Gapfill; OR

Crosswalk to 1.80 TIMES 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 1.80 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

Panel Recommendation: Gapfill (Majority); OR

Two members recommended a crosswalk to 1.80 TIMES 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 1.80 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

CMS Decision: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill

code 81437, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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)*)

Commenter Recommendations: Gapfill; OR

Two members recommended a crosswalk to 1.40 TIMES 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 1.40 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

Panel Recommendation: Gapfill; OR

Crosswalk to 1.40 TIMES 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 1.40 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

CMS Decision: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 81438, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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)*)

Commenter Recommendations: Gapfill; OR

Crosswalk to 2.50 TIMES 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 2.50 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

Panel Recommendation: Gapfill; OR

Two members recommended a crosswalk to 2.50 TIMES 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 2.50 TIMES code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

CMS Decision: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 81442, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 81490 (*Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score*)

Commenter Recommendations: Gapfill

Panel Recommendation: Gapfill. OR

Two members recommended a crosswalk to 12 TIMES 83520.

CMS Decision: Gapfill

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 81490, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: Gapfill

Panel Recommendation: Gapfill OR

One member recommended a crosswalk to 81292.

CMS Decision: Gapfill

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill

code 81493 since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: Gapfill (unanimous)

Panel Recommendation: Gapfill.

CMS Decision: Gapfill

Rationale: CMS agrees with the unanimous CDLT Advisory Panel recommendation to gapfill code 81525, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: Crosswalk to G0464: Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3) (Calendar Year 2015 formula, which is crosswalk to codes 81315: Pml/raralpha com breakpoints, PLUS 81275: Kras gene, PLUS 82274: Assay test for blood fecal; OR

Crosswalk to 81275: Kras gene, PLUS 82274: Assay test for blood fecal PLUS 81288: promotor methylation analysis

Panel Recommendation: Crosswalk to G0464: Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3) (Calendar Year 2015 formula, which is crosswalk to codes 81315: Pml/raralpha com breakpoints, PLUS 81275: Kras gene, PLUS 82274: Assay test for blood fecal. (unanimous)

CMS Decision: Crosswalk to codes 81315 PLUS 81275 PLUS 82274.

Rationale: We believe that the 2015 pricing of code G0464 is the correct reimbursement rate, and this molecular pathology test is replacing that code. Commenters recommended other formulas. While we appreciate the view of commenters suggesting that payment of this test should be based on various mathematical equations, it is our belief that the crosswalk to the

current 3 codes best represent this test. The CDLT Advisory Panel also agreed.

Code: 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*)

Commenter Recommendations: Gapfill

Panel Recommendation: Gapfill OR Crosswalk to 87903

CMS Decision: Crosswalk to 2 TIMES 88239 PLUS 87900

Rationale: We continue to believe and a significant portion of the CDLT Advisory Panel agreed that there are codes available for crosswalking. However, after further review, we believe that 88239 *Tissue culture for neoplastic disorders; solid tumor* more closely matches the initial resources needed for the first part of the procedure. However, as multiple drug sensitivities are commonly performed, we believe that 2 times that code more accurately reflects the typical resources for these tests. In addition, 87900 *Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics* is a closer match to the drug sensitivities performed in this setting than 87904. The combination of these codes approximates the resources needed for this test. However, neither the public nor the Advisory Panel has had the opportunity to comment on this crosswalk recommendation even though we believe that it is a more appropriate crosswalk. We invite public comment on this final determination and, if desired, a request for reconsideration during the 60 day comment period following the release of these final determinations which will then be considered at the 2016 Annual Public Lab Meeting.

Code: 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)*)

Commenter Recommendations: Gapfill

Panel Recommendation: Gapfill OR 87904.

CMS Decision: Crosswalk to code 87900

Rationale: We continue to believe and a significant portion of the Panel agreed that there are codes available for crosswalking. However, after further review, we believe that drug sensitivity testing in this setting is better represented by 87900 and are crosswalking 81536 to this code. However, we recognize that neither the public nor the Advisory Panel had the opportunity to comment on this crosswalk recommendation; however, we believe that it is a more appropriate crosswalk. We invite public comment on this final determination and, if desired, a request for

reconsideration during the 60 day comment period following the release of these final determinations which will then be considered at the 2016 Annual Public Lab Meeting.

Code: 81538 (*Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival*)

Commenter Recommendations: Gapfill

Panel Recommendation: Gapfill (majority) or three panel members recommended crosswalking to 8 TIMES 83789.

CMS Decision: Gapfill

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 81538, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: Gapfill

Panel Recommendation: Gapfill (unanimous)

CMS Decision: Gapfill.

Rationale: CMS agrees with the unanimous CDLT Advisory Panel recommendation to gapfill code 81540, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 81545 (*Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)*)

Commenter Recommendations: Gapfill

Panel Recommendation: Gapfill (unanimous).

CMS Decision: Gapfill.

Rationale: CMS agrees with the unanimous CDLT Advisory Panel recommendation to gapfill code 81545, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: Gapfill

Panel Recommendation: Gapfill (unanimous).

CMS Decision: Gapfill.

Rationale: CMS agrees with the unanimous CDLT Advisory Panel recommendation to gapfill code 81595, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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*)

Commenter Recommendations: No new payment recommendations.

Panel Recommendation: Gapfill. (unanimous)

CMS Decision: Gapfill.

Rationale: The CDLT Advisory Panel members unanimously recommended gapfill this molecular pathology test. CMS agrees with this rationale. We do not find other similar tests that are currently priced on the CLFS. This will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

Code: 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)

Commenter Recommendations: Crosswalk to code 84153: PSA, PLUS 2.0 TIMES code 84154: PSA free, PLUS code 83520: Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified.

Panel Recommendation: Gapfill (majority). Two members recommended crosswalking to 84153 TIMES 2 PLUS 84154 PLUS 83520. One member recommended a crosswalk to an unspecified immunoassay.

CMS Decision: Gapfill.

Rationale: The majority of CDLT Advisory Panel members recommended gapfill this non-molecular pathology test. CMS agrees with this rationale. We do not find other similar tests that are currently priced on the CLFS. This will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.