Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Preliminary 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 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 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 to respond to our proposal as well as comment and discussion at the Annual Laboratory Public Meeting.

Section 216 of the Protecting Access to Medicare Act (PAMA) of 2014 replaces the current pricing methodology for the CLFS with one based on the weighted median of private payor rates for each laboratory test code collected directly from laboratories on a periodic basis, beginning July 1, 2017. Public commenters suggested using the CPT drugs of abuse testing codes and developing claims processing logic that groups codes into tiered payments based on volume or discount payment based in the presence of multiple test codes. We do not believe that such a methodology would be permitted under the PAMA.

After further consideration of this issue, several meetings with the public, and in consultation with the advisory panel on clinical diagnostic laboratory tests (established under the PAMA), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office of

National Drug Control Policy, we are proposing to modify our proposal for coding and payment of drugs of abuse testing as follows:

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:

Code: 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)*

Commenter Recommendations: Not recommended by Commenters.

Panel Recommendation: One panel member suggested this option off line.

CMS Recommendation: 0.5 TIMES G0434: Drug screen, other than chromatographic; any number of drug classes, by clia waived test or moderate complexity test, per patient encounter

Rationale: GXXX1 & GXXX2 split the current G0434 into direct optical reading and instrument assisted optical reading. G0434 is priced to cover the instrument assisted reading. GXXX1 is only direct reading of cups/dipsticks and we believe 50% of the current code recognizes the resources required.

Code: 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)*

Commenter Recommendations: G0434: Drug screen, other than chromatographic; any number of drug classes, by clia waived test or moderate complexity test, per patient encounter

Panel Recommendation: G0434: Drug screen, other than chromatographic; any number of drug classes, by clia waived test or moderate complexity test, per patient encounter

CMS Recommendation: G0434.

Rationale: Since the code descriptor now no longer includes cups/dipsticks, it legitimately represents the work envisioned in G0434.

Code: 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)*

Commenter Recommendations: G0431: Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter

Panel Recommendation: G0431: Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter

CMS Recommendation: 3 TIMES G0434.

Rationale: The services in G0434 typically can only perform 10-15 tests. The more sophisticated machines in this code can perform 2-4 times the number of tests. We believe crosswalking to 3 times the current code appropriately recognizes the work involved.

4. For definitive drug testing, create four tiered G codes:

Code: 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)*

Commenter Recommendations: Crosswalk to 82542: *(*Column chromatography/mass spectrometry (eg, GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; quantitative, single stationary and mobile phase), and bill separately.

Panel Recommendation: Crosswalk to 82542: (Column chromatography/mass spectrometry (eg, GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; quantitative, single stationary and mobile phase), and bill separately.

CMS Recommendation: 2 TIMES 82542 PLUS 5 TIMES 82542 TIMES 0.10

Rationale: When the AMA CPT created the new AMA CPT drug testing codes for CY 2015, it created families of codes, many with three tiers with a typical pattern of 1-2 tests in the first tier, 3-4 tests in the second tier and 5 or more tests in the third tier. CMS received public recommendations in 2014 for these codes. In every family, the recommendations established a crosswalk for the base code and then recommended a price for the 2nd tier at 1.1 * base code and 1.2 * base code for the third tier. Essentially, this represents a 10% increase over the base code for each additional 2 tests. We used this process for pricing these tiered G codes. We accepted the recommended crosswalk of 82542 but modified the multiples of that CPT code based on the CY 2014 Annual Lab Meeting recommendations. We crosswalk the first two codes at 100% and the remaining codes in that tier at 10%. Since the fourth tier does not have a maximum number of tests, we selected 50 tests as that is in the middle of the range of the number of tests that many commenters suggested would be in the top tier.

Code: 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)*

Commenter Recommendations: Crosswalk to 82542: (Column chromatography/mass spectrometry (eg, GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; quantitative, single stationary and mobile phase) TIMES 8.

Panel Recommendation: Crosswalk to 82542: (Column chromatography/mass spectrometry (eg, GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; quantitative, single stationary and mobile phase) TIMES 8.

CMS Recommendation: 2 TIMES 82542 PLUS 12 TIMES 82542 TIMES 0.10

Code: 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)*

Commenter Recommendations: Crosswalk to 82542: (Column chromatography/mass spectrometry (eg, GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; quantitative, single stationary and mobile phase) TIMES 8, PLUS (82542 TIMES 8 TIMES 0.25).

Panel Recommendation: Crosswalk to 82542: (Column chromatography/mass spectrometry (eg, GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; quantitative, single stationary and mobile phase) TIMES 8, PLUS (82542 TIMES 8 TIMES 0.25).

CMS Recommendation: 2 TIMES 82542 PLUS 32 TIMES 82542 TIMES 0.10

Rationale: When the AMA CPT created the new AMA CPT drug testing codes for CY 2015, it created families of codes, many with three tiers with a typical pattern of 1-2 tests in the first tier, 3-4 tests in the second tier and 5 or more tests in the third tier. CMS received public recommendations in 2014 for these codes. In every family, the recommendations established a crosswalk for the base code and then recommended a price for the 2nd tier at 1.1 * base code and 1.2 * base code for the third tier. Essentially, this represents a 10% increase over the base code for each additional 2 tests. We used this process for pricing these tiered G codes. We accepted the recommended crosswalk of 82542 but modified the multiples of that CPT code based on the CY 2014 Annual Lab Meeting recommendations. We crosswalk the first two codes at 100% and the remaining codes in that tier at 10%. Since the fourth tier does not have a maximum number of tests, we selected 50 tests as that is in the middle of the range of the number of tests that many commenters suggested would be in the top tier.

Code: 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)*

Commenter Recommendations: Crosswalk to 82542: (Column chromatography/mass spectrometry (eg, GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; quantitative, single stationary and mobile phase) TIMES 8, PLUS (82542 TIMES 16 TIMES 0.25).

Panel Recommendation: Crosswalk to 82542: (Column chromatography/mass spectrometry (eg, GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; quantitative, single stationary and mobile phase) TIMES 8, PLUS (82542 TIMES 16 TIMES 0.25).

CMS Recommendation: 2 TIMES 82542 PLUS 48 TIMES 82542 TIMES 0.10

Rationale: When the AMA CPT created the new AMA CPT drug testing codes for CY 2015, it created families of codes, many with three tiers with a typical pattern of 1-2 tests in the first tier, 3-4 tests in the second tier and 5 or more tests in the third tier. CMS received public recommendations in 2014 for these codes. In every family, the recommendations established a crosswalk for the base code and then recommended a price for the 2nd tier at 1.1 * base code and 1.2 * base code for the third tier. Essentially, this represents a 10% increase over the base code for each additional 2 tests. We used this process for pricing these tiered G codes. We accepted the recommended crosswalk of 82542 but modified the multiples of that CPT code based on the CY 2014 Annual Lab Meeting recommendations. We crosswalk the first two codes at 100% and the remaining codes in that tier at 10%. Since the fourth tier does not have a maximum number of tests, we selected 50 tests as that is in the middle of the range of the number of tests that many commenters suggested would be in the top tier.

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: Crosswalk to codes 82274 (Assay test for blood fecal), PLUS 81401 (Molecular pathology procedure, level 2); OR

Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers); OR

Keep the same formula as 2015 final determination (crosswalk to codes 81315 (Pml/raralpha com breakpoints), PLUS 81275 (Kras gene), PLUS 82274 (Assay test for blood fecal)

Panel Recommendation: Maintain the current crosswalk.

CMS Recommendation: 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 800XA. 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 (not on CLFS), PLUS 86900: Blood typing, ABO, PLUS 86901: Blood typing, Rh (D); OR

Crosswalk to codes 80055 (not on CLFS), PLUS 87389: HIV code HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result

Panel Recommendation: 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 (not on CLFS), PLUS 86900: Blood typing, ABO, PLUS 86901: Blood typing, Rh (D); OR

Crosswalk to codes 80055 (not on CLFS), PLUS 87389: HIV code HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result

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

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 proposing the priced recommendation for 80081. We will also recommend crosswalks for 80055 and 86850.

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 Annual Public Lab Meeting

Panel Recommendation: Not discussed at Annual Public Lab Meeting

CMS Recommendation: Crosswalk to 80081 MINUS 87389: HIV code HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result.

Rationale: CPT code 80055 is not currently priced on the CLFS. It is identical to 80081 except for the addition of one test 87389 which is priced on the CLFS at $32.77. We are proposing to crosswalk this code to the 80081 minus 87389.

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

Commenter Recommendations: Not discussed at Annual Public Lab Meeting

Panel Recommendation: Not discussed at Annual Public Lab Meeting

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

Rationale: CPT code 86850 is not currently priced on the CLFS. We are proposing to crosswalk this code to a similar CPT code, 86902.

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

CMS Recommendation: Crosswalk to code 86803.

Rationale: CMS agrees with the commenters and the Clinical Laboratory Diagnostic Test 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(ie, 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

Panel Recommendation: 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(ie, 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

CMS Recommendation: Crosswalk to codes 0.90 TIMES 81211 PLUS 0.90 TIMES 81213.

Rationale: CMS agrees with the commenters and the majority vote by the Clinical Laboratory Diagnostic Test Panel recommending the crosswalk to codes 81211 plus 81213, based on similarities in function of this test with the components of the new test. However, we believe that economies of scale are present when combining the work and therefore, propose a 10 percent decrease for each test crosswalked.

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)

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)

CMS Recommendation: Crosswalk to code 81235.

Rationale: CMS agrees with the commenters and the unanimous vote by the Clinical Laboratory Diagnostic Test 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)

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)

CMS Recommendation: Crosswalk to code 81235.

Rationale: CMS agrees with the commenters and the unanimous vote by the Clinical Laboratory Diagnostic Test 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)

Panel Recommendation: 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)

CMS Recommendation: Crosswalk to code 81245.

Rationale: CMS agrees with the commenters and the unanimous vote by the Clinical Laboratory Diagnostic Test 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)

CMS Recommendation: Crosswalk to code 81235.

Rationale: CMS agrees with the commenters and the unanimous vote by the Clinical Laboratory Diagnostic Test 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

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)

CMS Recommendation: 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

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

CMS Recommendation: Crosswalk to code 81275.

Rationale: CMS agrees with the commenters and the unanimous vote by the Clinical Laboratory Diagnostic Test 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 2.00 TIMES code 81275: KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis; variants in codons 12 and 13

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

CMS Recommendation: Crosswalk to 1.50 TIMES code 81275.

Rationale: CMS agrees with the majority of commenters and the unanimous vote by the Clinical Laboratory Diagnostic Test 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)

CMS Recommendation: 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)

Rationale: CMS disagrees with commenters and the Lab Panel and believes this code should be crosswalked to code 81245. Both codes are performing gene analysis on 2 exons while the recommended 81235 lists 6. 81245 more closely approximates the services of 81314.

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: Crosswalk to code 81292: MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis; 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.

CMS Recommendation: Gapfill.

Rationale: CMS agrees with the gapfill recommendation, 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: Crosswalk to code 81292: MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis; OR

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: 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 Recommendation: Gapfill.

Rationale: CMS believes the code should be gapfilled, 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: Crosswalk to code 81292: MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis; 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; 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

CMS Recommendation: Gapfill.

Rationale: CMS believes the code should be gapfilled, 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: Crosswalk to code 81292: MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis; 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; 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

CMS Recommendation: Gapfill.

Rationale: CMS believes the code should be gapfilled, 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: Crosswalk to code 81292: MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis; 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; 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

CMS Recommendation: Gapfill.

Rationale: CMS believes the code should be gapfilled, 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: Crosswalk to code 81292: MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis; 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

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 Recommendation: Gapfill.

Rationale: CMS believes the code should be gapfilled, 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: Crosswalk to code 81292: MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis; 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

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 Recommendation: Gapfill.

Rationale: CMS believes the code should be gapfilled, 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: Crosswalk to 12 TIMES code 83520: Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified; OR

Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill.

CMS Recommendation: Crosswalk to 12 TIMES code 83520.

Rationale: CMS agrees with the crosswalk to 12 TIMES code 83520. Code 83520 represents a single immunoassay and code 81490 analyzes 12 biomarkers, thus supporting a crosswalk to 12 TIMES 83520.

***** *Subject to revision based on final PAMA policy.*

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: Crosswalk to code 81292: MLHI gene analysis; full sequence analysis; OR

Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill

CMS Recommendation: Crosswalk to code 81292.

Rationale: CMS believes that we should crosswalk when possible to codes that are priced on the CLFS. We have a recommendation to crosswalk to 81292 which is currently priced on the CLFS and agree with that recommendation.

***** *Subject to revision based on final PAMA policy.*

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: Crosswalk to code 81292: MLHI gene analysis; full sequence analysis; OR

Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill.

CMS Recommendation: Crosswalk to code 81292.

Rationale: CMS believes that we should crosswalk when possible to codes that are priced on the CLFS. We have a recommendation to crosswalk to 81292 which is currently priced on the CLFS and agree with that recommendation.

***** *Subject to revision based on final PAMA policy.*

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 code 81292: MLHI gene analysis; full sequence analysis; OR

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.

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.

CMS Recommendation: 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 comments 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 Clinical Laboratory Diagnostic Test 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: Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill.

CMS Recommendation: Crosswalk to code 87903: Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; first through 10 drugs tested.

Rationale: CMS believes that we should crosswalk when possible to codes that are priced on the CLFS. Code 87903 describes a service very similar to that described by code 81535. Thus, we are recommending a crosswalk to code 87903.

***** *Subject to revision based on final PAMA policy.*

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: Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill.

CMS Recommendation: Crosswalk to code 87904: Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; each additional drug tested (List separately in addition to code for primary procedure).

Rationale: While the majority of the commenters recommended that this non-molecular pathology test crosswalk to tests that are currently contractor priced, the majority panel members voted to gapfill this test. CMS disagrees with this rationale. CMS believes that we should crosswalk when possible to codes that are priced on the CLFS. Code 87904 describes each additional tissue culture drug response which is quite similar to the description for code 81536. Thus, we are recommending a crosswalk to code 87904.

***** *Subject to revision based on final PAMA policy.*

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: Crosswalk to code 83789: Mass spectrometry and tandem mass spectrometry, analyte not elsewhere specified, quantitative, each specimen; OR

Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill.

CMS Recommendation: Crosswalk to 8 TIMES code 83789: Mass spectrometry and tandem mass spectrometry, analyte not elsewhere specified, quantitative, each specimen.

Rationale: CMS believes that we should crosswalk when possible to codes that are priced on the CLFS. CMS agrees with some public comments, as well as one panel member, who recommended a crosswalk to code 83789. However, CMS believes this non-molecular test should be crosswalked to 8 times the existing code, since there are 8 proteins measured in the test.

***** *Subject to revision based on final PAMA policy.*

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: Crosswalk to code 81214: BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb); OR

Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill.

CMS Recommendation: Crosswalk to code 81214.

Rationale: CMS believes that we should crosswalk when possible to codes that are priced on the CLFS. We have recommendations that this molecular pathology test crosswalk to code 81214, which analyzes a similar number of genes and we agree with that recommendation.

***** *Subject to revision based on final PAMA policy.*

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: Crosswalk to code 81214: BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb); OR

Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill.

CMS Recommendation: Crosswalk to 1.50 TIMES code 81214.

Rationale: CMS believes that we should crosswalk when possible to codes that are priced on the CLFS. Code 81545 is a similar code to 81540 except that 142 genes are analyzed rather than the 92 in code 81540. Based on this increased amount of work, CMS believes that this test should be crosswalked to 1.50 TIMES code 81214.

***** *Subject to revision based on final PAMA policy.*

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: Crosswalk to code 81292: MLHI gene analysis; full sequence analysis; OR

Crosswalk to tests that are currently contractor priced.*****

Panel Recommendation: Gapfill.

CMS Recommendation: Crosswalk to code 81292.

Rationale: CMS believes that we should crosswalk when possible to codes that are priced on the CLFS. We have a recommendation to crosswalk to 81292 which is currently priced on the CLFS and agree with that recommendation.

***** *Subject to revision based on final PAMA policy.*

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 payment recommendations.

Panel Recommendation: Gapfill.

CMS Recommendation: Gapfill.

Rationale: The panel members unanimously voted to 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.

CMS Recommendation: Gapfill.

Rationale: The majority of panel members voted to 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.