Calendar Year (CY) 2018 Clinical Laboratory Fee Schedule (CLFS) Final Determinations

The following are CMS's final determinations for codes to be either cross walked or gap filled for CY 2018 according to the requirements at 42 CFR § 414.508(a) and § 414.507(g).

A. New Test Codes

Molecular Pathology

1. 81105 (81X15)   Human Platelet Antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-1a/b (L33P)

Commenter Recommendations: Crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Final Determination: Crosswalk to code 81376.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81105. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81376 is more appropriate based on similarities in function of this test with the components of the new test.

2. 81106 (81X16)   Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein Ib [platelet], alpha polypeptide [GPIba]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-2a/b (T145M)

Commenter Recommendations: Crosswalk to CPT 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Final Determination: Crosswalk to code 81376.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81106. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81376 is more appropriate based on similarities in function of this test with the components of the new test.

3. 81107 (81X17)   Human Platelet Antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex], antigen CD41 [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-3a/b (I843S)

Commenter Recommendations: Crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Final Determination: Crosswalk to code 81376.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81107. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81376 is more appropriate based on similarities in function of this test with the components of the new test.

4. 81108 (81X18)   Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-4a/b (R143Q)

Commenter Recommendations: Crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Final Determination: Crosswalk to code 81376.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81108. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a

crosswalk to code 81376 is more appropriate based on similarities in function of this test with the components of the new test.

5. 81109 (81X19)   Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant (eg, HPA-5a/b (K505E))

Commenter Recommendations: Crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Final Determination: Crosswalk to code 81376.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81109. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81376 is more appropriate based on similarities in function of this test with the components of the new test.

6. 81110 (81X20)   Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61] [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-6a/b (R489Q)

Commenter Recommendations: Crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Final Determination: Crosswalk to code 81376.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81110. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81376 is more appropriate based on similarities in function of this test with the components of the new test.

7. 81111 (81X21)   Human Platelet Antigen 9 genotyping (HPA-9w), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex, antigen CD41] [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-9a/b (V837M)

Commenter Recommendations: Crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Final Determination: Crosswalk to code81376.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81111. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81376 is more appropriate based on similarities in function of this test with the components of the new test.

8. 81112 (81X22)   Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-15a/b (S682Y)

Commenter Recommendations: Crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Final Determination: Crosswalk to code 81376.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81112. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81376 is more appropriate based on similarities in function of this test with the components of the new test.

9. 81120 (81X23)   IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)

Commenter Recommendations: Crosswalk to code 81275 (KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variants in exon 2 (eg, codons 12 and 13)).

Panel Recommendation: The majority recommended crosswalk to code 81275.

CMS Final Determination: Crosswalk to code 81275.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81120. However, after further review,

we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81275 is more appropriate based on similarities in function of this test with the components of the new test.

10. 81121 (81X24)   IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)

Commenter Recommendations: Crosswalk to 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)).

Panel Recommendation: The majority recommended to crosswalk to code 81311.

CMS Final Determination: Crosswalk to code 81311.

Rationale: We initially believed that a crosswalk to code 81227 was appropriate based on similarities in sequencing methodology properties to code 81121. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81311 is more appropriate based on similarities in function of this test with the components of the new test.

11. 81175 (81X04)   ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia) gene analysis; full gene sequence

Commenter Recommendations: Crosswalk to code 81317 (PMS2 (postmeiotic segregation increased 2 [s. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis)

Panel Recommendation: Majority recommended to crosswalk to code 81317.

CMS Final Determination: Crosswalk to code 81317.

Rationale: We initially believed that a crosswalk to code 81295 was appropriate based on similarities in full gene sequencing methodology to code 81175. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81317 is more appropriate based on similarities in function of this test with the components of the new test.

12. 81176 (81X05)   ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia) gene analysis; targeted sequence analysis (eg, exon 12)

Commenter Recommendations: Crosswalk to code 81218 (CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence)

Panel Recommendation: Majority recommended to crosswalk to code 81218.

CMS Final Determination: Crosswalk to code 81218.

Rationale: We initially believed that a crosswalk to code 81272 was appropriate based on similarities in sequencing methodology properties of code 81176. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81218 is more appropriate based on similarities in function of this test with the components of the new test.

13. 81230 (81X30)   CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *22)

Commenter Recommendations: Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)), **OR** Crosswalk to 2 **TIMES** code 81227.

Panel Recommendation: Majority recommended to crosswalk to 2 **TIMES** code 81374 (HLA class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, b*27), each); however, a minority recommended to crosswalk to code 81227.

CMS Final Determination: Crosswalk to code 81227.

Rationale: We agree with the commenters and a minority recommendation of the CDLT Advisory Panel to crosswalk to code 81227. We believe code 81227 and code 81230 appear to use a similar sequencing methodology to identify specific common variants.

14. 81231 (81X31)   CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism) gene analysis, common variants (eg, *2, *3, *4, *5 *6, *7)

Commenter Recommendations: Crosswalk to code 81225 (CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)).

Panel Recommendation: Majority recommended crosswalk to code 81225; however, a minority recommended to crosswalk to code 81227.

CMS Final Determination: Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)).

Rationale: We agree with the Panel members that identified code 81227 as a feasible crosswalk for the new code 81231. Both 81227 and 81231 appear to use a similar sequencing methodology to identify specific common variants.

15. 81232 (81X32) DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism) gene analysis, common variant(s) (eg, *2A, *4, *5, *6)

Commenter Recommendations: Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)).

Panel Recommendation: Majority recommended crosswalk to code 81227.

CMS Final Determination: Crosswalk to code 81227.

Rationale: We agree with the commenters and the majority recommendation of the CDLT Advisory Panel to crosswalk to code 81227. Both 81227 and 81232 appear to use a similar sequencing methodology to identify specific common variants.

16. 81238 (81X25) F9 (coagulation factor IX) (eg, hemophilia B) full gene sequence

Commenter Recommendations: Crosswalk to code 81321 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis).

Panel Recommendation: Majority recommended crosswalk to code 81321; however, a minority recommended to crosswalk to 2 **TIMES** code 81374 (HLA Class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, B*27), each).

CMS Final Determination: Crosswalk to code 81321.

Rationale: We initially believed that a crosswalk to code 81295 was appropriate based on similarities sequencing methodology properties to code 81238. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81321 is more appropriate based on similarities in function of this test with the components of the new test.

17. 81247 (81X37) G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; common variant(s) (eg, A, A-)

Commenter Recommendations: Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), **OR** crosswalk to code 81374 (HLA class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, b*27), each) **TIMES** 2.

Panel Recommendation: The panel was split between crosswalking to code 81227, **OR** crosswalking to code 81374 **TIMES** 2, OR code 81215 (BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant).

CMS Final Determination: Crosswalk to code 81227.

Rationale: We agree with the recommendation to crosswalk to code 81227. Both 81227 and 81247 appear to use a similar sequencing methodology to identify specific, known variants.

18. 81248 (81X38)   G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; known familial variant(s)

Commenter Recommendations: Crosswalk to code 81215 (BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant).

Panel Recommendation: Crosswalk to code 81215.

CMS Final Determination: Crosswalk to code 81215.

Rationale: We agree with commenters and the majority vote of the CDLT Advisory Panel recommendation to crosswalk to code 81215 based on similar sequencing methodology to identify familial variants.

19. 81249 (81X40)   G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; full gene sequence

Commenter Recommendations: Crosswalk to code 81321 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis).

Panel Recommendation: The majority recommended crosswalk to code 81321. However, some panel members recommended a crosswalk to code 81161 (DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed).

CMS Final Determination: Crosswalk to code 81321.

Rationale: We initially believed that a crosswalk to code 81295 was appropriate based on similarities in sequencing methodology properties to code 81249. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81321 is more appropriate based on similarities in function of this test with the components of the new test.

20. 81258 (81X58)   HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant

Commenter Recommendations: Crosswalk to code 81215 **TIMES** 2 (BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant), **OR** crosswalk to code 81241 (F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant).

Panel Recommendation: The majority recommended crosswalk to code 81215 **TIMES** 2.

CMS Final Determination: Crosswalk to code 81215.

Rationale: We agree with the commenters and majority recommendation of the CDLT Advisory Panel to crosswalk to code 81215. However, there was insufficient rationale for the use of a 2 multiplier for code 81215.

21. 81259 (81X59)   HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence

Commenter Recommendations: Crosswalk to code 81321 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis), **OR** 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: The majority recommended crosswalk to code 81321.

CMS Final Determination: Crosswalk to code 81321.

Rationale: We initially believed that a crosswalk to code 81295 was appropriate based on similarities in sequencing methodology properties to code 81259. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81321 is more appropriate based on similarities in function of this test with the components of the new test.

22. 81269 (81X69)   HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants

Commenter Recommendations: Crosswalk to code 81323 **TIMES** 2 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant), **OR** crosswalk to code 81294 (MLH1 (mutL homolog 1, colon

cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants).

Panel Recommendation: The majority recommended crosswalk to code 81294. However, there were some panel members who recommended a crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each).

CMS Final Determination: Crosswalk to code 81294.

Rationale: We agree with the commenters and the majority of the CDLT Advisory Panel recommendation to crosswalk to code 81294, because this test appears to use a similar sequencing technology to identify duplication/deletion variants as does the new code 81269.

23. 81283 (81X33)   IFNL3 (interferon, lambda 3) (eg, drug response) gene analysis, rs12979860 variant

Commenter Recommendations: Crosswalk to code 81241 (F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant).

Panel Recommendation: The majority recommended crosswalk to code 81241.

CMS Final Determination: Crosswalk to code 81241.

Rationale: We initially believed that a crosswalk to code 81322 was appropriate based on similarities in sequencing methodology properties to code 81283. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81241 is more appropriate based on similarities in function of this test with the components of the new test.

24. 81328 (81X34)   SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction) gene analysis, common variant(s) (eg, *5)

Commenter Recommendations: Crosswalk to code 81376 (HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each), **OR** crosswalk to code 81381 (HLA Class I typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, B*57:01P), each).

Panel Recommendation: The majority recommended crosswalk to code 81376, although there were some votes to crosswalk to code 81381.

CMS Final Determination: Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily c, polypeptide 9) (eg, drug metabolism)).

Rationale: We continue to disagree with the recommendations to crosswalk to either code 81376 OR code 81381, and believe that code 81227 is a more appropriate better crosswalk, as this test appears to use similar sequencing methodology to identify common variants as does the new code 81328.

25. 81334 (813XX)   RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy) gene analysis, targeted sequence analysis (eg, exons 3-8)

Commenter Recommendations: Crosswalk to 2 **TIMES** 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)) OR crosswalk to 1.5 **TIMES** 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)).

Panel Recommendation: The majority recommended crosswalk to 2 **TIMES** code 81235.

CMS Final Determination: Crosswalk to 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)).

Rationale: We continue to disagree with the recommendation to crosswalk to code 81235 with the proposed multiplies. We continue to believe code 81272 is a better crosswalk, as this test appears to use similar sequencing methodology to perform a targeted sequence analysis as does the new code 81334. Finally, there was insufficient rationale for the use of a 1.5 multiplier for code 81272.

26. 81335 (81X35)   TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants (eg, *2, *3)

Commenter Recommendations: Crosswalk to 2 **TIMES** 81374 (HLA Class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, B*27), each), **OR** crosswalk to code 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)).

Panel Recommendation: The panel was nearly split evenly recommending either a crosswalk to 2 **TIMES** code 81374 or a crosswalk to 81227, though a slight majority recommended crosswalk to 2 **TIMES** code 81374.

CMS Final Determination: Crosswalk to code 81227.

Rationale: We disagree with the recommendations to crosswalk to 2 **TIMES** code 81374, and believe that code 81227 is a better crosswalk, as this test appears to use similar sequencing methodology to identify common variants as does the new code 81335.

27. 81346 (81X36)   TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism) gene analysis, common variant(s) (eg, tandem repeat variant)

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

Panel Recommendation: The panel recommended a 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 Final Determination: Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily c, polypeptide 9) (eg, drug metabolism)).

Rationale: We continue to disagree with the recommendation to crosswalk to code 81245, and believe that code 81227 is a more appropriate crosswalk, as this test appears to use a similar sequencing methodology to identify common variants as does the new code 81346.

28. 81361 (813X1)   HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)

Commenter Recommendations: Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily c, polypeptide 9) (eg, drug metabolism)).

Panel Recommendation: The panel recommended a crosswalk to code 81227.

CMS Final Determination: Crosswalk to code 81227.

Rationale: We agree with the commenters and the CDLT Advisory Panel recommendation to crosswalk to code 81227, as this test appears to use a similar sequencing methodology to identify common variants as does the new code 81361.

29. 81362 (813X2)   HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)

Commenter Recommendations: Crosswalk to code 81275 (KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variants in exon 2 (eg, codons 12 and 13)), **OR** crosswalk to 2 **TIMES** code 81215 (BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant).

Panel Recommendation: The majority recommended to crosswalk to 2 **TIMES** code 81215.

CMS Final Determination: Crosswalk to code 81215.

Rationale: We agree with commenters and majority recommendation of the CDLT Advisory Panel to crosswalk to code 81215. However, there was insufficient rationale for the use of a 2 multiplier for code 81215.

30. 81363 (813X3) HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)

Commenter Recommendations: Crosswalk to code 81294 (MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants).

Panel Recommendation: Crosswalk to code 81294.

CMS Final Determination: Crosswalk to code 81294.

Rationale: We agree with the commenters and the CDLT Advisory Panel recommendation to crosswalk to code 81294, as this test appears to use similar sequencing methodology to identify duplication/deletion variants as does the new code 81363.

31. 81364 (813X4) HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); 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: Majority recommended crosswalk to code 81235.

CMS Final Determination: Crosswalk to code 81235.

Rationale: We initially believed that a crosswalk to code 81295 was appropriate based on similarities in sequencing methodology to code 81364. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81235 is more appropriate based on similarities in function of this test with the components of the new test.

Genomic Sequencing and Other Molecular Multianalyte Assays

32. 81448 (814X5) Hereditary peripheral neuropathies panel (eg, Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include

sequencing of at least 5 peripheral neuropathy-related genes (eg, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, and SPTLC1)

Commenter Recommendations: Crosswalk to code 81439 (Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN), **OR** crosswalk to 3 **TIMES** code 81439.

Panel Recommendation: The majority recommended a crosswalk to code 81439.

CMS Final Determination: Crosswalk to code 81435 (Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11).

Rationale: We agree with the panel recommendation to crosswalk to code 81439. However, because code 81439 was new to the CLFS after the data reporting period, we did not receive a private payer rate in CY 2017 and we are unable to use it as a crosswalk. Therefore, we will crosswalk code 81448 to code 81435 (Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11). We believe that codes 81435 and 81439 use similar sequencing methodology as that of the new code 81448.

Multianalyte Assays with Algorithmic Analyses

33. 81520 (815XX)   Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score

Commenter Recommendations: Crosswalk to code 0008M (Oncology (breast), mRNA analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (FFPE) tissue, prognostic algorithm reported as a risk score).

Panel Recommendation: The majority recommended a crosswalk to code 0008M, with a dissenting vote for code 87501 (Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, includes reverse transcription, when performed, and amplified probe technique, each type or subtype).

CMS Final Determination: Crosswalk to code 0008M.

Rationale: We initially believed that a crosswalk to code 81528 was appropriate based on similarities in gene expression analysis with code 81520. However, after further review, we

agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 0008M is appropriate since 81520 is the same test as 0008M.

34. 81521 (815X2)   Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis

Commenter Recommendations: Crosswalk to code 81519 (Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score).

Panel Recommendation: The majority recommended a crosswalk to code 81519.

CMS Final Determination: Crosswalk to code 81519.

Rationale: We initially believed that a crosswalk to code 81528 was appropriate based on similarities in gene expression analysis of RNA with code 81521. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81519 is more appropriate based on similarities in function of this test with the components of the new test.

35. 81541 (81X41)   Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a disease-specific mortality risk score

Commenter Recommendations: Crosswalk to code 81519 (Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score).

Panel Recommendation: The majority of the Panel recommended to gapfill. A minority of Panel members recommended a crosswalk to code 81519.

CMS Final Determination: Crosswalk to code 81519.

Rationale: We initially believed that a crosswalk to code 81528 was appropriate based on similarities in gene expression analysis methodology to code 81541. However, after further review, we agree with commenters and the minority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81519 is more appropriate based on similarities in function of this test with the components of the new test.

36. 81551 (815X1)   Oncology (prostate), promoter methylation profiling by real-time PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin

embedded tissue, algorithm reported as a likelihood of prostate cancer detection on repeat biopsy

Commenter Recommendations: Gapfill.

Panel Recommendation: The majority recommended a crosswalk to code 0008M (Oncology (breast), mRNA analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (FFPE) tissue, prognostic algorithm reported as a risk score).

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 81528 was appropriate based on similarities gene expression analysis methodology. However after further review, we agree with the commenter recommendation and believe that gapfilling code 81551 is more appropriate. Gapfilling will allow CMS and its contractors the opportunity to gather current information about the manner in which the test is performed and the resources necessary to provide it, so that CMS can set an appropriate payment rate for this test.

Immunology

37. 86008 (8600X)   Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each

Commenter Recommendations: Crosswalk to code 86157 (Cold agglutinin; titer), **OR** crosswalk to code 86003 (Allergen specific IgE; quantitative or semiquantitative, each allergen), **OR** crosswalk to 5 **TIMES** code 86003, OR crosswalk to 86235 (Extractable nuclear antigen, antibody to, any method (eg, nRNP, SS-A, SS-B, Sm, RNP, Sc170, J01), each antibody).

Panel Recommendation: The majority of the Panel recommended to gapfill. A minority of Panel members recommended to crosswalk to code 86157, **OR** crosswalk to 4 **TIMES** code 86003, **OR** crosswalk to 5 **TIMES** code 86003.

CMS Final Determination: Crosswalk to code 86235.

Rationale: We initially believed that a crosswalk to code 86003 was appropriate based on similarities in methodology to code 86008. However, after further review, we agree with commenters and believe that a crosswalk to code 86235 is more appropriate based on similarities in function of this test with the components of the new test.

38. 86794 (86X7X)   Zika virus, IgM

Commenter Recommendations: Crosswalk to code 86356 (Mononuclear cell antigen, quantitative (eg, flow cytometry), not otherwise specified, each antigen), **OR** crosswalk to code 86790 (Allergen specific IgE; quantitative or semiquantitative, each allergen).

Panel Recommendation: The majority of the panel recommended a crosswalk to code 86788 (Antibody; West Nile virus, IgM). However, some panel members recommended a crosswalk to code 86356 (Mononuclear cell antigen, quantitative (eg, flow cytometry), not otherwise specified, each antigen).

CMS Final Determination: Crosswalk to code 86788.

Rationale: We agree with the recommendation to crosswalk to code 86788, and believe this code uses similar methodology to the new code 86794. Both codes assess IgM titres.

Microbiology

39. 87634 (876XX)   Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique

Commenter Recommendations: Crosswalk to code 87801 (Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique).

Panel Recommendation: The majority of the panel recommended a crosswalk to code 87801. However, some panel members recommended a crosswalk to code 87798 (Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism).

CMS Final Determination: Crosswalk to code 87801.

Rationale: We initially believed that a crosswalk to code 87798 was appropriate based on similarities in methodology to code 87634. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 87801 is more appropriate based on similarities in function of this test with the components of the new test.

40. 87662 (87X6X)   Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique

Commenter Recommendations: Crosswalk to code 87501 (Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, includes reverse transcription, when performed, and amplified probe technique, each type or subtype), **OR** crosswalk to code 87502 (Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types), **OR** crosswalk to code 87798 (Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique).

Panel Recommendation: The majority of the panel recommended a crosswalk to code 87502. However, some panel members recommended a crosswalk to either code 87501 or code 87798.

CMS Final Determination: Crosswalk to code 87501.

Rationale: We initially believed that a crosswalk to code 87798 was appropriate based on similarities in methodology to code 87662. However, after further review, we agree with commenters and the minority vote of the CDLT Advisory Panel and believe that a crosswalk to code 87501 is more appropriate based on similarities in function of this test with the components of the new test.

Proprietary Laboratory Analyses

41. 0001U   Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported

Commenter Recommendations: Crosswalk to code 81403 (Molecular pathology procedure, level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons) ang (angiogenin, ribonuclease, RNAse a family, 5) (eg, amyotrophic lateral sclerosis), full gene sequence arx (aristaless-related homeobox) (eg, x-linked lissencephaly with ambiguous genitalia, x-linked mental retardation), duplication/deletion analysis CEL (carboxyl ester lipase [bile salt-stimulated lipase]) (eg, maturity-onset diabetes of the young [mody]), targeted sequence analysis of exon 11 (eg, c.1785delc, c.1686delt) CTNNB1 (catenin [cadherin-associated protein], beta 1, 88kda) (eg, desmoid tumors), targeted sequence analysis (eg, exon 3) DAZ/SRY (deleted in azoospermia and sex determining region y) (eg, male infertility), common deletions (eg, azfa, azfb, azfc, azfd) dnmt3a (DNA [cytosine-5-]-methyltransferase 3 alpha) (eg, acute myeloid leukemia), targeted sequence analysis (eg, exon 23) epcam (epithelial cell adhesion molecule) (eg, lynch syndrome), duplication/deletion analysis f8 (coagulation factor viii) (eg, hemophilia a),).

Panel Recommendation: The majority of the panel recommended gapfill. However, some panel members recommended a crosswalk to code 81403.

CMS Final Determination: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation and believe that gapfilling code 0001U is more appropriate. Gapfilling 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.

42. 0002U   Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem

mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps

Commenter Recommendations: Gapfill.

Panel Recommendation: Gapfill.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 83789 was appropriate based on similarities in methodology. However, after further review, CMS agrees with the commenters and majority CDLT Advisory Panel recommendation and believe that gapfilling code 0002U is more appropriate. Gapfilling 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.

43. 0003U   Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score

Commenter Recommendations: Crosswalk to 1.25 **TIMES** code 81539 (Oncology (high-grade prostate cancer), biochemical assay of four proteins (total PSA, free PSA, intact PSA, and human kallikrein-2 [HK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score).

Panel Recommendation: The majority recommended gapfill, but there were votes for either crosswalk to 1.25 **TIMES** code 81539, **OR** crosswalk to code 81539.

CMS Final Determination: Crosswalk to 1.25 **TIMES** code 0010M (Oncology (high-grade prostate cancer), biochemical assay of four proteins (total psa, free psa, intact psa and human kallidrein 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).

Rationale: We agree with the minority recommendation of the CDLT Advisory Panel to crosswalk to 1.25 **TIMES** code 81539, as this test uses similar methodologies to 0003U; however, since code 81539 is being crosswalked to code 0010M, we will crosswalk code 0003U to code 0010M. An additional multiplier of 1.25 was applied to account for the analysis of an additional protein.

44. 0004U   Infectious disease (bacterial), DNA, 27 resistance genes, PCR amplification and probe hybridization in microarray format (molecular detection and identification of AmpC, carbapenemase and ESBL coding genes), bacterial culture colonies, report of genes detected or not detected, per isolate

Commenter Recommendations: Crosswalk to 10 **TIMES** code 87150 (Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed), OR crosswalk to 27 **TIMES** code 87150.

Panel Recommendation: Some of the panel members recommended gapfill, but there were votes for either crosswalk to 10 **TIMES** code 87150, **OR** crosswalk to code 87507 (Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, clostridium difficile, e. coli, salmonella, shigella, norovirus, giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets), **OR** crosswalk to code 87633 (Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets).

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 87798 was appropriate based on similarities in methodology. However, after further review, CMS agrees with the CDLT Advisory Panel recommendation to gapfill, and believe that gapfilling code 0004U is more appropriate. Gapfilling 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.

45. 0005U   Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score

Commenter Recommendations: Crosswalk to code 81539 (Oncology (high-grade prostate cancer), biochemical assay of four proteins (total PSA, free PSA, intact PSA, and human kallikrein-2 [HK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score).

Panel Recommendation: The majority recommended gapfill, but there were votes to crosswalk to code 81539.

CMS Final Determination: Crosswalk to code 0010M (Oncology (high-grade prostate cancer), biochemical assay of four proteins (total psa, free psa, intact psa and human kallidrein 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)..

Rationale: We agree with the minority recommendation of the CDLT Advisory Panel to crosswalk to code 81539, as this test uses similar methodologies to 0005U; however, since code 81539 is being crosswalked to code 0010M, we will crosswalk code 0005U to code 0010M.

46. 0006U   Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service

Commenter Recommendations: Crosswalk to 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 (e.g., ia, eia, elisa, emit, fpia) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed).

Panel Recommendation: The majority recommended gapfill, but there were votes to crosswalk to code G0483.

CMS Final Determination: Crosswalk to code G0483.

Rationale: We agree with commenters and the minority CDLT Advisory Panel recommendation to crosswalk to code G0483, as this test uses a similar methodology and resources to 0006U.

47. 0007U   Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service

Commenter Recommendations: Crosswalk to code 81265 (Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)) **PLUS** 0.5 **TIMES** code 80307 (Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service) **PLUS** 0.5 **TIMES** 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 (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed).

Panel Recommendation: The majority recommended gapfill, but there were votes to crosswalk to code G0480, OR crosswalk to code 81265.

CMS Final Determination: Crosswalk to code G0480.

Rationale: We initially believed that a crosswalk to the sum of half of codes 80307 and G0480 was appropriate based on similarities in methodology to code 0007U. However, after further review, CMS agrees with the minority of the CDLT Advisory Panel recommendation and believe that a crosswalk to code G0480 is more appropriate based on similarities in resource utilization.

48. 0008U   Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin

Commenter Recommendations: N/A.

Panel Recommendation: Gapfill.

CMS Final Determination: Crosswalk to code 81445 (Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed).

Rationale: We continue to disagree with the recommendation to gapfill as there are CPT codes with similar methodologies. We specifically believe that code 81445 is an appropriate crosswalk as this test appears to use similar sequencing methodologies as 0008U.

49. 0009U   Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin fixed paraffin embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified

Commenter Recommendations: Crosswalk to 86152 (Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood) **PLUS** 88249 (Chromosome analysis for breakage syndromes; score 100 cells, clastogen stress (eg, diepoxybutane, mitomycin C, ionizing radiation, UV radiation)).

Panel Recommendation: The majority recommended gapfill.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 86320 was appropriate based on similarities in methodology. However, after further review, CMS agrees with the majority CDLT Advisory Panel recommendation and believe that gapfilling code 0009U is more appropriate. Gapfilling 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.

50. 0010U   Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate

Commenter Recommendations: Crosswalk to 3 **TIMES** code 87153 (Culture, typing; identification by nucleic acid sequencing method, each isolate (eg, sequencing of the 16s rRNA gene)) **PLUS** code 87900 (Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics).

Panel Recommendation: The majority recommended gapfill, while there were other votes to crosswalk 3 **TIMES** code 87153 **PLUS** code 87900, **OR** crosswalk code 87153 **PLUS** code 87900, **OR** crosswalk to code 87153.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 87153 was appropriate based on similarities in sequencing methodology. However, after further review, CMS agrees with the majority CDLT Advisory Panel recommendation and believe that gapfilling code 0010U is more appropriate. Gapfilling 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.

51. 0011U   Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites

Commenter Recommendations: Crosswalk to 1.5 **TIMES** 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 (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed).

Panel Recommendation: The majority recommended gapfill, while there were other votes to crosswalk to code G0480, **OR** crosswalk code 81265 (Comparative analysis using short tandem repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other

germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)).

CMS Final Determination: Crosswalk to code G0480.

Rationale: We agree with the minority CDLT Advisory Panel recommendation to crosswalk to code G0480, as this test uses similar resources and methodologies to code 0011U. However, there was insufficient rationale for the use of a 1.5 multiplier for code G0480.

52. 0012U   Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)

Commenter Recommendations: Crosswalk to 2 **TIMES** code 81316 (PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative) **PLUS** code 81450 (Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed).

Panel Recommendation: The majority recommended gapfill, while there were other votes to crosswalk to code 81316, **OR** crosswalk 2 **TIMES** code 81316 **PLUS** code 81450.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 81445 was appropriate based on similarities in sequencing methodology. However, after further review, CMS agrees with the majority CDLT Advisory Panel recommendation and believe that gapfilling code 0012U is more appropriate. Gapfilling 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.

53. 0013U   Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)

Commenter Recommendations: Crosswalk to 2 **TIMES** code 81316 (PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative) **PLUS** code 81445 (Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA,

PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed).

Panel Recommendation: The majority recommended gapfill, while there were other votes to crosswalk to code 81316, **OR** crosswalk 2 **TIMES** code 81316 **PLUS** code 81445.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 81445 was appropriate based on similarities in sequencing methodology. However, after further review, CMS agrees with the majority CDLT Advisory Panel recommendation and believe that gapfilling code 0013U is more appropriate. Gapfilling 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.

54. 0014U   Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)

Commenter Recommendations: Crosswalk to 2 **TIMES** code 81316 (PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative) **PLUS** code 81450 (Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed)

Panel Recommendation: The majority recommended gapfill, while there were other votes to crosswalk to code 81316, **OR** crosswalk 2 **TIMES** code 81316 **PLUS** code 81450.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 81445 was appropriate based on similarities in sequencing methodology. However, after further review, CMS agrees with the majority CDLT Advisory Panel recommendation and believe that gapfilling code 0014U is more appropriate. Gapfilling 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.

55. 0015U   Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support

Commenter Recommendations: Crosswalk to 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, BRIP2, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53)

Panel Recommendation: The votes were even between recommending gapfill, or crosswalk to code 81432.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 81528 was appropriate based on similarities in gene expression methodology. However, after further review, CMS agrees with the CDLT Advisory Panel recommendation and believe that gapfilling code 0015U is more appropriate. Gapfilling 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.

56. 0016U   Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation

Commenter Recommendations: N/A.

Panel Recommendation: Crosswalk to code 81206 (BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative) **OR** crosswalk to 0.5 **TIMES** code 81207 (BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative) **PLUS** code 81206.

CMS Final Determination: Crosswalk to code 81206.

Rationale: We agree with the minority CDLT Advisory Panel recommendation to crosswalk to code 81206 based on similarities in function and resource utilization.

57. 0017U   Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended a crosswalk to code 81275 (KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variants in exon 2 (eg, codons 12 and 13)), while another recommendation was to crosswalk to code 81275 **PLUS**

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

CMS Final Determination: Crosswalk to code 81270 (JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant).

Rationale: We disagree with the recommended crosswalk codes. We believe that crosswalking to code 81270 as this test uses similar sequencing methodologies to identify known variants as 0017U.

Other

58. G0499   Hepatitis B screening in non-pregnant, high risk individual includes hepatitis B surface antigen (HBsAg) followed by a neutralizing confirmatory test for initially reactive results, and antibodies to HBsAg (anti-HBs) and hepatitis B core antigen (anti-HBc)

Commenter Recommendations: Crosswalk to code 87340 (Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg)) OR crosswalk to code 87340 **PLUS** code 87341 (Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg) neutralization) **PLUS** code 86704 (Hepatitis B core antibody (HBcAb); total) **PLUS** code 86706 (Hepatitis B surface antibody (HBsAb)).

Panel Recommendation: The majority recommended a crosswalk to code 87340 (Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg)) **PLUS** code 87341 (Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg) neutralization) **PLUS** code 86704 (Hepatitis B core antibody (HBcAb); total). A few members recommended to crosswalk to code 87340 **PLUS** code 87341 **PLUS** code 86704 **PLUS** code 86706.

CMS Final Determination: Crosswalk to code 87340 **PLUS** 0.05 **TIMES** code 87341 **PLUS** code 86704 **PLUS** 0.5 **TIMES** code 86706.

Rationale: We agree with the commenters and the minority crosswalk code recommendation of the CDLT Advisory Panel.. However we believe the most appropriate multipliers for code 86706 is 0.5, and a multiplier of 0.05 for code 87341 (hepatitis surface antigen neutralization test) since 0.05 is more likely to reflect the frequency of performing this laboratory test.

B. Reconsidered Test Codes

59. 81327   SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis

Commenter Recommendations: Crosswalk to code 81288 (MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis).

Panel Recommendation: The majority recommended a crosswalk to code 81288, but there was another vote to maintain the original crosswalk to code 81287 (Mgmt (o-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme), methylation analysis).

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 81287 was appropriate based on similar properties. However, after further review, we believe that gapfilling code 81327 is more appropriate, 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.

C. Codes That Were New for CY 2017 and for Which CMS Received No Applicable Information to Calculate Medicare Payment Rates Based on Weighted Median of Private Payor Rates

During the August 01, 2017 CDLT Advisory Panel Meeting CMS proposed to maintain the same crosswalks for codes deliberated by the CDLT Advisory Panel on July 18, 2016. CMS in its preliminary determinations for these codes also maintained the crosswalks finalized in November 2016. All of the subsequent Panel Recommendations for the codes in this section reflect those from the July 28, 2016 CDLT Advisory Panel meeting.

60. 80305   Drug test(s), presumptive, any number of drug classes, qualitative, 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: Commenters questioned use of code G0477 because it was deleted for CY 2017.

Panel Recommendation: The majority recommended a crosswalk to code G0477 (Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service).

CMS Final Determination: Crosswalk to code G0477.

Rationale: We agree with the panel recommendation to maintain the crosswalk to code G0477, finalized in November, 2016. We note that code G0477 was the code that represented the test during the data collection period.

61. 80306 Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures, (eg, immunoassay) read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service

Commenter Recommendations: Commenters questioned use of code G0478 because it was deleted for CY 2017.

Panel Recommendation: The majority recommended a crosswalk to code G0478 (Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service).

CMS Final Determination: Crosswalk to code G0478.

Rationale: We agree with the panel recommendation to maintain the crosswalk to code G0478, finalized in November, 2016. We note for that code G0478 was the code that represented the test during the data collection period.

62. 80307 Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service

Commenter Recommendations: Commenters questioned use of code G0479 because it was deleted for CY 2017.

Panel Recommendation: The majority recommended a crosswalk to code G0479 (Drug test(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).

CMS Final Determination: Crosswalk to code G0479.

Rationale: We agree with the panel recommendation to maintain the crosswalk to G0479, finalized in November, 2016. We note that code G0479 was the code that represented the test during the data collection period..

63. 81413   Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended a crosswalk to code 81435 (Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11).

CMS Final Determination: Crosswalk to code 81435.

Rationale: We agree with the CDLT Advisory Panel recommendation to maintain the crosswalk finalized in November, 2016 to crosswalk code 81413 to code 81435.

64. 81414   Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended a crosswalk to code 81436 (Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, Familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11).

CMS Final Determination: Crosswalk to code 81436.

Rationale: We agree with the CDLT Advisory Panel recommendation to maintain the crosswalk finalized in November, 2016 to crosswalk code 81414 to code 81436.

65. 81422   Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood

Commenter Recommendations: Crosswalk to code 81420 (Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21).

Panel Recommendation: Gapfill.

CMS Final Determination: Crosswalk to code 81420.

Rationale: We initially believed that a crosswalk to code 81436 was appropriate based on similarities in methodology and resources to code 81422. However, after further review, we agree with commenters and believe that a crosswalk to code 81420 is appropriate. We continue to disagree with the majority vote of the CDLT Advisory Panel recommendation to gapfill and believe that a crosswalk to code 81420 is more appropriate based on similarities in function of this test with the components of the new test.

66. 81439   Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended a crosswalk to code 81435 (Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTENPTEN, SMAD4, and STK11).

CMS Final Determination: Crosswalk to code 81435.

Rationale: We agree with the CDLT Advisory Panel recommendation to maintain the crosswalk finalized in November, 2016 to crosswalk code 81439 to code 81435.

67. 81539   Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score

Commenter Recommendations: Crosswalk to code 0010M (Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total, PSA, Free PSA, Intact Psa and human kallidrein 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).

Panel Recommendation: The voting was split between gapfill **OR** crosswalk to 3 **TIMES** code 84153 (Prostate specific antigen (PSA); total) **PLUS** code 84154 (Prostate specific antigen (PSA); free).

CMS Final Determination: Crosswalk to code 0010M.

Rationale: We agree with the commenter recommendation to crosswalk code 81539 to code 0010M. We note for that code 0010M was the code that represented the test during the data collection period.

68. 84410   Testosterone; bioavailable, direct measurement (eg, differential precipitation).

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended a crosswalk code 84402 (Testosterone; free) **PLUS** code 84403 (Testosterone; total). However, there was also a vote to crosswalk 3 **TIMES** code 84403.

CMS Final Determination: Crosswalk code 84402 **PLUS** code 84403.

Rationale: We agree with the CDLT Advisory Panel recommendation to maintain the crosswalk finalized in November, 2016 to crosswalk code 84410 to code 84402 **PLUS** code 84403.

69. 87483   Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes simplex virus type 1 and 2, human herpes virus 6, cytomegalovirus, varicella zoster virus, Cryptococcus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 87633 (Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets).

CMS Final Determination: Crosswalk code 87633.

Rationale: We agree with the CDLT Advisory Panel recommendation to maintain the crosswalk finalized in November, 2016 to crosswalk code 87483 to code 87633.

70. G0475   HIV antigen/antibody, combination assay, screening

Commenter Recommendations: Crosswalk to code 87806.

Panel Recommendation: The majority recommended crosswalk code 87389 (Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result).

CMS Final Determination: Crosswalk code 87389.

Rationale: We agree with the CDLT Advisory Panel recommendation to maintain the crosswalk finalized in November, 2016 to crosswalk code G0475 to code 87389.

71. G0476   Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) for cervical cancer screening, must be performed in addition to pap test

Commenter Recommendations: Crosswalk to code 87624 (Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)).

Panel Recommendation: The majority recommended crosswalk code 87624 (Infectious agent detection by nucleic acid (DNADNA or RNARNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)).

CMS Final Determination: Crosswalk code 87624.

Rationale: We agree with the CDLT Advisory Panel recommendation to maintain the crosswalk finalized in November, 2016 to crosswalk code G0476 to code 87624.

72. G0659   Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per

specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

CMS Final Determination: Crosswalk to code G0479 (Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, gc, hplc), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service).

Rationale: We agree with maintaining the crosswalk to G0479, finalized in November, 2016. We note that code G0479 was the code that represented the test during the data collection period.

D. Codes With No Applicable Information to Calculate Medicare Payment Rates Based on Weighted Median of Private Payor Rates

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73. 80410   Calcitonin stimulation panel (eg, calcium, pentagastrin) this panel must include the following: Calcitonin (82308 x 3)

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended to crosswalk to 4 **TIMES** code 82308.

CMS Final Determination: Crosswalk 3 **TIMES** code 82308 (Calcitonin).

Rationale: We agree with the majority of the CDLT Advisory Panel recommendation to crosswalk code 80410 to code 82308. However, we believe that a multiplier of THREE is more appropriate based on similar properties noted in the code descriptor.

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74. 80418   Combined rapid anterior pituitary evaluation panel This panel must include the following: Adrenocorticotropic hormone (ACTH) (82024 x 4) Luteinizing hormone (LH) (83002 x 4) Follicle stimulating hormone (FSH) (83001 x 4) Prolactin (84146 x 4) Human growth hormone (HGH) (83003 x 4) Cortisol (82533 x 4) Thyroid stimulating hormone (TSH) (84443 x 4)

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended to crosswalk 4 **TIMES** code 82024 (Adrenocorticotropic hormone (ACTH)) **PLUS** 4 **TIMES** code 83002 (Gonadotropin; luteinizing hormone (LH)) **PLUS** 4 **TIMES** code 83001 (Gonadotropin; follicle stimulating hormone (FSH)) **PLUS** 4 **TIMES** code 84146 (Prolactin) **PLUS** 4 **TIMES** code 83003 (Growth hormone, human (HGH) (somatotropin)) **PLUS** 4 **TIMES** code 82533 (Creatine kinase (CK), (CPK); MB fraction only) **PLUS** 4 **TIMES** code 84443 (Thyroid stimulating hormone (TSH)).

CMS Final Determination: Crosswalk 4 **TIMES** code 82024 (Adrenocorticotropic hormone (ACTH)) **PLUS** 4 **TIMES** code 83002 (Gonadotropin; luteinizing hormone (LH)) **PLUS** 4 **TIMES** code 83001 (Gonadotropin; follicle stimulating hormone (FSH)) **PLUS** 4 **TIMES** code 84146 (Prolactin) **PLUS** 4 **TIMES** code 83003 (Growth hormone, human (HGH) (somatotropin)) **PLUS** 4 **TIMES** code 82533 (Creatine kinase (CK), (CPK); MB fraction only) **PLUS** 4 **TIMES** code 84443 (Thyroid stimulating hormone (TSH)).

Rationale: We agree with the majority CDLT Advisory Panel recommendation and believe that this crosswalk calculation to code 80418 is appropriate based on similar properties noted in the code descriptor.

75. 80435   Insulin tolerance panel; for growth hormone deficiency this panel must include the following: Glucose Human growth hormone (HGH)

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended to crosswalk 5 **TIMES** 82947 **PLUS** 5 **TIMES** code 83003.

CMS Final Determination: Crosswalk 5 **TIMES** code 82947 (Glucose; quantitative, blood (except reagent strip)) **PLUS** 5 **TIMES** code 83003 (Growth hormone, human (HGH) (somatotropin)).

Rationale: We agree with the majority CDLT Advisory Panel recommendation to crosswalk code 80435 to 5 **TIMES** 82947 **PLUS** 5 **TIMES** code 83003, based on similar properties noted in the code descriptor.

76. 81316   PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative

Commenter Recommendations: Crosswalk to 81315 (PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative).

Panel Recommendation: The majority recommended crosswalk 1.5 **TIMES** code 81315. A minority recommended crosswalk code 81206 (BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative) or code 81315.

CMS Final Determination: Crosswalk 81315.

Rationale: We initially believed that a crosswalk to code 81206 was appropriate based on similarities in test type to code 81316. However, after further review, we agree with commenters and the minority vote of the CDLT Advisory Panel and believe that a crosswalk to code 81315 is more appropriate based on similarities in function of this test with the components of the new test.

77. 81326   PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; known familial variant

Commenter Recommendations: Crosswalk to 81215 (BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant).

Panel Recommendation: The majority recommended crosswalk code 81215.

CMS Final Determination: Crosswalk 81322 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant).

Rationale: We disagree with the recommendation to crosswalk to code 81215, because we believe that crosswalk 81322 appears to be a similar type of test (e.g., methodology, gene analysis, known familial variant) to code 81326.

78. 81425   Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended gapfill.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 81445 was appropriate based on similarities in test type (e.g., methodology). However, after further review, we agree with the majority CDLT Advisory Panel recommendation and believe that gapfilling code 81425 is more appropriate. Gapfilling 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.

79. 81426   Genome (eg, unexplained constitutional or heritable disorder or syndrome);
             sequence analysis, each comparator genome (eg, parents, siblings) (list separately
             in addition to code for primary procedure)

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended gapfill.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 81445 was appropriate based on similarities in test type (e.g., methodology). However, after further review, we agree with the majority CDLT Advisory Panel recommendation and believe that gapfilling code 81426 is more appropriate. Gapfilling 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.

80. 81427   Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-
             evaluation of previously obtained genome sequence (eg, updated knowledge or
             unrelated condition/syndrome)

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended gapfill.

CMS Final Determination: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 81427. Gapfilling 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.

81. 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 USH2

Commenter Recommendations: Crosswalk to 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, PTENPTEN, RAD51C, STK11, and TP53).

Panel Recommendation: The majority recommended crosswalk code 81432.

CMS Final Determination: Crosswalk code 81445 (Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed).

Rationale: We disagree with the recommendation and believe that code 81445 is more appropriate, since this laboratory test appears to be a similar type of test (e.g., methodology, next generation sequencing) to code 81434.

82. 81470   X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2.

Commenter Recommendations: Crosswalk to 2 **TIMES** 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).

Panel Recommendation: The majority recommended crosswalk 2 **TIMES** code 81432.

CMS Final Determination: Gapfill.

Rationale: CMS disagrees with the majority CDLT Advisory Panel recommendation to crosswalk to 2 **TIMES** code 81432. We initially believed that a crosswalk to code 81445 was appropriate based on similarities in test type (e.g., methodology, next generation sequencing). However, after further review, we believe that gapfilling code 81470 is more appropriate. Gapfilling 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.

83. 81471   X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk 2 **TIMES** code 81436.

CMS Final Determination: Gapfill.

Rationale: CMS disagrees with the majority CDLT Advisory Panel recommendation to crosswalk to 2 **TIMES** code 81436. We initially believed that a crosswalk to code 81433 was appropriate based on similarities in test type (e.g., methodology, duplication/deletion, next generation sequencing). However, after further review, we believe that gapfilling code 81471 is more appropriate. Gapfilling 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.

84. 81506   Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score

Commenter Recommendations: N/A.

Panel Recommendation: The majority of the panel recommended to crosswalk to code 82728 (Ferritin) **PLUS** 82947 (Glucose; quantitative, blood (except reagent strip)) **PLUS** 83036 (Hemoglobin; glycosylated (Hgb A1c)) **PLUS** 83525 (Insulin; total) **PLUS** 86141 (C-reactive protein; high sensitivity (hs-CRP)) **PLUS** 2 **TIMES** 83520 (Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified).

CMS Final Determination: Crosswalk code 82728 (Ferritin) **PLUS** 82947 (Glucose; quantitative, blood (except reagent strip)) **PLUS** 83036 (Hemoglobin; glycosylated (Hgb A1c)) **PLUS** 83525 (Insulin; total) **PLUS** 86141 (C-reactive protein; high sensitivity (hs-CRP)) **PLUS** 83520 (Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified).

Rationale: We agree with the majority CDLT Advisory Panel recommendation and believe that the crosswalk to code 81506 is appropriate based on similar properties. However, we believe that within the crosswalk calculation, 83520 should not be multiplied by 2. Additionally, 84999 Adiponectin is an unlisted code and not included in the calculation of the proposed payment for 81506.

85. 82286   Bradykinin

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 83520.

CMS Final Determination: Crosswalk code 82310 (Calcium; total).

Rationale: We continue to disagree with the majority CDLT Advisory Panel recommendation to crosswalk code 82286 to code 83520. We believe that a crosswalk to code 82310 is appropriate based on similar properties.

86. 82387   Cathepsin-d

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 82373 Carbohydrate deficient transferrin).

CMS Final Determination: Crosswalk code 82373 (Carbohydrate deficient transferrin).

Rationale: We agree with the majority of CDLT Advisory Panel recommendation e that a crosswalk to code 82373 is appropriate based on similar properties.

87. 82759   Galactokinase, RBC

Commenter Recommendations: Crosswalk to code 82963 (Glucosidase, beta).

Panel Recommendation: The majority recommended crosswalk code 82963.

CMS Final Determination: Crosswalk to code 82963 (Glucosidase, beta).

Rationale: We initially believed that a crosswalk to code 82775 was appropriate based on similarities in properties to code 82759. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 82963 is more appropriate based on similarities in function of this test with the components of the new test.

88. 82979   Glutathione reductase, RBC

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended to crosswalk code 84220 (Pyruvate kinase).

CMS Final Determination: Crosswalk code 84220 (Pyruvate kinase).

Rationale: We initially believed that a crosswalk to code 82977 was appropriate based on similarities in enzyme properties to code 82979. However, after further review, we agree with the unanimous vote of the CDLT Advisory Panel and believe that a crosswalk to code 84220 is more appropriate based on similarities in function of this test with the components of the new test.

89. 83662   Fetal lung maturity assessment; foam stability test

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended to crosswalk code 83663 (Fetal lung maturity assessment; fluorescence polarization).

CMS Final Determination: Crosswalk code 83663.

Rationale: We agree with the CDLT Advisory Panel recommendation to crosswalk code 83662 to code 83663 based on similar properties.

90. 83857   Methemalbumin

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 84165.

CMS Final Determination: Crosswalk code 84165 (Protein; electrophoretic fractionation and quantitation, serum).

Rationale: We agree with the majority of the CDLT Advisory Panel recommendation to crosswalk code 83857 to code 84165 based on similar properties.

91. 83987   pH; exhaled breath condensate

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 83986 (pH; body fluid, not otherwise specified).

CMS Final Determination: Crosswalk code 83986 (pH; body fluid, not otherwise specified).

Rationale: We initially believed that a crosswalk to code 82075 was appropriate based on similarities in properties to code 83987. However, after further review, we agree with the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 83986 is more appropriate based on similarities in function of this test with the components of the new test.

92. 84085   Phosphogluconate, 6-, dehydrogenase, RBC

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 84220 (Pyruvate kinase).

CMS Final Determination: Crosswalk code 84220 (Pyruvate kinase).

Rationale: We initially believed that a crosswalk to code 82977 was appropriate based on similarities in assessing enzymes. However, after further review, we agree with the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 84220 is more appropriate based on similarities in function of this test with the components of the new test.

93. 84485   Trypsin; duodenal fluid

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 82977 (Glutamyltransferase, gamma (GGT)).

CMS Final Determination: Crosswalk code 82977 (Glutamyltransferase, gamma (GGT)).

Rationale: We agree with the majority of the CDLT Advisory Panel recommendation to crosswalk code 84485 to code 82977 based on similar properties.

94. 84577   Urobilinogen, feces, quantitative

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 82710 (Fat or lipids, feces; quantitative).

CMS Final Determination: Crosswalk code 82710 (Fat or lipids, feces; quantitative).

Rationale: We agree with the majority of the CDLT Advisory Panel recommendation to crosswalk code 84577 to code 82710based on similar properties.

95. 84580   Urobilinogen, urine; quantitative, timed specimen

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended crosswalk code 82615 (Cystine and homocystine, urine, qualitative).

CMS Final Determination: Crosswalk code 82615 (Cystine and homocystine, urine, qualitative).

Rationale: We agree with the CDLT Advisory Panel recommendation to crosswalk code 84580 to code 82615 based on both 82615 and 84580 assessing urine analytes.

96. 85170   Clot retraction

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 0.80 **TIMES** 85175 (Clot lysis time, whole blood dilution).

CMS Final Determination: Crosswalk code 0.8 **TIMES** 85175 (Clot lysis time, whole blood dilution).

Rationale: We agree with the majority CDLT Advisory Panel recommendation and believe that a crosswalk to code 85175 **TIMES** 0.80 is appropriate since codes 85170 and 85175 are assessing different aspects of blood clotting.

97. 85337   Thrombomodulin

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 83520 (Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified).

CMS Final Determination: Crosswalk to code 83520 (Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified).

Rationale: We initially believed that a crosswalk to code 85300 was appropriate based on similarities in properties to code 85337. However, after further review, we agree with the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 83520 is more appropriate based on similarities in function of this test with the components of the new test.

98. 85400   Fibrinolytic factors and inhibitors; plasmin

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended crosswalk code 85410 (Fibrinolytic factors and inhibitors; alpha-2 antiplasmin).

CMS Final Determination: Crosswalk code 85410 (Fibrinolytic factors and inhibitors; alpha-2 antiplasmin).

Rationale: We agree with the CDLT Advisory Panel recommendation and believe that a crosswalk to code 85410 is appropriate based on similar properties.

99. 85530   Heparin-protamine tolerance test

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 85520 (Heparin assay).

CMS Final Determination: Crosswalk code 85520 (Heparin assay).

Rationale: We agree with the majority of the CDLT Advisory Panel recommendation and believe that a crosswalk to code 85520 is appropriate based on similar properties.

100. 86327   Immunoelectrophoresis; crossed (2-dimensional assay)

Commenter Recommendations: Crosswalk to code 86320 (Immunoelectrophoresis; serum).

Panel Recommendation: The majority recommended crosswalk code 86320 (Immunoelectrophoresis; serum).

CMS Final Determination: Crosswalk code 86320 (Immunoelectrophoresis; serum).

Rationale: We agree with the commenters and majority CDLT Advisory Panel recommendation and believe that a crosswalk to code 86320 is appropriate as both codes appear to have similar properties.

101. 86729   Antibody; lymphogranuloma venereum

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 86631 (Antibody; Chlamydia).

CMS Final Determination: Crosswalk code 86631 (Antibody; Chlamydia).

Rationale: We initially believed that a crosswalk to code 86632 was appropriate based on similarities in test function to code 86729. However, after further review, we agree with the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 86631 is more appropriate based on similarities in function of this test with the components of the new test.

102. 86821   HLA typing; lymphocyte culture, mixed (mlc)

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 86822 (HLA typing; lymphocyte culture, primed (PLC)).

CMS Final Determination: Crosswalk code 86822 (HLA typing; lymphocyte culture, primed (PLC)).

Rationale: We agree with the majority CDLT Advisory Panel recommendation and believe that a crosswalk to code 86822 is appropriate as both codes appear to have similar properties.

103. 86829   Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens

Commenter Recommendations: Crosswalk to code 86828 (Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens).

Panel Recommendation: N/A. The Panel did not fully discuss or vote on this code.

CMS Final Determination: Crosswalk code 86828.

Rationale: We initially believed that a crosswalk to code 86822 was appropriate based on similarities in properties to code 86829. However, after further review, we agree with commenters and believe that a crosswalk to code 86828 is more appropriate based on similarities in function of this test with the components of the new test.

104. 87152   Culture, typing; identification by pulse field gel typing

Commenter Recommendations: Crosswalk to code 87158 (Culture, typing; other methods).

Panel Recommendation: The Panel unanimously recommended crosswalk code 87158 (Culture, typing; other methods).

CMS Final Determination: Crosswalk code 87158 (Culture, typing; other methods).

Rationale: We agree with the commenters and majority CDLT Advisory Panel recommendation and believe that a crosswalk to code 87158 is appropriate as both codes appear to have similar properties.

105. 87267   Infectious agent antigen detection by immunofluorescent technique; Enterovirus, direct fluorescent antibody (DFA)

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended crosswalk code 87271 Infectious agent antigen detection by immunofluorescent technique; Cytomegalovirus, direct fluorescent antibody (DFA).

CMS Final Determination: Crosswalk code 87271 (Infectious agent antigen detection by immunofluorescent technique; Cytomegalovirus, direct fluorescent antibody (DFA)).

Rationale: We agree with the CDLT Advisory Panel recommendation and believe that a crosswalk to code 87271 is appropriate as both codes appear to have similar properties.

106. 87475   Infectious agent detection by nucleic acid (DNA or RNA); Borrelia burgdorferi, direct probe technique

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended crosswalk code 87480 (Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique DNA or RNA).

CMS Final Determination: Crosswalk code 87480 (Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique DNA or RNA).

Rationale: We agree with the majority CDLT Advisory Panel recommendation and believe that a crosswalk to code 87480 is appropriate as both codes appear to have similar properties.

107. 87485   Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, direct probe technique

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended crosswalk code 87480 (Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique).

CMS Final Determination: Crosswalk code 87480 (Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique).

Rationale: We agree with the majority CDLT Advisory Panel recommendation and believe that a crosswalk to code 87480 is appropriate as both codes appear to have similar properties.

108. 87495   Infectious agent detection by nucleic acid (DNA or RNA); Cytomegalovirus, direct probe technique

Commenter Recommendations: Crosswalk to code 87797 (Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism).

Panel Recommendation: The majority recommended crosswalk code 87797 (Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism).

CMS Final Determination: Crosswalk code 87797 (Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism).

Rationale: We initially believed that a crosswalk to code 87480 was appropriate based on similarities in properties to code 87495. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 87797 is more appropriate based on similarities in function of this test with the components of the new test.

109. 87528   Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, direct probe technique

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended crosswalk code 87480 (Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique).

CMS Final Determination: Crosswalk code 87480 (Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique).

Rationale: We agree with the CDLT Advisory Panel recommendation and believe that a crosswalk to code 87480 is appropriate as both codes appear to have similar properties.

110. 87537   Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, direct probe technique

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 87534 (Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, direct probe technique).

CMS Final Determination: Crosswalk code 87534 (Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, direct probe technique).

Rationale: We initially believed that a crosswalk to code 87480 was appropriate based on similarities in properties to code 87537. However, after further review, we agree with the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 87534 is more appropriate based on similarities in function of this test with the components of the new test.

111. 87557   Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, quantification

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 87592 (Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, quantification).

CMS Final Determination: Crosswalk code 87592 (Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, quantification).

Rationale: We agree with the majority CDLT Advisory Panel recommendation and believe that a crosswalk to code 87592 is appropriate as this code appears to have similar properties to 87557.

112. 87562   Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria avium-intracellulare, quantification

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 87592 (Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, quantification).

CMS Final Determination: Crosswalk code 87592 (Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, quantification).

Rationale: We agree with the majority CDLT Advisory Panel recommendation and believe that a crosswalk to code 87592 is appropriate as this code appears to have similar properties to 87562.

113. 88130   Sex chromatin identification; Barr bodies

Commenter Recommendations: Crosswalk to code 87209 (Smear, primary source with interpretation; complex special stain (eg, trichrome, iron hemotoxylin) for ova and parasites).

Panel Recommendation: The majority recommended crosswalk code 87209 (Smear, primary source with interpretation; complex special stain (eg, trichrome, iron hemotoxylin) for ova and parasites).

CMS Final Determination: Crosswalk code 87209

Rationale: We initially believed that a crosswalk to code 88148 was appropriate based on similarities in properties to code 88130. However, after further review, we agree with commenters and the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 87209 is more appropriate based on similarities in function of this test with the components of the new test.

114. 88245   Chromosome analysis for breakage syndromes; baseline Sister Chromatid Exchange (SCE), 20-25 cells

Commenter Recommendations: Crosswalk to code 88264 (Chromosome analysis; analyze 20-25 cells).

Panel Recommendation: The majority recommended crosswalk code 88248.

CMS Final Determination: Crosswalk code 88248 (Chromosome analysis for breakage syndromes; baseline breakage, score 50-100 cells, count 20 cells, 2 karyotypes (eg, for ataxia telangiectasia, Fanconi anemia, fragile X)).

Rationale: We agree with the majority of the CDLT Advisory Panel recommendation to crosswalk code 88245 to code 88248, based on similar properties.

115. 88741   Hemoglobin, quantitative, transcutaneous, per day; methemoglobin

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended crosswalk code 88740.

CMS Final Determination: Crosswalk code 88740 (Hemoglobin, quantitative, transcutaneous, per day; carboxyhemoglobin).

Rationale: We agree with the CDLT Advisory Panel recommendation to crosswalk code 88741 to code 88740, based on similar properties.

116. 89329   Sperm evaluation; hamster penetration test

Commenter Recommendations: N/A.

Panel Recommendation: The Panel unanimously recommended crosswalk code 89331.

CMS Final Determination: Crosswalk code 89331 (Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)).

Rationale: We agree with the CDLT Advisory Panel recommendation to crosswalk code 89329 to code 89331, based on similar properties.

117. 0002M   Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and alcoholic steatohepatitis (ash)

Commenter Recommendations: Crosswalk to code 82172 (Apolipoprotein, each) **PLUS** code 82247 (Bilirubin; total) **PLUS** code 82465 (Cholesterol, serum or whole blood, total) **PLUS** code 82947 (Glucose; quantitative, blood (except reagent strip)) **PLUS** code 82977 (Glutamyltransferase, gamma (GGT)) **PLUS** code 83010 (Haptoglobin; quantitative) **PLUS** code 83883 (Nephelometry, each analyte not elsewhere specified) **PLUS** code 84450 (Transferase; aspartate amino (AST) (SGOT)) **PLUS** code 84460 (Transferase; alanine amino (ALT) (SGPT)) **PLUS** code 84478 (Triglycerides).

Panel Recommendation: The majority recommended crosswalk code 82172 (Apolipoprotein, each) **PLUS** code 82247 (Bilirubin; total) **PLUS** code 82465 (Cholesterol, serum or whole blood, total) **PLUS** code 82947 (Glucose; quantitative, blood (except reagent strip)) **PLUS** code 82977 (Glutamyltransferase, gamma (GGT)) **PLUS** code 83010 (Haptoglobin; quantitative) **PLUS** code 83883 (Nephelometry, each analyte not elsewhere specified) **PLUS** code 84450 (Transferase; aspartate amino (AST) (SGOT)) **PLUS** code 84460 (Transferase; alanine amino (ALT) (SGPT)) **PLUS** code 84478 (Triglycerides).

CMS Final Determination: Crosswalk code 0003M (Liver disease, ten biochemical assays (ALT, A2-macroglobulin, Apolipoprotein A-1, Total Bilirubin, GGT, Haptoglobin, AST, Glucose, Total cholesterol and Triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and   nonalcoholic steatohepatitis (NASH)).

Rationale: We continue to disagree with the recommendations and believe that a crosswalk to code 0003M is appropriate based on 0002M and 0003M appearing to have similar methodologies.

118. 0004M   Scoliosis, DNA analysis of 53 single nucleotide polymorphisms (SNPS), using saliva, prognostic algorithm reported as a risk score

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended gapfill.

CMS Final Determination: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 0004M. Gapfilling 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.

119. 0006M   Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended gapfill.

CMS Final Determination: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 0006M. Gapfilling 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.

120. 0007M   Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index

Commenter Recommendations: Crosswalk to code 81519 (Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score).

Panel Recommendation: The majority recommended gapfill.

CMS Final Determination: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 0007M. Gapfilling 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.

121. 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: N/A.

Panel Recommendation: The majority recommended gapfill.

CMS Final Determination: Gapfill.

Rationale: CMS agrees with the majority CDLT Advisory Panel recommendation to gapfill code 00049M. Gapfilling 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.

122. P2028   Cephalin floculation, blood

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 82040.

CMS Final Determination: Crosswalk to code 82040 (Albumin; serum, plasma or whole blood).

Rationale: We agree with the majority of the CDLT Advisory Panel recommendation to crosswalk code P2028 to code 82040, based on similar properties.

123. P2029   Congo red, blood

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 82120 (Amines, vaginal fluid, qualitative). However, a minority recommended crosswalk code 82040 (Albumin; serum, plasma or whole blood).

CMS Final Determination: Crosswalk to code 82040 (Albumin; serum, plasma or whole blood).

Rationale: We agree with the minority of the CDLT Advisory Panel recommendation to crosswalk code P2029 to code 82040, based on similar properties.

124. P2031   Hair analysis (excluding arsenic)

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 82120 (Amines, vaginal fluid, qualitative). However, a minority recommended crosswalk code 82040 (Albumin; serum, plasma or whole blood).

CMS Final Determination: Crosswalk to code 82040 (Albumin; serum, plasma or whole blood).

Rationale: We agree with the minority of the CDLT Advisory Panel recommendation to crosswalk code P2031 to code 82040, based on similar properties.

125. P2033   Thymol turbidity, blood

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 82120 (Amines, vaginal fluid, qualitative). However, a minority recommended crosswalk code 82040 (Albumin; serum, plasma or whole blood).

CMS Final Determination: Crosswalk to code 82040 (Albumin; serum, plasma or whole blood).

Rationale: We agree with the minority of the CDLT Advisory Panel recommendation to crosswalk code P2033 to code 82040, based on similar properties.

126. P2038   Mucoprotein, blood (seromucoid) (medical necessity procedure)

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 82120 (Amines, vaginal fluid, qualitative). However, a minority recommended crosswalk code 82040 (Albumin; serum, plasma or whole blood).

CMS Final Determination: Crosswalk to code 82040 (Albumin; serum, plasma or whole blood).

Rationale: We agree with the minority of the CDLT Advisory Panel recommendation to crosswalk code P2038 to code 82040, based on similar properties.

127. Q0113   Pinworm examinations

Commenter Recommendations: N/A.

Panel Recommendation: The majority recommended crosswalk code 87172 (Pinworm exam (eg, cellophane tape prep)).

CMS Final Determination: Crosswalk to code 87172.

Rationale: We initially believed that a crosswalk to code Q0111 was appropriate based on similarities in properties to code Q0113. However, after further review, we agree with the majority vote of the CDLT Advisory Panel and believe that a crosswalk to code 87172 is more appropriate based on similarities in function of this test with the components of the new test.

E. Codes Being Deleted from the CLFS

128. 80050   General health panel. This panel must include the following: Comprehensive metabolic panel (80053), 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), Thyroid stimulating hormone (TSH (84443).

CMS Final Determination: Delete code 80050.

Rationale: HCPCS code 80050 is being deleted from the applicable information HCPCS codes for the CLFS. This code is not payable under Medicare.