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

The following are CMS's preliminary 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). CMS is accepting comments until *October 23, 2017*. Comments must be submitted electronically by this date to the following CMS mailbox: CLFS_Annual_Public_Meeting@cms.hhs.gov.

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 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant).

Panel Recommendation: The majority recommended crosswalk to code 81376.

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

Rationale: We disagree with the recommendation to crosswalk to code 81376. We believe code 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81105.

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 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant).

Panel Recommendation: The majority recommended crosswalk to code 81376.

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

Rationale: We disagree with the recommendation to crosswalk to code 81376. We believe code 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81106.

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 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant).

Panel Recommendation: The majority recommended crosswalk to code 81376.

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

Rationale: We disagree with the recommendation to crosswalk to code 81376. We believe CPT 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81107.

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 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant).

Panel Recommendation: The majority recommended crosswalk to code 81376.

CMS Preliminary Determination: Crosswalk to code 81227 (2c9 (cytochrome p450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism)).

Rationale: We disagree with the recommendation to crosswalk to code 81376. We believe CPT 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81108.

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 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant).

Panel Recommendation: The majority recommended crosswalk to code 81376.

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

Rationale: We disagree with the recommendation to crosswalk to code 81376. We believe CPT 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81109.

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 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant).

Panel Recommendation: The majority recommended crosswalk to code 81376.

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

Rationale: We disagree with the recommendation to crosswalk to code 81376. We believe CPT 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81110.

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 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant).

Panel Recommendation: The majority recommended crosswalk to code 81376.

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

Rationale: We disagree with the recommendation to crosswalk to code 81376. We believe CPT 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81111.

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 (PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant).

Panel Recommendation: The majority recommended crosswalk to code 81376.

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

Rationale: We disagree with the recommendation to crosswalk to code 81376. We believe CPT 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81112.

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

Rationale: We disagree with the recommendation to crosswalk to code 81275. We believe CPT 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81120.

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: Crosswalk to code 81311.

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

Rationale: We disagree with the recommendation to crosswalk to code 81311. We believe CPT 81227 is a more appropriate crosswalk since this test appears to use similar sequencing methodology to identify specific, known variants as does the new code 81121.

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 chose crosswalk to code 81317.

CMS Preliminary Determination: Crosswalk to code 81295 (MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis).

Rationale: We disagree with the recommendation to crosswalk to code 81317. We believe CPT 81295 is a more appropriate crosswalk since this test appears to use similar full gene sequencing methodology as does the new code 81175.

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 chose crosswalk to code 81218 .

CMS Preliminary 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 disagree with the recommendation to crosswalk to code 81218. We believe that code 81272 is a better crosswalk, since this test appears to use a similar sequencing methodology to perform a targeted sequence analysis as dose the new code 81176.

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 code 81227 **TIMES** 2.

Panel Recommendation: Majority chose crosswalk to code 81374 (HLA class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, b*27), each); however, there were some votes for crosswalking to code 81227.

CMS Preliminary Determination: Crosswalk to code 81227.

Rationale: We agree with the Presenters and some Panel members that identified code 81227 as a feasible crosswalk for the new code 81230. Both 81227 and 81230 appear to use a similar sequencing methodology to identify specific, known 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 chose crosswalk to code 81225; however, there were some votes for crosswalking to code 81227.

CMS Preliminary Determination: Crosswalk to code 81227.

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, known 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 chose crosswalk to code 81227.

CMS Preliminary Determination: Crosswalk to code 81227.

Rationale: We agree with the recommendation to crosswalk to code 81227. Both 81227 and 81232 appear to use a similar sequencing methodology to identify specific, known 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 chose crosswalk to code 81321; however, some panel members recommended crosswalk to 2 **TIMES** code 81374 (HLA Class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, B*27), each).

CMS Preliminary Determination: Crosswalk to code 81295 (MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis).

Rationale:
We disagree with the recommendation to crosswalk to code 81321, and believe that code 81295 is a better crosswalk, since this test appears to use a similar sequencing methodology to the new code 81238 to perform a full sequence analysis.

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.

CMS Preliminary 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 Preliminary Determination: Crosswalk to code 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. We believe that a better crosswalk is 81322, as both 81322 and the new code 81248 appear to use 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 Preliminary Determination: Crosswalk to code 81295 (MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis).

Rationale:
We disagree with the recommendation to crosswalk to either codes 81321 or 81161. We believe that code 81295 is a better crosswalk, since this test appears to use a similar sequencing methodology to perform a full sequence analysis as the new code 81249.

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 Preliminary Determination: Crosswalk to code 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. We believe that a better crosswalk is to code 81322, as this test appears to use a similar a sequencing methodology to identify familial variants as does the new code 81258.

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 Preliminary Determination: Crosswalk to code 81295 (MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis).

Rationale: We disagree with the recommendations, and believe that code 81295 is a better crosswalk. 81295 appears to use a similar sequencing methodology to perform a full sequence analysis as does the new code 81259.

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 Preliminary Determination: Crosswalk to code 81294.

Rationale: We agree with the 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 Preliminary Determination: Crosswalk to code 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 81241, and believe that a better crosswalk is to code 81322. Code 81322 appears to use a similar sequencing methodology to identify familial variants as does the new code 81283.

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

Rationale: We disagree with the recommendations to crosswalk to either code 81376 **OR** code 81381, 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 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)).

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

CMS Preliminary 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 disagree with the recommendation to crosswalk to 2 **TIMES** code 81235, and believe that 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.

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), eachh), **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 Preliminary 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.

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

Rationale: We disagree with the recommendation to crosswalk to code 81245, and believe that code 81227 is a better 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 Preliminary Determination: Crosswalk to code 81227.

Rationale: We agree with the 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 Preliminary Determination: Crosswalk to code 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 2 **TIMES** code 81215, and believe a more appropriate crosswalk is to code 81322 as this test uses similar a sequencing methodology to identify known familiar variants as does the new code 81362.

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 Preliminary Determination: Crosswalk to code 81294.

Rationale: We agree 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: Crosswalk to code 81235.

CMS Preliminary Determination: Crosswalk to code 81295 (MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis).

Rationale: We disagree with the recommendation to crosswalk to code 81235. We believe that code 81295 is more appropriate crosswalk, since this test appears to use a similar sequencing methodology to perform a full sequence analysis to that of the new code 81364.

Genomic Sequencing and Other Molecular Multianalyte Assays

In recommending crosswalk codes, and in the absence of specific information about the test's algorithm, we are assuming that the algorithm in the new test is similar to the algorithm in the crosswalk.

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 Preliminary Determination: Crosswalk to code 81445 (Targeted genomic sequence analysis panel, solid organ neoplasm, DNADNA analysis, and RNARNA 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 to crosswalk to code 81439. We believe that code 81445 is more appropriate, since 81445 appears to use similar sequencing methodology as that of the new code 81448.

Multianalyte Assays with Algorithmic Analyses

In recommending crosswalk codes, and in the absence of specific information about the test's algorithm, we are assuming that the algorithm in the new test is similar to the algorithm in the crosswalk

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 Preliminary Determination: Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result).

Rationale: We disagree with the recommendation to crosswalk to code 0008M or code 87501; we believe that code 81528 is more appropriate, since 81528 appears to use a similar gene expression analysis, to that of the new code 81520.

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 Preliminary Determination: Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result).

Rationale: We disagree with the recommendation to crosswalk to code 81519, and believe that code 81528 is more appropriate, since we believe that code 81528 uses a similar gene expression analysis of RNA.

35. 81541 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 recommended a crosswalk to code 81519.

CMS Preliminary Determination: Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result).

Rationale: We disagree with the recommendation to crosswalk to code 81519. We believe code 81528 is more appropriate, as this test appears to use a similar gene expression analysis methodology.

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 Preliminary Determination: Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result).

Rationale: We disagree with the recommendation to crosswalk to code 0008M, and believe that code 81528 is more appropriate, as this test uses a similar gene expression analysis methodology.

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.

Panel Recommendation: The panel was split, between crosswalk to code 86157, **OR** crosswalk to 4 **TIMES** code 86003, **OR** crosswalk to 5 TIMES code 86003.

CMS Preliminary Determination: Crosswalk to code 86003.

Rationale: We agree with the recommendation to crosswalk to code 86003, and believe this code appears to have similar methodology as illustrated in the code descriptor of the new code 86008.

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 Preliminary 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 Preliminary Determination: Crosswalk to code 87798.

Rationale: We agree with the recommendation to crosswalk to code 87798, and believe that this code has similar methodology to the new code 87634.

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 Preliminary Determination: Crosswalk to code 87798.

Rationale: We agree with the recommendation to crosswalk to code 87798, and believe that this code has similar methodology to the new code 87662.

Proprietary Laboratory Analyses

In recommending crosswalk codes, and in the absence of specific information about the test's algorithm, we are assuming that the algorithm in the new test is similar to the algorithm in the crosswalk.

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 Preliminary Determination: Gapfill.

Rationale: Although the majority of the panel recommended a crosswalk of 81403, this is priced by contractors and therefore is not an eligible code to which 0001U can be crosswalked. We agree with the recommendation to gapfill; at this time there do not appear to be CPT codes that have similar methodologies.

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 Preliminary Determination: Crosswalk to code 83789 (Mass spectrometry and tandem mass spectrometry (eg, MS, MS/MS, MALDI, MS-TOF, QTOF), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen).

Rationale: We disagree with the recommendations to gapfill. We believe code 83789 is the appropriate crosswalk to this new code as it uses similar methodologies to 0002U.

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 Preliminary Determination: Crosswalk to 1.25 **TIMES** code 81539.

Rationale: We agree with the recommendation to crosswalk to 1.25 **TIMES** code 81539, as this test uses similar methodologies to 0003U; an additional multiplier of 0.25 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: The majority 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 Preliminary Determination: Crosswalk to code 87798 (Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism).

Rationale: We disagree with the recommended crosswalk codes, as we believe code 87798 uses similar methodologies to 0004U. We believe both code descriptors cite an individual isolate/organism.

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 Preliminary Determination: Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result).

Rationale: We disagree with the recommendation to crosswalk to code 81539, and believe that code 81528 is more appropriate, since we believe that code 81528 uses a similar gene expression analysis methodology.

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 Preliminary Determination: Crosswalk to code G0483.

Rationale: We agree with the 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 G0483, OR crosswalk to code 81265.

CMS Preliminary Determination: Crosswalk to 0.5 **TIMES** code 80307 **PLUS** 0.5 **TIMES** code G0480.

Rationale: We disagree with the recommendations to gapfill or to crosswalk to code 81265. We believe a more appropriate crosswalk is to the sum of half of codes 80307 and G0480, as these tests use similar methodologies to 0007U, but approximately half of the resources of both.

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 Preliminary 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 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: N/A

Panel Recommendation: The majority recommended gapfill.

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

Rationale: We disagree with the recommendation to gapfill as there are CPT codes with similar methodologies. We specifically believe that code 86320 is an appropriate crosswalk, as this test uses similar methodologies as 0009U.

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 Preliminary Determination: Crosswalk to code 87153.

Rationale: We agree with the recommendation to crosswalk to code 87153, as this laboratory test uses similar sequencing methodologies to the new code 0010U.

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 Preliminary Determination: Crosswalk to code G0480.

Rationale: We agree with the recommendation to crosswalk to code G0480, as this test uses similar resources and methodologies to 0011U.

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 Preliminary 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 disagree with the recommendation to gapfill as there are CPT codes with similar methodologies. We believe that code 81445 is more appropriate, as this test uses similar sequencing methodologies to 0012U.

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 Preliminary Determination: Crosswalk to code 81445.

Rationale: We disagree with the recommendation to gapfill as there are CPT codes with similar methodologies. We believe that crosswalk to code 81445 is most appropriate, as this test uses similar sequencing methodologies to 0013U.

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 Preliminary 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 disagree with the recommendation to gapfill as there are CPT codes with similar methodologies. We believe that crosswalk to code 81445 is most appropriate, as this test uses similar sequencing methodologies to 0014U.

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 Preliminary Determination: Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result).

Rationale: We disagree with the recommendation to gapfill, there are CPT codes with similar methodologies, or crosswalking to code 81432, and believe that code 81528 is a more appropriate crosswalk. Code 81528 uses similar gene expression analysis methodologies to the new code 0015U

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 Preliminary Determination: Crosswalk to code 81206.

Rationale: We agree with the recommendation to crosswalk to code 81206.

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 Preliminary 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: N/A

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).

CMS Preliminary 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 crosswalk code recommendations. However we believe the most appropriate multipliers for 86706 is 0.5, and a multiplier of 0.05 for 87341 (hepatitis surface antigen neutralization test) since 0.05 is more likely to reflect the frequency of performing this laboratory test.

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 Preliminary Determination: Maintain crosswalk to code 81287.

Rationale: We continue to disagree that the crosswalk to this code should change, since we believe that the original crosswalk code has similar properties as this code.

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

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: N/A

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 Preliminary Determination: Crosswalk to code G0477.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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: N/A

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 Preliminary Determination: Crosswalk to code G0478.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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: N/A

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 Preliminary Determination: Crosswalk to code G0479.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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 Preliminary Determination: Crosswalk to code 81435.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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 Preliminary Determination: Crosswalk to code 81436.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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: N/A

Panel Recommendation: Gapfill.

CMS Preliminary Determination: 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).

Rationale: We do not agree with the panel recommendation to gapfill. The methodology and resources for 81422 are similar to those used for CPT 81436. Thus we believe a crosswalk to CPT 81436 is appropriate.

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 Preliminary Determination: Crosswalk to code 81435.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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: N/A

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 Preliminary Determination: Maintain finalized gapfill payment from 2016.

Rationale: We believe the gapfill payment finalized in November, 2016 is the correct rate for this test code.

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 Preliminary Determination: Crosswalk code 84402 **PLUS** code 84403.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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 Preliminary Determination: Crosswalk code 87633.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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

Commenter Recommendations: N/A

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 Preliminary Determination: Crosswalk code 87389.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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: N/A

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 Preliminary Determination: Crosswalk code 87624.

Rationale: We agree with the panel recommendation to maintain the crosswalk finalized in November, 2016.

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 Preliminary Determination: Crosswalk to 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).

Rationale: We agree with maintaining the crosswalk finalized in November, 2016.

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

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

Commenter Recommendations: N/A

Panel Recommendation: N/A.

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

Rationale: We believe that this crosswalk calculation to code 80410 is appropriate based on similar properties noted in the code descriptor.

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: N/A.

CMS Preliminary 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 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: N/A.

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

Rationale: We believe that this crosswalk calculation to code 80435 is appropriate 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: N/A.

CMS Preliminary Determination: Crosswalk 81206 (BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative).

Rationale: We disagree with the recommended crosswalk, and believe that a crosswalk to code 81206 is appropriate, since 81206 appears to be a similar type of test (e.g., methodology, translocation analysis, and breakpoint) to 81316.

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: N/A.

CMS Preliminary 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 81326.

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

Commenter Recommendations: N/A

Panel Recommendation: N/A.

CMS Preliminary 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 believe that code 81445 since this code appears to be a similar type of test (e.g., methodology) to 81425.

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: N/A.

CMS Preliminary 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 believe that code 81445 is an appropriate crosswalk, since 81445 appears to be a similar type of test (e.g., methodology) to CPT 81426.

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: N/A.

CMS Preliminary Determination: Crosswalk code 0.5 **TIMES** 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 believe that a multiplier of 0.5 for the crosswalk 81445 is appropriate since the work of this laboratory test is a re-evaluation of a previously obtained genome sequence. We also believe code 81445 is an appropriate crosswalk, since it appears to be a similar type of test (e.g., methodology) to CPT 81427, but uses fewer resources as 81427 is a re-evaluation of a previously obtained genome.

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 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: N/A

CMS Preliminary 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 CPT 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: N/A.

CMS Preliminary 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 CPT 81470.

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: N/A.

CMS Preliminary Determination: Crosswalk code 81433 (Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11).

Rationale: We believe that code 81433 is appropriate, since this laboratory test appears to be a similar type of test (e.g., methodology, duplication/deletion, next generation sequencing) to CPT 81471.

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: N/A.

CMS Preliminary 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 believe that this crosswalk calculation to code 81506 is appropriate based on similar properties. 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: N/A.

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

Rationale: We believe that a crosswalk to code 82310 is appropriate based on similar properties.

86. 82387 Cathepsin-d

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe 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: N/A.

CMS Preliminary Determination: Crosswalk code 82775 (Galactose-1-phosphate uridyl transferase; quantitative).

Rationale: We disagree with the recommendation and believe that a crosswalk to code 82775 is appropriate based on similar properties.

88. 82979 Glutathione reductase, RBC

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 82977 is appropriate based on similar enzyme properties.

89. 83662 Fetal lung maturity assessment; foam stability test

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk code 83663 (Fetal lung maturity assessment; fluorescence polarization).

Rationale: We believe that a crosswalk to code 83663 is appropriate based on similar properties.

90. 83857 Methemalbumin

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 84165 is appropriate based on similar properties.

91. 83987 pH; exhaled breath condensate

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk code 82075 (Alcohol (ethanol), breath).

Rationale: We believe that a crosswalk to code 82075 is appropriate based on similar properties.

92. 84085 Phosphogluconate, 6-, dehydrogenase, RBC

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 82977 is appropriate based on both 82977 and 84085 assessing enzymes.

93. 84485 Trypsin; duodenal fluid

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 82977 is appropriate based on both 82799 and 84484 assessing enzymes.

94. 84577 Urobilinogen, feces, quantitative

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 82710 is appropriate based on similar properties.

95. 84580 Urobilinogen, urine; quantitative, timed specimen

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 82615 is appropriate based on both 82615 and 84580 assessing urine analytes.

96. 85170 Clot retraction

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 85175 is appropriate since 85170 both are assessing different aspects of blood clots.

97. 85337 Thrombomodulin

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk code 85300 (Clotting inhibitors or anticoagulants; antithrombin III, activity).

Rationale: We believe that a crosswalk to code 85300 is appropriate based as both codes appear to have similar properties.

98. 85400 Fibrinolytic factors and inhibitors; plasmin

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 85410 is appropriate based as both codes have similar properties.

99. 85530 Heparin-protamine tolerance test

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 85520 is appropriate as both codes appear to have similar properties.

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

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

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk code 86320.

Rationale: We agree with the 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: N/A.

CMS Preliminary Determination: Crosswalk code 86632 (Antibody; chlamydia, IgM).

Rationale: We believe that a crosswalk to code 86632 is appropriate based on similar function of this test with the components of 86329.

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

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We 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: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 86822 is appropriate in that both codes appear to have similar properties. Both codes assess tissue typing using HLA as the foundation for both codes.

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

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

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk code 87158.

Rationale: We agree with the 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: N/A.

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

Rationale: We 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: N/A.

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

Rationale: We 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: N/A.

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

Rationale: We 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 87797 (Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism).

Panel Recommendation: N/A.

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

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

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

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We 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: N/A.

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

Rationale: We believe that a crosswalk to code 87480 is appropriate as 87480 appears to have similar properties to 87537.

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

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We 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: N/A.

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

Rationale:
We believe that a crosswalk to code 87592 is appropriate as this code appears to have similar properties to 87562.
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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: N/A.

CMS Preliminary Determination: Crosswalk code 88148 (Cytopathology smears, cervical or vaginal; screening by automated system with manual rescreening under physician supervision).

Rationale: We disagree with the recommendation and believe that a crosswalk to code 88148 is appropriate as 88148 appears to have similar properties to 88130.

114. 88166 Cytopathology, slides, cervical or vaginal (the Bethesda system); with manual screening and computer-assisted rescreening under physician supervision

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk code 88164 (Cytopathology, slides, cervical or vaginal (the Bethesda system); manual screening under physician supervision).

Rationale: We believe that a crosswalk to code 88164 is appropriate based on similar properties.

115. 88167 Cytopathology, slides, cervical or vaginal (the Bethesda system); with manual screening and computer-assisted rescreening using cell selection and review under physician supervision

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk code 88164 (Cytopathology, slides, cervical or vaginal (the Bethesda system); manual screening under physician supervision).

Rationale: We believe that a crosswalk to code 88164 is appropriate based on similar properties.

116. 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: N/A.

CMS Preliminary 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 disagree with the recommendation and believe that a crosswalk to code 88248 is appropriate as this code appears to have similar properties to 88245.

117. 88741 Hemoglobin, quantitative, transcutaneous, per day; methemoglobin

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 88740 is appropriate as this code appears to have similar properties to 88741.

118. 89329 Sperm evaluation; hamster penetration test

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that a crosswalk to code 89331 is appropriate as this code appears to have similar properties to 89329.

119. 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: N/A.

CMS Preliminary 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 disagree with the recommendations and believe that a crosswalk to code 0003M is appropriate based on 0002M and 0003M appearing to have similar methodologies

120. 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: N/A.

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

Rationale: We believe that code 81322 has more familial variants to this code.

121. 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: N/A.

CMS Preliminary Determination: Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result).

Rationale: We believe that code 81528 is appropriate, since we believe that code 81528 has standard RT-PCR, mRNA and/or mircroarray gene expression methodology.

122. 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: N/A.

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk to code 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result).

Rationale: We believe that code 81528 is appropriate, since we believe that code 81528 has standard RT-PCR, mRNA and/or mircroarray gene expression methodology.

123. 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: N/A.

CMS Preliminary 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 believe that code 81272 is an appropriate crosswalk, since this code has more familial variants to this code.

124. G0147 Screening cytopathology smears, cervical or vaginal, performed by automated system under physician supervision

Commenter Recommendations: Crosswalk to code 88147 (Cytopathology smears, cervical or vaginal; screening by automated system under physician supervision).

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk to code 88147.

Rationale: We agree with the recommendation that code 88147 is an appropriate crosswalk, based on similar properties.

125. P2028 Cephalin floculation, blood

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that code 82040 is an appropriate crosswalk, based on similar properties.

126. P2029 Congo red, blood

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that code 82040 is an appropriate crosswalk, based on similar properties.

127. P2031 Hair analysis (excluding arsenic)

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that code 82040 is an appropriate crosswalk, based on similar properties.

128. P2033 Thymol turbidity, blood

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that code 82040 is an appropriate crosswalk, based on similar properties.

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

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

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

Rationale: We believe that code 82040 is an appropriate crosswalk, based on similar properties.

130. Q0113 Pinworm examinations

Commenter Recommendations: N/A.

Panel Recommendation: N/A.

CMS Preliminary Determination: Crosswalk to code Q0111 (Wet mounts, including preparations of vaginal, cervical or skin specimens).

Rationale: We believe that code Q0111 is an appropriate crosswalk, based on similar properties.