Calendar Year (CY) 2019 Clinical Laboratory Fee Schedule (CLFS) Final Determinations[1]

A. Summary of CY 2019 CLFS Final Determinations

In the CY 2019 CLFS Preliminary Determinations document posted on the CMS CLFS website on September 21, 2018, we provided information on the use of multipliers, stacking and bundling of codes, codes with large quantities of genes, and BRCA crosswalks. Although our goal was to provide additional information and insight into how crosswalks and gap fill recommendations are made, we received a few comments where stakeholder's interpreted the information as policy changes, deviations from previous interpretations of statute, or changes in the application of regulations. These commenters suggested that we were setting new precedents regarding the use of crosswalks, multipliers and gapfilling.

We appreciate receiving these comments, as it gives us the opportunity to provide further clarification of the information provided. We did not intend for the information to be interpreted as policy statements, but rather as broad rationale for sets of codes that had common qualities, such as the use of multipliers. As evidenced in both the preliminary and now final recommendations, our policies have not changed and our interpretation of statute and regulations remains consistent. In particular, we want to assure commenters that we intend to continue to use multipliers where appropriate. Again, we thank the public for the thoughtful discourse as we continue to make recommendations on payment rates for the CLFS.

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B. CY 2019 Clinical Laboratory Fee Schedule (CLFS) Final Determinations

The following are CMS's final determinations for codes to be either crosswalked or gapfilled for CY 2019 according to the requirements at 42 CFR 414.508(a) and 414.507(g).

Reconsidered Test Codes

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

Panel Recommendations: The majority (seven votes) recommended crosswalk to code 81215. However a minority (two votes) recommended to maintain the same crosswalk as was made in 2017 to 81322. One vote recommended to gapfill and one vote recommended a crosswalk to code 81259.

CMS Final Determination: Maintain crosswalk to 2017 final determination of code 81322 (referred to in preliminary recommendations as crosswalk to code 81326).

Rationale: CMS agrees with a minority of the panel to maintain the crosswalk as is. CMS did not see ample justification to change the previously recommended crosswalk.

2. 81334 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 code 81259 (HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence).

Panel Recommendations: The majority (nine votes) recommended crosswalk to code 81259. Two votes recommended a crosswalk to code 81334.

CMS Final Determination: Maintain existing crosswalk to code 81272 (Kit gene, targeted sequence analysis).

Rationale: CMS disagrees with both the panel and commenter recommendations. In particular, the descriptor of 81334 is for a targeted sequence analysis, whereas 81259 is for a full gene sequence. CMS did not find ample justification to change the previously recommended crosswalk.

New Test Codes

3. 0011M Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk

Commenter Recommendations: Crosswalk to code 0005U x 1.5 (Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score)

Panel Recommendations: Five panel members voted to crosswalk to code 0005U x 1. A minority (three votes) of the panel recommended a crosswalk of 0005U x 1.5. Two votes recommended to gapfill and one member abstained from voting.

CMS Final Determination: Crosswalk to code 0005U (Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score).

Rationale: CMS agrees with the panel and commenter recommendations to crosswalk 0011M to 0005U x 1. Both 0011M and 0005U appear to use similar methods to analyze genetic material. However, CMS did not see ample justification to apply a multiplier of 1.5 to the crosswalk. Therefore CMS recommends a crosswalk of 0011M to 0005U x 1.

4. 0012M Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma

Commenter Recommendations: Crosswalk to code 0005U (Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score)

Panel Recommendations: A majority (nine votes) recommended crosswalk to code 0005U. Two votes recommended to gapfill.

CMS Final Determination: Crosswalk to code 0005U (Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score).

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk 0012M to 0005U. Both 0012M and 0005U appear to use similar methods to analyze genetic material.

5. 0013M Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2),

utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma

Commenter Recommendations: Crosswalk to code 0005U (Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score)

Panel Recommendations: A majority (nine votes) recommended crosswalk to code 0005U. Two votes recommended to gapfill.

CMS Final Determination: Crosswalk to code 0005U (Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score).

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk 0013M to 0005U. Both 0013M and 0005U appear to use similar methods to analyze genetic material.

6. 0018U Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy A3

Commenter Recommendations: No recommendations

Panel Recommendations: Five panel members recommended a crosswalk to code 81525. Two votes recommended a crosswalk to code 81545. Less than half (four votes) of the panel recommended to Gapfill.

CMS Final Determination: Gapfill

Rationale: We agree with the minority of the panel to gapfill this code. CMS did not find any existing CLFS codes that were similar enough to 0018U to justify a crosswalk.

7. 0019U Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents.

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 Recommendations: The panel was split on recommendations. Five panel members recommended a crosswalk to code 81415. Three members recommended a crosswalk to code 81519, and three members recommended to gapfill.

CMS Final Determination: Gapfill

Rationale: CMS agrees with the minority of the panel to gapfill this code. CMS did not find any existing code that was similar enough in methodology or resources to crosswalk to 0019U.

8. 0020U* Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, with specimen verification including DNA authentication in comparison to buccal DNA, per date of service.

***This code was deleted effective September 30, 2018**

9. 0021U Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score.

Commenter Recommendations: No recommendations

Panel Recommendations: The panel was split on recommendations. Four members recommended a crosswalk to code 81490, four members recommended to gapfill, and three members abstained from voting.

CMS Final Determination: Gapfill

Rationale: We agree with the minority of the panel to gapfill this code. CMS did not find any existing CLFS codes that were similar enough to 0021U to justify a crosswalk.

10. 0022U Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider.

Commenter Recommendations: Crosswalk to code 81408 (MolPath Tier 2).

Panel Recommendations: A slight majority (five votes) recommended crosswalk to code 81445. A minority (three votes) of the panel recommended crosswalk to code 81408. One member recommended a crosswalk to code 81445x3, one member recommended to gapfill, and one member abstained from voting.

CMS Final Determination: Gapfill.

Rationale: We disagree with the public to crosswalk to code 81408, but agree with other commenters to gapfill and recommend revising our previous preliminary determination recommendation which was to crosswalk to code 81445. Although code 0022U and code 81445 appear to have similar sequencing technology to identify sequence variants, after considering public comments, we believe that gapfilling code 0022U is more appropriate, since this will

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

11. 0023U Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin.

Commenter Recommendations: Crosswalk to code 81245 (FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)) + 81246 (FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis: tyrosine kinase domain (TKD) variants (eg D835, I836).

Panel Recommendations: The panel unanimously (eleven votes) recommended crosswalk to codes 81245+81246.

CMS Final Determination: Gapfill

Rationale: CMS disagrees with recommendations to crosswalk 0023U to the sum of each individual component code. Gapfilling this code will allow for a closer look at the resources necessary to perform this test.

12. 0024U Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative.

Commenter Recommendations: Crosswalk to code 83704 (Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed)

Panel Recommendations: The panel unanimously (eleven votes) recommended crosswalk to code 83704.

CMS Final Determination: Crosswalk to code 83704 (Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 0024U to 83704. CMS agrees the resources described in 83704 are similar to those described in 0024U.

13. 0025U Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative.

Commenter Recommendations: No recommendations.

Panel Recommendations: The majority (ten votes) recommended crosswalk to code G0480. One member recommended to gapfill.

CMS Final Determination: Crosswalk to G0480

Rationale: CMS agrees with the majority of the panel to crosswalk 0025U to G0480. Both 0025U and G0480 appear to use similar methods and resources.

14. 0026U Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive, high probability of malignancy" or "Negative, low probability of malignancy").

Commenter Recommendations: Crosswalk to code 81545 (Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)//Afirma® Gene Expression Classifier).

Panel Recommendations: A slight majority (six votes) recommended crosswalk to code 81545. A minority (four votes) of the panel recommended gapfill. One member recommended a crosswalk to code 81455.

CMS Final Determination: Crosswalk to code 81545 (Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)//Afirma® Gene Expression Classifier).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 0026U to 81545. Both 0026U and 81545 appear to use similar resources to analyze gene expression.

15. 0027U JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15.

Commenter Recommendations: Crosswalk to code 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) + 0017U(33%).

Panel Recommendations: A majority (six votes) recommended a crosswalk to code 0017Ux1.33. A minority (three votes) of the panel recommended a crosswalk to code 81529, one panel member recommended a crosswalk to code 0017U x 1 and one panel member recommended a crosswalk to code 81404.

CMS Final Determination: Crosswalk to code 0017U x 1.33 (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).

Rationale: CMS originally proposed a crosswalk to code 0017U x 1. However, upon review of additional information, CMS agrees with commenter and panel recommendations to crosswalk

code 0027U to code 0017U x 1.33. Both code 0027U and code 0017U appear to use similar sequencing methodologies to perform a sequence analysis, and the multiplier of 1.33 accounts for additional resources necessary to complete the test.

16. 0028U* CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, copy number variants, common variants with reflex to targeted sequence analysis.

***This code is being deleted effective September 30, 2018.**

17. 0029U Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and rs12777823).

Commenter Recommendations: Crosswalk to codes 81225 (CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)) + 81226 (CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)) + 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)) + 81230 x4 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities) + 81231 (CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *7)) + 81328 (F9 (coagulation factor IX) (eg, hemophilia B), full gene sequence) +81355 VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c.173+1000C>T)).

Panel Recommendations: There was no agreement among the panel for recommendations. Three members recommended to gapfill, three members recommended a crosswalk to code 81407, two members recommended a crosswalk to code 81432, two members recommended a crosswalk to codes 81225+81226+81227+81230x4+81231+81328+81355 and one member recommended a crosswalk to codes 81225+81226+81227+81230+81231+81328+81355.

CMS Final Determination: Gapfill

Rationale: CMS agrees with the minority of the panel vote to gapfill 0029U. CMS did not find sufficient evidence to crosswalk to an existing test on the CLFS that had similar resources. Gapfilling this code will allow for a closer look at the resources necessary to perform this test.

18. 0030U Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823).

Commenter Recommendations: Crosswalk to codes 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)) + 81230 x 2 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities) + 81355 VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c.173+1000C>T)).

Panel Recommendations: A majority (six votes) recommended gapfill. Three members recommended a crosswalk to codes xwalk 81227 + (81355 x 3), one member recommended a crosswalk to codes 81227 + (81230 x 2) + 81355 and one member recommended a crosswalk to codes 81227 + 81230 + 81355.

CMS Final Determination: Gapfill

Rationale: CMS agrees with the majority panel votes for gapfill 0030U. Gapfilling this code will allow for a closer look at the resources necessary to perform this test.

19. 0031U CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7).

Commenter Recommendations: 1. Crosswalk to code 81230 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities). 2. Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism).

Panel Recommendations: A majority (nine votes) recommended a crosswalk to code 81227. Two members recommended a crosswalk to code 81230.

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

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk 0031U to 81227. Both 0031U and 81227 appear to use similar sequencing technologies to perform a genetic analysis for common variants.

20. 0032U COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680) variant.

Commenter Recommendations: 1. Crosswalk to code 81227 (CYP2c9 (cytochrome p450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism). 2. Crosswalk to code 81230 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic

regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities).

Panel Recommendations: A majority (nine votes) recommended a crosswalk to code 81230. Two members recommended a crosswalk to code 81227.

CMS Final Determination: Crosswalk to code 81230 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities)

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk 0032U to 81230. Both 0032U and 81230 appear to use similar technologies to identify specific variants.

21. 0033U HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G]).

Commenter Recommendations: Crosswalk to code 81230 x 2 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities).

Panel Recommendations: A slight majority (six votes) recommended crosswalk to code 81230. Five members recommended a crosswalk to code 81230 x 2.

CMS Final Determination: Crosswalk to code 81230 + 81230 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities).

Rationale: CMS originally proposed a crosswalk to CPT 81230 x 1. Upon further review of additional material, however, CMS agrees with the public comments and minority of the panel to crosswalk each component of this test to code 81230. We agree that both genes in the CPT descriptor can each be crosswalked to code 81230. Therefore, CMS is finalizing a crosswalk of 0033U to code 81230 + code 81230.

22. 0034U TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(eg, thiopurine metabolism), gene analysis, common variants (ie, TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5).

Commenter Recommendations: Crosswalk to codes 81225 (CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)) + 81335 (TPMT (thiopurine S-methyltransferase) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3))).

Panel Recommendations: A majority (ten votes) recommended a crosswalk to codes 81225+81335. One member recommended to gapfill.

CMS Final Determination: Crosswalk to codes 81225+81335.

Rationale: CMS originally recommended to Gapfill 0034U. Upon further review of additional information, CMS agrees with the public comments and panel recommendations to crosswalk each component of this test to appropriate similar tests, namely 81225 and 81335. Therefore, CMS is finalizing a crosswalk of 0034U to codes 81225 + 81335.

23. 0035U Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative.

Commenter Recommendations: 1. Crosswalk to codes 81225 (CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)) + 81335 (TPMT (thiopurine S-methyltransferase) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3)) . 2. Gapfill.

Panel Recommendations: All eleven members recommended to gapfill.

CMS Final Determination: Gapfill

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to gapfill 0035U. CMS disagrees with recommendations to crosswalk 0035U to the sum of each individual component code. Gapfilling this code will allow for a closer look at the resources necessary to perform this test.

24. 0036U Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses.

Commenter Recommendations: 81415 (Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis).

Panel Recommendations: A majority (eight votes) recommended a crosswalk to code 81415. Two members recommended to gapfill, and one member abstained from voting.

CMS Final Determination: Crosswalk to code 81415 (Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis).

Rationale: CMS agrees with the majority of the panel and commenter recommendations to crosswalk 0036U to 81415. Both 0036U and 81415 appear to use similar sequencing technologies to perform an exome analysis.

25. 0038U Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative.

Commenter Recommendations: Crosswalk to code 82306 x 1.75 (Vitamin D; 25 hydroxy includes fraction(s), if performed).

Panel Recommendations: A majority (ten votes) recommended a crosswalk to code 82306 x 1. One member recommended a crosswalk to code 82306 x 1.75.

CMS Final Determination: Crosswalk to code 82306 (Vitamin D; 25 hydroxy includes fraction(s), if performed).

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk 0038U to 82306 x 1. Both 0038U and 82306 appear to use similar resources. CMS did notfind sufficent evidence to justify a multiplier of 1.75. Therefore CMS recommends a crosswalk of 0038U to 82306 x 1.

26. 0039U Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity.

Commenter Recommendations: Crosswalk to code 86225 (Deoxyribonucleic acid (DNA) antibody; native or double stranded).

Panel Recommendations: A majority (nine votes) recommended crosswalk to code 86225. Two members abstained from voting.

CMS Final Determination: Crosswalk to code 86225 (Deoxyribonucleic acid (DNA) antibody; native or double stranded).

Rationale: CMS agrees with the majority of the panel and commenter recommendations to crosswalk 0039U to 86225. Both 0039U and 86225 have nearly identical descriptors and appear to use the same resources for antibody analysis.

27. 0040U BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative.

Commenter Recommendations: Crosswalk to code 81206 (BCR/ABL1 (t(9;22)) (eg chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative. x 2.5.

Panel Recommendations: A slight majority (six votes) recommended crosswalk to code 81206 x 1. A minority (five votes) of the panel recommended a crosswalk of 81206 x 2.5

CMS Final Determination: Crosswalk to code 81206 x 2.5 (BCR/ABL1 (t(9;22)) (eg chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative.

Rationale: CMS originally agreed with the majority of the panel and commenter recommendations to crosswalk 0040U to 81206 x 1. Upon further review of additional information, however, CMS agreed the resources needed to perform the test justified a multiplier of 2.5.

28. 0041U Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM.

Commenter Recommendations: 1. Crosswalk to code 86617 x 1 (Antibody Borrelia burgdorferi (Lyme Disease) confirmatory test (e.g., Western blot or immunoblot)). 2. Crosswalk to code 86617 x 8 (Antibody Borrelia burgdorferi (Lyme Disease) confirmatory test (e.g., Western blot or immunoblot)). 3. Crosswalk to code 86617 x 2 (Antibody Borrelia burgdorferi (Lyme Disease) confirmatory test (e.g., Western blot or immunoblot)).

Panel Recommendations: Four panel members recommended a crosswalk to code 86617 x 2. Six members recommended to gapfill and one member recommended a crosswalk to code 86617 x 1.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 86617 times 2 was appropriate based on similarities in properties to code 86617. However after extensive review of the methodology and of the public comments we believe that gapfilling code 0041U is appropriate, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

29. 0042U Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG.

Commenter Recommendations: 1. Crosswalk to code 86617 (Antibody Borrelia burgdorferi (Lyme Disease) confirmatory test (e.g., Western blot or immunoblot)). 2. Crosswalk to code 86617 (Antibody Borrelia burgdorferi (Lyme Disease) confirmatory test (e.g., Western blot or immunoblot)) x 8.

Panel Recommendations: Five panel members recommended a crosswalk to code 86617 x 2 five panel members recommended to gapfill and one member recommended a crosswalk to code 86617 x 1.

CMS Final Determination: Gapfill

Rationale: We initially believed that a crosswalk to code 86617 times 2 was appropriate based on similarities in properties to code 86617. However after extensive review of the methodology and of the public comments we believe that gapfilling code 0042U is appropriate, since this will allow CMS and its contractors the opportunity to gather current information about the manner in

which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

30. 0043U Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM.

Commenter Recommendations: 1. Crosswalk to code 86619 (Antibody Borrelia (Relapsing fever)). 2. Crosswalk to code 86617 (Antibody Borrelia burgdorferi (Lyme Disease) confirmatory test (e.g., Western blot or immunoblot)) x 7.

Panel Recommendations: Five panel members recommended a crosswalk to code 86617 x 2 five panel members recommended to gapfill and one member recommended a crosswalk to code 86617 x 1.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 86617 times 2 was appropriate based on similarities in properties to code 86617. However after extensive review of the methodology and of the public comments we believe that gapfilling is a more appropriate, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

31. 0044U Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG.

Commenter Recommendations: 1. Crosswalk to code 86619 (Antibody Borrelia (Relapsing fever)). 2. Crosswalk to code 86617 (Antibody Borrelia burgdorferi (Lyme Disease) confirmatory test (e.g., Western blot or immunoblot)) x 7.

Panel Recommendations: Five panel members recommended a crosswalk to code 86617 x 2 five panel members recommended to gapfill and one member recommended a crosswalk to code 86617 x 1.

CMS Final Determination: Gapfill.

Rationale: We initially believed that a crosswalk to code 86617 times 2 was appropriate based on similarities in properties to code 86617. However after extensive review of the methodology and of the public comments we believe that gapfilling is a more appropriate, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

32. 0045U Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence 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 Recommendations: A majority (seven votes) recommended a crosswalk to code 81525. A minority (two votes) recommended a crosswalk to code 81519. Two members recommended to gapfill.

CMS Final Determination: 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).

Rationale: CMS agrees with the minority of the panel and with commenter recommendations to crosswalk 0045U to 81519. Both 0045U and 81519 appear to use the same methodologies to measure gene expression.

33. 0046U FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative

Commenter Recommendations: No recommendations

Panel Recommendations: A majority (seven votes) recommended to gapfill. A minority (three votes) recommended a crosswalk to code 81245, and one member recommended a crosswalk to code 81310.

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

Rationale: CMS agrees with the minority of the panel recommendation to crosswalk 0046U to code 81245. Both 0046U and 81245 appear to use similar resources to perform analysis of specific variants.

34. 0047U Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a 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 Recommendations: A majority (seven votes) recommended crosswalk to code 81519. Two members recommended to gapfill and two members recommended a crosswalk to 81525.

CMS Final Determination: 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).

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk 0047U to 81519. Both 0047U and 81519 appear to use the same methodologies to measure gene expression.

35. 0048U Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)

Commenter Recommendations: Crosswalk to code 81455 (Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed).

Panel Recommendations: All eleven panel members recommended a crosswalk to code 81455.

CMS Final Determination: Gapfill

Rationale: CMS disagrees with the panel recommendation and instead is recommending to gapfill 0048U. We believe that gapfilling is a more appropriate, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

36. 0049U NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative

Commenter Recommendations: No recommendations

Panel Recommendations: A majority (six votes) recommended a crosswalk to code 81310. Three members recommended to gapfill and one member recommended a crosswalk to code 81206. One panel member abstained from voting.

CMS Final Determination: Crosswalk to code 81310 (NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants).

Rationale: CMS agrees with the majority of the panel recommendation to crosswalk 0049U to 81310. Both 0049U and 81310 appear to use similar methodologies to perform a genetic analysis.

37. 0050U Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements

Commenter Recommendations: No recommendations

Panel Recommendations: All eleven panelists recommended a crosswalk to code 81455.

CMS Final Determination: Gapfill

Rationale: CMS disagrees with the panel recommendation and instead is recommending to gapfill 0050U. We believe that gapfilling is a more appropriate, since this will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests.

38. 0051U Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service

Commenter Recommendations: No recommendations

Panel Recommendations: All eleven panelists recommended crosswalk to code G0483.

CMS Final Determination: 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed).

Rationale: CMS agrees with the majority of the panel recommendation to crosswalk 0051U to G0483. Both 0051U and G0483 appear to perform a similar analysis using similar resources.

39. 0052U Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation

Commenter Recommendations: 83719 VLDL-C + 83695 Lp(a)C + 83721 LDL-C; + 83718 HDL-C; + 84999 IDL-C; + 82465 Total Chol; + 83701 HDL, LDL+VLDL subclasses

Panel Recommendations: Three members recommended a crosswalk to codes 83719 + 83695 + 83721 + (83718 x 2) + 82465 + 83701. Four members recommended a crosswalk to codes 83719 + 83695 + 83721 + 83718 + 82465 + 83701 and three members recommended a crosswalk to code 83701. One member recommended to gapfill.

CMS Final Determination: Crosswalk to 83701

Rationale: CMS agrees with a minority of the panel to crosswalk to code 83701. CMS disagrees with recommendations to crosswalk 0052U to the sum of each individual component code. CMS did not find sufficient evidence to show why 0052U is significantly different from 83701 and therefore believes it is an appropriate crosswalk.

40. 0053U Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade

Commenter Recommendations: Gapfill

Panel Recommendations: A majority (ten votes) recommended to gapfill. One member abstained from voting.

CMS Final Determination: Gapfill

Rationale: CMS agrees with the majority of the panel to gapfill this code. CMS did not find any existing test on the CLFS that was similar enough in methodology or resources to crosswalk to 0055U.

41. 0054U Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service

Commenter Recommendations: 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) + G0480 (Drug test(s), definitive, utilizing (1) 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)), (2) stable isotope or

other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed).

Panel Recommendations: A majority (ten votes) recommended crosswalk to code G0482. One member recommended a crosswalk to codes G0480+80307.

CMS Final Determination: Crosswalk to G0482 (Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed).

Rationale: CMS agrees with the majority of the panel to crosswalk 0054U to G0482. Both 0054U and G0482 appear to use similar resources to perform similar analyses.

42. 0055U Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma

Commenter Recommendations: Crosswalk to code 81595 (Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score).

Panel Recommendations: The majority (nine votes) recommended gapfill. One member recommended a crosswalk to code 81595x 0.2, and one member recommended a crosswalk to 81595.

CMS Final Determination: Gapfill

Rationale: CMS agrees with the majority of the panel to gapfill this code. CMS did not find any existing test on the CLFS that was similar enough in methodology or resources to crosswalk to 0055U.

43. 0056U Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s).

Commenter Recommendations: Gapfill

Panel Recommendations: A majority (seven votes) recommended crosswalk to code 0014U. A minority (two votes) recommended to Gapfill. Two members voted to crosswalk to code 81455.

CMS Final Determination: Gapfill

Rationale: CMS agrees with the minority of the panel and with commenter recommendations to gapfill this code, as no similar existing codes were found on the CLFS.

44. 0057U Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank.

Commenter Recommendations: Crosswalk to code 81455 (Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed).

Panel Recommendations: The majority (nine votes) recommended crosswalk to code 81455 x 0.5. One member recommended a crosswalk to code 81455, and one member abstained from voting.

CMS Final Determination: Gapfill

Rationale: CMS disagrees with the panel recommendation and instead is recommending to gapfill 0057U. CMS believes the gapfill process will yield better information about the resources required to perform this test.

45. 0058U Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative

Commenter Recommendations: Crosswalk to code 86835 (Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); semi-quantitative panel (eg, titer), HLA Class II).

Panel Recommendations: A majority (nine votes) recommended a crosswalk to code 86835. One member recommended a crosswalk to code 86617 and one member recommended to gapfill.

CMS Final Determination: Crosswalk to code 86835 (Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); semi-quantitative panel (eg, titer), HLA Class II).

Rationale: CMS agrees with the majority panel and commenter recommendations to crosswalk 0058U to 86835. Both 0058U and 86835 appear to use similar methodologies to analyze antibodies.

46. 0059U Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative

Commenter Recommendations: Crosswalk to code 86835 (Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); semi-quantitative panel (eg, titer), HLA Class II).

Panel Recommendations: A majority (nine votes) recommended a crosswalk to code 86835. One member recommended a crosswalk to code 86617 and one member recommended to gapfill.

CMS Final Determination: Crosswalk to code 86835 (Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); semi-quantitative panel (eg, titer), HLA Class II).

Rationale: CMS agrees with the majority panel and commenter recommendations to crosswalk 0059U to 86835. Both 0059U and 86835 appear to use similar methodologies to analyze antibodies.

47. 0060U Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood

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

Panel Recommendations: A majority (seven votes) recommended a crosswalk to code 81507 (Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy). A minority (three votes) recommended a crosswalk to code 81420. One member abstained from voting.

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

Rationale: CMS agrees with the minority of the panel and with commenter recommendations to crosswalk 0060U to 81420. Both 0060U and 81420 appear to use similar sequence analysis technology to analyze genetic material.

48. 0061U Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis

Commenter Recommendations: Crosswalk to code xwalk: 88732 (Hemoglobin (Hgb), quantitative, transcutaneous) x 12.

Panel Recommendations: All eleven panel members recommended a crosswalk to code 88738 x 5.

CMS Final Determination: Crosswalk to 88738 (Hemoglobin (Hgb), quantitative, transcutaneous) x 5.

Rationale: CMS initially recommended a crosswalk to 88738x2. Upon further review of the test methodologies CMS agrees with the panel and commenter recommendations to crosswalk 0061U to 88738 x 5.

49. 81345 (80X00) TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)

Commenter Recommendations: Crosswalk to code 81121 (IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)).

Panel Recommendations: The majority (ten votes) recommended a crosswalk to code 81121. A minority (one vote) recommended a crosswalk to code 81403.

CMS Final Determination: Crosswalk to code 81403. (Tier 2 MolPath, level 4)

Rationale: CMS disagrees with the majority of the panel and with commenter recommendations, and instead believes the code descriptors of 81345 and 81403 both appear to describe a similar sequencing methodology for targeted sequence analysis.

50. 82642 (80X01) Dihydrotestosterone (DHT)

Commenter Recommendations: Crosswalk to code 82634 (Deoxycortisol, 11-)

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 82634.

CMS Final Determination: Crosswalk to code 82634 (Deoxycortisol, 11-)

Rationale: CMS agrees with the panel and with commenter recommendations to crosswalk 80X01 to 82634. Both 82642 to 82634 appear to use similar resources.

51. 81333 (813X0) TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)

Commenter Recommendations: Crosswalk to code 81230 (CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)).

Panel Recommendations: The majority (eight votes) recommended a crosswalk to code 81401. A minority (three votes) recommended a crosswalk to code 81230.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with the majority of the panel to crosswalk 81333 to 81401. Both of the code descriptors of 81333 and 81401 appear to describe a similar sequencing methodology for common variant analysis.

52. 81596 (815X0) Infectious disease, chronic Hepatitis C Virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver

Commenter Recommendations: Crosswalk to code 0001M x 1.5 (Infectious disease, HCV, six biochemical assays (ALT, A2 macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver).

Panel Recommendations: A majority (nine votes) recommended a crosswalk to code 0001M x 1. A minority (two votes) recommended a crosswalk to code 0001M x 1.5.

CMS Final Determination: Crosswalk to code 0001M x 1 (Infectious disease, HCV, six biochemical assays (ALT, A2 macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver).

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk code 81596 to code 0001M x 1. Both codes 815X0 and 0001M appear to use similar resources to perform a near identical analysis. CMS did not find sufficient justification to apply any multiplier and therefore recommends a crosswalk of 81596 to code 0001M x 1.

53. 81518 (816X0) Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy

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 Recommendations: A majority (seven votes) recommended a crosswalk to code 81525. A minority (three votes) recommended to gapfill and one member recommended a crosswalk to code 81519.

CMS Final Determination: 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).

Rationale: CMS agrees with the commenter recommendations to crosswalkcode 81518 to code 81519. Both codes 81518 and 81519 appear to use similar techniques to measure gene expression.

54. 81236 (81X07) EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence

Commenter Recommendations: Crosswalk to code 81175 (ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence).

Panel Recommendations: A majority (seven votes) recommended a crosswalk to code 81175. A minority (four votes) of the panel recommended a crosswalk to code 81406.

CMS Final Determination: Crosswalk to code 81406 (Tier 2 MolPath, level 7); full sequence analysis

Rationale: CMS agrees with the minority of the panel to crosswalk 81236 to 81406. The code descriptors of 81236and 81406 both appear to describe a similar sequencing methodology for full gene sequencing.

55. 81237 (81X08) EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)

Commenter Recommendations: Crosswalk to code 81210 (BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s).

Panel Recommendations: A majority (ten votes) recommended a crosswalk to code 81210. One member recommended a crosswalk to code 81208.

CMS Final Determination: Crosswalk to code 81210 (BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s).

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk 81X08 to 81210. Both 81237 and 81210 appear to use similar resources to analyze specific variants.

56. 81233 (81X09) BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)

Commenter Recommendations: Crosswalk to code 81210 (BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81210.

CMS Final Determination: Crosswalk to code 81210 (BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)

Rationale: CMS agrees with the panel and with commenter recommendations to crosswalk 81233 to 81210. Both 81233 and 81210 appear to use similar methodologies to analyze specific variants.

57. 81320 (81X10) PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)

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)); common variant(s).

Panel Recommendations: A majority (ten votes) recommended crosswalk to code 81225. However, a minority (one vote) recommended crosswalk to code 81210.

CMS Final Determination: 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)); common variant(s).

Rationale: Although CMS originally proposed a crosswalk to code 81210, upon review of additional information, CMS agrees with the majority panel and public comments to crosswalk code 81320 to code 81225. CMS agrees that both codes 81320 and 81225 are more similar in resource utilization.

58. 81305 (81X11) MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom’s macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant

Commenter Recommendations: Crosswalk to code 81210 (BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s).

Panel Recommendations: All eleven panelists recommended a crosswalk to code 81210.

CMS Final Determination: Crosswalk to code 81210 (BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s).

Rationale: CMS agrees with the majority of the panel and with commenter recommendations to crosswalk 81305 to 81210. Both codes 81305 and 81210 appear to use similar resources to analyze specific variants.

59. 81443 (81X43) Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH).

Commenter Recommendations: Crosswalk to code 81412 (Ashkenazi Jewish associated disorders, must include sequencing of at least 9 genes).

Panel Recommendations: All eleven panelists recommended a crosswalk to code 81412.

CMS Final Determination: Crosswalk to code 81412 (Ashkenazi Jewish associated disorders, must include sequencing of at least 9 genes).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81443 to 81412. Both codes 81443 and 81412 appear to use a similar sequencing methodology to analyze multiple genes.

60. 81163 (81X78) BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis

Commenter Recommendations: 1. Crosswalk to code 81408 (Tier 2 MolPath, level 9). 2. Crosswalk to code 81162 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis) x 40%.

Panel Recommendations: Five panel members recommended a crosswalk to code 81408. Four members recommended a crosswalk to codes 81406 (Tier 2 MolPath, level 7) + 81407 (Tier 2

MolPath, level 8). One member recommended a crosswalk to code 81162 x 0.4 and one member recommended to Gapfill.

CMS Final Determination: Crosswalk to codes 81406 (Tier 2 MolPath, level 7) + 81216 (BRCA2 gene analysis; full sequence analysis).

Rationale: CMS agrees with the concept to crosswalk 81X78 with codes that are specific for full sequence analysis of BRCA1 and BRCA2. That is CMS agrees with the minority recommendation to crosswalk the BRCA 1 component to 81406 as this Tier 2 MolPath, level 7 code describes the full sequence analysis for BRCA1. However, to account for the BRCA2 portion of 81163, CMS instead recommends a crosswalk to the existing BRCA2 Tier 1 MolPath code 81216 (BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis) already on the CLFS. Thus CMS recommends a crosswalk of 81406 + 81216.

61. 81164 (81X79) BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)

Commenter Recommendations:
1. Crosswalk to code 81213 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants).
2. Crosswalk to code 81162 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis) x 20%.

Panel Recommendations: A majority (six votes) recommended a crosswalk to code 81405 (Tier 2 MolPath, level 6). A minority (four votes) of the panel recommended a crosswalk to 81213 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants). One member recommended a crosswalk to code 81162 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis) x 20%.

CMS Final Determination: Crosswalk to code 81405 + 81406 (Tier 2 MolPath, level 6 + Tier 2 MolPath, level 7); evaluation of duplication/deletion variants.

Rationale: CMS agrees with the concept to crosswalk 81164 with tests that are specific for evaluation of BRCA1 and BRCA2 duplication/deletion variants. That is CMS agrees with the majority of the panel to crosswalk 81164 to 81405 to account for the BRCA1 duplication/deletion evaluation. However, to account for the BRCA2 duplication/deletion analysis CMS believes adding 81406 (Tier 2 MolPath, level 7) is justified. Therefore CMS recommends a crosswalk of 81405 + 81406.

62. 81165 (81X81) BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis.

Commenter Recommendations:
1. Crosswalk to code 81408 (Tier 2 MolPath, level 9) x 50%.
2. Crosswalk to code 81162 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis) x 80% of 50% of 81162 (i.e., (80% (81162 x 50%)).

Panel Recommendations: A majority (seven votes) recommended a crosswalk to code 81406 (Tier 2 MolPath, level 7; full sequence analysis). A minority (three votes) recommended a crosswalk to code 81408 (Tier 2 MolPath, level 9) x 50% and one member recommended a crosswalk to code 81162 x 10%.

CMS Final Determination: Crosswalk to code 81406 (Tier 2 MolPath, level 7); full sequence analysis.

Rationale: CMS agrees with the majority of the panel to crosswalk 81165 to 81406 ((Tier 2 MolPath, level 7); full sequence analysis). The description of 81406 is similar to the analysis described for the BRCA1 full sequence.

63. 81166 (81X82) BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements).

Commenter Recommendations:
1. Crosswalk to code 81213 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants) x 50%.
2. Crosswalk to code 81222 (CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants).
3. Crosswalk to code 81162 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis) x 20% of 50% of 81162 (i.e., (20%(81162 x 50%)).

Panel Recommendations: A majority (six votes) of the panel recommended a crosswalk to 81405 (Tier 2 MolPath, Level 6). A minority (four votes) of the panel recommended a crosswalk to 81213 x 0.5. One member recommended a crosswalk to code 81162 x 10%.

CMS Final Determination: Crosswalk to code 81405 (Tier 2 MolPath, level 6); evaluation of duplication/deletion variants.

Rationale: CMS agrees with the majority of the panel to crosswalk 81166 to 81405 (Tier 2 MolPath, Level 6). The description of 81405 is similar to the analysis described for the BRCA1 duplication/deletion analysis.

64. 81167 (81X83) BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)

Commenter Recommendations:
1. Crosswalk to code 81213 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants) x 50%.
2. Crosswalk to code 81222 (CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants).
3. Crosswalk to code xwalk: 81162 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis) x 20% of 50% of 81162 (i.e., (20% (81162 x 50%)).

Panel Recommendations: A majority (seven votes) recommended a crosswalk to code 81406. A minority (three votes) recommended a crosswalk to 81213 x 50% and one member recommended a crosswalk to 81162 x 10%.

CMS Final Determination: Crosswalk to code 81406 (Tier 2 MolPath, level 7); evaluation of duplication/deletion variants.

Rationale: CMS agrees with the majority of the panel to crosswalk 81167 to 81406 (Tier 2 MolPath, level 7). The code descriptor of 81406 is similar to the analysis described for the BRCA2 duplication/deletion analysis.

65. 83722 (837X0) Lipoprotein, direct measurement; small dense LDL cholesterol

Commenter Recommendations: Crosswalk to code 83704 (Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed).

Panel Recommendations: All members (eleven votes) recommended crosswalk to code 83704.

CMS Final Determination: Crosswalk to code 83704 (Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed).

Rationale: CMS agrees with the the panel and with commenter recommendations to crosswalk 83722 to 83704. Both 83722 and 83704 appear to use similar resources to perform similar analyses.

66. 81306 (8X000) NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)

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)); common variant(s).

Panel Recommendations: All members (eleven votes) recommended crosswalk to code 81225.

CMS Final Determination: 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)); common variant(s).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81306 to 81225. Both 81306 and 81225 appear to use the same sequencing methodologies to analyze common variants.

67. 81171 (8X001) AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81171 to 81401. The description of 81171 is identical to that listed under code 81401.

68. 81172 (8X002) AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)

Commenter Recommendations: Crosswalk to code 81404 (Tier 2 MolPath, level 5); characterization of alleles (eg expanded size and methylation status).

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81404.

CMS Final Determination: Crosswalk to code 81404 (Tier 2 MolPath, level 5); characterization of alleles (eg expanded size and methylation status).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81172 to 81404. The description of 81172 is identical to that listed under 81404.

69. 81204 (8X003) AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2) Characterization of alleles (eg expanded size or methylation status).

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2) Characterization of alleles (eg expanded size or methylation status).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81204 to 81401. The description of 81204 is identical to that listed under 81401.

70. 81173 (8X004) AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence

Commenter Recommendations: Crosswalk to code 81405 (Tier 2 MolPath; level 6).

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81405.

CMS Final Determination: Crosswalk to code 81405 (Tier 2 MolPath; level 6).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81173 to 81405. The description of 81173 is identical to that listed under 81405.

71. 81174 (8X005) AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant

Commenter Recommendations: Crosswalk to code 81403 (Tier 2 MolPath, level 4); known familial variant.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81403.

CMS Final Determination: Crosswalk to code 81403 (Tier 2 MolPath, level 4); known familial variant.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81174 to 81403. The code descriptors of 81174 and 81403 both appear to describe a similar sequencing methodology for known familial variants.

72. 81177 (8X006) ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81177 to 81401. The description of 81177 is identical to that listed under 81401.

73. 81178 (8X007) ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81178 to 81401. The description of 81178 is identical to that listed under 81401.

74. 81183 (8X008) ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members(eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81183 to 81401. The description of 81183 is identical to that listed under 81401.

75. 81179 (8X009) ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81179 to 81401. The description of 81179 is identical to that listed under 81401.

76. 81180 (8X010) ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81180 to 81401. The description of 81180 is identical to that listed under 81401.

77. 81181 (8X011) ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81181 to 81401. The description of 81181 is identical to that listed under 81401.

78. 81182 (8X012) ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81182 to 81401. The description of 81182 is identical to that listed under 81401.

79. 81184 (8X013) CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81184 to 81401. The description of 81184 is identical to that listed under 81401.

80. 81185 (8X014) CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence

Commenter Recommendations: Crosswalk to code 81407 (Tier 2 MolPath, level 8).

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81407.

CMS Final Determination: Crosswalk to code 81407 (Tier 2 MolPath, level 8).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81185 to 81407. The description of 81185 is identical to that listed under 81407.

81. 81186 (8X015) CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant

Commenter Recommendations: Crosswalk to code 81403 (Tier 2 MolPath, level 4).

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81403.

CMS Final Determination: Crosswalk to code 81403 (Tier 2 MolPath, level 4).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81186 to 81403. The descriptors of 81186 and 81403 both appear to describe a similar sequencing methodology for known familiar variants.

82. 81187 (8X016) CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81187 to 81401. The description of 81187 is identical to that listed under 81401.

83. 81188 (8X017) CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: A majority (ten votes) recommended a crosswalk to code 81401. One member abstained from voting.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81188 to 81401. The description of 81188 is identical to that listed under 81401.

84. 81189 (8X018) CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; full gene sequence

Commenter Recommendations: Crosswalk to code 81404 (Tier 2 MolPath, level 5); full gene sequence.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81404.

CMS Final Determination: Crosswalk to code 81404 (Tier 2 MolPath, level 5); full gene sequence.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81189 to 81404. The description of 81189 is identical to that listed under 81404.

85. 81190 (8X019) CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)

Commenter Recommendations: Crosswalk to code 81403 (Tier 2 MolPath, level 4); full gene sequence.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81403.

CMS Final Determination: Crosswalk to code 81403 (Tier 2 MolPath, level 4); full gene sequence.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81190 to 81403. Both 81190 and 81403 appear to describe a similar sequencing methodology to identify known familial variants.

86. 81234 (8X020) DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: The majority (ten votes) recommended a crosswalk to code 81401. One member abstained from voting.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81234 to 81401. The description of 81234 is identical to that listed under 81401.

87. 81239 (8X021) DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)

Commenter Recommendations: Crosswalk to code 81404 (Tier 2 MolPath, level 5); full gene sequence.

Panel Recommendations: The majority (ten votes) recommended a crosswalk to code 81404. One member recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81404 (Tier 2 MolPath, level 5); full gene sequence.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81239 to 81404. The description of 81239 is nearly identical to that listed under 81404.

88. 81284 (8X022) FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2).

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81284 to 81401. The description of 81284 is identical to that listed under 81401.

89. 81285 (8X023) FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)

Commenter Recommendations: Crosswalk to code 81404 (Tier 2 MolPath, level 5); characterization of alleles (eg expanded size).

Panel Recommendations: The majority (nine votes) recommended a crosswalk to code 81404. Two members recommended a crosswalk to code 81401 (Tier 2 MolPath, level 2).

CMS Final Determination: Crosswalk to code 81404 (Tier 2 MolPath, level 5); characterization of alleles (eg expanded size).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81285 to 81404. The code descriptors of 81285 and 81404 both appear to describe a similar sequencing methodology for the characterization of alleles.

90. 81286 (8X024) FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence

Commenter Recommendations: Crosswalk to code 81404 (Tier 2 MolPath, level 5); characterization of alleles (eg expanded size).

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81404.

CMS Final Determination: Crosswalk to code 81404 (Tier 2 MolPath, level 5); characterization of alleles (eg expanded size).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81286 to 81404. The description of 81286 is identical to that listed under 81404.

91. 81289 (8X025) FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)

Commenter Recommendations: Crosswalk to code 81403 (Tier 2 MolPath, level 4); characterization of alleles (eg expanded size).

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81403.

CMS Final Determination: Crosswalk to code 81403 (Tier 2 MolPath, level 4); characterization of alleles (eg expanded size).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81289 to 81403. The code descriptors of 81289 and 81403 both appear to describe a similar sequencing methodology for known familial variants.

92. 81271 (8X026) HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81271 to 81401. The description of 81271 is identical to that listed under 81401.

93. 81274 (8X027) HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)

Commenter Recommendations: Crosswalk to code 81404 (Tier 2 MolPath, level 5); characterization of alleles (eg expanded size) .

Panel Recommendations: The majority (ten votes) recommended a crosswalk to code 81404. One member recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81404 (Tier 2 MolPath, level 5); characterization of alleles (eg expanded size) .

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81274 to 81404. The code descriptors of 81274 and 81404 both appear to describe a similar sequencing methodology for the characterization of alleles.

94. 81312 (8X028) PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81312 to 81401. The description of 81312 is identical to that listed under 81401.

95. 81329 (8X032) SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis, includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81329 to 81401. The description of 81329 is identical to that listed under 81401.

96. 81336 (8X033) SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) 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 Recommendations: A slight majority (six votes) recommended a crosswalk to code 80405. Four members recommended a crosswalk to code 81317 and one member recommended a crosswalk to code 81307 (we believe this was an error as there is no code 81307 on the CLFS).

CMS Final Determination: Crosswalk to code 81405 (Tier 2 MolPath; level 6).

Rationale: CMS agrees with the majority of the panel to crosswalk 81336 to 81405. The description of 81336 is identical to that listed under 81405.

97. 81337 (8X034) SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)

Commenter Recommendations:
1. Crosswalk to code 81403 (Tier 2 MolPath, level 4); known familial variant
2. Crosswalk to code 81401 (Tier 2 MolPath); known familial variant.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81403.

CMS Final Determination: Crosswalk to code 81403 (Tier 2 MolPath, level 4); known familial variant.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81337 to 81403. The description of 81337 is identical to that listed under 81403.

98. 81343 (8X035) PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81343 to 81401. The description of 81343 is identical to that listed under 81401.

99. 81344 (8X036) TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

Commenter Recommendations: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Panel Recommendations: All members (eleven votes) recommended a crosswalk to code 81401.

CMS Final Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2); evaluation to detect abnormal (eg expanded) alleles.

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 81344 to 81401. The description of 81344 is identical to that listed under 81401.