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

A. Summary of CY 2019 CLFS Preliminary Determinations

We received approximately 100 new codes for implementation on the CLFS beginning January 1, 2019. In the majority of the new codes we support the recommendations submitted by commenters and/or the majority vote of the Medicare Advisory Panel on Clinical Diagnostic Laboratory Test (the Panel) to either crosswalk or gapfill the new codes. For any codes, particularly those new codes which we are making payment recommendations other than what was recommended by the Public or the Panel, we welcome public comment. In the interest of transparency, we have not only given a rationale for each new codes' recommendation, but have also identified four themes for approximately 15 new codes which may further explain our rationale for disagreement. We would ask that when submitting public comment, please refer to the specific codes' rationale as opposed to the general themes, so that we may best respond in the final determinations.

1. **Justification for utilization of multipliers**: Commenters and/or the Panel recommended the use of crosswalks in conjunction with multipliers greater than 1 (i.e. crosswalk to 89999 x 2.5) for approximately 10 new codes. While we agree with the commenters' and Panel's recommendation of the CPT code to use as a crosswalk, there were inconsistent justifications and insufficient rationales for the use of multipliers for these new codes. We argue that a successful crosswalk is made by finding an existing code that uses similar methods and resources. If a crosswalk is correct, the application of a multiplier should be made very rarely. In an effort to maintain consistency across the entirety of recommendations, in most cases we support and recommend to crosswalk the new codes without multipliers to the most comparable existing code in terms of methods and resources.

2. **Stacking/Bundling existing CDLT codes**: Recommendations for a few new CLFS codes were to crosswalk the new codes to a bundle of several existing CDLTs on the CLFS. These new CDLTs are all categorized under a new category of codes from the American Medical Association (AMA) Current Procedural Terminology® (CPT) Editorial Panel called Proprietary Laboratory Analysis (PLA) tests. For each of these tests, commenters recommended a crosswalk that represented the sum total of each individual test within the bundled new code. We are concerned with these recommendations generally because we are unable to make an informed decision regarding crosswalks that recommend stacking or bundling of CLFS CDLT codes, and we believe these recommendations may not account for any economy of scale. Therefore, for AMA PLA tests where a recommendation reflected a payment based on stacking or bundling of current CLFS CDLTs, we recommend to gapfill the tests. Gapfilling will allow CMS and its contractors the opportunity to gather current

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information about the manner in which the test is performed and the resources necessary to provide the test so that CMS can develop an appropriate payment rate for the tests.

3. **Codes that analyze a large quantity of genes**: There are a few new test codes with descriptors that indicate the abilty to analyze large numbers of genes. Commenters recommended crosswalking these tests to a code that generically analyses 51 genes or more (e.g. one test analyzed **194 genes**). Because the only code available for crosswalk to these new codes is fairly generic (i.e. greater than 51 genes) we recommend to gapfill these tests. This will allow CMS and contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide these tests. Additionally, we welcome public comment on specific evaluation recommendations (i.e. vetting, examination, etc.) for how CMS should approach payment determinations for these tests.

4. **Determining crosswalk codes for new BRCA codes**: The American Medical Association (AMA) Current Procedural Terminology® (CPT) Editorial Panel's revisions to the code set that includes CDLTs for the assessment of BRCA 1 and BRCA 2 resulted in the deletion, revision and creation of new codes. Our preliminary determinations for these new codes were supported by the majority vote of the Panel and are consistent with the methodology used to crosswalk other CDLTs on the CLFS. Specifically, for the new BRCA test codes, Tier 2 MoPath codes were used to compare the amount of genetic material and type of analysis (full sequencing or duplication/deletion analysis) required to perform these new test codes.

   Although we received recommendations to crosswalk the BRCA codes to a percentage of the National Limit Amount (NLA) for CPT code 81162, we are concerned that this recommendation is inconsistent how CMS determines crosswalks for new codes in general. Specifically, our recommended crosswalk codes from the CLFS support a one to one (1:1) crosswalk to the new BRCA codes, therefore eliminating the need to crosswalk the codes to an approximated percentage of code 81162's current NLA. In addition, current market-based research of available BRCA tests codes suggest rates that are consistent with our payment methodology and recommended crosswalk codes. Lastly, we believe the comparable lower payment rate will support a more competitive landscape for these tests to be accessible to a greater Medicare beneficiary population.

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

The following are CMS's preliminary 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). CMS is accepting comments until October 22, 2018. Comments must be submitted electronically by this date to the following CMS mailbox: CLFS_Annual_Public_Meeting@cms.hhs.gov.

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 crosswalk to 81326. One vote recommended to gapfill and one vote recommended a crosswalk to code 81259.

CMS Preliminary Determination: Maintain same crosswalk to 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 Preliminary Determination: Crosswalk to code 81404 (Tier 2 MolPath); 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. Upon further review of this code, the code descriptors of 81334 and 81404 both appear to describe a similar sequencing methodology for targeted sequence analysis. CMS welcomes public feedback on this new suggestion of a crosswalk.

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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary 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 is being 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 Preliminary 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 Preliminary Determination: Crosswalk to code 81445 (Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 5-50 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).

Rationale: CMS agrees with the majority of the panel to crosswalk 0022U to 81445. Both 0022U and 81445 appear to use similar sequencing technology to identify sequence variants.

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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary Determination: 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).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 0027U to 0017U x 1. Both 0027U and 0017U appear to use similar sequencing methodologies to perform a sequence analysis. CMS did not find sufficient evidence to justify the use of a 1.33 multiplier with the crosswalk code 0017U.

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 Preliminary 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 Preliminary Determination: Gapfill

Rationale: CMS disagrees with recommendations to crosswalk 0030U to the sum of each individual component code. 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 Preliminary 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 Preliminary 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 81230x2.

CMS Preliminary Determination: Crosswalk to code 81230 x 1 (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 0033U to 81230 x 1. Both 0033U and 81230 appear to use similar technologies to identify specific variants. CMS did not find sufficient evidence to justify a multiplier of 2.

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 Preliminary Determination: Gapfill

Rationale: CMS disagrees with recommendations to crosswalk 0034U 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.

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 Preliminary 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 Preliminary Determination: 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 Preliminary 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 Preliminary 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 Preliminary Determination: Crosswalk to code 81206 x 1 (BCR/ABL1 (t(9;22)) (eg chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative.

Rationale: CMS agrees with the majority of the panel and commenter recommendations to crosswalk 0040U to 81206 x 1. Both 0040U and 81206 appear to use the same resources for breakpoint analysis. CMS did notfind sufficient evidence to justify a multiplier of 2.5. Therefore CMS recommends a crosswalk of 0040U to 81206 x 1.

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

Rationale: CMS agrees with the panel and commenter recommendations to crosswalk 0041U to 86617. Both 0041U and 86617 appear to use similar methods to detect protein groups. CMS also agrees with the panel recommendations that a multiplier of 2 is appropriate to account for a difference in resources between 0041U and 86617. Therefore, CMS recommends a crosswalk of 0041U to 86617 x 2.

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

Rationale: CMS agrees with the panel and commenter recommendations to crosswalk 0042U to 86617. Both 0042U and 86617 appear to use similar methods to detect protein groups. CMS agrees with the panel recommendations that a multiplier of 2 is appropriate to account for a difference in resources between 0042U and 86617. Therefore CMS recommends a crosswalk of 0042U to 86617x2.

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

Rationale: CMS agrees with the panel and commenter recommendations to crosswalk 0043U to 86617. Both 0043U and 86617 appear to use similar methods to detect protein groups. CMS agrees with the panel recommendations that a multiplier of 2 is appropriate to account for a difference in resources between 0043U and 86617. Therefore CMS recommends a crosswalk of 0043U to 86617 x 2.

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

Rationale: CMS agrees with the panel and commenter recommendations to crosswalk 0044U to 86617. Both 0044U and 86617 appear to use similar methods to detect protein groups. CMS agrees with the panel recommendations that a multiplier of 2 is appropriate to account for a difference in resources between 0044U and 86617. Therefore CMS recommends a crosswalk of 0044U to 86617 x 2.

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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary Determination: Gapfill

Rationale: CMS disagrees with the panel recommendation and instead is recommending to gapfill 0048U. CMS believes the gapfill process will give us better information about the resources required to perform this test.

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 Preliminary 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 Preliminary Determination: Gapfill

Rationale: CMS disagrees with the panel recommendation and instead is recommending to gapfill 0050U. CMS believes the gapfill process will give us better information about the resources required to perform this test.

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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary 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.2, and one member recommended a crosswalk to 81595.

CMS Preliminary 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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary 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 Preliminary Determination: Crosswalk to 88738 (Hemoglobin (Hgb), quantitative, transcutaneous) x 2

Rationale: CMS agrees with the panel and commenter recommendations to crosswalk 0061U to 88738. However, CMS believes a modifier of 2 is sufficient to estimate the resources for performing 0061U.

49. 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 Preliminary 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 80X00 and 81403 both appear to describe a similar sequencing methodology for targeted sequence analysis.

50. 80X01 Dihydrotestosterone (DHT)

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

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

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

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

51. 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 Preliminary 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 813X0 to 81401. Both of the code descriptors of 813X0 and 81401 appear to describe a similar sequencing methodology for common variant analysis.

52. 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 Preliminary 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 815X0 to 0001M x 1. Both 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 815X0 to 0001M x 1.

53. 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 Preliminary 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 crosswalk 816X0 to 81519. Both 816X0 and 81519 appear to use similar techniques to measure gene expression.

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

Rationale: CMS agrees with the minority of the panel to crosswalk 81X07 to 81406. The code descriptors of 81X07 and 81406 both appear to describe a similar sequencing methodology for full gene sequencing.

55. 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 Preliminary 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 81X08 and 81210 appear to use similar resources to analyze specific variants.

56. 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 Preliminary 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 81X09 to 81210. Both 81X09 and 81210 appear to use similar methodologies to analyze specific variants.

57. 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 Preliminary 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 minority of the panel to crosswalk 81X10 to 81210. Both 81X10 and 81210 appear to use similar resources to analyze specific variants.

58. 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 Preliminary 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 81X08 and 81210 appear to use similar resources to analyze specific variants.

59. 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 Preliminary 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 81X43 to 81412. Both 81X43 and 81412 appear to use a similar sequencing methodology to analyze multiple genes.

60. 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 Preliminary 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 81X78, 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. 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 Preliminary 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 81X79 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 81X79 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. 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 Preliminary Determination: Crosswalk to code 81406 (Tier 2 MolPath, level 7); full sequence analysis.

Rationale: CMS agrees with the majority of the panel to crosswalk 81X81 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. 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 Preliminary 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 81X82 to 81405 (Tier 2 MolPath, Level 6). The description of 81405 is similar to the analysis described for the BRCA1 duplication/deletion analysis.

64. 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 Preliminary 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 81X83 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. 8372X 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 Preliminary 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 8372X to 83704. Both 8372X and 83704 appear to use similar resources to perform similar analyses.

66. 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 Preliminary 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 8X000 to 81225. Both 8X000 and 81225 appear to use the same sequencing methodologies to analyze common variants.

67. 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 Preliminary 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 8X001 to 81401. The description of 8X001 is identical to that listed under 81401.

68. 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 Preliminary 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 8X002 to 81404. The description of 8X002 is identical to that listed under 81404.

69. 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 Preliminary 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 8X003 to 81401. The description of 8X003 is identical to that listed under 81401.

70. 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 Preliminary Determination: Crosswalk to code 81405 (Tier 2 MolPath; level 6).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X004 to 81405. The description of 8X004 is identical to that listed under 81405.

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

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X005 to 81403. The code descriptors of 8X005 and 81403 both appear to describe a similar sequencing methodology for known familial variants.

72. 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 Preliminary 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 8X006 to 81401. The description of 8X006 is identical to that listed under 81401.

73. 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 Preliminary 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 8X007 to 81401. The description of 8X007 is identical to that listed under 81401.

74. 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 Preliminary 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 8X008 to 81401. The description of 8X008 is identical to that listed under 81401.

75. 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 Preliminary 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 8X009 to 81401. The description of 8X009 is identical to that listed under 81401.

76. 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 Preliminary 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 8X010 to 81401. The description of 8X010 is identical to that listed under 81401.

77. 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 Preliminary 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 8X011 to 81401. The description of 8X011 is identical to that listed under 81401.

78. 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 Preliminary 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 8X012 to 81401. The description of 8X012 is identical to that listed under 81401.

79. 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 Preliminary 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 8X013 to 81401. The description of 8X013 is identical to that listed under 81401.

80. 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 Preliminary Determination: Crosswalk to code 81407 (Tier 2 MolPath, level 8).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X014 to 81407. The description of 8X014 is identical to that listed under 81407.

81. 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 Preliminary Determination: Crosswalk to code 81403 (Tier 2 MolPath, level 4).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X015 to 81403. The descriptors of 8X015 and 81403 both appear to describe a similar sequencing methodology for known familiar variants.

82. 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 Preliminary 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 8X016 to 81401. The description of 8X016 is identical to that listed under 81401.

83. 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 Preliminary 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 8X017 to 81401. The description of 8X017 is identical to that listed under 81401.

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

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X018 to 81404. The description of 8X019 is identical to that listed under 81404.

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

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X019 to 81403. Both 8X019 and 81403 appear to describe a similar sequencing methodology to identify known familial variants.

86. 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 Preliminary 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 8X020 to 81401. The description of 8X020 is identical to that listed under 81401.

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

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X021 to 81404. The description of 8X021 is nearly identical to that listed under 81404.

88. 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 Preliminary Determination: Crosswalk to code 81401 (Tier 2 MolPath, level 2).

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X022 to 81401. The description of 8X022 is identical to that listed under 81401.

89. 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 Preliminary 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 8X023 to 81404. The code descriptors of 8X023 and 81404 both appear to describe a similar sequencing methodology for the characterization of alleles.

90. 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 Preliminary 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 8X024 to 81404. The description of 8X024 is identical to that listed under 81404.

91. 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 Preliminary 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 8X025 to 81403. The code descriptors of 8X025 and 81403 both appear to describe a similar sequencing methodology for known familial variants.

92. 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 Preliminary 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 8X026 to 81401. The description of 8X026 is identical to that listed under 81401.

93. 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 Preliminary 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 8X027 to 81404. The code descriptors of 8X027 and 81404 both appear to describe a similar sequencing methodology for the characterization of alleles.

94. 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 Preliminary 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 8X028 to 81401. The description of 8X028 is identical to that listed under 81401.

95. 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 Preliminary 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 8X032 to 81401. The description of 8X032 is identical to that listed under 81401.

96. 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 Preliminary Determination: Crosswalk to code 81405 (Tier 2 MolPath; level 6).

Rationale: CMS agrees with the majority of the panel to crosswalk 8X033 to 81405. The description of 8X033 is identical to that listed under 81405.

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

Rationale: CMS agrees with commenter and panel recommendations to crosswalk 8X034 to 81403. The description of 8X034 is identical to that listed under 81403.

98. 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 Preliminary 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 8X035 to 81401. The description of 8X035 is identical to that listed under 81401.

99. 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 Preliminary 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 8X036 to 81401. The description of 8X036 is identical to that listed under 81401.