Calendar Year 2013
Centers for Medicare and Medicaid Services (CMS)
New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes
And Preliminary Payment Determinations

Reconsideration Code
86386

Reconsideration Code Description
Nuclear Matrix Protein 22 (NMP22), qualitative

Industry Recommended Payment Decision
Change crosswalk from 82487 – Chromotography, qualitative; paper, 1-dimensional, analyte not elsewhere specified to 86294 – Immunoassay for tumor antigen, qualitative or semiquantitative (eg, bladder tumor antigen)

CMS Preliminary Payment Decision
Retain current crosswalk to 82487.

Rationale
We recommend that the current crosswalk to code 82487 be retained. Like lateral flow immunochromatography performed for 86386, code 82487 uses a one dimensional flow chromatography. For code 82487, a chemical reaction is utilized to characterize results while code 86386 utilizes an immune reaction. Therefore, we believe that the current crosswalk is appropriate and should not be changed.

New Codes
812XX through 81408

New Code Description
Molecular Pathology Procedures – Tier 1 and Tier 2

Industry Recommended Payment Decision
Either 1) Crosswalking using existing stacked code methodology; or 2) Gapfill.

CMS Preliminary Payment Decision
Gapfill – This draft recommendation applies ONLY for those Molecular Pathology Procedures that CMS determines should be paid under the Clinical Laboratory Fee Schedule (CLFS).

Rationale
Please note that the draft recommendation of gapfilling would apply ONLY to those Molecular Pathology Procedures that would be paid under the CLFS. The American Medical Association (AMA) created a series of new Current Procedural Terminology (CPT) codes for molecular tests and will be deleting the existing stacking codes that are currently used to bill for some of these

tests. Other new test codes are currently billed using unlisted codes. Commenters at the public meeting generally suggested that these codes be crosswalked back to the stacking codes but did not provide us with specific cross-walks of the stacking codes to the new codes. Previously, we have requested this information from the laboratory industry and have agreed to accept it in multiple formats. We appreciate the information that has been submitted to us. However, we know that the same test is often being billed using different stacks. It is also possible that the stacks have changed over time. For these reasons, we are recommending that the series of new molecular pathology codes be gapfilled for 2013. This will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests. We note that, as discussed in the notice of the public meeting in CY 2012 for new clinical laboratory test payment determinations (77 FR 31620, 31621), CMS may decide, based on comments received in response to the proposals set forth in the CY 2013 Physician Fee Schedule (PFS), that some of the codes on this list are not clinical diagnostic laboratory test codes. We will post our final payment determinations only for the new test codes that we determine are clinical diagnostic laboratory test codes that will be paid under the CLFS. We intend to post these final payment determinations in November (at the same time as the CY 2013 final rule with comment period is published).

New Codes

815XX1 through 815XX7 and XXXX1M through XXXX3M

New Code Description

Multi-analyte Assays with Algorithmic Analyses (MAAAs)

Industry Recommended Payment Decision

Various crosswalks or gapfilling.

CMS Preliminary Payment Decision

CMS uses other codes for payment of the underlying clinical laboratory tests on which the MAAA is done and does not recommend separately pricing the MAAAs codes.

Rationale

A MAAA is a numeric score(s) or a probability (i.e., “p-score”) based on the results of laboratory tests and, in some cases, patient information. Medicare does not recognize a calculated or algorithmically derived rate or result as a clinical laboratory test since the calculated or algorithmically derived rate or result alone does not indicate the presence or absence of a substance or organism in the body. Medicare uses other codes for payment of the underlying clinical laboratory tests on which the MAAA is done and we continue to recommend not separately pricing the MAAAs codes.

New Code
827XX

New Code Description
Galectin-3

Industry Recommended Payment Decision
86252 – Dihydroxy Vitamin D, 1, 25 **OR** 83880 – Natriuretic Peptide

CMS Preliminary Payment Decision
Crosswalk to 83520 (Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified

Rationale
We recommend a crosswalk to code 83520. One of the presenters at the public meeting stated that 827XX and 83520 use the same testing methodology. Per the CPT application to the AMA CPT Editorial Panel, providers currently report this test with code 83520. Other commenters suggested a crosswalk to code 82652 or code 83880 without explanation of a rationale other than stating without documentation that these codes represent comparable resources.

New Code
861XX

New Code Description
Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)

Industry Recommended Payment Decision
88239 – Tissue culture for neoplastic disorders; solid tumor **OR** 88283 – Chromosome analysis; additional specialized banding technique (eg, NOR, C-banding) **OR** 88249 – Chromosome analysis for breakage syndromes; score 100 cells, clastogen stress (eg, diepoxybutane, mitomycin C, ionizing radiation, UV radiation) **OR** Gapfill

CMS Preliminary Payment Decision
Gapfill

Rationale
One commenter stated that this test incorporates three steps: cell isolation and extraction, immunostaining, and cell analysis and enumeration. These are similar to the processes utilized for flow cytometry. For flow cytometry, the specimen is processed to isolate and extract white blood cells, the cells are stained with fluoresceinated antibodies (immunostaining), and are run through the flow cytometer to identify and quantify the positively stained cells. The major methodologic difference between flow cytometry and the new test is that the flow cytometer determines the percentage of cells positive of the marker being tested while the new test requires microscopic review of the positively staining cells. Test code 88184 (Flow cytometry, cell

surface, cytoplasmic, or nuclear marker, technical component only; first marker) is paid as a technical component on the PFS, not the CLFS, so we believe that the new test code would have to be gapfilled as a payment recommendation in order to be able to take the PFS resources into account. Another commenter did recommend that this new test code be gapfilled.

New Code
867XX

New Code Description
JC (John Cunningham) virus

Industry Recommended Payment Decision
86757 – Antibody; Rickettsia **OR** 84446 – Tocopherol alpha (Vitamin E) **OR** 86789 – Antibody; West Nile virus

CMS Preliminary Payment Decision
Crosswalk to 86789

Rationale
We recommend crosswalking to 86789 as suggested by one commenter. We believe the crosswalk between two viruses in the same antibody code range is appropriate. Antibodies to microorganisms are reported with codes 86710 through 86793. The National Limitation Amounts (NLAs) for these codes generally range between $17.80 and $21.67; the only exception being code 86757 which has an NLA of $27.41. Other commenters recommended crosswalks to various codes in the code range without any specific logic except for one commenter who recommended a crosswalk to code 86757. The commenter's rationale is that both tests are low frequency and only available from a limited number of laboratories. We disagree that this test is sufficiently different from the other tests in the 86710 through 86793 code range to justify selecting 86757 as the basis for the crosswalk.

New Code
868XX1

New Code Description
Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads; ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens

Industry Recommended Payment Decision
86806 – Lymphocytotoxicity assay; without titration **OR** 86807 – Serum screening for cytotoxic percent reactive antibody (PRA); standard method

CMS Preliminary Payment Decision
Crosswalk to 86807

Rationale
We recommend a crosswalk to code 86807 as this crosswalk was suggested by the commenters, and we agree that qualitative assessment of the presence or absence of antibodies is a methodological match to the new test.

New Code
868XX2

New Code Description
Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens

Industry Recommended Payment Decision
(3/4) of 86806 – Lymphocytotoxicity assay; without titration **OR** 86808 – Serum screening for cytotoxic percent reactive antibody (PRA); quick method

CMS Preliminary Payment Decision
Crosswalk to 86808

Rationale
We recommend a crosswalk to code 86808 as this crosswalk was suggested by the commenters. It uses a similar methodology to the new test – testing for antibodies to HLA antigens.

New Code
868XX3

New Code Description
Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I

Industry Recommended Payment Decision
(2 TIMES) 86806 – Lymphocytotoxicity assay; without titration **OR** (7 TIMES) 83516 – Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method

CMS Preliminary Payment Decision
Crosswalk to (7 TIMES) 83516

Rationale
We agree with the recommendation of the commenters to crosswalk to 7 times code 83516. We agree with several commenters who suggested that codes 868XX3 through 868XX8 be priced at a multiple of code 83516. Code 83516 is a code that could be utilized for ELISA testing which is one of the methodologies listed in the code descriptor for the new tests. Although other commenters wanted to price these codes based on multiples of lymphocytoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytoxicity is not a methodology utilized for the new codes being priced.

New Code
868XX4

New Code Description
Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II

Industry Recommended Payment Decision
(2 TIMES) 86806 – Lymphocytotoxicity assay; without titration **OR** (6 TIMES) 83516 - Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method

CMS Preliminary Payment Decision
Crosswalk to (6 TIMES) 83516

Rationale
We agree with the recommendation of the commenters to crosswalk to 6 times code 83516. We agree with several commenters who suggested that codes 868XX3 through 868XX8 be priced at a multiple of code 83516. Code 83516 is a code that could be utilized for ELISA testing which is one of the methodologies listed in the code descriptor for the new tests. Although other commenters wanted to price these codes based on multiples of lymphocytoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytoxicity is not a methodology utilized for the new codes being priced.

New Code
868XX5

New Code Description
Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class I

Industry Recommended Payment Decision
(3 TIMES) 86806 – Lymphocytotoxicity assay; without titration **OR** (11 TIMES) 83516 - Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method

CMS Preliminary Payment Decision
Crosswalk to (11 TIMES) 83516

Rationale
We agree with the recommendation of the commenters to crosswalk to 11 times 83516. We agree with several commenters who suggested that codes 868XX3 through 868XX8 be priced at a multiple of code 83516. Code 83516 is a code that could be utilized for ELISA testing which is one of the methodologies listed in the code descriptor for the new tests. Although other commenters wanted to price these codes based on multiples of lymphocytoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytoxicity is not a methodology utilized for the new codes being priced.

New Code
868XX6

New Code Description
Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class II

Industry Recommended Payment Decision
(3 TIMES) 86806 – Lymphocytotoxicity assay; without titration **OR** (10 TIMES) 83516 - Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method

CMS Preliminary Payment Decision
Crosswalk to (10 TIMES) 83516.

Rationale
We agree with the recommendation of the commenters to crosswalk to 10 times code 83516. We agree with several commenters who suggested that codes 868XX3 through 868XX8 be priced at a multiple of code 83516. Code 83516 is a code that could be utilized for ELISA testing which is one of the methodologies listed in the code descriptor for the new tests. Although other commenters wanted to price these codes based on multiples of lymphocytoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytoxicity is not a methodology utilized for the new codes being priced.

New Code
868XX7

New Code Description
Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (eg, titer), HLA Class I

Industry Recommended Payment Decision
(7 1/2 TIMES) 86806 – Lymphocytotoxicity assay; without titration **OR** (31 TIMES) 83516 - Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method

CMS Preliminary Payment Decision
Crosswalk to (31 TIMES) 83516.

Rationale
We agree with the recommendation of the commenters to crosswalk to 31 times code 83516. We agree with several commenters who suggested that codes 868XX3 through 868XX8 be priced at a multiple of code 83516. Code 83516 is a code that could be utilized for ELISA testing which is one of the methodologies listed in the code descriptor for the new tests. Although other commenters wanted to price these codes based on multiples of lymphocytoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytoxicity is not a methodology utilized for the new codes being priced.

New Code
868XX8

New Code Description
Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (eg, titer), HLA Class II

Industry Recommended Payment Decision
(7 1/2 TIMES) 86806 – Lymphocytotoxicity assay; without titration **OR** (28 TIMES) 83516 - Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method

CMS Preliminary Payment Decision
Crosswalk to (28 TIMES) 83516.

Rationale
We agree with the recommendation of the commenters to crosswalk to 28 times 83516. We agree with several commenters who suggested that codes 868XX3 through 868XX8 be priced at a multiple of code 83516. Code 83516 is a code that could be utilized for ELISA testing which is one of the methodologies listed in the code descriptor for the new tests. Although other commenters wanted to price these codes based on multiples of lymphocytoxicity

testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytoxicity is not a methodology utilized for the new codes being priced.

New Code
876XX1

New Code Description
Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 3-5 targets

Industry Recommended Payment Decision
87502 – Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, multiplex reverse transcription and amplified probe technique, first 2 types or sub-types **PLUS** 87503 – influenza virus, for multiple types or sub-types, multiplex reverse transcription and amplified probe technique, each additional influenza virus type or sub-type beyond 2 (List separately in addition to code for primary procedure)
OR
87502 **PLUS** (2 TIMES) 87503

CMS Preliminary Payment Decision
Crosswalk to 87502 **PLUS** (2 TIMES) 87503.

Rationale
We recommend that this code be crosswalked using a combination of other multiplex reverse transcription and amplified probe technique codes, specifically code 87502 and code 87503. These codes describe the same methodology for influenza virus testing. We recommend that this code be priced for 4 targets (1 times 87502 PLUS 2 times 87503. Most commenters agreed with this pricing.

New Code
876XX2

New Code Description
Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 6-11 targets

Industry Recommended Payment Decision
87502 – Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, multiplex reverse transcription and amplified probe technique, first 2 types or sub-types **PLUS** (6 TIMES) 87503 – influenza virus, for multiple types or sub-types, multiplex

reverse transcription and amplified probe technique, each additional influenza virus type or sub-type beyond 2 (List separately in addition to code for primary procedure)

CMS Preliminary Payment Decision
87502 **PLUS** (6 TIMES) 87503

Rationale
We recommend that this code be priced for 8 targets (1 times 87502 PLUS 6 times 87503). All commenters suggested pricing this code at 8 targets (87502 consists of 2 probes, 87503 consists of 6 probes).

New Code
876XX3

New Code Description
Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 12-25 targets

Industry Recommended Payment Decision
87502 – Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, multiplex reverse transcription and amplified probe technique, first 2 types or sub-types **PLUS** (15 TIMES) 87503 – influenza virus, for multiple types or sub-types, multiplex reverse transcription and amplified probe technique, each additional influenza virus type or sub-type beyond 2 (List separately in addition to code for primary procedure)
OR
87502 **PLUS** (16 TIMES) 87503

CMS Preliminary Payment Decision
Crosswalk to 87502 PLUS (16 TIMES) 87503.

Rationale
We recommend that this code be priced for 18 targets (1 times 87502 PLUS 16 times 87503). All commenters suggested pricing this code at 17 or 18 targets.

New Code
879XX1

New Code Description
Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus

Industry Recommended Payment Decision

87902 – Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis C virus **OR** 87901 - Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

CMS Preliminary Payment Decision
Crosswalk to 87902.

Rationale
We recommend crosswalking this code to code 87902. Each assay tests for different infectious agents using similar genotype analysis methodology and might be priced similarly. All commenters agreed with the pricing although some wanted to crosswalk to 87902 and others to 87901; however, both of these yield the same NLA.

New Code
879XX2

New Code Description
Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis B virus

Industry Recommended Payment Decision
87902 – Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis C virus **OR** 87901 - Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions

CMS Preliminary Payment Decision
Crosswalk to 87902.

Rationale
We recommend crosswalking this code to code 87902. Each assay tests for different infectious agents using similar genotype analysis methodology and might be priced similarly. All commenters agreed with the pricing although some wanted to crosswalk to 87902 and others to 87901; however, both of these yield the same NLA.