

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

**Reconsideration Code**

86386

***Reconsideration Code Description***

Nuclear Matrix Protein 22 (NMP22), qualitative

***Industry Recommended Payment Decision***

Change crosswalk from 82487 – Chromatography, qualitative; paper, 1-dimensional, analyte not elsewhere specified to 86294 – Immunoassay for tumor antigen, qualitative or semiquantitative (e.g., bladder tumor antigen)

***CMS Final 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**

81201 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 Final Payment Decision***

Gapfill

***Rationale***

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.

**New Codes**

81500 through 81512 and 0001M through 0003M

***New Code Description***

Multi-analyte Assays with Algorithmic Analyses (MAAAs)

***Industry Recommended Payment Decision***

Various crosswalks or gapfilling.

***CMS Final Payment Decision***

CMS will not recognize these MAAA codes as valid for Medicare purposes under the CLFS for CY 2013.

***Rationale***

The MAAA category is a new category that has been created by the AMA for the 2013 CPT. The new codes that are included in the MAAAs section of the 2013 CPT are comprised of multiple clinical laboratory tests currently paid under the Clinical Laboratory Fee Schedule (CLFS) using existing Healthcare Common Procedure Coding System (HCPCS) codes together with an algorithm. Most of the comments we received were not specific to these new codes for 2013, but instead addressed other tests that have an algorithmic component and are currently being paid for using unclassified or other codes. Based on our review of the comments and our understanding of these nine MAAA codes, we will not recognize these nine MAAA codes for CY 2013 because we believe that we need to further study these codes before we pay for them under the CLFS. Therefore, we are instructing laboratories to continue using the existing HCPCS codes. We intend to solicit more information about this category of tests during the annual public notice process next year.

**New Code**

82777

***New Code Description***

Galectin-3

***Industry Recommended Payment Decision***

86252 – Dihydroxy Vitamin D, 1, 25 **OR** 83880 – Natriuretic Peptide

***CMS Final 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 82777 and 83520 use the same testing methodology. BG Medicine acknowledges that providers have been reporting code 83520 for this test for over a year. Providers did not choose to report an unlisted chemistry code (84999) which would have permitted the Medicare Administrative Contractors (MACs) to price the test (higher or lower) and, as a result, these providers were accepting the payment for code 83520 as representative of this test.

**New Code**

86152

***New Code Description***

Cell enumeration using immunologic selection and identification in fluid specimen (e.g., 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 (e.g., NOR, C-banding) **OR** 88249 – Chromosome analysis for breakage syndromes; score 100 cells, clastogen stress (e.g., diepoxybutane, mitomycin C, ionizing radiation, UV radiation) **OR** Gapfill

***CMS Final 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**

86711

***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 Final 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***

86828

***New Code Description***

Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., 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 Final 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**

86829

***New Code Description***

Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., 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 Final 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**

86830

***New Code Description***

Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., 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 Final 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 86830 through 86835 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 lymphocytotoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytotoxicity is not a methodology utilized for the new codes being priced.

**New Code**

86831

***New Code Description***

Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., 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 Final 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 86830 through 86835 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 lymphocytotoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytotoxicity is not a methodology utilized for the new codes being priced.

**New Code**

86832

***New Code Description***

Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (e.g., 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 Final 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 86830 through 86835 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 lymphocytotoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytotoxicity is not a methodology utilized for the new codes being priced.

**New Code**

86833

***New Code Description***

Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (e.g., 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 Final 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 86830 through 86835 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 lymphocytotoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytotoxicity is not a methodology utilized for the new codes being priced.

**New Code**

86834

***New Code Description***

Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (e.g., 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 Final 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 86830 through 86835 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 lymphocytotoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytotoxicity is not a methodology utilized for the new codes being priced.

**New Code**

86835

***New Code Description***

Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (e.g., 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 Final 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 86830 through 86835 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 lymphocytotoxicity testing (code 86806) which is a methodology currently used for HLA antibody identification, lymphocytotoxicity is not a methodology utilized for the new codes being priced.

**New Code**

87631

***New Code Description***

Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., 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 Final 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***

87632

***New Code Description***

Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., 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 Final 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**

87633

***New Code Description***

Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., 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 Final 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**

87910

***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 Final 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**

87912

***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 Final 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.