Calendar Year (CY) 2011
Centers for Medicare & Medicaid Services (CMS)
New Clinical Laboratory Fee Schedule Test Codes
And Final Payment Determinations

Reconsideration Code
84145

Reconsideration Code Description
Procalcitonin (PCT)

Industry Recommended Crosswalk
83880—Natriuretic peptide; **OR** 84146—Prolactin

CMS Final Crosswalk Decision
82308—Calcitonin

Rationale
CMS received comments supporting both crosswalks as outlined above as well as additional suggestions. One of the concerns presented was that the PCT test is a high complexity test, while the Prolactin test is not. In addition, data was presented by some laboratories showing that the current crosswalk (which reflects a payment of $27.76) is not sufficient to cover the cost of the test kit from the manufacturer, much less the staff time and additional costs incurred in performing the test. Commenters generally support the assertion that, most of the time, the Procalcitonin test is performed stat, which means that it cannot be processed in a batched manner. Finally, commenters continue to assert that the Prolactin test is dissimilar to the Procalcitonin test for other reasons, such as the fact that the Procalcitonin test provides results about a possible life-threatening infection, while the Prolactin test provides results about hormone levels.

CMS has thoroughly considered all of these comments. We continue to believe that a crosswalk to Natriuretic peptide would not be appropriate. However, we recognize that there may be an alternative crosswalk that is more appropriate than Prolactin. During the comment period, a crosswalk to Calcitonin was suggested as a viable alternative. Procalcitonin is a prohormone of the calcium modulating hormone Calcitonin. Both Procalcitonin and Calcitonin belong to the class of "sandwich" assays. Both tests are performed on blood involving similar steps, and both Procalcitonin and Calcitonin have identical sequences. In addition, a crosswalk to Calcitonin would yield a payment of $38.36 which would cover the current cost of the test kit.

Commenters were generally supportive of our FINAL recommendation to crosswalk Procalcitonin to Calcitonin.

Reconsideration Code
84431

Reconsideration Code Description
Thromboxane metabolites, including thromboxane if performed, urine

Industry Recommended Crosswalk
83880—Natriuretic peptide; **OR** 83520—Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified

CMS Final Crosswalk Decision
84443—Thyroid stimulating hormone (TSH)

Rationale
Even though CMS originally adopted a crosswalk recommendation that was supported by some commenters last year, the manufacturer continues to be dissatisfied with CMS' crosswalk decision on this test. CMS would like to point out, again, that the Current Procedural Terminology (CPT) committee has provided separate instructions requiring the reporting of urine concentration in conjunction with this test using CPT test code 82570 ($7.41). We note that the TSH test is one of many tests that could be construed as similar to the Thromboxane metabolites test because both of these tests are enzyme immunoassay (EIA) tests - the TSH test screens for disorders associated with the thyroid while the Thromboxane metabolites test measures aspirin sensitivity. In addition, a crosswalk to TSH would yield a payment of $24.06 which would cover the current cost of the test kit, certainly in conjunction with the separate payment of $7.41 for performing the urine test along with the Thromboxane metabolites test.

The manufacturer continues to be the sole commenter that is dissatisfied with our decision, commenting that our revised crosswalk decision was more satisfactory, but not completely satisfactory to them. The manufacturer points out that the similarity between its test (84431) and the crosswalked test (84443) is limited by the fact that they are both EIA tests. We did note this in the above rationale. The manufactuer also admitted in its most recent comments that it recognizes that the urine test that routinely accompanies this test is paid additionally, not as part of this test. Therefore, we continue to believe that our FINAL recommendation is appropriate.

Reconsideration Code
86352

Reconsideration Code Description
Cellular function assay involving stimulation (e.g., mitogen or antigen) and detection of biomarker (e.g., ATP)

Industry Recommended Crosswalk
4 TIMES 86353—Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis PLUS 4 TIMES 86359—T-cells; total count PLUS 4 TIMES 82397—Chemiluminescent assay; **OR** Gapfill

CMS Final Crosswalk Decision
2 TIMES 86353—Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis PLUS 2 TIMES 82397—Chemiluminescent assay

Rationale
Commenters suggested that CMS neglected to include a crosswalk for the "selection" step that is performed as part of this test. However, we continue to believe that the "CD4 T-cell Selection & ATP Release" step is accurately reflected in our methodology. Last year, this test was crosswalked to a combination of CPT code 86353 and CPT code 82397. While CPT code 86353 does reflect cell stimulation, the process utilized for this test code is more complicated than that utilized in the Cylex stimulation step. As a result, if CMS were to include an additional code crosswalk to specifically reflect the "selection" step, the "stimulation" step crosswalk to CPT code 86353 would have to reflect less than 100 percent of the payment for this test code in order to be accurate. By allowing a 100 percent crosswalk to CPT code 86353, we are recognizing the value of the additional "selection" step that involves using an endpoint bead aggregation assay - a much simpler process than the sophisticated and expensive flow cytometry methodology recommended by the commenters as a separate crosswalk to represent this step. There is agreement between the commenters and CMS that the crosswalk to CPT code 82397 accurately reflects the third step in the test process - detection and measurement by chemiluminescent assay.

Additionally, commenters asserted that the payment for the crosswalked test codes should be multiplied by four since the test is performed on a stimulated and unstimulated patient plus a stimulated and unstimulated control subject. CMS disagrees with this approach; however, we do recognize that the test requires separate stimulated and unstimulated preparations. As a result, we believe that a crosswalk of two (2) times CPT code 86353 plus two (2) times CPT code 82397 is appropriate and addresses the concerns of the commenters.

The manufacturer continues to express dissatisfaction with our crosswalk decision. However, cost data from the manufacturer has been inconsistent. Therefore, we continue to believe that our FINAL recommendation is appropriate.

Reconsideration Code
G0430

Reconsideration Code Description
Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

Industry Recommended Crosswalk
G0430—Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure; **OR** 80101—Drug screen, qualitative, single drug class method (e.g., immunoassay, enzyme assay), each drug class

CMS Final Crosswalk Decision
Delete

Rationale
This temporary test code is no longer necessary; therefore, CMS recommends the deletion of it. CMS recognizes that the CPT committee created new CPT code 801XX in order to represent the programmatic need for G0430. However, CMS has discovered that neither of these test codes is properly described in order to control improper billing and utilization of these types of tests.

Reconsideration Code
G0431

Reconsideration Code Description
Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter

Industry Recommended Crosswalk
80101—Drug screen, qualitative, single drug class method (e.g., immunoassay, enzyme assay), each drug class

CMS Final Crosswalk Decision
5 TIMES G0430—Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

Rationale
CMS recommends changing the descriptor for this test code to more accurately reflect the high complexity confirmatory drug screening tests performed in the laboratory setting. By setting the payment at a multiple of five (5) times the price of testing for one drug of abuse, we are recognizing that multiple drugs are often tested through one specimen and that the high complexity tests that are performed in the laboratory setting require more resources than the simple dipstick test kit tests performed outside the laboratory setting.

CMS received comments from the industry suggesting multiples of up to 12 when pricing this code. Commenters confirmed that the tests performed in the laboratory setting require additional resources to perform. CMS believes that a multiplier of five (5) accurately represents the average number of confirmatory tests that might be required from one specimen. This is a FINAL recommendation.

New Code
80104

New Code Description
Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

Industry Recommended Crosswalk
G0430—Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure; **OR** 80101—Drug screen, qualitative, single drug class method (e.g., immunoassay, enzyme assay), each drug class

CMS Final Crosswalk Decision
No recommendation.

Rationale
See the CMS Recommendation Comments under temporary test code G0430 for the discussion. CMS recommends that this test code not be priced under Medicare as the descriptor does not accurately reflect the types of tests that need to be captured for accurate billing and payment here. Instead, the descriptor for G0431 has been edited, and new test code G0434 has been created. See all these discussions for a complete picture of the drugs of abuse testing codes and how CMS proposes to price them under Medicare.

New Code
G0434

New Code Description
Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

Industry Recommended Crosswalk
Commenters stated that they do not have enough information to provide a recommendation at this time.

CMS Final Crosswalk Decision
G0430—Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

Rationale
CMS created this new test code based on a programmatic need to accurately reflect both CLIA waived and moderate complexity testing for drugs of abuse per patient encounter rather than per dipstick test. As a result, CMS also recommends changing the descriptor to more accurately reflect this goal. This reflects the fact that in any given patient encounter, no matter how many drugs of abuse tests are performed and no matter whether these tests are CLIA waived (simple dipstick test kit) or moderate complexity (reader outside the laboratory setting), proper billing would be one time per patient.

Commenters expressed that further clarification from CMS concerning this test code would be appreciated, especially concerning the moderate complexity level of testing. CMS will be issuing a Medlearn article to provide further guidance concerning the drugs of abuse. Commenters also appreciated the distinction between the simpler quantitative drugs of abuse tests and the more complex qualitative drugs of abuse tests. This is a FINAL recommendation.

New Code
82930

New Code Description
Gastric acid analysis, includes pH if performed, each specimen

Industry Recommended Crosswalk
82928—Gastric acid, free or total, each specimen

CMS Final Crosswalk Decision
82926—Gastric acid, free and total, each specimen

Rationale
CPT code 82928 has a descriptor of "gastric acid, free OR total, each specimen" while CPT code 82926 has a descriptor of "gastric acid, free AND total, each specimen." CMS believes that CPT code 82926 is a more accurate reflection of this test as it applies to both free and total results.

We received no further comments on this recommendation.

New Code
83861

New Code Description
Microfluidic analysis utilizing an integrated collection and analysis device; tear osmolarity

Industry Recommended Crosswalk
83909—Molecular diagnostics; separation and identification by high-resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation PLUS 83935—Osmolality; urine; **OR** Gapfill

CMS Final Crosswalk Decision
83909—Molecular diagnostics; separation and identification by high-resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation

Rationale
CMS believes that a direct crosswalk to CPT code 83909 is reasonable as this crosswalk accurately reflects the cost of the test as well as the steps involved. While the manufacturer cited a higher cost for performing this test, we believe that a more accurate calculation of the labor portion of the cost brings the test cost in line with the payment for the recommended crosswalk to CPT code 83909 alone.

In addition, we believe that a crosswalk to CPT code 83909 completely recognizes both the sample collection and analysis steps utilizing quantitative electrochemical impedance spectroscopy. Therefore, the utilization of an additional test code crosswalk would be redundant.

We received no further comments on this recommendation.

New Code
84112

New Code Description
Placental alpha microglobulin-1 (PAMG-1), cervicovaginal secretion, qualitative

Industry Recommended Crosswalk
82731—Fetal fibronectin, cervicovaginal secretions, semi-quantitative

CMS Final Crosswalk Decision
82731—Fetal fibronectin, cervicovaginal secretions, semi-quantitative

Rationale
CMS agrees with the unanimous recommendation of the commenters to crosswalk this test to CPT code 82731.

We received no further comments on this recommendation.

New Code
85598

New Code Description
Phospholipid neutralization; hexagonal phospholipid

Industry Recommended Crosswalk
85597—Platelet neutralization

CMS Final Crosswalk Decision
85597—Platelet neutralization

Rationale
CMS agrees with the unanimous recommendation of the commenters to crosswalk this test to CPT code 85597.

We received no further comments on this recommendation.

New Code
86481

New Code Description
Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon producing T-cells in cell suspension

Industry Recommended Crosswalk
86480—Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response; **OR** 86480—Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response PLUS 86359—T-cells; total count

CMS Final Crosswalk Decision
86480—Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response

Rationale
All commenters recommended at least a crosswalk to CPT code 86480 for this test as CPT code 86480 has similar performance characteristics and provides equivalent information. Some commenters recommended that an additional crosswalk to CPT 86359 be added to represent the step that executes the enumeration of T cells. CMS does not agree with this additional recommendation. CPT code 86359 represents flow cytometry – a sophisticated and expensive methodology. The methodology used here to detect T cells is visual enumeration – a process where T cells are visually counted and recorded since they show up as dark blue spots and can be visually observed using either a stereomicroscope or magnifying glass. Therefore, we believe that a single crosswalk to CPT code 86480 is appropriate and addresses the concerns of the commenters.

One additional commenter supported our crosswalk recommendation.

New Code
86902

New Code Description
Blood typing; antigen testing of donor blood using reagent serum, each antigen test

Industry Recommended Crosswalk
86903—Blood typing; antigen screening for compatible blood unit using reagent serum, per unit screened

CMS Final Crosswalk Decision
86905—Blood typing; RBC antigens, other than ABO or Rh(D), each

Rationale
While all commenters suggested a crosswalk to CPT code 86903 for this test, CMS believes that a crosswalk to CPT code 86905 is more appropriate because there is a more direct correlation between the new test and CPT code 86905. CPT code 86905 (Blood typing; RBC antigens, other than ABO or Rh(D), each) describes the same procedure for patient or other red blood cells (RBCs) as is performed during the procedure coded as CPT code 86902 on donor RBCs. That is, a suspension of RBCs is mixed with the reagent serum, incubated if necessary, and evaluated for agglutination in both the new test and CPT code 86905. On the other hand, CPT code 86903 (Blood typing; antigen screening for compatible blood unit using reagent serum, per unit screened) is priced "per unit of blood" rather than "each antigen test." The distinction is significant. For patients with more than one serum RBC antibody, each unit of blood might require testing for more than one antigen. Thus, CPT code 86903 is priced so that it would be reported once per unit of blood tested whether one, two, three, or more RBC antigens were tested. Thus, it is priced higher than the test for each antigen tested.

We received no further comments on this recommendation.

New Code
87501

New Code Description
Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, reverse transcription and amplified probe technique, each type or subtype

Industry Recommended Crosswalk
87798—Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism PLUS 83902—Molecular diagnostics; reverse transcription

CMS Final Crosswalk Decision
87521—Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique PLUS 83902—Molecular diagnostics; reverse transcription

Rationale
CMS disagrees with the unanimous recommendation of the commenters to crosswalk this test to CPT code 87798 PLUS CPT code 83902, each with one unit of service. CMS recommends a more specific crosswalk to CPT code 87521 (instead of CPT code 87798)

PLUS CPT code 83902, each with one unit of service. Rather than use a "not otherwise specified" test code (such as CPT code 87798), we believe that a crosswalk to a test code that utilizes the same methodology, but is more specific, is more appropriate.

We received no further comments on this recommendation.

New Code
87502

New Code Description
Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, reverse transcription and amplified probe technique, first 2 types or sub-types

Industry Recommended Crosswalk
87801—Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique PLUS 83902—Molecular diagnostics; reverse transcription; **OR** 2 TIMES 87798—Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism PLUS 2 TIMES 83902—Molecular diagnostics; reverse transcription

CMS Final Crosswalk Decision
87801—Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique PLUS 83902—Molecular diagnostics; reverse transcription

Rationale
CMS agrees with the majority of the commenters who recommended a crosswalk to CPT code 87801 PLUS CPT code 83902, each with one unit of service. CMS disagrees with the recommendation to build a crosswalk using two units of service for each of the two codes. Each of the two steps described by the crosswalked codes is performed once.

We received no further comments on this recommendation.

New Code
87503

New Code Description
Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, multiplex for multiple types or sub-types, multiplex reverse transcription and amplified probe technique, each additional influenza virus type or sub-type beyond two (List separately in addition to code for primary procedure)

Industry Recommended Crosswalk
83901—Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (List separately in addition to code for primary procedure) PLUS 83896—Molecular diagnostics; nucleic acid probe, each; **OR** 87798—Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism PLUS 83902—Molecular diagnostics; reverse transcription; **OR** 83902—Molecular diagnostics; reverse transcription PLUS 83896—Molecular diagnostics; nucleic acid probe, each

CMS Final Crosswalk Decision
83901—Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (List separately in addition to code for primary procedure) PLUS 83896—Molecular diagnostics; nucleic acid probe, each

Rationale
CMS agrees with the majority of the commenters who recommended a crosswalk to CPT code 83901 PLUS CPT code 83896, each with one unit of service. CMS believes that CPT code 83901 better describes the amplification step than other recommended codes.

We received no further comments on this recommendation.

New Code
87906

New Code Description
Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (eg, integrase, fusion)

Industry Recommended Crosswalk
87901—Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease

CMS Final Crosswalk Decision
87901—Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease

Rationale
While all commenters recommended a crosswalk to CPT code 87901, CMS notes that this test examines two regions rather than each region, as defined by the new test code. Therefore, we believe that the recommended crosswalk overstates the scope of the test. We note that splitting the payment for CPT code 87901 in half would address the one region versus two regions issue and, as a result, is more in line with the complexity of the new test. Therefore, we believe that a crosswalk to CPT code 87901 at half the payment is appropriate.

Several commenters believe that our crosswalk decision is incorrect because they point out that, whether one region is examined or two regions are examined, similar amounts of time and resources are required to complete the test. However, no cost data was provided to us to support this comment. We recognize that different regions of the body may require different levels of work or supplies when performing testing. We continue to believe that our recommendation is appropriate.

New Code
G9143

New Code Description
Pharmacogenomic testing for Warfarin response

Industry Recommended Crosswalk
Put on hold for further testing.

CMS Final Crosswalk Decision
CPT code 83891—Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (i.e., DNA or RNA) PLUS 3 TIMES CPT code 83896—Molecular diagnostics; nucleic acid probe, each PLUS CPT code 83900—Molecular diagnostics; amplification, target, multiplex, first 2 nucleic acid sequences PLUS CPT code 83901—Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (List separately in addition to code for primary procedure) PLUS 3 TIMES CPT code 83908—Molecular diagnostics; amplification, signal, each nucleic acid sequence PLUS CPT code 83912—Molecular diagnostics; interpretation and report

Rationale
The need for the new test code G9143 arose from the requirements of the National Coverage Determination (NCD) for this diagnostic clinical laboratory service. In order to facilitate post-coverage tracking, a specific G code was needed to identify the specific test performed under this NCD, with a two-character modifier to show this test's use within a Medicare-approved Coverage with Evidence Development (CED) study. The new test code G9143 (with its modifier) is not intended to be used by all laboratories doing such testing but only by the relatively few laboratories approved by Medicare for participation in this CED effort.

CMS examined available data from laboratories reflecting tests performed that reflected each step of applicable genetic tests in order to select the appropriate CPT codes to stack in order to accurately represent the Warfarin response test.

We received no further comments on this recommendation.

New Code
G0432

New Code Description
Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and / or HIV-2, screening (SHORT DESCRIPTOR: ELA HIV-1/HIV-2 SCREEN)

Industry Recommended Crosswalk
86703—Antibody, HIV-1 and HIV-2, single assay

CMS Fianl Crosswalk Decision
86703—Antibody, HIV-1 and HIV-2, single assay

Rationale
CMS agrees with the unanimous recommendation of the commenters to crosswalk this test to CPT code 86703.

We received no further comments on this recommendation.

New Code
G0433

New Code Description
Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening (SHORT DESCRIPTOR: ELISA HIV-1/HIV-2 screen)

Industry Recommended Crosswalk
86703—Antibody, HIV-1 and HIV-2, single assay

CMS Final Crosswalk Decision
86703—Antibody, HIV-1 and HIV-2, single assay

Rationale
CMS agrees with the unanimous recommendation of the commenters to crosswalk this test to CPT code 86703.

We received no further comments on this recommendation.

New Code
G0435

New Code Description
Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening (SHORT DESCRIPTOR: Oral HIV-1/HIV-2 screen)

Industry Recommended Crosswalk
86703—Antibody, HIV-1 and HIV-2, single assay

CMS Final Crosswalk Decision
87804—Infectious agent antigen detection by immunoassay with direct optical observation; Influenza

Rationale
CMS disagrees with the recommendation of the commenters to crosswalk this new test to CPT code 86703 because this new test in the series is performed on saliva whereas the earlier new tests in this series are performed on blood. Due to the fact that it is simpler to extract and test saliva, CMS recommends a crosswalk to CPT code 87804 as this is also a saliva test performed to detect a virus, rather than a bacteria.

We received no further comments on this recommendation.