

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

Reconsideration Code

84145

Reconsideration Code Description

Procalcitonin (PCT)

Industry Recommended Crosswalk

83880—Natriuretic peptide; **OR** 84146—Prolactin

CMS Preliminary 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.

Therefore, for all these reasons, we believe that a crosswalk to Calcitonin is appropriate and addresses the concerns of the commenters.

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 Preliminary 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.

Therefore, we believe that a crosswalk to TSH is appropriate and addresses the concerns of the commenters.

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 Preliminary 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.

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 Preliminary 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), each specimen

Industry Recommended Crosswalk

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

CMS Preliminary 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.

New Code

801XX

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 Preliminary 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 GXXX1 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

GXXX1

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 Preliminary 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.

New Code

829XX

New Code Description

Gastric acid analysis, includes pH if performed, each specimen

Industry Recommended Crosswalk

82928—Gastric acid, free or total, each specimen

CMS Preliminary 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.

New Code

838XX

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 Preliminary 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.

New Code

841XX

New Code Description

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

Industry Recommended Crosswalk

82731—Fetal fibronectin, cervicovaginal secretions, semi-quantitative

CMS Preliminary 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.

New Code

855XX

New Code Description

Phospholipid neutralization; hexagonal phospholipid

Industry Recommended Crosswalk

85597—Platelet neutralization

CMS Preliminary Crosswalk Decision

85597—Platelet neutralization

Rationale

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

New Code

864XX

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 Preliminary 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.

New Code

869XX

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 Preliminary 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 869XX 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.

New Code

875XX1

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 Preliminary 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.

New Code

875XX2

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 Preliminary 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.

New Code

875XX3

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 Preliminary 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.

New Code

879XX

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 Preliminary 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.

New Code

G9143

New Code Description

Pharmacogenomic testing for Warfarin response

Industry Recommended Crosswalk

Put on hold for further testing.

CMS Preliminary 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.

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 Preliminary 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.

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 Preliminary 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.

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 Preliminary 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.