

**Calendar Year 2014**  
**Centers for Medicare and Medicaid Services (CMS)**  
**New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes**  
**And Final Payment Determinations**

**Reconsideration Codes**

0001M, 0002M, 0003M, 81500, 81503, 81506, 81509, 81510, 81511, 81512

***Reconsideration Code Descriptions***

0001M: Infectious disease, HCV, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver

0002M: Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and alcoholic steatohepatitis (ASH)

0003M: Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and nonalcoholic steatohepatitis (NASH)

81500: Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score

81503: Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score

81506: Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score

81509: Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score

81510: Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score

81511: Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)

81512: Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score  
Infectious disease, HCV, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver

***Industry Recommended Payment Decision***

Either 1) Gapfill, or 2) Various combined crosswalk calculations to multiple existing laboratory codes

***CMS Final Payment Decision***

Gapfill if the Medicare contractor determines the code is payable.

***Rationale***

Medicare pays for diagnostic tests that are used by the patient's treating practitioner to determine the appropriate course of treatment if all other Medicare statutes, regulations, and/or policy requirements are met. The above codes have been classified beginning in the 2013 CPT as Multianalyte Assays with Algorithmic Analysis (MAAA). However, we do not believe there is a single consistent definition for a MAAA that allows us to make a categorical determination of whether these codes constitute diagnostic laboratory tests. We will continue to consider each individual test that is classified by the CPT as a MAAA on its own merits.

***Reconsideration Code***

82777

***Reconsideration Code Description***

Galectin-3

***Industry Recommended Payment Decision***

Crosswalk to 83937: Assay of osteocalcin.

***CMS Final Payment Decision***

Crosswalk to 84244: Assay of renin.

***Rationale***

After further consideration, CMS agrees that its original decision to crosswalk this test to existing test code 83520 (Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified) should be revised. CMS believes that a closer crosswalk would be Assay of renin (code 84244), which is used in the detection and diagnosis of high blood pressure (Galectin-3 is used in the detection and diagnosis of heart failure). The two analytes are similar in molecular weight and approach to lab analysis. CMS has received comments agreeing with our preliminary determination.

***New Code***

80155

***New Code Description***

Therapeutic Drug Assay: Caffeine

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 82491: Chromotography quant sing, or 2) Crosswalk to 80198: Assay of theophylline.

***CMS Final Payment Decision***

Crosswalk to 80198: Assay of theophylline.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80155 code to that of code 80198, the assay of theophylline. These two drug molecules are closely related, part of the same chemical family, the methylated xanthines. The assay kit for caffeine (for example, the Syva EMIT Caffeine Assay Kit) is similar in methodology (immunoassay) to the assay of theophylline (for instance, the Dupont Theophylline Assay Kit). Crosswalking to the chromatography code 82491 is not consistent with how the 80155 assay of caffeine can be performed. There were no comments addressed to our preliminary decision.

***New Code***

80159

***New Code Description***

Therapeutic Drug Assay: Clozapine

***Industry Recommended Payment Decision***

Crosswalk to 80154: Assay of benzodiazepines.

***CMS Final Payment Decision***

Crosswalk to 80154: Assay of benzodiazepines.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80154 code to that of code 80159, the assay of clozapine. These two drug molecules used in treating psychosis and other indications are closely related. This kit is similar in methodology to the 80154 assay of benzodiazepines. There were no comments addressed to our preliminary decision.

***New Code***

80169

***New Code Description***

Therapeutic Drug Assay: Everolimus

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 80195: Assay of sirolimus, 2) Crosswalk to 82542: Column chromatography quant, or 3) Crosswalk to 80158: Assay of cyclosporine.

***CMS Final Payment Decision***

Crosswalk to 80195: Assay of sirolimus.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80169 code to that of code 80195, the assay of sirolimus. These two drug molecules are closely related and are both used for immune suppression, for example, in patients who have received transplants. An example of a recent everolimus assay is QMS Everolimus Assay Kit cleared in 2013 by FDA for use in kidney transplant patients. This kit is similar in methodology (immunoassay) to the assay of sirolimus. Crosswalking to the chromatography code for cyclosporine (80158) is not consistent with how the assay of everolimus can be performed. There were no comments addressed to our preliminary decision.

**New Code**

80171

***New Code Description***

Therapeutic Drug Assay: Gabapentin

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 82491: Chromotography quant sing, or 2) Crosswalk to 80157: Assay carbamazepine free.

***CMS Final Payment Decision***

Crosswalk to 80157: Assay carbamazepine free.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80171 code to that of code 80157, the assay of free carbamazepine. These two drug molecules with anticonvulsant and other uses, are of similar molecular weight. The assay kit for gabapentin (for example, the ARK Gabapentin Assay) uses a similar methodology (immunoassay) to that (EMIT) used in the Syva assay for free carbamazepine (FDA cleared in 1993). Crosswalking to the chromatography code 82491 is not consistent with how the assay of gabapentin can be performed. There were no comments addressed to our preliminary decision.

**New Code**

80175

***New Code Description***

Therapeutic Drug Assay: Lamotrigine

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 82542: Column chromatography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

***CMS Final Payment Decision***

Crosswalk to 80157: Assay carbamazepine free.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80175 code to that of code 80157, the assay of free carbamazepine. These two drug molecules are closely related, with anticonvulsant and other uses. The assay kit (e.g., ARK Lamotrigine Assay) is based on a similar methodology (immunoassay) to that used for free carbamazepine. Crosswalking to the chromatography code 82542 is not consistent with how the assay of lamotrigine can be performed. Despite a comment recommending a crosswalk to code 82542, CMS believes that doing so would be inconsistent with the performance of this particular assay.

**New Code**

80177

***New Code Description***

Therapeutic Drug Assay: Levetiracetam

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 82542: Column chromatography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

***CMS Final Payment Decision***

Crosswalk to 80157: Assay carbamazepine free.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80177 code to that of code 80157, the assay of carbamazepine. These two drug molecules are closely related in their molecular size and their clinical indications for anticonvulsant use. For instance, the ARK Levetiracetam Assay, approved by FDA in 2010, is based on a similar methodology (immunoassay) to that used in measuring free carbamazepine levels. Crosswalking to the chromatography code 82542 is not consistent with how the assay of levetiracetam can be performed. Despite a comment recommending a crosswalk to code 82542, CMS believes that doing so would be inconsistent with the performance of this particular assay.

**New Code**

80180

***New Code Description***

Therapeutic Drug Assay: Mycophenolate (mycophenolic acid)

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 82542: Column chromatography quant, or 2) Crosswalk to 80158: Assay of cyclosporine.

***CMS Final Payment Decision***

Crosswalk to 80158: Assay of cyclosporine.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80180 code to that of code 80158, the assay of cyclosporine. These two drugs, both used for immunosuppression in patients after transplantation and for other indications, can both be measured by assays based on an immunoassay methodology. Crosswalking to the chromatography code 82542 is not consistent with how the assay of mycophenolate can be performed. Despite a comment recommending a crosswalk to code 82542, CMS believes that doing so would be inconsistent with the performance of this particular assay.

**New Code**

80183

***New Code Description***

Therapeutic Drug Assay: Oxcarbazepine

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 82542: Column chromatography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

***CMS Final Payment Decision***

Crosswalk to 80157: Assay carbamazepine free.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80183 code to that of code 80157, the assay of free carbamazepine. These two drug molecules are closely related, because oxcarbazepine is structurally very similar to carbamazepine, and they have similar clinical uses including anticonvulsant treatment and other indications. The assay kit for measuring oxcarbazepine is similar in methodology to the assay kit for free carbamazepine. Crosswalking to the chromatography code 82542 is not consistent with how the assay of oxcarbazepine can be performed. Despite a comment recommending a crosswalk to code 82542, CMS believes that doing so would be inconsistent with the performance of this particular assay.

**New Code**

80199

***New Code Description***

Therapeutic Drug Assay: Tiagabine

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 82542: Column chromatography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

***CMS Final Payment Decision***

Crosswalk to 82542: Column chromatography quant.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80199 code to that of code 82542, the general quantitative chromatographic assay code. An FDA-approved or cleared tiagabine assay kit by immunoassay methods is not yet available. Crosswalking to the chromatography code 82542 is consistent with how the assay of tiagabine can be performed. There were no comments addressed to our preliminary decision.

**New Code**

80203

***New Code Description***

Therapeutic Drug Assay: Zonisamide

***Industry Recommended Payment Decision***

Either 1) Crosswalk to 82542: Column chromatography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

***CMS Final Payment Decision***

Crosswalk to 80157: Assay carbamazepine free.

***Rationale***

CMS agrees with recommending a crosswalk for reimbursement of the 80203 code to that of code 80157, the assay of carbamazepine. The FDA-cleared zonisamide assay kit (e.g., ARK Zonisamide Assay) uses a similar methodology to that used for free carbamazepine. Crosswalking to the chromatography code 82542 is not consistent with how the assay of zonisamide can be performed. Despite a comment recommending a crosswalk to code 82542, CMS believes that doing so would be inconsistent with the performance of this particular assay.

**New Code**

81161

***New Code Description***

DMD (dystrophin) (e.g., Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed

***Industry Recommended Payment Decision***

Either 1) Code Stacking, or 2) Gapfill.

***CMS Final Payment Decision***

Gapfill.

***Rationale***

CMS agrees with the commenters recommending gapfilling, since this will be consistent with the previous year's decision to gapfill new molecular codes.

**New Code**

81287

***New Code Description***

MGMT (O-6-methylguanine-DNA methyltransferase) (e.g., glioblastoma multiforme), methylation analysis

***Industry Recommended Payment Decision***

Either 1) Code Stacking, or 2) Gapfill.

***CMS Final Payment Decision***

Gapfill.

***Rationale***

CMS agrees with the commenters recommending gapfilling, since this will be consistent with the previous year's decision to gapfill new molecular codes. There were no comments addressed to our preliminary decision.

**New Codes**

0004M, 81504, 81507, 81508

***New Code Descriptions***

0004M: Scoliosis, DNA analysis of 53 single nucleotide polymorphisms (SNPs), using saliva, prognostic algorithm reported as a risk score

81504: Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as tissue similarity scores

81507: Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy

81508: Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score

***Industry Recommended Payment Decision***

Gapfill, for codes 0004M, 81504, and 81507, and either 1) Gapfill, or 2) Crosswalk to 84163:

Pappa serum PLUS 84702: Chorionic gonadotropin test, for code 81508.

***CMS Final Payment Decision***

Gapfill if the Medicare contractor determines the code is payable.

***Rationale***

Medicare pays for diagnostic tests that are used by the patient's treating practitioner to determine the appropriate course of treatment if all other Medicare statutes, regulations, and/or policy requirements are met. The above codes have been classified beginning in the 2013 CPT as Multianalyte Assays with Algorithmic Analysis (MAAA). However, we do not believe there is a single consistent definition for a MAAA that allows us to make a categorical determination of



whether these codes constitute diagnostic laboratory tests. We will continue to consider each individual test that is classified by the CPT as a MAAA on its own merits.

**New Code**

87661

***New Code Description***

Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique

***Industry Recommended Payment Decision***

Crosswalk to either 1) 87511: Gardner vag dna amp probe, or 2) 87481: Candida dna amp probe.

***CMS Final Payment Decision***

Crosswalk to 87511: Gardner vag dna amp probe.

***Rationale***

CMS agrees with the commenters recommending the crosswalk to code 87511, based on similarities in function. There were no comments addressed to our preliminary decision.