Calendar Year 2014
Centers for Medicare and Medicaid Services (CMS)
New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes
And Preliminary 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, apoliproprotein 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, HbAlc, insulin, hs-CRP, adoponectin, 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 scoreInfectious 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 Preliminary Payment Decision

CMS will not recognize these MAAA codes as valid for Medicare purposes under the CLFS for CY 2014.

Rationale

At this time, it does not appear that there is a single, consistent definition for a MAAA. It can be a numeric score(s) or a probability (i.e., "p-score") finding based on an analysis of the results of laboratory tests that already exist on the Clinical Laboratory Fee Schedule (CLFS) and, in some cases, patient information. An algorithm is not a clinical diagnostic test. The CLFS only pays for clinical diagnostic laboratory tests. Therefore, CMS considers this MAAA code to be not payable under CLFS. As we have previously stated, we will continue to consider each individual test that comprises a MAAA code on its own merits.

Reconsideration Code

82777

Reconsideration Code Description

Galectin-3

Industry Recommended Payment Decision

Crosswalk to 83937: Assay of osteocalcin.

CMS Preliminary 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.

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 Preliminary 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.

New Code
80159

New Code Description
Therapeutic Drug Assay: Clozapine

Industry Recommended Payment Decision
Crosswalk to 80154: Assay of benzodiazepines.

CMS Preliminary 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.

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 chromotography quant, or 3) Crosswalk to 80158: Assay of cyclosporine.

CMS Preliminary 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.

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 Preliminary 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.

New Code
80175

New Code Description
Therapeutic Drug Assay: Lamotrigine

Industry Recommended Payment Decision
Either 1) Crosswalk to 82542: Column chromotography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

CMS Preliminary 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.

New Code
80177

New Code Description
Therapeutic Drug Assay: Levetiracetam

Industry Recommended Payment Decision
Either 1) Crosswalk to 82542: Column chromotography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

CMS Preliminary 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.

New Code
80180

New Code Description
Therapeutic Drug Assay: Mycophenolate (mycophenolic acid)

Industry Recommended Payment Decision
Either 1) Crosswalk to 82542: Column chromotography quant, or 2) Crosswalk to 80158: Assay of cyclosporine.

CMS Preliminary 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.

New Code
80183

New Code Description

Therapeutic Drug Assay: Oxcabazepine

Industry Recommended Payment Decision
Either 1) Crosswalk to 82542: Column chromotography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

CMS Preliminary 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 oxcabazepine is structurally very similar to carbamazepine, and they have similar clinical uses including anticonvulsant treatment and other indications. The assay kit for measuring oxcabazepine 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 oxcabazepine can be performed.

New Code
80199

New Code Description
Therapeutic Drug Assay: Tiagabine

Industry Recommended Payment Decision
Either 1) Crosswalk to 82542: Column chromotography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

CMS Preliminary 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.

New Code
80203

New Code Description
Therapeutic Drug Assay: Zonisamide

Industry Recommended Payment Decision
Either 1) Crosswalk to 82542: Column chromotography quant, or 2) Crosswalk to 80157: Assay carbamazepine free.

CMS Preliminary 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.

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 Preliminary 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 Preliminary 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 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 Preliminary Payment Decision
CMS will not recognize these MAAA codes as valid for Medicare purposes under the CLFS for CY 2014.

Rationale
At this time, it does not appear that there is a single, consistent definition for a MAAA. It can be a numeric score(s) or a probability (i.e., "p-score") finding based on an analysis of the results of laboratory tests that already exist on the Clinical Laboratory Fee Schedule (CLFS) and, in some cases, patient information. An algorithm is not a clinical diagnostic test. The CLFS only pays for clinical diagnostic laboratory tests. Therefore, CMS considers this MAAA code to be not payable under CLFS. As we have previously stated, we will continue to consider each individual test that comprises a MAAA code 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 Preliminary 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.