

## **Clinical Laboratory Fee Schedule (CLFS) Final Determinations**

**Codes 80300 through 80377 (63 codes)**

**Industry Recommendation:** Various, from crosswalking to specific existing codes (e.g., G0434, G0431, etc.), to gapfilling.

**CMS Recommendation:** Delay in pricing.

**Rationale:** These codes represent various drugs of abuse testing codes, many of which are specific to individual drug testing.

In the 2015 clinical laboratory fee schedule preliminary determinations file that we released to the public on October 9, 2015, we proposed to not pay for new CPT codes for drugs of abuse tests. We stated our concern about the potential for overpayment when billing for each individual drug test rather than a single code that pays the same amount regardless of the number of drugs that are being tested. Therefore, we recommended delaying pricing for these codes at this time, until further information and education is obtained.

Commenters have advised us that several of the tests reported by codes deleted by the CPT Editorial Panel were to be reported by the new codes that we are not recognizing. We continue to believe that we need additional time and input from the public to determine Medicare payment for drugs of abuse testing that will not lead to overpayment. Until such time, we believe that Medicare should not recognize the additional codes created by CPT for drugs of abuse tests. However, we agree with the commenters that there will not be sufficient codes available to bill for drugs of abuse tests if we finalize our proposal. For this reason, we are maintaining the 2014 status quo for 2015 and creating alphanumeric G codes to replace the 2014 CPT codes that are being deleted for 2015. For 2015, providers are to use these G codes in the same manner in which they used the corresponding CPT codes for 2014.

In addition, for some of the drugs of abuse testing codes, CPT did not delete the 2014 code numbers, but revised the instructions or code descriptors in the 2015 CPT Manual. For billing CLFS in 2015, we are instructing the public to use these codes exactly as they used them for 2014, regardless of the 2015 instruction or code descriptor changes. The following are some examples of the application of this policy:

- The prefatory language for the Therapeutic Drug Assay section of the CPT Manual changed between 2014 and 2015. In the 2014 CPT Manual, this section allows for testing urine specimens. In the 2015 CPT Manual, the section *does not* allow for urine testing. For 2015, bill Medicare according to the prefatory language that applied to the Therapeutic Drug Assay section of the 2014 CPT Manual.
- The procedure specific codes (chromatography, mass spectrometry, etc) for drug analytes that are not specified elsewhere are in the Chemistry section of the 2014 CPT Manual. The 2015 CPT Manual has prefatory and parenthetical language that instructs providers to not use Chemistry section codes for drug screening tests (unless there is a specific

analyte code) and refers them to the new CPT codes that we decided not to pay for in 2015. In one group of 4 codes, the descriptors have been changed to “non-drug.” For 2015, use the instructions in the Drug Testing section and Chemistry section of the 2014 CPT Manual and ignore the 2015 prefatory and parenthetical language, as well as the change in descriptors for CPT codes 82541, 82542, 82543, & 82544, that prohibit the use of CPT codes in the Chemistry Section for testing for drugs.

As we further consider coding and payment for these services in 2016, we will be looking to balance beneficiary access with appropriate payment for medically necessary services under the Medicare program.

<b>Test</b>	<b>2014 Code</b>	<b>2015 Code</b>	<b>Descriptor</b>
Acetaminophen	82003	G6039	Acetaminophen
Alcohol (ethanol); any specimen except breath (including ethyl alcohol)	82055	G6040	Alcohol (ethanol); any specimen except breath
Alkaloids, urine, quantitative (including quantitative codiene)	82101	G6041	Alkaloids, urine, quantitative
Amitriptyline	80152	G6030	Amitriptyline
Amobarbital, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Amphetamine or methamphetamine	82145	G6042	Amphetamine or methamphetamine
Amphetamine or methamphetamine, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Barbiturates, not elsewhere specified (including amobarbital)	82205	G6043	Barbiturates, not elsewhere specified
Barbiturates, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Benzodiazepines	80154	G6031	Benzodiazepines
Carbon tetrachloride	84600	82441	Chlorinated hydrocarbons, screen
Cocaine or metabolite	82520	G6044	Cocaine or metabolite
Cocaine, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Codeine, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Desipramine	80160	G6032	Desipramine
Dichloroethane	84600	82441	Chlorinated hydrocarbons, screen
Dichloromethane	84600	82441	Chlorinated

<b>Test</b>	<b>2014 Code</b>	<b>2015 Code</b>	<b>Descriptor</b>
			hydrocarbons, screen
Dihydrocodeinone	82646	G6045	Dihydrocodeinone
Dihydrocodeinone, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Dihydromorphinone	82649	G6046	Dihydromorphinone
Dihydromorphinone, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Dihydrotestosterone	82651	G6047	Dihydrotestosterone
Dimethadione	82654	G6048	Dimethadione
Dimethadione, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Doxepin	80166	G6034	Doxepin
Drug confirmation, each procedure	80102	G6058	Drug confirmation, each procedure
Epiandrosterone	82666	G6049	Epiandrosterone
Ethchlorvynol	82690	G6050	Ethchlorvynol
Flurazepam	82742	G6051	Flurazepam
Flurazepam, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Gold	80172	G6035	Gold
Heroin	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Heroin screen	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Imipramine	80174	G6036	Imipramine
Isopropyl alcohol	84600	84600	Volatiles (eg, acetic anhydride, diethylether)
Marijuana	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Meprobamate	83805	G6052	Meprobamate
Meprobamate, qualitative analysis	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Methadone	83840	G6053	Methadone
Methanol	84600	84600	Volatiles (eg, acetic anhydride, diethylether)
Methodone, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Methsuximide	83858	G6054	Methsuximide
Nicotine	83887	G6055	Nicotine
Nortriptyline	80182	G6037	Nortriptyline
Opiate(s), drug and metabolites, each	83925	G6056	Opiate(s), drug and metabolites, each

Test	2014 Code	2015 Code	Descriptor
procedure (including nalorphine)			procedure
Phencyclidine (PCP), qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Phenothiazine (including chlorpromazine)	84022	G6057	Phenothiazine
Phenothiazine, qualitative	Follow 2014 CMS guidance including the use of G0431, G0434 and 80102 as appropriate		
Salicylates (including aspirin)	80196	G6038	Salicylate

**Code 80163** (*Digoxin; free*).

**Industry Recommendation:** Crosswalk to Code 80162 (Digoxin).

**CMS Recommendation:** Crosswalk to Code 80162 (Digoxin).

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 80162, based on similarities in function.

**Code 80165** (*Valproic acid (dipropylacetic acid); free*).

**Industry Recommendation:** Crosswalk to Code 80164 (Dipropylacetic acid (valproic acid)).

**CMS Recommendation:** Crosswalk to Code 80164 (Dipropylacetic acid (valproic acid)).

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 80164, based on similarities in function.

**Code 81246** (*FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)*).

**Code 81288** (*MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis*).

**Code 81313** (*PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (eg, prostate cancer)*).

**Industry Recommendations:** Various crosswalks to other Tier 1 codes.

**CMS Recommendation:** Gapfill.

**Rationale:** As we have done with past molecular codes, our final recommendation is that this series of new Tier 1 molecular pathology codes be gapfilled for 2015. 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.

**Codes 81410 through 81471** (*21 codes*)

**Industry Recommendation:** Various crosswalks to other codes or gapfill.

**CMS Recommendation:** Gapfill.

**Rationale:** As we have done with past molecular codes, our final recommendation is that this series of new Tier 2 molecular pathology codes be gapfilled for 2015. 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.

**Code 0006M** (*Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier*).

**Code 0007M** (*Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index*).

**Code 0008M** (*Oncology (breast), mRNA analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (FFPE) tissue, prognostic algorithm reported as a risk score*).

**Code 81519** (*Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score*).

**Industry Recommendations:** Gapfill.

**CMS Recommendation:** Gapfill if the Medicare contractor determines the code is payable.

**Rationale:** The above codes have been classified beginning in 2015 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. The Medicare Administrator Contractor will continue to consider each individual test that is classified by the CPT as a MAAA for coverage and payment.

**Code 83006** (*Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)*).

**Industry Recommendation:** Crosswalk to Code 82777 (Galectin-3).

**CMS Recommendation:** Crosswalk to Code 82777.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 82777, based on similarities in function.

**Code 87505** (*Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets*).

**Industry Recommendation:** Crosswalk to code 87631 (Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, 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).

**CMS Recommendation:** Crosswalk to code 87631.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 87631, based on similarities in function.

**Code 87506** (*Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets*).

**Industry Recommendation:** Crosswalk to Code 87632 (Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, 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).

**CMS Recommendation:** Crosswalk to Code 87632.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 87632, based on similarities in function.

**Code 87507** (*Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets*).

**Industry Recommendation:** Crosswalk to Code 87633 (Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, 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).

**CMS Recommendation:** Crosswalk to Code 87633.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 87633, based on similarities in function.

**Code 87623** (*Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44).*)

**Industry Recommendation:** Crosswalk to Code 87621 (Infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, amplified probe technique).

**CMS Recommendation:** Crosswalk to Code 87621.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 87621, based on similarities in function.

**Code 87624** (*Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68).*)

**Industry Recommendation:** Crosswalk to Code 87621 (Infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, amplified probe technique).

**CMS Recommendation:** Crosswalk to Code 87621.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 87621, based on similarities in function.

**Code 87625** (*Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed).*

**Industry Recommendation:** Crosswalk to Code 87621 (Infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, amplified probe technique).

**CMS Recommendation:** Crosswalk to Code 87621.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 87621, based on similarities in function

**Code 87806** (*Infectious agent antigen detection by immunoassay with direct optical observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies).*

**Industry Recommendations:** Crosswalk to Code 87390 (Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; HIV-1) PLUS Code 86703 (Antibody; HIV-1 and HIV-2, single result); OR Crosswalk to Code 87389 (Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result).

**CMS Recommendation:** Crosswalk to code 87389.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 87389, based on similarities in function. CMS disagrees with the commenters recommending the crosswalk to both Code 87390 and Code 86703 because those two codes together do much more in comparison to the new Code 87806. Therefore, the one-to-one crosswalk to Code 87389 is more accurate.

**Code 89337** (*Cryopreservation, mature oocyte(s)*).

**Industry Recommendation:** Crosswalk to Code 89258 (This code is not on the CLFS).

**CMS Recommendation:** This test should not be priced on the CLFS.

**Rationale:** This test code represents embryo storage; therefore, it is not a clinical diagnostic laboratory test.

**Code G0464** (*Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3)*).

**Industry Recommendation:** Crosswalk to Code 81315 (PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative) PLUS Code 81275 (Kras (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13) PLUS Code 82274 (Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations).

**CMS Recommendation:** Crosswalk to Code 81315 PLUS Code 81275 PLUS Code 82274.

**Rationale:** CMS agrees with the commenters recommending the crosswalk to Code 81315 PLUS Code 81275 PLUS Code 82274, based on similarities in function of these tests with the components of the new test.