

**Calendar Year (CY) 2017 Clinical Laboratory Fee Schedule (CLFS)
Preliminary Determinations**

A. Reconsidered Tests

For 2016, CMS implemented four new G codes for definitive drug testing:

G0480 Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.

G0481 Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.

G0482 Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed.

G0483 Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed.

CMS priced these codes using a crosswalking formula. The first two tests performed would be paid at the full price of the crosswalk CPT code 82542 and the remaining tests within that code would be paid at 25% of the crosswalk price. See our 2016 Final Determination file (URL: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html) for further discussion. The crosswalking exercise resulted in the following prices:

CPT Code	Crosswalk Formula	Price
G0480	$2*82542 + 5*.25*82542$	\$ 79.95
G0481	$2*82542 + 12*.25*82542$	\$ 123.00
G0482	$2*82542 + 19*.25*82542$	\$ 166.05
G0483	$2*82542 + 27*.25*82542$	\$ 215.25

Commenter/Panel Recommendations:

The majority of the presenters at the 2016 Annual Laboratory Public Meeting and at the Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel Meeting, and the Advisory Panel, recommended a modification of the formula with the following prices:

CPT Code	Crosswalk Formula	Price
G0480	$6*82542 + 0*.25*82542$	\$ 147.60
G0481	$6*82542 + 8*.25*82542$	\$ 196.80
G0482	$6*82542 + 16*.25*82542$	\$ 246.00
G0483	$6*82542 + 24*.25*82542$	\$ 295.20

The presenters at the 2016 Annual Laboratory Public Meeting and the CDLT Advisory Panel Meeting also raised concerns that much of the high volume of claims containing G0483 that were billed the first part of 2016 were being performed by physician office labs that lacked the quality control and multiple calibrations necessary for accurate results. They recommended that CMS develop a system to pay for these tests in a separate manner.

CMS Preliminary Determinations

CMS agrees that the current prices may understate the costs incurred by most labs performing drug testing. We also remain concerned that inappropriate testing continues to occur including simplified testing billed at the higher code with suspect results. Thus, we are making two proposals:

1. Modify the current formula to establish the price for these codes to allow 4 tests to be priced at the full crosswalk price:

CPT Code	Crosswalk Formula	Price
G0480	$4*82542 + 3*.25*82542$	\$ 116.85
G0481	$4*82542 + 10*.25*82542$	\$ 159.90
G0482	$4*82542 + 17*.25*82542$	\$ 202.95
G0483	$4*82542 + 25*.25*82542$	\$ 252.15

2. Create a new G code that would recognize those labs that are performing a less sophisticated version of these tests than is usually performed in drug testing laboratories:

GCCCC: Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase), performed in a single machine run without drug or class specific calibrations; qualitative or quantitative, all sources, includes specimen validity testing, per day.

The work performed in this test approximates the work performed in G0479 (proposed to be replaced by new CPT code 80307). Therefore, we propose to price this new code at the same amount as G0479/80307.

B. New Test Codes

Code: 80305 *(Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service)*

Commenter Recommendations: Crosswalk to code G0477 *(Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service)*

Panel Recommendation: Crosswalk to code G0477.

CMS Preliminary Determination: Crosswalk to code G0477, then delete G0477.

Rationale: This new CPT Code mimics the current G code and we propose to crosswalk it directly to the G code as recommended by commenters and the CDLT Advisory Panel.

Code: 80306 *(Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures, (eg, immunoassay) read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service)*

Commenter Recommendations: Crosswalk to code G0478 *(Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service)*

Panel Recommendation Crosswalk to code G0478.

CMS Preliminary Determination: Crosswalk to code G0478, then delete G0478.

Rationale: This new CPT code mimics the current G code and we propose to crosswalk it directly to the G code as recommended by commenters and the CDLT Advisory Panel.

Code: 80307 (*Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service.*)

Commenter Recommendations: Crosswalk to code G0479 (*Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service.*):

Panel Recommendation: Crosswalk to code G0479.

CMS Preliminary Determination: Crosswalk to code G0479, then delete G0479.

Rationale: This new CPT code mimics the current G code and we propose to crosswalk it directly to the G code as recommended by commenters and the CDLT Advisory Panel.

Code: 81327 (*SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis.*)

Commenter Recommendations: Several commenters proposed crosswalking to codes 81288 ((MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis). One commenter recommended crosswalking to CPT code 81287.

Panel Recommendation: Crosswalk to codes 81288 ((MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis).). Three Panel members recommended to gapfill.

CMS Preliminary Determination: Crosswalk to code 81287 ((MGMT (0-6 methylguanine-DNA methyltransferase) (eg., glioblastoma, multiforme), methylation analysis) .

Rationale: CPT code 81288 includes “promoter methylation analysis” within the descriptor while the new code mimics CPT code 81287 by including “methylation analysis” in the descriptor. We

believe the new code more closely matches CPT code 81287.

Code: 81413 (*Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A*)

Commenter Recommendations: Crosswalk to code 81435 (*Hereditary colon cancer disorders (eg, Lynch syndrome PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11*).

Panel Recommendation: Crosswalk to code 81435. One panel member recommended to gapfill.

CMS Preliminary Determination: Crosswalk to code 81435.

Rationale: CMS agrees with the commenter and the CDLT Advisory Panel recommendations to crosswalk this code to 81435.

Code: 81414 (*Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1*.)

Commenter Recommendations: Crosswalk to code 81436 (*Hereditary colon cancer disorders (eg, Lynch syndrome PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11*).

Panel Recommendation: The majority recommended a crosswalk to code 81436. Five members recommended to gapfill. One member recommended a crosswalk to 0.5 TIMES 81436.

CMS Preliminary Determination: Crosswalk to code 81436.

Rationale: CMS agrees with the commenters and the CDLT Advisory Panel recommendation to crosswalk to code 81436, based on similarities in function of this test with the components of the new test.

Code: 81422 (*Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge*

syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood.)

Commenter Recommendations: A majority recommended Gapfill OR Crosswalk to code 81435 (*Hereditary colon cancer disorders (eg, Lynch syndrome PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11).*)

Panel Recommendation: Gapfill OR Crosswalk to 81435.

CMS Preliminary Determination: Gapfill AND instruct MACs to also gapfill 81420.

Rationale: CMS agrees with the commenters and majority vote by the CDLT Advisory Panel recommendation to gapfill.

Code: 81439 (*Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN.*)

Commenter Recommendations: Crosswalk to code 81435 (*Hereditary colon cancer disorders (eg, Lynch syndrome PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11).*)

Panel Recommendation: Crosswalk to code 81435 OR Gapfill.

CMS Preliminary Determination: Crosswalk to code 81435.

Rationale: CMS agrees with the commenters and the CDLT Advisory Panel recommendation to crosswalk to code 81435, based on similarities in function of this test with the components of the new test.

Code: 81539 (*Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score.*)

Commenter Recommendations: Gapfill OR Crosswalk to code 84153 (*Prostate specific antigen (PSA); total*) TIMES 3 PLUS code 84154 (*Prostate specific antigen (PSA; free)*)

Panel Recommendation: Crosswalk to 0010M (\$0.00); if not feasible, then Gapfill OR Crosswalk to code 84153 TIMES 3 PLUS code 84154.

CMS Preliminary Determination: Crosswalk to 3 TIMES code 84153 PLUS code 84154.

Rationale: CMS agrees with the commenters and the CDLT Advisory Panel recommendation to crosswalk to 3 TIMES code 84153, based on similarities in function of this test with the components of the new test.

Code: 84410 (*Testosterone; bioavailable, direct measurement (eg, differential precipitation)*)

Commenter Recommendations: Crosswalk to code 84402 (*Testosterone; free*) PLUS code 84403 (*Testosterone; total*)

Panel Recommendation: Crosswalk to code 84402 PLUS code 84403 OR Crosswalk to 3 TIMES code 84403.

CMS Preliminary Determination: Crosswalk to code 84402 PLUS code 84403.

Rationale: CMS agrees with the commenters and the majority vote by the CDLT Advisory Panel recommending to crosswalk to code 84402 PLUS code 84403, based on similarities in function of this test with the components of the new test.

Code: 87483 (*Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes simplex virus type 1 and 2, human herpes virus 6, cytomegalovirus, varicella zoster virus, Cryptococcus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets.*)

Commenter Recommendations: 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.*)

Panel Recommendation: A majority recommended a Crosswalk to code 87633 OR Gapfill.

CMS Preliminary Determination: Crosswalk to code 87633.

Rationale: CMS agrees with the commenters and the majority vote by the CDLT Advisory Panel

recommending to crosswalk to code 87633 based on similarities in function of this test with the components of the new test.

Code: G0475 (*HIV antigen/antibody, combination assay, screening.*)

Commenter Recommendations: 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.*)

Panel Recommendation: Crosswalk to code 87389 OR Crosswalk to code 87806 (*Infectious agent antigen detection by immunoassay with direct optical observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies.*)

CMS Preliminary Determination: Crosswalk to code 87389.

Rationale: CMS agrees with the commenters and the majority vote by the CDLT Advisory Panel recommending to crosswalk to code 87389, based on similarities in function of this test with the components of the new test.

Code: G0476 (*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) for cervical cancer screening, must be performed in addition to pap test.*)

Commenter Recommendations: Crosswalk to 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).*)

Panel Recommendation: Crosswalk to code 87624 OR Gapfill.

CMS Preliminary Determination: Crosswalk to code 87624.

Rationale: CMS agrees with the commenters and the majority vote by the CDLT Advisory Panel recommending to crosswalk to code 87624, based on similarities in function of this test with the components of the new test.