Clinical Laboratory Fee Schedule (CLFS)
Preliminary 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 drug screening codes, many of which are specific to individual drug testing. While we appreciate the recommendations for these tests, we are concerned about the potential for overpayment when billing for each individual drug test rather than a single code that pays the same regardless of the number of drugs that are being tested for. Therefore, it is our recommendation to delay pricing for these codes at this time, until further information and education is obtained.

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, we are recommending 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, we are recommending 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 namogram 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.