CPT® Proprietary Laboratory Analyses (PLA) Codes: Long Descriptors

Most recent changes to the CPT® Proprietary Laboratory Analyses (PLA) Long Descriptor document

- Revision of Proprietary laboratory analyses (PLA) code guidelines, addition of symbol "⧺" to denote duplicate PLA tests, and addition of two parenthetical notes following codes 0007U and 0020U.

►Proprietary laboratory analyses (PLA) codes describe proprietary clinical laboratory analyses and can be either provided by a single ("sole-source") laboratory or licensed or marketed to multiple providing laboratories (eg, cleared or approved by the Food and Drug Administration [FDA]).

This subsection includes advanced diagnostic laboratory tests (ADLTs) and clinical diagnostic laboratory tests (CDLTs), as defined under the Protecting Access to Medicare Act (PAMA) of 2014. These analyses may include a range of medical laboratory tests including, but not limited to, multianalyte assays with algorithmic analyses (MAAA) and genomic sequencing procedures (GSP). The descriptor nomenclature follows, where possible, existing code conventions (eg, MAAA, GSP).

These codes are not required to fulfill the Category I criteria. The standards for inclusion in this section are:

- The test must be commercially available in the United States for use on human specimens and
- The clinical laboratory or manufacturer that offers the test must request the code.

For similar laboratory analyses that fulfill Category I criteria, see codes listed in the numeric 80000 series.

When a PLA code is available to report a given proprietary laboratory service, that PLA code takes precedence. The service should not be reported with any other CPT code(s) and other CPT code(s) should not be used to report services that may be reported with that specific PLA code. These codes encompass all analytical services required for the analysis (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, hybridization and detection). For molecular analyses, additional procedures that are required prior to cell lysis (eg, microdissection [codes 88380 and 88381]) may be reported separately.

Codes in this subsection are released on a quarterly basis to expedite dissemination for reporting. PLA codes will be published electronically on the AMA CPT website (www.ama-assn.org/practice-management/cpt-pla-codes), distributed via CPT data files on a quarterly basis, and, at a minimum, made available in print annually in the CPT codebook. Go to www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/cpt-pla-codes-long.pdf for the most current listing.

All codes that are included in this section are also included in Appendix O, with the procedure's proprietary name. In order to report a PLA code, the analysis performed must fulfill the code descriptor and must be the test represented by the proprietary name listed in Appendix O. In some instances, the descriptor language of PLA codes may be identical and the code may only be differentiated by the listed proprietary name in Appendix O. When more than one PLA has an identical descriptor, it is denoted by the symbol "⧺".◄

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Proprietary Name and Clinical Laboratory and/or Manufacturer	Code	Long Code Descriptor	Published to AMA Website	Effective Date	Publication
PreciseType® HEA Test Immucor, Inc.	●0001U	Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported	December 2, 2016	February 1, 2017	CPT® 2018
PolypDX™ Atlantic Diagnostic Laboratories, LLC Metabolomic Technologi Inc.	●0002U	Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps	December 2, 2016	February 1, 2017	CPT® 2018
Overa (OVA1 Next Generation) Aspira Labs, Inc. Vermillion, Inc.	●0003U	Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score	December 2, 2016	February 1, 2017	CPT® 2018
Gram-Negative Bacterial Resistance Gene PCR Panel Mayo Clinic Check-Points Health BV, Wageningen, Netherlands	●0004U	Infectious disease (bacterial), DNA, 27 resistance genes, PCR amplification and probe hybridization in microarray format (molecular detection and identification of AmpC, carbapenemase and ESBL coding genes), bacterial culture colonies, report of genes detected or not detected, per isolate	March 1, 2017	May 1, 2017	CPT® 2018

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ExosomeDx® Prostate (IntelliScore) Exosome Diagnostics, Inc.	●0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score	March 1, 2017	May 1, 2017	CPT® 2018
Aegis Drug-Drug Interact Test Aegis Sciences Corporat	●0006U	Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service	June 1, 2017	August 1, 2017	CPT® 2018
ToxProtect Genotox Laboratories LT	⚡●0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service ►(For additional PLA code with identical clinical descriptor, see 0020U. See Appendix O to determine appropriate code assignment)◄	June 1, 2017	August 1, 2017	CPT® 2018
AmHPR Helicobacter pylori Antibiotic Resistance Next Generation Sequencing Panel American Molecular Laboratories, Inc.	●0008U	Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin-embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin	June 1, 2017	August 1, 2017	CPT® 2018
DEPArray™ HER2 PacificDx	●0009U	Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin-fixed paraffin-embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified	June 1, 2017	August 1, 2017	CPT® 2018

Bacterial Typing by Whole Genome Sequencing Mayo Clinic	●0010U	Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate	June 1, 2017	August 1, 2017	CPT® 2018
Cordant CORE™ Cordant Health Solutions	●0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites	June 1, 2017	August 1, 2017	CPT® 2018
MatePair Targeted Rearrangements, Congenital Mayo Clinic	●0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)	June 1, 2017	August 1, 2017	CPT® 2018
MatePair Targeted Rearrangements, Oncology Mayo Clinic	●0013U	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)	June 1, 2017	August 1, 2017	CPT® 2018
MatePair Targeted Rearrangements, Hematologic Mayo Clinic	●0014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)	June 1, 2017	August 1, 2017	CPT® 2018
OneOme RightMed Pharmacogenomic Test OneOme, LLC	●0015U	Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support	June 1, 2017	August 1, 2017	CPT® 2018

BCR-ABL1 major and minor breakpoint fusion transcripts University of Iowa, Department of Pathology, Asuragen	●0016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation	June 1, 2017	August 1, 2017	CPT® 2018
JAK2 Mutation University of Iowa, Department of Pathology	●0017U	Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected	June 1, 2017	August 1, 2017	CPT® 2018
ThyraMIR Interpace Diagnostics Interpace Diagnostics	●0018U	Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy	August 31, 2017	October 1, 2017	CPT® 2019
OncoTarget/ OncoTreat Columbia University Department of Pathology and Cell Biology Darwin Health	●0019U	Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents	August 31, 2017	October 1, 2017	CPT® 2019
ToxLok InSource Diagnostics Agena Bioscience, Inc.	⚡●0020U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, with specimen verification including DNA authentication in comparison to buccal DNA, per date of service ►(For additional PLA code with identical clinical descriptor, see 0007U. See Appendix O to determine appropriate code assignment)◄	August 31, 2017	October 1, 2017	CPT® 2019

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Apifiny® Armune BioScience, Inc.	●0021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score	August 31, 2017	October 1, 2017	CPT® 2019
Oncomine™ Dx Target Test Thermo Fisher Scientific	●0022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider	August 31, 2017	October 1, 2017	CPT® 2019
LeukoStrat® CDx FLT3 Mutation Assay LabPMM LLC, an Invivoscribe Technologies, Inc. company Invivoscribe Technologies, Inc.	●0023U	Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin	August 31, 2017	October 1, 2017	CPT® 2019

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