Table of Contents

Meeting Background and Purpose

This meeting provides an opportunity for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the CDLT Panel) to publicly convene and make recommendations to the Secretary of the Department of Health and Services and the Administrator of CMS regarding crosswalking and gapfilling for new and reconsidered laboratory tests discussed during the CLFS Annual Public Meeting for CY 2026. The CDLT Panel may also provide input on any other CY 2026 CLFS issues that are designated in the Panel's charter and specified in this agenda. Notice of this meeting and additional supplemental information regarding the CDLT Panel were published in the Federal Register on April 21, 2025 (CMS-1841-N; 75 FR 16687).

Meeting Format

- The CDLT Panel interim Co-Chairs will direct the presentation and discussion of each laboratory test code on the agenda.
- Each laboratory test code under consideration will be introduced and discussed by the CDLT Panel. The focus of discussion is payment of the laboratory test code either through crosswalking the laboratory test code to another existing laboratory test code on the CLFS, or to use the gapfill methodology to determine payment. During the discussion the CDLT Panel and CMS staff may ask questions of the representative of the laboratory that owns the test. Once CDLT Panel discussions are concluded, the suggestions from the Panel are summarized and the Panel votes on their recommendation for payment.
- The meeting is divided into two sessions, one session on each date of the meeting. Session times are approximate and subject to change. The codes and order of discussion in each session are provided in Appendix 3.

Meeting Address and Building Entry

- CMS Central Building Address: 7500 Security Boulevard, Baltimore, MD 21244
- The hybrid meeting will be held in a Federal government building; therefore, Federal security measures are applicable.
- In planning your arrival time, we recommend allowing additional time to clear security. We suggest that you arrive at the CMS campus and parking facilities between 9:00 a.m. and 10:00 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 10:00 a.m. E.D.T. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. We note that the public may not enter the CMS building earlier than 9:15 a.m. E.D.T. (45 minutes before the convening of the meeting).
- Security measures include the following:
    - Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.

- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set- up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Virtual Connection Instructions and Details

- **Listen-in via audio and watch via Zoom connection only** details are provided using instructions described in Appendix 1.
- Please note that the video or audio recordings of the meeting will not be immediately available after the conclusion of the meeting.

AGENDA

Wednesday July 23 and Thursday July 24, 2025

Time	Topic	Supporting Resource
9:30 a.m.	**Check-In and Audio/Video Connection Test Check** CMS Central Building Address: 7500 Security Boulevard, Baltimore, MD 21244	
10:00 a.m.	**Welcome and Panel Introductions:** Sarah Harding, interim- Designated Federal Officer (DFO) and Meeting Facilitator from the Division of Ambulatory Services. Dr. Chris Chong and Dr. Jochen Lennerz, Interim CDLT Panel Co-Chairs	
10:15 -12:30 p.m.	**Day 1 and 2 Morning Session:** Please view Appendix 3 for exact order of codes.	Appendix 3
12:30- 1:30pm	**Lunch Break** **Please Note:** All speakers please reconnect by 1:20pm	
1:30-4:00 p.m.	**Day 1 and 2 Afternoon Session:** Please view Appendix 3 for exact order of codes.	Appendix 3
4:00 p.m.	**Meeting Adjourns**	

*****Please note that the order of the agenda and content of the appendices are subject to change.*****

Appendix 1: Audio and/or Video Access
Join the meeting by Zoom.

Step 1: Please click the link below to register for the webinar:

https://cms.zoomgov.com/webinar/register/WN_rD0b5QEuS4apqeiyejFG4Q
Passcode: 989493
Note: This link provides attendees with the ability to view and listen to the meeting. Only confirmed stand-by speakers will have the ability to speak during the meeting.

Step 2: All attendees and participants will be requested to provide their name and email address before joining the meeting.

Step 3: Click "Register."

Appendix 2: Access to CLFS CY 2026 New and Reconsidered Codes and Other Information.

1. For a list of CY 2026 new and reconsidered codes that will be discussed during the CDLT Panel meeting, please go to the CLFS Annual Laboratory Meeting website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings

   Scroll down to "Test Code Updates" for access to the CY 2026 new and reconsidered code list.

2. For the CLFS Annual Laboratory Public meeting agenda from June 27, 2025, please see: https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/annual-public-meetings#

3. For a recording of the CFLS Annual Laboratory Public Meeting from June 27, 2025, please see links below:
   a. Recording: https://cms.zoomgov.com/rec/share/nm698yyn8ypa_sdSCv6u-3uA6VXW0G23QBho6uQOxDmmJLFelLQy0scfmYlNB8Ef.fUrg2YlZe1ITISC5
   b. Passcode: +ytDsGy7

4. For a copy of CY 2025 - Clinical Laboratory Fee Schedule Test Codes Final Payment Determinations that were discussed during last year's CLFS Annual Laboratory Meeting and the Medicare Advisory Panel for Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting, please see link: https://www.cms.gov/files/zip/cy-2025-final-payment-determinations.zip

Appendix 3: Summary of codes

*Subcommittees: Chemistry, Hematology, Immunology, Microbiology (CHIM); Molecular Pathology, Genomic Sequencing (MoG)
** Per 72 FR 66278, 42 CFR 414.509, code is being removed from list.

Corrections to order of codes:

a. None currently.

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
1	0533U	0533U	NEW- PLA	Genome Sequencing Procedures	Pharmacogenomics	MOG	Drug metabolism (adverse drug reactions and drug response), genotyping of 16 genes (ie, ABCG2, CYP2B6, CYP2C9, CYP2C19, CYP2C, CYP2D6, CYP3A5, CYP4F2, DPYD, G6PD, GGCX, NUDT15, SLCO1B1, TPMT, UGT1A1, VKORC1), reported as metabolizer status and transporter function
2	0423U	0423U	RECONSIDERED	Genomic Sequencing Procedures; Targeted Variant Analysis	Pharmacogenomics	MOG	Psychiatry (e.g., depression, anxiety), genomic analysis panel, including variant analysis of 26 genes, buccal swab, report including metabolizer status and risk of drug toxicity by condition
3	0552U	0552U	NEW- PLA	Molecular Pathology	Preimplantation	MOG	Reproductive medicine (preimplantation genetic assessment), analysis for known genetic disorders from trophectoderm biopsy, linkage analysis of disease-causing locus, and when possible, targeted mutation analysis for known familial variant, reported as low-risk or high-risk for familial genetic disorder
4	0553U	0553U	NEW- PLA	Molecular Pathology	Preimplantation	MOG	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, and a mitochondrial DNA score, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, or mosaic, per embryo tested
5	0554U	0554U	NEW- PLA	Molecular Pathology	Preimplantation	MOG	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from trophectoderm biopsy for aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal (euploidy), monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested
6	0555U	0555U	NEW- PLA	Molecular Pathology	Preimplantation	MOG	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested
7	81195	81195	RECONSIDERED	Molecular Pathology; Optical Genome Mapping	OGM	MOG	Cytogenomic genome-wide analysis, hematologic malignancy, structural variations and copy number variations, optical genome mapping (OGM)

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
8	8XXX4	TBD	NEW	Molecular Pathology; Optical Genome Mapping	OGM	MOG	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of structural and copy number variants, optical genome mapping (OGM)
9	X159U	TBD	NEW	Genomic Sequencing Procedures; RT-PCR; ddPCR	MicroRNA	MOG	Transplantation medicine (liver allograft rejection), miRNA gene expression profiling by RT-PCR of 4 genes (miR-122, miR-885, miR-23a housekeeping, spike-in control), serum, algorithm reported as risk of liver allograft rejection
10	0534U	0534U	NEW- PLA	MAAA	MicroRNA	MOG	Oncology (prostate), microRNA, single-nucleotide polymorphisms (SNPs) analysis by RT-PCR of 32 variants, using buccal swab, algorithm reported as a risk score
11	0531U	0531U	NEW- PLA	Microbiology; infectious disease	ID NGS	CHIM	Infectious disease (acid-fast bacteria and invasive fungi), DNA (673 organisms), next-generation sequencing, plasma
12	X177U	TBD	NEW	Microbiology; Infectious Disease	ID NGS	CHIM	Infectious disease (bacterial and fungal), DNA of 44 organisms (34 bacteria, 10 fungi), urine, next-generation sequencing, reported as positive or negative for each organism
13	871XX	TBD	NEW- CAT 1	Microbiology; Infectious Disease	ID immunoassay	CHIM	Susceptibility studies, antimicrobial agent; carbapenemase enzyme detection (eg, Klebsiella pneumoniae carbapenemase [KPC], New Delhi metallo-beta-lactamase [NDM], Verona integron-encoded metallo-beta-lactamase [VIM]), multiplex immunoassay, qualitative, per isolate
14	8XXXX	TBD	NEW	Microbiology; Infectious Disease	ID immunoassay	CHIM	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and influenza virus types A and B
15	X166U	TBD	NEW	Microbiology; Infectious Disease	ID immunoassay	CHIM	Borrelia burgdorferi, antibody detection of 24 recombinant protein groups, by immunoassay, IgG
16	X182U	TBD	NEW	Microbiology; Infectious Disease	ID immunoassay	CHIM	Infectious disease (sepsis), semiquantitative measurement of pancreatic stone protein concentration, whole blood, reported as risk of sepsis
17	0574U	0574U	NEW- PLA	Microbiology; Infectious Disease	ID LCMS	CHIM	Mycobacterium tuberculosis, culture filtrate protein-10-kDa (CFP-10), serum or plasma, liquid chromatography mass spectrometry (LC-MS)
18	0556U	0556U	NEW- PLA	Microbiology; Infectious Disease	ID MOL	CHIM	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific DNA and RNA by real-time PCR, 12 targets, nasopharyngeal or oropharyngeal swab, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
19	0557U	0557U	NEW- PLA	Microbiology; Infectious Disease	ID MOL	CHIM	Infectious disease (bacterial vaginosis and vaginitis), real-time amplification of DNA markers for Atopobium vaginae, Gardnerella vaginalis, Megasphaera types 1 and 2, bacterial vaginosis associated bacteria-2 and -3 (BVAB-2, BVAB-3), Mobiluncus species, Trichomonas vaginalis, Neisseria gonorrhoeae, Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. glabrata, C. krusei), Herpes simplex viruses 1 and 2, vaginal fluid, reported as detected or not detected for each organism

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
20	0563U	0563U	NEW- PLA	Microbiology; Infectious Disease	ID MOL	CHIM	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
21	0564U	0564U	NEW- PLA	Microbiology; Infectious Disease	ID MOL	CHIM	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
22**	87626	87626	No Longer RECONSIDERED	Microbiology; Infectious Disease	ID MOL	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), separately reported high-risk types (e.g., 16, 18, 31,45, 51, 52) and high-risk pooled result(s)
23	X171U	TBD	NEW	Microbiology; Infectious Disease	ID MOL	CHIM	Infectious disease (bacterial or viral), 32 genes (29 informative and 3 housekeeping), immune response mRNA, gene expression profiling by split-well multiplex reverse transcription loop-mediated isothermal amplification (RT-LAMP), whole blood, reported as continuous risk scores for likelihood of bacterial and viral infection and likelihood of severe illness within the next 7 days
24	X183U	TBD	NEW	Microbiology; Infectious Disease	ID MOL	CHIM	Infectious disease (tropical fever pathogens), vector-borne and zoonotic pathogens, including 2 viruses (Chikungunya virus and Dengue virus serotypes 1, 2, 3, and 4), 1 bacterium (Leptospira species), and 1 parasite with species differentiation (Plasmodium species, Plasmodium falciparum, and Plasmodium vivax/ovale), real-time RT-PCR, whole blood, each pathogen reported as detected or not detected
25	0536U	0536U	NEW- PLA	Molecular Pathology; PCR	Prenatal	MOG	Red blood cell antigen (fetal RhD), PCR analysis of exon 4 of RHD gene and housekeeping control gene GAPDH from whole blood in pregnant individuals at 10+ weeks gestation known to be RhD negative, reported as fetal RhD status
26	0523U	0523U	NEW- PLA	Molecular Pathology	Tumor FFPE	MOG	Oncology (solid tumor), DNA, qualitative, next-generation sequencing (NGS) of single- nucleotide variants (SNV) and insertion/deletions in 22 genes utilizing formalin-fixed paraffin- embedded tissue, reported as presence or absence of mutation(s), location of mutation(s), nucleotide change, and amino acid change
27	0538U	0538U	NEW- PLA	Genome Sequencing Procedures	Tumor FFPE	MOG	Oncology (solid tumor), next- generation targeted sequencing analysis, formalin-fixed paraffin- embedded (FFPE) tumor tissue, DNA analysis of 600 genes, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and copy number alterations, microsatellite instability, tumor mutation burden, reported as actionable variant
28	0543U	0543U	NEW- PLA	Genome Sequencing Procedures	Tumor FFPE	MOG	Oncology (solid tumor), next- generation sequencing of DNA from formalin-fixed paraffin-embedded (FFPE) tissue of 517 genes, interrogation for single- nucleotide variants, multi- nucleotide variants, insertions and deletions from DNA, fusions in 24 genes and splice variants in 1 gene from RNA, and tumor mutation burden

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
29	X164U	TBD	NEW	Genomic Sequencing Procedures; RT-PCR; ddPCR	Tumor FFPE	MOG	Oncology (cutaneous melanoma), RNA, gene expression profiling by real-time qPCR of 10 genes (8 content and 2 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reports a binary result, either low-risk or high-risk for sentinel lymph node metastasis and recurrence
30	X172U	TBD	NEW	Genome Sequencing Procedures	Tumor FFPE	MOG	Oncology, mRNA, gene expression profiling of 216 genes (204 targeted and 12 housekeeping genes), RNA expression analysis, formalin-fixed paraffin-embedded (FFPE) tissue, quantitative, reported as log2 ratio per gene
31	X185U	TBD	NEW	Genome Sequencing Procedures	Tumor FFPE	MOG	Oncology (breast), RNA expression profiling of 329 genes by targeted next-generation sequencing and 20 proteins by multiplex immunofluorescence, formalin-fixed paraffin-embedded (FFPE) tissue, algorithmic analyses to determine tumor-recurrence risk score
32	0527U	0527U	NEW- PLA	Microbiology; Infectious Disease	ID AMP	CHIM	Herpes simplex virus (HSV) types 1 and 2 and Varicella zoster virus (VZV), amplified probe technique, each pathogen reported as detected or not detected
33	0528U	0528U	NEW- PLA	Microbiology; Infectious Disease	ID AMP	CHIM	Lower respiratory tract infectious agent detection, 18 bacteria, 8 viruses, and 7 antimicrobial- resistance genes, amplified probe technique, including reverse transcription for RNA targets, each analyte reported as detected or not detected with semiquantitative results for 15 bacteria
34	871X1	TBD	NEW- CAT 1	Microbiology; Infectious Disease	ID AMP	CHIM	Susceptibility studies, antimicrobial agent; carbapenem resistance genes (eg, blaKPC, blaNDM, blaVIM, blaOXA-48, blaIMP), amplified probe technique, per isolate
35	87513	87513	RECONSIDERED	Microbiology; Infectious Disease	ID AMP	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Helicobacter pylori (H. pylori), clarithromycin resistance, amplified probe technique
36	8XXX9	TBD	NEW	Microbiology; Infectious Disease	ID AMP	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); joint space pathogens and drug resistance genes, multiplex amplified probe technique, 26 or more targets
37	8XXX2	TBD	NEW	Microbiology; Infectious Disease	ID AMP	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique
38	X180U	TBD	NEW	Microbiology; Infectious Disease	ID AMP	CHIM	Infectious disease (genitourinary pathogens), DNA, 46 targets (28 pathogens, 18 resistance genes), RT-PCR amplified probe technique, urine, each analyte reported as detected or not detected
39	G0567	G0567	NEW	Microbiology; Infectious Disease	ID AMP	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, screening, amplified probe technique
40	0540U	0540U	NEW- PLA	Genome Sequencing Procedures; cfDNA	Cf transplant	MOG	Transplantation medicine, quantification of donor- derived cell-free DNA using next-generation sequencing analysis of plasma, reported as percentage of donor- derived cell free DNA to determine probability of rejection
41	0530U	0530U	NEW- PLA	Genome Sequencing Procedures	Cf solid tumor	MOG	Oncology (pan-solid tumor), ctDNA, utilizing plasma, next-generation sequencing (NGS) of 77 genes, 8 fusions, microsatellite instability, and tumor mutation burden, interpretative report for single-nucleotide variants, copy-number alterations, with therapy association

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
42	0539U	0539U	NEW- PLA	Genome Sequencing Procedures	Cf solid tumor	MOG	Oncology (solid tumor), cell- free circulating tumor DNA (ctDNA), 152 genes, next- generation sequencing, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, copy number alterations, and microsatellite instability, using whole-blood samples, mutations with clinical actionability reported as actionable variant
43	0560U	0560U	NEW- PLA	Genome Sequencing Procedures	Cf solid tumor	MOG	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood and tumor tissue, baseline assessment for design and construction of a personalized variant panel to evaluate current MRD and for comparison to subsequent MRD assessments
44	0561U	0561U	NEW- PLA	Genome Sequencing Procedures	Cf solid tumor	MOG	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood, subsequent assessment with comparison to initial assessment to evaluate for MRD
45	0562U	0562U	NEW- PLA	Genome Sequencing Procedures	Cf solid tumor	MOG	Oncology (solid tumor), targeted genomic sequence analysis, 33 genes, detection of single-nucleotide variants (SNVs), insertions and deletions, copy-number amplifications, and translocations in human genomic circulating cell-free DNA, plasma, reported as presence of actionable variants
46	0571U	0571U	NEW- PLA	Genome Sequencing Procedures	Cf solid tumor	MOG	Oncology (solid tumor), DNA (80 genes) and RNA (10 genes), by next-generation sequencing, plasma, including single-nucleotide variants, insertions/deletions, copy-number alterations, microsatellite instability, and fusions, reported as clinically actionable variants
47	X169U	TBD	NEW	Genome Sequencing Procedures	Cf solid tumor	MOG	Targeted genomic sequence analysis panel, solid organ neoplasm, circulating cell-free DNA (cfDNA) analysis from plasma of 521 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, and microsatellite instability, report shows identified mutations, including variants with clinical actionability
48	0524U	0524U	NEW- PLA	Immunology	OB	CHIM	Obstetrics (preeclampsia), sFlt- 1/PlGF ratio, immunoassay, utilizing serum or plasma, reported as a value
49	0550U	0550U	NEW- PLA	Immunology	Tumor marker	CHIM	Oncology (prostate), enzyme- linked immunosorbent assays (ELISA) for total prostate- specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer
50	0558U	0558U	NEW- PLA	Immunology	Tumor marker	CHIM	Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression
51	0559U	0559U	NEW- PLA	Immunology	Tumor marker	CHIM	Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
52	0573U	0573U	NEW- PLA	Chemistry	Tumor marker	CHIM	Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and gastricsin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous
53	X178U	TBD	NEW	Immunology	Tumor marker	CHIM	Oncology (prostate cancer), biochemical analysis of 3 proteins (total PSA, free PSA, and HE4), plasma, serum, prognostic algorithm incorporating 3 proteins and digital rectal examination, results reported as a probability score for clinically significant prostate cancer
54	X187U	TBD	NEW	Immunology	Tumor marker	CHIM	Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19-9, serum, diagnostic algorithm reported as positive or negative
55	X162U	TBD	NEW	Immunology	Tumor marker	CHIM	Oncology (ovarian), serum, analysis of 39 glycoproteins by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in multiple reaction monitoring mode, reported as likelihood of malignancy
56	0549U	0549U	NEW- PLA	Molecular Pathology	Tumor MOL	MOG	Oncology (urothelial), DNA, quantitative methylated real- time PCR of TRNA-Cys, SIM2, and NKX1-1, using urine, diagnostic algorithm reported as a probability index for bladder cancer and/or upper tract urothelial carcinoma (UTUC)
57	0565U	0565U	NEW- PLA	Genome Sequencing Procedures	Tumor MOL	MOG	Oncology (hepatocellular carcinoma), next-generation sequencing methylation pattern assay to detect 6626 epigenetic alterations, cell-free DNA, plasma, algorithm reported as cancer signal detected or not detected
58	0566U	0566U	NEW- PLA	Molecular Pathology, Algorithm	Tumor MOL	MOG	Oncology (lung), qPCR-based analysis of 13 differentially methylated regions (CCDC181, HOXA7, LRRC8A, MARCHF11, MIR129-2, NCOR2, PANTR1, PRKCB, SLC9A3, TBR1_2, TRAP1, VWC2, ZNF781), pleural fluid, algorithm reported as a qualitative result
59	0569U	0569U	NEW- PLA	Genome Sequencing Procedures; Methylation; Algorithm	Tumor MOL	MOG	Oncology (solid tumor), next-generation sequencing analysis of tumor methylation markers (>20000 differentially methylated regions) present in cell-free circulating tumor DNA (ctDNA), whole blood, algorithm reported as presence or absence of ctDNA with tumor fraction, if appropriate
60	0572U	0572U	NEW- PLA	Microbiology	Tumor MOL	MOG	Oncology (prostate), high-throughput telomere length quantification by FISH, whole blood, diagnostic algorithm reported as risk of prostate cancer
61**	0464U	0464U	No Longer RECONSIDERED	Genomic Sequencing Procedures; Methylation Analysis	Tumor MOL	MOG	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result
62	0420U	0420U	RECONSIDERED	Genomic Sequencing Procedures; RT-PCR; ddPCR	Tumor MOL	MOG	Oncology (urothelial), mRNA expression profiling by real-time quantitative PCR of MDK, HOXA13, CDC2, IGFBP5, and CXCR2 in combination with droplet digital PCR ddPCR) analysis of 6 single-nucleotide polymorphisms (SNPs) genes TERT and FGFR3, urine, algorithm reported as a risk score for urothelial carcinoma

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
63	8XXX0	TBD	NEW	Genomic Sequencing Procedures; Methylation Analysis	Tumor MOL	MOG	Oncology (central nervous system tumor), DNA methylation analysis of at least 10,000 methylation sites, utilizing DNA extracted from formalin-fixed tumor tissue, algorithm(s) reported as probability of matching a reference tumor family and class, and MGMT (O-6-methylguanine-DNA methyltransferase) promoter methylation status, if performed
64	X179U	TBD	NEW	Genome Sequencing Procedures	Tumor FFPE	MOG	Oncology (hematolymphoid neoplasms), DNA, targeted genomic sequence of 417 genes, interrogation for gene fusions, translocations, rearrangements, utilizing formalin-fixed paraffin-embedded (FFPE) tumor tissue, results report clinically significant variant(s)
65	0535U	0535U	NEW- PLA	Immunology	Toxicology	CHIM	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
66	0541U	0541U	NEW- PLA	MAAA; Immunology	Cardiovascular	CHIM	Cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), serum, algorithm reported as prediction of coronary artery disease (pCAD) score
67	0542U	0542U	NEW- PLA	Chemistry	Transplant renal	CHIM	Nephrology (renal transplant), urine, nuclear magnetic resonance (NMR) spectroscopy measurement of 84 urinary metabolites, combined with patient data, quantification of BK virus (human polyomavirus 1) using real-time PCR and serum creatinine, algorithm reported as a probability score for allograft injury status
68	X161U	TBD	NEW	Chemistry	Toxicology	CHIM	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 24 PFAS compounds by high-performance liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
69	X165U	TBD	NEW	Immunology	Renal	CHIM	Nephrology (diabetic chronic kidney disease), enzyme-linked immunosorbent assay (ELISA) of apolipoprotein A4 (APOA4), CD5 antigen-like (CD5L) combined with estimated glomerular filtration rate (GFR), age, plasma, algorithm reported as a risk score for kidney function decline
70	X170U	TBD	NEW	Chemistry	TDM	CHIM	Therapeutic drug monitoring, 60-150 drugs and metabolites, urine, saliva, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), specimen validity, and algorithmic analyses for presence or absence of drug or metabolite, risk score predicted for adverse drug effects
71	X181U	TBD	NEW	Immunology	Transplant	CHIM	Transplantation medicine, antibody to non-human leukocyte antigens (non-HLA), blood specimen, flow cytometry, single-antigen bead technology, 39 targets, individual positive antibodies reported
72	X186U	TBD	NEW	Immunology	GI	CHIM	Gastroenterology (irritable bowel syndrome), IgG antibodies to 18 food items by microarray-based immunoassay, whole blood or serum, report as elevated (positive) or normal (negative) antibody levels
73	0529U	0529U	NEW- PLA	Molecular Pathology; Microarray	Hematology	MOG	Hematology (venous thromboembolism [VTE]), genome-wide single-nucleotide polymorphism variants, including F2 and F5 gene analysis,

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
							and Leiden variant, by microarray analysis, saliva, report as risk score for VTE
74	0532U	0532U	NEW- PLA	Genome Sequencing Procedures	Hereditary	MOG	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome and mitochondrial DNA sequencing for single- nucleotide variants, insertions/deletions, copy number variations, peripheral blood, buffy coat, saliva, buccal or tissue sample, results reported as positive or negative
75	X168U	TBD	NEW	Genome Sequencing Procedures	Hereditary	MOG	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome comparator DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, blood, saliva, tissue sample, variants reported with proband results (List separately in addition to primary procedure)
76	0567U	0567U	NEW- PLA	Genome Sequencing Procedures	Hereditary	MOG	Rare diseases (constitutional/heritable disorders), whole-genome sequence analysis combination of short and long reads, for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy-number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variants
77	X167U	TBD	NEW	Genome Sequencing Procedures	Hereditary	MOG	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, blood, saliva, tissue sample, variants reported
78	0544U	0544U	NEW- PLA	Molecular Pathology; PCR	Cf transplant	MOG	Nephrology (transplant monitoring), 48 variants by digital PCR, using cell-free DNA from plasma, donor-derived cell-free DNA, percentage reported as risk for rejection
79	X160U	TBD	NEW	Genome Sequencing Procedures	Cf transplant	MOG	Transplantation medicine (liver allograft rejection), quantitative donor-derived cell-free DNA (cfDNA) by whole genome next-generation sequencing, plasma and mRNA gene expression profiling by multiplex real-time PCR of 56 genes, whole blood, combined algorithm reported as a rejection risk score
80	X163U	TBD	NEW	Immunology	Neurology	CHIM	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative (For additional PLA code with identical clinical descriptor, see 0035U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)
81	0570U	0570U	NEW- PLA	Immunology	Neurology	CHIM	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non-elevated based on threshold comparison
82	X184U	TBD	NEW	Immunology	Neurology	CHIM	Neurology (Alzheimer disease), plasma, 3 distinct isoform-specific peptides (APOE2, APOE3, and APOE4) by liquid chromatography

FACA Panel Item #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee*	Long Code Descriptor
							with tandem mass spectrometry (LC-MS/MS), reported as an APOE prototype
83	0521U	0521U	NEW- PLA	Immunology	Rheumatology	CHIM	Rheumatoid factor IgA and IgM, cyclic citrullinated peptide (CCP) antibodies, and scavenger receptor A (SR-A) by immunoassay, blood
84	0522U	0522U	NEW- PLA	Immunology	Rheumatology	CHIM	Carbonic anhydrase VI, parotid specific/secretory protein and salivary protein 1 (SP1), IgG, IgM, and IgA antibodies, chemiluminescence, semiqualitative, blood
85	0525U	0525U	NEW- PLA	Therapeutic Drug Assay; Oncology	Chemoresponsiveness	CHIM	Oncology, spheroid cell culture, 11-drug panel (carboplatin, docetaxel, doxorubicin, etoposide, gemcitabine, niraparib, olaparib, paclitaxel, rucaparib, topotecan, veliparib) ovarian, fallopian, or peritoneal response prediction for each drug
86	0526U	0526U	NEW- PLA	Immunology	Transplant renal	CHIM	Nephrology (renal transplant), quantification of CXCL10 chemokines, flow cytometry, urine, reported as pg/mL creatinine baseline and monitoring over time
87	0545U	0545U	NEW- PLA	Immunology	Neurology	CHIM	Acetylcholine receptor (AChR), antibody identification by immunofluorescence, using live cells, reported as positive or negative
88	0546U	0546U	NEW- PLA	Immunology	Neurology	CHIM	Low-density lipoprotein receptor-related protein 4 (LRP4), antibody identification by immunofluorescence, using live cells, reported as positive or negative
89	0547U	0547U	NEW- PLA	Immunology	Neurology	CHIM	Neurofilament light chain (NfL), chemiluminescent enzyme immunoassay, plasma, quantitative
90	0548U	0548U	NEW- PLA	Immunology	Neurology	CHIM	Glial fibrillary acidic protein (GFAP), chemiluminescent enzyme immunoassay, using plasma
91	0551U	0551U	NEW- PLA	Immunology	Neurology	CHIM	Tau, phosphorylated, pTau217, by single-molecule array (ultrasensitive digital protein detection), using plasma
92	0568U	0568U	NEW- PLA	Immunology	Neurology	CHIM	Neurology (dementia), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio), tau-protein phosphorylated at residue (eg, pTau217), neurofilament light chain (NfL), and glial fibrillary acidic protein (GFAP), by ultra-high sensitivity molecule array detection, plasma, algorithm reported as positive, intermediate, or negative for Alzheimer pathology