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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 2025. The CDLT Panel may also provide input on any other CY 2025 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 16, 2024 (CMS-1824-N; 88 FR 23084).

Meeting Format

- ***__**IMPORTANT NOTE**__**:** Please note that although we hoped to facilitate an in-person meeting this year, due to the current building issues, **__the CLFS CDLT Panel meeting will use a virtual-only platform and will not have in-person attendance.__** While we are disappointed that we will not be able to interact with attendees and speakers at CMS headquarters, we look forward to hosting an in-person meeting in 2025!
- 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 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 discussed in each session are provided in Appendix 3.
- On Thursday and Friday (if needed), following lunch, the CDLT Panel will hold a discussion on the overall CDLT rate setting process. This session will be for Panel discussion only, although members of the public will be able to ask questions via the Q&A section of the Zoom chat.

Meeting 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

Thursday July 25 and Friday July 26, 2024

Time	Topic	Supporting Resource
9:30 a.m.	**Check-In and Audio/Video Connection Test Check**	
10:00 a.m.	**Welcome and Panel Introductions:** Rasheeda Arthur, PhD, 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- 1:15pm	**Lunch Break** **Please Note:** All speakers please reconnect by 1:00pm	
1:15- 1:45pm	**Day 1 and Day 2: Panel Discussion: CDLT rate setting process**	
1:45-4:00 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_xvGPnLreQ0Kw7VVBVKL-eQ

Note: This link provides attendees 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 2025 New and Reconsidered Codes and Other Information.

1. For a list of CY 2025 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 2024 new and reconsidered code list.

2. For CLFS Annual Laboratory Public meeting agenda from June 25, 2024, please see: https://www.cms.gov/files/document/june-25-2024-clfs-public-meeting-agenda-v3.pdf

3. For a recording of the CFLS Annual Laboratory Public Meeting from June 25, 2024, please see links below:
   a. Recording: https://cms.zoomgov.com/rec/share/2jQakqNnZtNNToCNxJxnc62trzrWzmBar60OC5y2zhNgK256MZ3GQODzGyUv23UD.Quqt-jAZ5LoO8lH_
   b. Passcode: v$Rf7#3J

4. For a copy of CY 2024 - 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-2024-final-payment-determinations.zip

Appendix 3: Summary of codes

*Subcommittees: Chemistry, Hematology, Immunology, Microbiology (CHIM); Molecular Pathology, Genomic Sequencing (MoG)
** Advanced Diagnostic Laboratory Tests (ADLT) status: code is removed from CDLT Panel discussion

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	0445U	0445U	New (PLA)	Immunology	Alzheimer	CHIM	B-amyloid (abeta42) and phospho tau (181p) (ptau181), electrochemiluminescent immunoassay (eclia), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
2	82XX0	TBD	New	Immunology	Alzheimer	CHIM	Beta-amyloid; 1-40 (Abeta 40)
3	82XX1	TBD	New	Immunology	Alzheimer	CHIM	Beta-amyloid; 1-42 (Abeta 42)
4	83XX0	TBD	NEW	Immunology	Alzheimer	CHIM	Neurofilament light chain (NfL)
5	86XX1	TBD	NEW	Immunology	Alzheimer	CHIM	Streptococcus pneumoniae antibody (IgG), serotypes, multiplex immunoassay, quantitative
6	8X3XX	TBD	New	Immunology	Alzheimer	CHIM	Tau, total (tTau)
7	XX42U	0462U	New (PLA)	Chemistry	Alzheimer	CHIM	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary
8	XX65U	TBD	NEW	Microbiology Infectious Disease	Alzheimer	CHIM	Infectious disease (bacteria, viruses, fungi, and parasites), cerebrospinal fluid (CSF), metagenomic next-generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification
9	86041	86041	Reconsidered	Immunology	Neurology	CHIM	Recommendation: Crosswalk code: 86341 Islet cell antibody
10	86042	86042	Reconsidered	Immunology	Neurology	CHIM	Acetylcholine receptor (AChR); blocking antibody
11	86043	86043	Reconsidered	Immunology	Neurology	CHIM	Acetylcholine receptor (AChR); modulating antibody
12	86366	86366	Reconsidered	Immunology	Neurology	CHIM	Muscle-specific kinase (MuSK) antibody
13	0431U	0431U	New (PLA)	Immunology	Neurology	CHIM	Glycine receptor alpha1 IgG, serum or cerebrospinal fluid (CSF), live cell-binding assay (LCBA), qualitative
14	0432U	0432U	New (PLA)	Immunology	Neurology	CHIM	Kelch-like protein 11 (KLHL11) antibody, serum or cerebrospinal fluid (CSF), cell-binding assay, qualitative
15	0443U	0443U	New (PLA)	Chemistry	Neurology	CHIM	Neurofilament light chain (nfl), ultra-sensitive immunoassay, serum or cerebrospinal fluid

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16	XX32U	0451U	New (PLA)	Chemistry	Neurology	CHIM	Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance
17	0394U	0394U	Reconsidered (PLA)	Chemistry	Chemistry	CHIM	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LCMS/MS), plasma or serum, quantitative
18	8X051	TBD	NEW	Microbiology	Chemistry	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacterium tuberculosis, rifampin resistance, amplified probe technique
19	8X3X0	TBD	New	Immunology	Chemistry	CHIM	Tau, phosphorylated (eg, pTau 181, pTau 217), each
20	8XX00	TBD	NEW	Microbiology Infectious Disease & Genome Sequencing Procedure	Chemistry	CHIM	Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for Atopobium vaginae, Atopobium species, and Megasphaera type 1, Bacterial Vaginosis–Associated Bacteria 2 (BVAB-2), utilizing vaginal-fluid specimens, algorithm reported as positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, when reported
21	0435U	0435U	New (PLA)	Molecular Pathology	Chemosensitivity	CHIM	Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on cytotoxicity percentage observed, minimum of 14 drugs or drug combinations
22	XX84U	TBD	NEW	Genomic Sequencing Procedures; Infectious Disease	Chemosensitivity	CHIM	Human papillomavirus (HPV), E6/E7 markers for high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), cervical cells, branched-chain capture hybridization, reported as negative or positive for high risk for HPV
23	XX89U	TBD	NEW	Genomic Sequencing Procedures; Infectious Disease	Therapeutic	CHIM	Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism
24	XX99U	TBD	NEW	Immunology	Therapeutic	CHIM	Gastroenterology (irritable bowel disease [IBD]), immunoassay for the quantitative determination of infliximab (IXL) levels in venous serum in patients undergoing infliximab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)
25	XX97U	TBD	NEW	Pharmacogenomics	Therapeutic	CHIM	Oncology (solid tumor), tumor cell culture in 3D microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug
26	XX98U	TBD	NEW	Immunology	Therapeutic	CHIM	Gastroenterology (irritable bowel disease [IBD]), immunoassay for the quantitative determination of adalimumab (ADL) levels in venous serum in patients undergoing adalimumab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)
27	0430U	0430U	New (PLA)	Chemistry	GI	CHIM	Gastroenterology, malabsorption evaluation of alpha-1-antitrypsin, calprotectin, pancreatic elastase and reducing substances, feces, quantitative

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28	0427U	0427U	New (PLA)	Hematology	Hematology	CHIM	Monocyte distribution width, whole blood (List separately in addition to code for primary procedure) (Use 0427U in conjunction with 85004, 85025)
29	X102U	TBD	NEW	Therapeutic Drug Assay	Hepatology	CHIM	Therapeutic drug monitoring, 200 or more drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications
30	XX85U	TBD	NEW	Immunology	Monoclonal antibody	CHIM	Neurology (Alzheimer disease), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio) and tau-protein (p-tau217, np-tau217, p-tau217/np-tau217 ratio), blood, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS), algorithm score reported as the likelihood of positive or negative for amyloid plaques
31	XX88U	TBD	NEW	Genomic Sequencing Procedures; Infectious Disease	Monoclonal antibody	CHIM	Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, real-time PCR, reported as positive or negative for each organism
32	87XX0	TBD	NEW	Microbiology Infectious Disease	Monoclonal proteins	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Pneumocystis jirovecii, amplified probe technique
33	87XX1	TBD	NEW	Microbiology Infectious Disease & Genome Sequencing Procedure	Monoclonal proteins	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), separately reported high-risk types (eg, 16, 18, 31,45, 51, 52) and high-risk pooled result(s)
34	XX48U	0468U	New (PLA)	MAAA	OB	CHIM	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis
35	0436U	0436U	New (PLA)	Molecular Pathology	Oncology proteins	CHIM	Oncology (lung), plasma analysis of 388 proteins, using aptamerbased proteomics technology, predictive algorithm reported as clinical benefit from immune checkpoint inhibitor therapy
36	0446U	0446U	New (PLA)	MAAA	Rheumatology	CHIM	Autoimmune diseases (systemic lupus erythematosus [sle]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity
37	0447U	0447U	New (PLA)	MAAA	Rheumatology	CHIM	Autoimmune diseases (systemic lupus erythematosus [sle]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare
38	X103U	TBD	NEW	Therapeutic Drug Assay	Rheumatology	CHIM	Therapeutic drug monitoring, 90 or more pain and mental health drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications
39	0429U	0429U	New (PLA)	Microbiology Infectious Disease	HPV	CHIM	Human papillomavirus (HPV), oropharyngeal swab, 14 high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)
40	XX39U	0458U	New (PLA)	Chemistry	HPV	CHIM	Oncology (breast cancer), S100A8 and S100A9, by enzyme linked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score

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41	X101U	TBD	NEW	Therapeutic Drug Assay	HPV	CHIM	Therapeutic drug monitoring, 80 or more psychoactive drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally and maximally effective dose of prescribed and non-prescribed medications
42	XX63U	TBD	NEW	Chemistry	HPV	CHIM	Obstetrics (preeclampsia), biochemical assay of soluble fms-like tyrosine kinase 1 (sFlT-1) and placental growth factor (PIGF), serum, ratio reported for sFlT-1/PIGF, with risk of progression for preeclampsia with severe features within 2 weeks
43	87593	87593	New* Missed from 2022	Microbiology Infectious Disease	ID	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each
44	0442U	0442U	New (PLA)	Microbiology Infectious Disease	ID	CHIM	Infectious disease (respiratory infection), myxovirus resistance protein a (mxa) and c-reactive protein (crp), fingerstick whole blood specimen, each biomarker reported as present or absent
45	XX38U	0457U	New (PLA)	Chemistry	ID	CHIM	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative
46	X104U	TBD	NEW	Therapeutic Drug Assay	ID	CHIM	Therapeutic drug monitoring, medications specific to pain, depression, and anxiety, LC-MS/MS, plasma, 110 or more drugs or substances, qualitative and quantitative therapeutic minimally effective range of prescribed, non-prescribed, and illicit medications in circulation
47	XX31U	0450U	New (PLA)	Chemistry	ID	CHIM	Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides
48	XX36U	0455U	New (PLA)	Microbiology Infectious Disease	ID	CHIM	Infectious agents (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified probe technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected
49	XX66U	TBD	NEW	MAAA; Microbiology	ID	CHIM	Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of fluoroquinolone resistance
50	XX43U	0463U	New (PLA)	Microbiology Infectious Disease & Genome Sequencing Procedures; RT-PCR	ID	CHIM	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker
51	8X050	TBD	NEW	Microbiology	ID GU	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Helicobacter pylori (H. pylori), clarithromycin resistance, amplified probe technique
52	XX52U	0472U	New (PLA)	MAAA	ID GU	CHIM	Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies,

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							enzyme-linked immunosorbent assay (ELISA), semiqualitative, blood, reported as predictive evidence of early Sjögren syndrome
53	XX62U	TBD	NEW	Immunology	ID GU	CHIM	Tau, phosphorylated, pTau217
54	XX72U	TBD	NEW	MAAA: Microbiology	ID GU	CHIM	Infectious disease (Mycoplasma genitalium), macrolide sensitivity (23S rRNA point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of macrolide resistance
55	0441U	0441U	New (PLA)	Microbiology Infectious Disease	ID non-mol	CHIM	Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability cytometry), whole blood, with algorithmic analysis and result reported as an index
56	XX40U	0459U	New (PLA)	Immunology	ID non-mol	CHIM	β-amyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
57	0420U	0420U	New (PLA)	Genome Sequencing Procedures; RT-PCR	Oncology urothelial	CHIM	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
58	XX95U	TBD	NEW	Augmented analysis	AI	MoG	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of MSI-High (MSI-H)
59	XX96U	TBD	NEW	Augmented analysis	AI	MoG	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) and homologous recombination deficiency (HRD) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker
60	0439U	0439U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Cardiology	MoG	Cardiology (coronary heart disease [chd]), dna, analysis of 5 single-nucleotide polymorphisms (snps) (rs11716050 [loc105376934], rs6560711 [wdr37], rs3735222 [scin/loc107986769], rs6820447 [intergenic], and rs9638144 [esyt2]) and 3 dna methylation markers (cg00300879 [transcription start site {tss200} of cnksr1], cg09552548 [intergenic], and cg14789911 [body of spatc1l]), qpcr and digital pcr, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic chd
61	0440U	0440U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Cardiology	MoG	Cardiology (coronary heart disease [chd]), dna, analysis of 10 single-nucleotide polymorphisms (snps) (rs710987 [linc010019], rs1333048 [cdkn2b-as1], rs12129789 [kcnd3], rs942317 [ktn1-as1], rs1441433 [ppp3ca], rs2869675 [prex1], rs4639796 [zbtb41], rs4376434 [linc00972], rs12714414 [tmem18], and rs7585056 [tmem18]) and 6 dna methylation markers (cg03725309 [sars1], cg12586707 [cxcl1, cg04988978 [mpo], cg17901584 [dhcr24-dt], cg21161138 [ahrr], and cg12655112 [ehd4]), qpcr and digital pcr, whole blood, algorithm reported as detected or not detected for chd

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62	XX46U	0466U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Cardiology	MoG	Cardiology (coronary artery disease [CAD]), DNA, genomewide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease
63	XX73U	TBD	NEW	Genomic Sequencing Procedures	Cellsearch	MoG	Oncology (cutaneous or uveal melanoma), circulating tumor cell selection, morphological characterization and enumeration based on differential CD146, high molecular–weight melanoma-associated antigen, CD34 and CD45 protein biomarkers, peripheral blood
64	XX75U	TBD	NEW	Genomic Sequencing Procedures	Cellsearch	MoG	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker–expressing cells, peripheral blood
65	XX74U	TBD	NEW	Genomic Sequencing Procedures	Cellsearch	MoG	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of PD-L1 protein biomarker–expressing cells, peripheral blood
66	0355U	0355U	Reconsidered (PLA)	Genomic Sequencing Procedures; targeted variant analysis	CKD	MoG	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)
67	XX83U	TBD	NEW	Genomic Sequencing Procedures	Hematology	MoG	Autoinflammatory disease (VEXAS syndrome), DNA, UBA1 gene mutations, targeted variant analysis (M41T, M41V, M41L, c.118-2A>C, c.118-1G>C, c.118-9_118-2del, S56F, S621C)
68	0437U	0437U	New (PLA)	Molecular Pathology	Psychiatry	MoG	Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score
69	XX37U	0456U	New (PLA)	MAAA	Rheumatology	MoG	Autoimmune (rheumatoid arthritis), next-generation sequencing (NGS), gene expression testing of 19 genes, whole blood, with analysis of anticyclic citrullinated peptides (CCP) levels, combined with sex, patient global assessment, and body mass index (BMI), algorithm reported as a score that predicts nonresponse to tumor necrosis factor inhibitor (TNFi) therapy
70	0428U	0428U	New (PLA)	Genomic Sequencing Procedures; cell free DNA	Cf breast	MoG	Oncology (breast), targeted hybrid-capture genomic sequence analysis panel, circulating tumor DNA (ctDNA) analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden
71	XX34U	0453U	New (PLA)	Genomic Sequencing Procedures; cell free DNA & Genomic Sequencing Procedures; methylation analysis	Cf colon	MoG	Oncology (colorectal cancer), cellfree DNA (cfDNA), methylationbased quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)

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72	XX87U	TBD	NEW	Genomic Sequencing Procedures	Cf colon	MoG	Oncology (colorectal), cell-free DNA, 8 genes for mutations, 7 genes for methylation by real-time RT-PCR, and 4 proteins by enzyme-linked immunosorbent assay, blood, reported positive or negative for colorectal cancer or advanced adenoma risk
73	XX80U	TBD	NEW	Genomic Sequencing Procedures	Cf colon	MoG	Oncology (colorectal), blood, quantitative measurement of cell-free DNA (cfDNA)
74	XX70U	TBD	NEW	Genomic Sequencing Procedures	Cf obstetrics	MoG	Obstetrics (fetal antigen noninvasive prenatal test), cell-free DNA sequence analysis for the detection of the fetal presence or absence of 1 or more of the Rh, C, c, D, E, Duffy (Fya), or Kell (K) antigen in alloimmunized pregnancies, reported as selected antigen(s) detected or not detected
75	XX76U	TBD	NEW	Genomic Sequencing Procedures	Cf obstetrics	MoG	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA sequence analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants, and relative mutation-dosage analysis based on molecular counts to determine the fetal inheritance of the maternal mutation, algorithm reported as a fetal risk score for the condition (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia)
76	XX82U	TBD	NEW	Genomic Sequencing Procedures	Cf obstetrics	MoG	Red blood cell antigen (fetal RhD gene analysis), next-generation sequencing of circulating cell-free DNA (cfDNA) of blood in pregnant individuals known to be RhD negative, reported as positive or negative
77	XX50U	0470U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Cf oropharynx	MoG	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma
78	81462	81462	Reconsidered	Genomic Sequencing Procedures; cell free DNA	Cf solid tumor	MoG	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements
79	81464	81464	Reconsidered	Genomic Sequencing Procedures; cell free DNA	Cf solid tumor	MoG	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements
80	0422U	0422U	New (PLA)	Genomic Sequencing Procedures; cell free DNA	Cf solid tumor	MoG	Oncology (pan-solid tumor), analysis of DNA biomarker response to anti-cancer therapy using cell-free circulating DNA, biomarker comparison to a previous baseline pre-treatment cell-free circulating DNA analysis using next-generation sequencing, algorithm reported as a quantitative change from baseline, including specific alterations, if appropriate
81	XX41U	0460U	New (PLA)	Genomic Sequencing Procedures; targeted variant analysis	Cf solid tumor	MoG	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes
82	XX69U	TBD	NEW	Genomic Sequencing Procedures	Cf solid tumor	MoG	Oncology (solid tumor), cell-free DNA and RNA by next-generation sequencing, interpretative report for germline mutations, clonal hematopoiesis of indeterminate potential, and tumor-derived single-

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							nucleotide variants, small insertions/deletions, copy number alterations, fusions, microsatellite instability, and tumor mutational burden
83	XX77U	TBD	NEW	Genomic Sequencing Procedures	Cf solid tumor	MoG	Oncology (pan-solid tumor), next-generation sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of methylation as a correlate of tumor fraction
84	8156X	TBD	New	Genome Sequencing Procedures; RT-PCR	Cf transplantation	MoG	Transplantation medicine (allograft rejection, kidney), mRNA, gene expression profiling by quantitative polymerase chain reaction (qPCR) of 139 genes, utilizing whole blood, algorithm reported as a binary categorization as transplant excellence, which indicates immune quiescence, or not transplant excellence, indicating subclinical rejection
85	XX78U	TBD	NEW	Genomic Sequencing Procedures	Cf transplantation	MoG	Transplantation medicine, quantification of donor-derived cell-free DNA using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA (cfDNA)
86	XX93U	TBD	NEW	Molecular Pathology	Cf transplantation	MoG	Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single-nucleotide polymorphism (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell-free DNA with risk for active rejection
87	XX94U	TBD	NEW	Molecular Pathology	Cf transplantation	MoG	Transplantation medicine, quantification of donor-derived cell-free DNA using up to 12 single-nucleotide polymorphism (SNPs) previously identified, plasma, reported as percentage of donor-derived cell-free DNA with risk for active rejection
88	0425U	0425U	New (PLA)	Genome Sequencing Procedures	Genomic sequencing	MoG	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis, each comparator genome (eg, parents, siblings)
89	0426U	0426U	New (PLA)	Genome Sequencing Procedures	Genomic sequencing	MoG	Genome (eg, unexplained constitutional or heritable disorder or syndrome), ultra-rapid sequence analysis
90	0449U	0449U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Genomic sequencing	MoG	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes (cftr, smn1, hbb, hba1, hba2)
91	XX49U	0469U	New (PLA)	Genome Sequencing Procedures	Genomic sequencing	MoG	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception), identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if performed, as comparators and/or maternal cell contamination

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92	0417U	0417U	Reconsidered	Genomic Sequencing Procedures; mitochondrial	Genomic sequencing	MoG	Rare diseases (constitutional/heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and categorization of mitochondrial disorder-associated genetic variants
93	0X00M	0020M	New	Genomic Sequencing Procedures; methylation analysis	Oncology brain	MoG	Oncology (central nervous system), analysis of 30000 DNA methylation loci by methylation array, utilizing DNA extracted from tumor tissue, diagnostic algorithm reported as probability of matching a reference tumor subclass
94	XX67U	TBD	NEW	Genomic Sequencing Procedure	Oncology brain	MoG	Isocitrate dehydrogenase 1 (IDH1), isocitrate dehydrogenase 2 (IDH2), and telomerase reverse transcriptase (TERT) promoter (eg, central nervous system [CNS] tumors), next-generation sequencing (single-nucleotide variants [SNV], deletions, and insertions)
95	0421U	0421U	New (PLA)	Genome Sequencing Procedures; RT-PCR	Oncology colorectal	MoG	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, GLN2) and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk
96	XX44U	0464U	New (PLA)	Genomic Sequencing Procedures; methylation analysis	Oncology colorectal	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
97	XX51U	0471U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Oncology colorectal	MoG	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalinfixed paraffin-embedded (FFPE), predictive, identification of detected mutations
98	XX68U	TBD	NEW	Genomic Sequencing Procedures	Oncology colorectal	MoG	Oncology (colorectal), next-generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation
99	XX86U	TBD	NEW	Genomic Sequencing Procedures	Oncology colorectal	MoG	Oncology (colorectal and lung), DNA from formalin-fixed paraffin-embedded (FFPE) tissue, next-generation sequencing of 8 genes (NRAS, EGFR, CTNNB1, PIK3CA, APC, BRAF, KRAS, and TP53), mutation detection
100	XX90U	TBD	NEW	Genomic Sequencing Procedures	Oncology esophagus	MoG	Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus
101	XX54U	0475U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Oncology hereditary	MoG	Hereditary prostate cancerrelated disorders, genomic sequence analysis panel using next-generation sequencing (NGS), Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer

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102	XX55U	0474U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Oncology hereditary	MoG	Hereditary pan-cancer (eg, hereditary sarcomas, hereditary endocrine tumors, hereditary neuroendocrine tumors, hereditary cutaneous melanoma), genomic sequence analysis panel of 88 genes with 20 duplications/deletions using nextgeneration sequencing (NGS), Sanger sequencing, blood or saliva, reported as positive or negative for germline variants, each gene
103	81432	TBD	REVISED	Genomic Sequencing Procedures	Oncology hereditary	MoG	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer, hereditary pancreatic cancer, hereditary prostate cancer)~~;~~, genomic sequence analysis panel, 5 or more genes, interrogation for sequence variants and copy number variants ~~must include sequencing of at least 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53~~
104	81435	TBD	REVISED	Genomic Sequencing Procedures	Oncology hereditary	MoG	Hereditary colon cancer-related disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis)~~;~~, genomic sequence analysis panel, 5 or more genes, interrogation for sequence variants and copy number variants ~~must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11~~
105	81437	TBD	REVISED	Genomic Sequencing Procedures	Oncology hereditary	MoG	Hereditary neuroendocrine tumor-related disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma)~~;~~, genomic sequence analysis panel, 5 or more genes, interrogation for sequence variants and copy number variants ~~must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL~~
106	0448U	0448U	New (PLA)	Genomic Sequencing Procedures; targeted variant analysis	Oncology lung	MoG	Oncology (lung and colon cancer), dna, qualitative, nextgeneration sequencing detection of single-nucleotide variants and deletions in egfr and kras genes, formalin-fixed paraffinembedded (ffpe) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options
107	XX61U	TBD	NEW	Molecular Pathology	Oncology lung	MoG	Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET, NTRK 1/2/3, ERBB2, and MET) in formalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection
108	XX91U	TBD	NEW	Genomic Sequencing Procedures	Oncology ovarian	MoG	Oncology (ovarian), DNA, whole-genome sequencing with 5-hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as cancer detected or not detected
109	XX92U	TBD	NEW	Augmented analysis	Oncology pancreas	MoG	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole-transcriptome data, reported as probability of predicted molecular subtype
110	81457	81457	Reconsidered	Genomic Sequencing Procedures	Oncology solid tumor	MoG	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability

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111	81458	81458	Reconsidered	Genomic Sequencing Procedures	Oncology solid tumor	MoG	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability
112	81459	81459	Reconsidered	Genomic Sequencing Procedures	Oncology solid tumor	MoG	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements
113	0444U	0444U	New (PLA)	Genomic Sequencing Procedures; targeted variant analysis	Oncology solid tumor	MoG	Oncology (solid organ neoplasia), targeted genomic sequence analysis panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using dna from formalin-fixed paraffin-embedded (ffpe) tumor tissue, report of clinically significant variant(s)
114 **	XX53U**	0473U**	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Oncology solid tumor	MoG	Oncology (solid tumor), next generation sequencing (NGS) of DNA from formalin-fixed paraffin embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden
115	XX71U	TBD	NEW	Genomic Sequencing Procedures	Oncology solid tumor	MoG	Oncology (solid tumor), cell-free circulating DNA, targeted genomic sequence analysis panel of 84 genes, interrogation for sequence variants, aneuploidy-corrected gene copy number amplifications and losses, gene rearrangements, and microsatellite instability
116	0424U	0424U	New (PLA)	Genome Sequencing Procedures; RT-PCR	Oncology urothelial	MoG	Oncology (prostate), exosome-based analysis of 53 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RTqPCR), urine, reported as no molecular evidence, low-, moderate- or elevated-risk of prostate cancer
117	0433U	0433U	New (PLA)	Genome Sequencing Procedures; RT-PCR	Oncology urothelial	MoG	Oncology (prostate), 5 DNA regulatory markers by quantitative PCR, whole blood, algorithm, including prostate-specific antigen, reported as likelihood of cancer
118	XX33U	0452U	New (PLA)	Genomic Sequencing Procedures; methylation analysis	Oncology urothelial	MoG	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer
119	XX45U	0465U	New (PLA)	Genomic Sequencing Procedures; methylation analysis	Oncology urothelial	MoG	Oncology (urothelial carcinoma), DNA, quantitative methylation specific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative
120	XX47U	0467U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Oncology urothelial	MoG	Oncology (bladder), DNA, next generation sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden
121	XX79U	TBD	NEW	Genomic Sequencing Procedures	Oncology urothelial	MoG	Oncology (prostate), analysis of circulating plasma proteins (tPSA, fPSA, KLK2, PSP94, and GDF15), germline polygenic risk score (60 variants), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer
122	XX81U	TBD	NEW	Genomic Sequencing Procedures	Oncology urothelial	MoG	Oncology (prostate), mRNA gene-expression profiling by real-time RT-PCR of 6 genes (FOXM1, MCM3, MTUS1, TTC21B, ALAS1,

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							and PPP2CA), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer
123	88XX0	TBD	NEW	Molecular Pathology; Optical Genome Mapping	Optical genome	MoG	Cytogenomic genome-wide analysis, hematologic malignancy, structural variations and copy number variations, optical genome mapping (OGM)
124	0413U	0413U	Reconsidered	Genomic Sequencing Procedures; optical genome mapping	Optical genome	MoG	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, dna from blood or bone marrow, report of clinically significant alterations
125	XX35U	0454U	New (PLA)	Genome Sequencing Procedures; dup/del analysis	Optical genome	MoG	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping
126	0423U	0423U	New (PLA)	Genomic Sequencing Procedures; targeted variant analysis	Pharmacogenetics	MoG	Psychiatry (eg, depression, anxiety), genomic analysis panel, including variant analysis of 26 genes, buccal swab, report including metabolizer status and risk of drug toxicity by condition
127	0434U	0434U	New (PLA)	Genomic Sequencing Procedures; targeted variant analysis	Pharmacogenetics	MoG	Drug metabolism (adverse drug reactions and drug response), genomic analysis panel, variant analysis of 25 genes with reported phenotypes
128	0438U	0438U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Pharmacogenetics	MoG	Drug metabolism (adverse drug reactions and drug response), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of CYP2D6, including reported phenotypes and impacted gene drug interactions
129	XX30U	0461U	New (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Pharmacogenetics	MoG	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes
130	XX64U	TBD	NEW	Molecular Pathology, Pharmacogenomics	Pharmacogenetics	MoG	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder [ADHD], schizophrenia), whole blood, buccal swab, pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis, and reported phenotypes
131	XX60U	TBD	NEW	Molecular Pathology, Pharmacogenomics	Pharmacogenetics	MoG	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder [ADHD], schizophrenia), whole blood, buccal swab, pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis, including impacted gene-drug interactions and reported phenotypes
132	X100U	TBD	NEW	Immunology	Pharmacogenetics	MoG	Drug metabolism, whole blood, pharmacogenomic genotyping of 40 genes and CYP2D6 copy number variant analysis, reported as metabolizer status