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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 2023. The CDLT Panel may also provide input on any other CY 2023 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 18, 2022 (CMS-1777-N; 87 FR 22895).

Meeting Format

- The CDLT Panel Chair 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.

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

Monday July 18, 2022

Time	Topic	Supporting Resource
8:30 a.m.	**Check-In and Audio/Video Connection Test Check**	
9:00 a.m.	**Welcome and Panel Introductions:** Karen Nakano, M.D., Panel Chair, CMS Physician and Rasheeda Arthur, PhD, Panel Designated Federal Officer	
9:15 -12:00 p.m.	**Session 1:** I. Chemistry II. Genomic Sequencing Related Tests III. Microbiology	Appendix 3
12:00-1:00pm	**Lunch Break** **Please Note:** All speakers please reconnect by 12:45pm	
1:00-4:30 p.m.	**Session 1: (continued):** I. Chemistry II. Genomic Sequencing Related Tests III. Microbiology	Appendix 3
4:30 p.m.	**Meeting Adjourns**	

Tuesday July 19, 2022

Time	Topic	Supporting Resource
8:30 a.m.	**Check-In and Audio/Video Connection Test Check**	
9:00 a.m.	**Reconvene Meeting:** Karen Nakano, M.D., Panel Chair, CMS Physician	
9:15 -12:00 p.m.	**Session 2:** IV. Hematology and Coagulation V. Tests with algorithm in code descriptor to report risk/likelihood/predictive score VI. Immunology	Appendix 4
12:00-1:00pm	**Lunch Break** **Please Note:** All speakers please reconnect by 12:45pm	
1:00-4:30 p.m.	**Session 2: (continued):** IV. Hematology and Coagulation V. Tests with algorithm in code descriptor to report risk/likelihood/predictive score VI. Immunology	Appendix 4
4:30 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

Please click the link below to join the webinar:

https://cms.zoomgov.com/webinar/register/WN_UGnBlaA3SUWVj5y_ZclGtQ

Webinar ID: 161 798 0314

Password: 709448

US: +1 669 254 5252 or +1 646 828 7666 or 833 568 8864 (Toll Free)

Appendix 2: Access to CLFS CY 2023 New and Reconsidered Codes and Other Information

1. For a list of CY 2023 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 2023 new and reconsidered code list.

2. For CLFS Annual Laboratory Public meeting agenda from June 23, 2022 please see: https://www.cms.gov/files/document/agenda-clfs-annual-laboratory-meeting-june-23-2022.pdf

3. For a recording of the CFLS Annual Laboratory Public Meeting from June 23, 2022, please see links below:
   a. Part I:
      https://cms.zoomgov.com/rec/play/vlFecgQcw7yNODq7QlMmmTNvhoWerjU3JYWY_Y3L5ouc4ITj1tvfR76El42A1OGubJsaIuI8_aZgB9VH.7QsML2bLJBxxhg0g
      Passcode: nd0?5!5j
   b. Part II:
      https://cms.zoomgov.com/rec/play/w8uTb3BRZlftdglD82moFjTCI9nUaf6fk0GV0f8b157HzE9DIIkwys46ka-cbeQZ2PQmqvL1_IRoB-0G.QBNyvw-bzEvHTWTg
      Passcode: nd0?5!5j

4. For a copy of CY 2022 - 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/cy2022-clfs-test-codes-final-payment-determinations.zip

Appendix 3: Session 1 – July 18, 2022 Summary of codes

Corrections to order of codes:

a. Item #32 code 81445 was moved to follow item #30 code 0022U.
b. Item #98 code 86364 was moved to follow item #95 code 86258
c. Item #102 code 87548 was moved to follow item #105 code 0x56U

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
1	75	CHIM	84XXX	NEW	Chemistry	Thiopurine S-methyltransferase (TPMT)
2	39	CHIM	80220	Reconsideration	Chemistry	Hydroxychloroquine
3	41	CHIM	83529	Reconsideration	Chemistry	Interleukin-6 (IL-6)
4	96	CHIM	0X46U	PLA	Chemistry	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH
5	98	CHIM	0X48U	PLA	Chemistry	Beta amyloid, Aβ40 and Aβ42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma
6	14	MoG	0298U	PLA	Genomic Sequencing Related Tests WHOLE GENOME; Drug metabolism pharmacogenomics/pharmacogenetics	Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal RNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and expression level and chimeric transcript identification
7	13	MoG	0297U	PLA	Genomic Sequencing Related Tests WHOLE GENOME; Drug metabolism pharmacogenomics/pharmacogenetics	Oncology (pan tumor), whole genome sequencing of paired malignant and normal DNA specimens, fresh or formalin fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and variant identification
8	15	MoG	0299U	PLA	Genomic Sequencing Related Tests WHOLE GENOME; Drug metabolism pharmacogenomics/pharmacogenetics	Oncology (pan tumor), whole genome optical genome mapping of paired malignant and normal DNA specimens, fresh frozen tissue, blood, or bone marrow, comparative structural variant identification
9	16	MoG	0300U	PLA	G Genomic Sequencing Related Tests	Oncology (pan tumor), whole genome sequencing and optical genome mapping of paired malignant and normal DNA specimens, fresh tissue, blood, or bone marrow, comparative sequence analyses and variant identification

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
					WHOLE GENOME; Drug metabolism pharmacogenomics/pharmacogenetics	
10	70	MoG	8X000	NEW	Genomic Sequencing Related Tests WHOLE GENOME; Drug metabolism pharmacogenomics/pharmacogenetics	Drug metabolism (eg, pharmacogenomics) genomic sequence analysis panel, must include testing of at least 6 genes, including CYP2C19, CYP2D6, and CYP2D6 duplication/deletion analysis
11	95	MoG	0X45U	PLA	Genomic Sequencing Related Tests TARGETED; Drug metabolism pharmacogenomics/pharmacogenetics	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis including reported phenotypes and impacted gene-drug interactions
12	97	MoG	0X47U	PLA	Genomic Sequencing Related Tests TARGETED; Drug metabolism pharmacogenomics/pharmacogenetics	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6
13	99	MoG	0X50U	PLA	Genomic Sequencing Related Tests TARGETED; Drug metabolism pharmacogenomics/pharmacogenetics	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes
14	100	MoG	0X51U	PLA	Genomic Sequencing Related Tests TARGETED; Drug metabolism pharmacogenomics/pharmacogenetics	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 16 gene report, with variant analysis and reported phenotypes
15	101	MoG	0X52U	PLA	Genomic Sequencing Related Tests TARGETED; Drug metabolism pharmacogenomics/pharmacogenetics	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes
16	2	MoG	0286U	PLA	Genomic Sequencing Related Tests TARGETED; Drug metabolism pharmacogenomics/pharmacogenetics	CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
17	67	MoG	0331U	PLA	Genomic Sequencing Related Tests WHOLE GENOME	Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alternations
18	88	MoG	0X38U	PLA	Genomic Sequencing Related Tests WHOLE GENOME	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent)
19	86	MoG	0X36U	PLA	Genomic Sequencing Related Tests WHOLE GENOME	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, fetal sample, identification and categorization of genetic variants
20	91	MoG	0X41U	PLA	Genomic Sequencing Related Tests WHOLE GENOME	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate
21	22	MoG	0306U	PLA	Genomic Sequencing Related Tests TARGETED; cell free DNA	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient-specific panel for future comparisons to evaluate for MRD (Do not report 0306U in conjunction with 0307U)
22	23	MoG	0307U	PLA	Genomic Sequencing Related Tests TARGETED; cell free DNA	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD (Do not report 0307U in conjunction with 0306U)
23	34	MoG	0318U	PLA	Genomic Sequencing Related Tests TARGETED; METHYLATION ANALYSIS	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood
24	57	MoG	0229U	Reconsideration/ Substantially Revised	Genomic Sequencing Related Tests TARGETED; METHYLATION ANALYSIS	BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis
25	40	MoG	81349	Reconsideration	Genomic Sequencing Related Tests TARGETED; CHROMOSOME	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
26	92	MoG	0X42U	PLA	Genomic Sequencing Related Tests TARGETED; CHROMOSOME	Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid
27	71	MoG	814XX	NEW	Genomic Sequencing Related Tests TARGETED	Inherited bone marrow failure syndromes (IBMFS) (eg, Fanconi anemia, dyskeratosis congenita, Diamond-Blackfan anemia, Shwachman-Diamond syndrome, GATA2 deficiency syndrome, congenital amegakaryocytic thrombocytopenia) sequence analysis panel, must include sequencing of at least 30 genes, including BRCA2, BRIP1, DKC1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, GATA1, GATA2, MPL, NHP2, NOP10, PALB2, RAD51C, RPL11, RPL35A, RPL5, RPS10, RPS19, RPS24, RPS26, RPS7, SBDS, TERT, and TINF2
28	85	MoG	0X35U	PLA	Genomic Sequencing Related Tests TARGETED; VARIANTS, REARRANGEMENTS, MICROSATELLITE INSTABILITY	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
29	82	MoG	0276U	Revision	Genomic Sequencing Related Tests TARGETED	Hematology (inherited thrombocytopenia), genomic sequence analysis of 42 genes, blood, buccal swab, or amniotic fluid
30	69	MoG	0022U	Reconsideration	Genomic Sequencing Related Tests TARGETED; VARIANTS; DNA and RNA	Targeted genomic sequence analysis panel, cholangiocarcinoma and non-small cell lung neoplasia, DNA and RNA analysis, 1-23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider
32	76	MoG	81445	NEW	Genomic Sequencing Related Tests TARGETED; VARIANTS, REARRANGEMENTS	Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis
31	72	MoG	814X1	NEW	Genomic Sequencing Related Tests TARGETED; VARIANTS, REARRANGEMENTS	Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis
33	74	MoG	814X3	NEW	Genomic Sequencing Related Tests TARGETED; VARIANTS, REARRANGEMENTS, ISOFORM or RNA EXPRESSION	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
34	62	MoG	0326U	PLA	Genomic Sequencing Related Tests TARGETED; VARIANTS, REARRANGEMENTS, MICORSATELLITE INSTABILITY	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
35	73	MoG	814X2	NEW	Genomic Sequencing Related Tests TARGETED VARIANTS, REARRANGEMENTS, ISOFORM or RNA EXPRESSION	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
36	90	MoG	0X40U	PLA	Genomic Sequencing Related Tests TARGETED; mRNA	Oncology (prostate), mRNA expression profiling of HOXC6 and DLX1, reverse transcription polymerase chain reaction (RT-PCR), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer
37	32	CHIM	0316U	PLA	Microbiology SINGLE PROTEIN	Borrelia burgdorferi (Lyme disease), OspA protein evaluation, urine
38	77	CHIM	862XX/ 8X002	NEW	Microbiology SINGLE IMMUNOASSAY IDENTIFICATION	Hepatitis B surface antigen (HBsAg), quantitative
39	68	CHIM	879X1/ 87913	NEW	Microbiology SINGLE GENOMIC IDENTIFICATION	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s)
40	78	CHIM	87X68/ 8X009	NEW	Microbiology SINGLE GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA or RNA); Anaplasma phagocytophilum, amplified probe technique
41	79	CHIM	87X70/ 8X010	NEW	Microbiology SINGLE GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA or RNA); Babesia microti, amplified probe technique
42	80	CHIM	87X77/ 8X011	NEW	Microbiology SINGLE GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA or RNA); Borrelia miyamotoi, amplified probe technique
43	81	CHIM	87X99 8X012	NEW	Microbiology SINGLE GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA or RNA); Ehrlichia chaffeensis, amplified probe technique
44	27	CHIM	0311U	PLA	Microbiology MORPHOKINETIC CELLULAR ANALYSIS	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)–based antimicrobial susceptibility for each organism identified (Do not report 0311U in conjunction with 87076, 87077, 0086U)

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45	17	CHIM	0301U	PLA	Microbiology PANEL GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR);
46	18	CHIM	0302U	PLA	Microbiology PANEL GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR); following liquid enrichment
47	37	CHIM	0321U	PLA	Microbiology PANEL GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique
48	59	CHIM	0323U	PLA	Microbiology PANEL GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites or fungi
49	66	CHIM	0330U	PLA	Microbiology PANEL GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
50	103	CHIM	0X54U	PLA	Microbiology PANEL GENOMIC IDENTIFICATION	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis–associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected
51	104	CHIM	0X55U	PLA	Microbiology PANEL GENOMIC IDENTIFICATION	Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected

Appendix 4: Session 2 – July 19, 2022 Summary of codes

Corrections to order of codes:

a. Item #32 code 81445 was moved to follow item #30 code 0022U.
b. Item #98 code 86364 was moved to follow item #95 code 86258
c. Item #102 code 87548 was moved to follow item #105 code 0x56U

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
52	19	CHIM	0303U	PLA	Hematology and Coagulation	Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; hypoxic
53	20	CHIM	0304U	PLA	Hematology and Coagulation	Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; normocytic
54	21	CHIM	0305U	PLA	Hematology and Coagulation	Hematology, red blood cell (RBC) functionality and deformity as a function of shear stress, whole blood, reported as a maximum elongation index
55	1	MoG	0285U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score CELL FREE DNA	Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported as a radiation toxicity score
56	3	MoG	0287U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score DNA and mRNA	Oncology (thyroid), DNA and mRNA, next generation sequencing analysis of 112 genes, fine needle aspirate or formalin fixed paraffin-embedded (FFPE) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result (low, intermediate, high)
57	4	MoG	0288U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score DNA and mRNA	Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score
58	5	MoG	0289U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score
59	6	MoG	0290U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as predictive risk score

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
60	7	MoG	0291U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144 genes, whole blood, algorithm reported as predictive risk score
61	8	MoG	0292U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score
62	9	MoG	0293U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score
63	10	MoG	0294U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score
64	11	CHIM	0295U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score PROTEINS	Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a recurrence risk score
65	24	CHIM	0308U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score PROTEINS	Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for obstructive CAD
66	65	MoG	0329U	PLA	Genomic Sequencing Related Tests TARGETED: EXOME TRANSCRIPTOME, VARIANTS, REARRANGEMENTS, MICORSATELLITE INSTABILITY	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations
67	25	CHIM	0309U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score PROTEINS	Cardiology (cardiovascular disease), analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for major adverse cardiac event
68	26	CHIM	0310U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score PROTEINS	Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NTproBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for D

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
69	63	MoG	0327U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score CELL FREE DNA	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed
70	33	MoG	0317U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score FISH	Oncology (lung cancer), four-probe FISH (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm generated evaluation reported as decreased or increased risk for lung cancer
71	35	MoG	0319U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score RNA, SELECT TRANSCRIPTOME	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection
72	36	MoG	0320U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score RNA, SELECT TRANSCRIPTOME	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection
73	30	MoG	0314U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)
74	31	MoG	0315U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B)
75	12	MoG	0296U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score mRNA	Oncology (oral and/or oropharyngeal cancer), gene expression profiling by RNA sequencing at least 20 molecular features (eg, human and/or microbial mRNA), saliva, algorithm reported as positive or negative for signature associated with malignancy
76	58	MoG	0245U	Reconsideration	Tests with algorithm in code descriptor to report risk/likelihood/predictive score DNA and RNA	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage)
77	29	MoG	0313U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score DNA and RNA	Oncology (pancreas), DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (ie, negative, low probability of neoplasia or positive, high probability of neoplasia)

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
78	60	MoG	0324U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score TUMOR CELL GROWTH	Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug
79	61	MoG	0325U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Oncology (ovarian), spheroid cell culture, poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), tumor response prediction for each drug
80	83	MoG	0X33U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score DNA	Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint–inhibitor therapy
81	84	MoG	0X34U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score CELL FREE DNA + PROTEINS	Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in high-risk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gamma-carboxy-prothrombin (DCP), algorithm reported as normal or abnormal result
82	94	MoG	0X44U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score EXOSOME	Oncology (prostate), exosome-based analysis of 442 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RT-qPCR), urine, reported as molecular evidence of no-, low-, intermediate- or high- risk prostate of cancer
83	38	CHIM	0322U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score/ CHEMISTRY	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma, results reported as negative or positive for risk of metabolic subtypes associated with ASD
84	64	CHIM	0328U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score CHEMISTRY	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient adverse event, per date of service
85	102	CHIM	0X53U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score PROTEIN	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP-10), and C-reactive protein, serum, algorithm reported as likelihood of bacterial infection
86	93	CHIM	0X43U	PLA	Tests with algorithm in code descriptor to report risk/likelihood/predictive score ELECTROCHEMILUMINESCENT IMMUNOASSAY (ECLIA)	Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline
87	28	CHIM	0312U	PLA	Immunology ELISA	Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement

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						activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment
88	42	CHIM	86015	Reconsideration	Immunology IMMUNOASSAY	Actin (smooth muscle) antibody (ASMA), each
89	43	CHIM	86036	Reconsideration	Immunology IMMUNOASSAY FLUORESCENT	ANCA screen, each
90	44	CHIM	86037	Reconsideration	Immunology IMMUNOASSAY FLUORESCENT	ANCA titer
91	45	CHIM	86051	Reconsideration	Immunology ELISA	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)
92	46	CHIM	86052	Reconsideration	Immunology IMMUNOFLUORESCENCE CELL-BASED	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each
93	47	CHIM	86053	Reconsideration	Immunology FLOW CYTOMETRY FLUORO CELL SORTING	Aquaporin-4, flow cytometry (ie, fluorescence-activated cell sorting [FACS])
94	48	CHIM	86231	Reconsideration	Immunology IMMUNOFLUORESCENCE	Endomysial antibody
95	49	CHIM	86258	Reconsideration	Immunology ELISA	Gliadin (deamidated) (DGP) antibody
98	52	CHIM	86364	Reconsideration	Immunology ELISA	Tissue transglutaminase, each immunoglobulin
96	50	CHIM	86362	Reconsideration	Immunology IMMUNOFLUORESCENCE CELL-BASED	MOG IgG1, cell-based immunofluorescence assay
97	51	CHIM	86363	Reconsideration	Immunology FLOW CYTOMETRY FLUORO CELL SORTING	MOG IgG1, flow cytometry (ie, fluorescence-activated cell sorting [FACS]
99	53	CHIM	86409	Reconsideration	Immunology LUMINESCENCE CELL FUNCTION	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer
100	54	CHIM	86413	Reconsideration	Immunology IMMUNOASSAY	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
101	55	CHIM	86596	Reconsideration	Immunology IMMUNOASSAY (RIA)	Voltage gated calcium channel antibody, each
103	87	CHIM	0X37U	PLA	Immunology	Oncology (plasma cell disorders and myeloma), circulating plasma cell immunologic selection, identification, morphological characterization,

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					IMMUNOMAGNETIC IMMUNOFLUORESCENT	and enumeration of plasma cells based on differential CD138, CD38, CD19, and CD45 protein biomarker expression, peripheral blood
104	89	MoG	0X39U	PLA	Immunology IMMUNOMAGNETIC IMMUNOFLUORESCENT	Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18, and 19, and CD45 protein biomarkers, and quantification of HER2 protein biomarker–expressing cells, peripheral blood
105	105	CHIM	0X56U	PLA	Microbiology PANEL GENOMIC IDENTIFICATION	Human papilloma virus (HPV), high-risk types (ie, 16, 18, 31, 33, 45, 52 and 58) qualitative mRNA expression of E6/E7 by quantitative polymerase chain reaction (qPCR)
102	56	CHIM	87428	Reconsideration	Microbiology IMMUNOMAGNETIC IMMUNOFLUORESCENT	Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B