

Clinical Laboratory Fee Schedule Annual Laboratory Meeting
Agenda
Centers for Medicare & Medicaid Services
Thursday, June 23, 2022

This meeting provides a forum for the public to make presentations and submit written comments on new and reconsidered Clinical Laboratory Fee Schedule (CLFS) codes for the calendar year (CY) 2023 and provide comments on other specified CLFS issues (as applicable). Please note that only codes listed in our Clinical Laboratory Fee Schedule CY 2023 Updates file, located on the web at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html, will be addressed.

Note: Session times are approximate and subject to change. Teleconference connection details are provided using instructions described in Appendices A and B. The presentation list is provided in Appendix C.

AGENDA

- 8:45 a.m.** Check-In and Audio/Video Connection Test Check
- 9:00 a.m.** Welcome and Introductions
Rasheeda Arthur, PhD
Meeting Facilitator, Hospital and Ambulatory Policy Group, CMS
- 9:20 a.m.** **Public Presentations on CY 2023 New and Reconsidered Codes (Appendix C)**
***Note:** This session will contain 10-minute presentations from pre-registered presenters on specific CLFS codes with recommendations for either gap-filling or crosswalking for code payment determinations.
- 12:00 p.m.** Lunch Break
- 1:00 p.m.** **Public Presentations on CY 2023 New and Reconsidered Codes (Appendix C) (continued)**
- 5:00 p.m.** Closing and Meeting Adjourns

Appendix A: Instructions to access the webinar via Zoom (view and listen only):

Please click the link below to join the webinar:

https://cms.zoomgov.com/webinar/register/WN_7PHYpgLMTNq7AFuh7GRagw

This link provides attendees the ability to view and listen to the meeting. Speakers should connect to the meeting following the customized instructions provided by meeting coordinators.

Appendix B: Instructions for Joining the Zoom Teleconference (listen only):

Join by phone (listen only):

Dial: US: +1 669 254 5252

Or +1 646 828 7666

Or 833 568 8864 (Toll Free)

Webinar ID: 160 288 9302

Webinar Passcode: 220088

Appendix C: List of presenters and codes to be reviewed.

#	Organization	Presenter (s)	Code number
1	Stemina Biomarker Discovery, Inc.	Elizabeth Donley	0322U
2	MDxHealth, Inc.	Mark Rayan	0X40U
3	Clinical Genomics Pathology, Inc.	Ed Rosen	0229U
4	Point of Care Testing Association/ McDermott Will & Emery LLP	Mike Ryan	87428, 83529
5	LungLife AI	Paul Pagano, PhD	0317U
6	Prevensio, Inc	James L. Januzzi Jr., MD	0308U, 0309U, 0310U
		Rhonda Rhyne, B. Pharm, MBA	
		Grady Barnes, PhD	
7	Mayo Clinic/Mayo Clinic Laboratories	Cheryl James	Reconsidered: 86596, 86015, 86036, 86053, 86363, 85258, 86364, 80220, 83529, 86231 New: 8X000, 862XX, 87913, 87X68, 87X70, 87X77, 87X99
		Joseph Yao, MD	
		Sean Pittock, MD	
8	Menarini Silicon Biosystems Inc/ Rogan Consulting	Daryl Spinner, PhD	0X37U and 0X39U
		Sara Lazaro	
		Frank Kuhr, PhD	
		Gerald Rogan, MD (consultant to Menarini Silicon Biosystems)	
9	University of Pittsburgh Medical Center (UPMC)	Marina Nikiforova, MD	0287U, 0313U
10	Quest Diagnostics	Joyce McAllister	0X48U
11	Association for Molecular Pathology	Jay Patel, MD	87913, 8X000, 814XX, 814X1, 814X2, 814X3, 8X009, 8X010, 8X011, 8X012, 81349, 81445
12	Verici Dx, Inc	Michael Donovan, PhD, MD	0319U, 0320U
13	John Hopkins University	Patricia Simner, PhD, D(ABMM)	0323U
14	Exagen, Inc	Tyler O'Malley	0312U
15	American College of Medical Genetics and Genomics (ACMG)	Kathleen Hruska, PhD	814XX, 8X000
16	Invitae/ Bruce Quinn Associates LLC	Bruce Quinn, MD (Consultant to Invitae)	81349

17	BioChip Laboratories	Vivien Sheehan, MD, PhD	0303U, 0304U, 0305U
		Umut Gurkan, PhD	
18	American Association for Clinical Chemistry (AACC)	Andrea Ferreira-Gonzalez, PhD	80220, 81349, 83529, 86015, 86036, 86037, 86051, 86052, 86053, 86231, 86258, 86362, 86363, 86364, 86409, 86596, 87913
19	Castle Biosciences, Inc.	Matthew Goldberg, MD	0314U, 0315U
20	Kiyatec, Inc.	Bruce Yeager	0324U and 0325U
21	Viome Life Sciences, Inc.	Guru Banavar, PhD	0296U
22	Variantyx, Inc	Shirel Weiss, PhD	0X36U and 0X38U
		Alex Kaplun, PhD	
		Christine Stanley, PhD	
23	MeMed Diagnostics Ltd.	Eran Eden, PhD	0X53U
		Troy Boutelle	
24	Helio Health	David Taggart, PhD, NRCC(CC)	0X34U
25	Immunovia, Inc	Thomas King, MD, PhD	0X43U
26	Myriad Genetics, Inc.	Kavita Bhat, PhD	0X47U
27	Prelude Corporation	Troy Bremer, PhD	0295U
		Daniel Forche	
28	ThermoFisher Scientific	Rob Dumanois	0022U
29	Galaxy Diagnostics	Amanda Elam, PhD	0301U, 0302U, 0316U
30	Coalition for 21st Century Medicine/ Foley Hoag LLP	Brian Carey	0312U, 0314U, 0315U, 0317U, 0326U, 0327U, 0329U, 0X35U, 0X40U, 0X47U
31	College of American Pathologists	Jan A. Nowak MD, PhD, FCAP	814X1, 814X2, 814X3, 81445
32	American Clinical Laboratory Association	Joan Kegerize	Multiple codes
33	Guardant Health	Mark McCoy	0326U, 0X35U
		Justin Odegaard	0326U, 0X35U
34	miR Scientific	Scot Nelson	0X44U
35	Exact Sciences	Rick Baehner, MD	0329U