

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests Centers for Medicare & Medicaid Services (CMS) Public Meeting

CMS Central Office Auditorium - Baltimore, Maryland
Monday, July 22, 2019 and Tuesday, July 23, 2019

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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 publically 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 2020. The CDLT Panel may also provide input on any other CY 2020 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 1, 2019 (CMS- 1725-N; <https://www.govinfo.gov/content/pkg/FR-2019-04-01/pdf/2019-06147.pdf>).

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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 the suggestions for payment.
- The meeting is divided into four sessions, two sessions on each date of the meeting. Session times are approximate and subject to change.

Federal Building Access and Security Guidelines

- The meeting will be held in a Federal government building. Per instructions described in the published Federal Registrar Notice for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CMS-1725-N; April 1, 2019), security measures require the “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.”

For information on the Foreign National Visitation approval processes, please see general instructions described in Appendix A.

Meeting Connection Instructions and Details

- **Listen-in via audio connection only** and live YouTube streaming connection details are provided using instructions described in Appendices B-D.
- Please note that the YouTube video recordings of the meeting will not be immediately available after the conclusion of the meeting.

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AGENDA

Monday July 22, 2019

Time	Topic	Supporting Resource
9:00 a.m.	Welcome and Panel Introductions: Karen Nakano, M.D., Panel Chair, CMS Physician	
9:15 -12:00 p.m.	Session 1: I. Microbiology II. Hematopoetic Related Tests	Appendix 1
12:00- 1:00pm	Lunch	
1:00-4:00 p.m.	Session 2: III. Chemistry	Appendix 2
4:00 -4:30 p.m.	Automated Chemistry Test Panel Discussion	
4:30 p.m.	Meeting Adjourns	

Tuesday July 23, 2019

Time	Topic	Supporting Resource
9:00 a.m.	Reconvene Meeting: Karen Nakano, M.D., Panel Chair, CMS Physician	
9:15 -12:00 p.m.	Session 3: IV. Other Methods of Sequencing V. Genomic Sequencing Related Tests	Appendix 3
12:00- 1:00pm	Lunch	
1:00-4:00 p.m.	Session 4: VI. Reconsidered Procedures VII. Drug Metabolism VIII. Solid Tumor Related Tests IX. Transplant Related Tests X. Chromosomal Related Tests	Appendix 4
4:00 -4:30 p.m.	Automated Chemistry Test Panel Discussion	
4:30 p.m.	Meeting Adjourns	

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

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Appendix A: Foreign National Visitation and Federal Building Access

General security instructions for foreign national visitors requesting access to the CMS campus:

All foreign nationals visiting any CMS facility must request prior approval at least 12 business days before the visit date in order to obtain foreign visitation access. To initiate the approval process, the following information must be submitted to the CDLT Panel resource box (CDLTPanel@cms.hhs.gov):

1. The full first and last name (s) of the visitor (as it appears on passport)
2. Gender
3. Country of origin and citizenship
4. Date of birth
5. Place of birth
6. Passport number
7. Passport issue date
8. Passport expiration date
9. Visa type
10. Date of visit
11. Company name
12. Position/Title

If visitation is approved, foreign national visitors are required to produce a valid passport issued by their country of origin on the day of the visit. Foreign national visitors who cannot produce a valid passport will be denied access, even if the visit has been approved. Approved foreign national visitors will be assigned a “Hosting Official” who is responsible for the visitor for the duration of their facility visit. In addition, an “Escort” may be required and is responsible for accompanying a visitor while the visitor has access to HHS facilities, maintaining visual and voice contact at all times in all non-escort free areas or areas to which the visitor is not permitted independent access.

If you are a foreign visitor and plan to attend the July 22-23, 2019, Medicare Advisory Panel Meeting on Clinical Diagnostic Laboratory Tests Meeting (CMS-1725-N; Published: April 1, 2019; Registration deadline was July 1, 2019), you must be registered as an attendee and provide the above information so your approval clearance process may be initiated. Once the process is initiated CMS will contact you directly with follow-up instructions for completing the approval request via the Foreign National Management System (FNMS).

Please submit inquiries to the CDLT Panel resource box (CDLTPanel@cms.hhs.gov) if you have questions regarding this matter and if you have CDLT Panel-related questions.

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Appendix B Audio Access: Join the meeting by WebEx or telephone

To start the session via WebEx

1. Go to <https://meetings-cms.webex.com/meetings-cms/k2/j.php?MTID=tb3f914fcb445c7d1e52ac3fee5e76abf>
 2. Log in to your account.
 3. Click "Start Now".
 4. Follow the instructions that appear on your screen.
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Audio conference information

To receive a call back, provide your phone number when you join the training session, or call the number below and enter the access code.

US Toll: +1-415-527-5035

Having trouble dialing in? Try these backup numbers:

US Toll: +1-415-527-5035

Global call-in numbers: <https://meetings-cms.webex.com/meetings-cms/globalcallin.php?serviceType=TC&ED=14676347&tollFree=0>

Access code: 905 447 999

To join Toll Free

1. Dial: 1-844-396-8222
2. Follow the instructions you hear on the phone.

Your WebEx Meeting Number: 905 447 999

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Appendix C Audio and Visual Access: Join the meeting using YouTube

NOTE: there is a different YouTube URL for each day, and each morning and afternoon session.

YouTube Public URLs: July 22, 2019

1. MORNING SESSION July 22, 2019 Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests <https://www.youtube.com/watch?v=cAtLvVW-qUw>
2. AFTERNOON SESSION July 22, 2019 Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests <https://www.youtube.com/watch?v=YnCSIK2GuJY>

YouTube Public URLs: July 23, 2019

1. MORNING SESSION July 23, 2019 Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests <https://www.youtube.com/watch?v=PYKqeVNbCYw>
2. AFTERNOON SESSION July 23, 2019 Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests <https://www.youtube.com/watch?v=tknHWLkqt9k>

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Appendix D: Access to CLFS CY 2020 New and Reconsidered Codes

1. For a list of CY 2020 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.html

Scroll down to “Code Updates” for access to the CY 2020 new and reconsidered code list.

2. For CLFS Annual Laboratory Public meeting agenda from June 24, 2019 please see:
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Annual-Laboratory-Meeting-Agenda.pdf>

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Appendix 1 Session 1 – July 22, 2019 Summary of codes

Name of Category /number of codes	Associated codes in order of review
I. Microbiology / 12	1. 0064U; 2. 0065U; 3. 0068U; 4. 0086U; 5. 0096U; 6. 0097U; 7. 0098U; 8. 0099U; 9. 0100U; 10. 8XXXX; 11. 0109U; 12. 0115U
II. Hematopoetic Related Tests/ 4	13. 0084U; 14. 0121U; 15. 0122U; 16. 0123U

Appendix 2 Session 2 - July 22, 2019 Summary of codes

Name of Category /number of codes	Associated codes in order of review
III. Chemistry/ 29	17. 0062U; 18. 0063U; 19. 0066U; 20. 0067U; 21. 0077U; 22. 0082U; 23. 0085U; 24. 0092U; 25. 0093U; 26. 0095U; 27. 80XX0; 28. 80XX1; 29. 80XX2; 30. 802X0; 31. 802XX; 32. 802X1; 33. 0105U; 34. 0106U; 35. 0107U; 36. 0108U; 37. 0110U; 38. 0116U; 39. 0117U; 40. 0119U; 41. 0124U; 42. 0125U; 43. 0126U; 44. 0127U; 45. 0128U

Appendix 3 Session 3 - July 23, 2019 Summary of codes

Name of Category /number of codes	Associated codes in order of review
IV. Other Methods of Sequencing/ 25	46. 813X1; 47. 813X2; 48. 8XX01; 49. 0069U; 50. 0078U; 51. 0081U; 52. 0089U; 53. 0090U; 54. 815X0; 55. 815XX; 56. 0111U; 57. 0112U; 58. 0113U; 59. 0114U; 60. 0120U; 61. 0129U; 62. 0130U; 63. 0131U; 64. 0132U; 65. 0133U; 66. 0134U; 67. 0135U; 68. 0136U; 69. 0137U; 70. 0138U
V. Genomic Sequencing Related Tests / 4	71. 0094U; 72. 0101U; 73. 0102U; 74. 0103U

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Appendix 4 Session 4 - July 23, 2019 Summary of codes

Name of Category /number of codes	Associated codes in order of review
VI. Reconsidered codes / 4	75. 81163; 76. 81165; 77. 0046U; 78. 0049U
VII. Drug Metabolism: / 7	79. 0070U; 80. 0071U; 81. 0072U; 82. 0073U; 83. 0074U; 84. 0075U; 85. 0076U
VIII. Solid Tumor Related Tests: Chemotherapy response and resistance / 1	86. 0083U
IX. Transplant Related Tests / 3	87. 0087U; 88. 0088U; 89. 0118U
X. Chromosomal Related Tests / 1	90. 8XX0X