

Laboratory Public Meeting: Payment New Clinical Laboratory Tests

Date: Monday, July 26, 2004 10:00am - 4:00pm e.s.t.
On-site check-in will begin at 9:30am

Place: Centers for Medicare & Medicaid Services (CMS) Auditorium
7500 Security Boulevard, Baltimore, MD 21244

The meeting is open to the general public to make recommendations on the assignment of payment levels for new codes to be included in the 2005 Medicare Clinical Laboratory Fee Schedule. The meeting announcement is published in the **Federal Register** on Friday May 28, 2004, pages 30658 - 30659. As discussed in more detail in the Federal Register notice, the meeting is intended to provide expert input on the nature of the new test codes and receive recommendations to either "cross-walk" or "gap-fill" for payment.

Registration will begin June 28, 2004. To register for the meeting, individuals should complete the Internet [registration form](#) by July 22, 2004. A confirmation will be sent upon receipt of the registration by CMS. Individuals who wish to make a presentation to recommend assignment of payment for one or more of the new test codes should complete this information on the registration form, prepare a brief presentation (not to exceed 15 minutes), and provide three written copies at the time of presentation. Presenters may also make copies available for up to 50 meeting participants. This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. Photo identification and registration confirmation will be required to enter the building. Vehicles are inspected, at entrance to the grounds, and persons must pass through a metal detector when entering the building. Directions and other information for visitors to the building are available at www.cms.hhs.gov/about/agency/visiting

Also, individuals may listen to the public meeting by dialing 877-357-7851, conference ID number 8402656. Registration is not required for audio listening. Registration, in-person attendance, and 3 written copies of the presentation are necessary to make a presentation on the assignment of payment levels at this meeting. Following the completion of the presentations, a question and answer period will be opened to both the participants in the room and the audio listeners. The moderator of the meeting will use discretion to monitor the question and answer period.

The following is a list of the newly created codes that require recommendations on the assignment of payment levels in order to be included in the clinical laboratory fee schedule. The coding changes have been developed by the American Medical Association's Current Procedural Terminology (CPT) Editorial Panel and will not be further discussed at the CMS public meeting. Numbering of the codes has not yet been finalized. However, the identifying information should be sufficient for those knowledgeable in coding for clinical laboratory services.

Chemistry

Code 82040 Albumin; serum

Code 82044: urine; microalbumin, semiquantitative (eg, reagent strip assay)

1) Code 8204x: ischemia modified

2) Code 8265x Elastase, pancreatic (EL-1), fecal, qualitative or semiquantitative

3) Code 8300x Helicobacter pylori; blood test analysis for urease activity, non-radioactive isotope (eg, C-13)

- 4) Code 8363x Lactoferrin, fecal, qualitative
- 5) Code 8416x Pregnancy-associated plasma protein-A (PAPP-A)
 - Code 84165 Protein, electrophoretic fractionation and quantitation; serum
- 6) Code 8416x other fluids with concentration (eg, urine, CSF)

Immunology

- 7) Code 8606x B cells, total count
 - Code 86334 Immunofixation electrophoresis; serum
- 8) Code 8633x other fluids with concentration (eg, urine, CSF)
- 9) Code 8637x Natural Killer (NK) cells, total count
- 10) Code 8658x Stem cells (i.e., CD34), total count

Microbiology

- Code 87802 Infectious agent antigen detection by immunoassay with direct optical observation; Streptococcus, group B
- 11) Code 8780x respiratory syncytial virus

In addition, the following is a list of the newly created codes for which CMS is requesting recommendations on the placement of these codes on the clinical laboratory fee schedule and if placed on the clinical laboratory fee schedule, recommendations on the assignment of payment levels.

Cytopathology

- Code 88180 deleted
- 12) Code 8818x Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
- 13) Code 8818x each additional marker (List separately in addition to code for first marker)
- 14) Code 8818x Flow cytometry, interpretation; 2 to 8 markers
- 15) Code 8818x 9 to 15 markers
- 16) Code 8818x 16 or more markers

Surgical Pathology

- 17) Code 8836x Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, each antibody; manual
- 18) Code 88361 (revised) using computer assisted technology

19) Code 88365 (revised) In situ hybridization (eg, FISH), each probe

20) Code 8836x Morphometric analysis, in situ hybridization, (quantitative or semi-quantitative) each probe; using computer-assisted technology

21) Code 8836x manual

The 2005 clinical laboratory fee schedule will be effective for services delivered January 1 to December 31, 2005. CMS will issue instructions and fees to Medicare carriers/intermediaries for implementation of the 2005 clinical laboratory fee schedule or after the last week of October 2004. Internet access to the Program Memorandum (PM) instructions should be available at www.cms.hhs.gov/manuals/memos/ and the data file should be available on or after the third week of November 2004 at www.cms.hhs.gov/paymentsystems For questions, contact Anita Greenberg by phone 410-786-4601 or agreenberg@cms.hhs.gov