

CMS Guidance Document	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Executive Guidance Number	Date:
Planned Web Site Address http://www.cms.hhs.gov/ClinicalLabFeeSched	Release planned:

PROGRAM AREA: Claims Processing

SUBJECT: New Tests to be included in 2008 Medicare Clinical Laboratory Fee Schedule

APPLIES TO: Contractors, Public comment

I. SUMMARY OF DOCUMENT: This provides a summary chart of payment recommendations received from the public, proposed payment determinations, and instructions for submission of written comments on the proposals.

II. CHANGES IN POLICY INSTRUCTIONS: (If not applicable, indicate N/A)

STATUS: R=REVISED, N=NEW, D=DELETED.

Status	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. CLEARANCES:

Clearance & Point of Contact (POC)	Name/Telephone/Component
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IV. TYPE (Check appropriate boxes for type of guidance)

<input type="checkbox"/>	Audit Guide
<input type="checkbox"/>	Change Request
<input type="checkbox"/>	HPMS
<input type="checkbox"/>	Joint Signature Memorandum/Technical Director Letter
<input type="checkbox"/>	Manual Transmittal/Non-Change Request
<input type="checkbox"/>	State Medicaid Director Letters
<input checked="" type="checkbox"/>	Other – Medicare Fee for Service Fee Development

V. STATUTORY OR REGULATORY AUTHORITY: Section 1833(h) of the Social Security Act
42 CFR 414.506

Public Meeting for New Clinical Laboratory Tests for 2008

Summary Chart of Payment Recommendations

Payment Determinations

New codes for clinical laboratory tests will become effective January 1, 2008 under the Medicare Part B clinical laboratory fee schedule for outpatient testing. The codes represent clinical laboratory tests important to Medicare beneficiaries for conditions such as renal function, inflammatory bowel disease, and vancomycin resistance. In accordance with regulation 42 CFR §414.506, the Centers for Medicare & Medicaid Services (CMS) hosted a public meeting on July 16, 2007 to receive payment recommendations for the new test codes. Notice of the meeting was announced in the Federal Register on May 27, 2007 and on the CMS website on June 18, 2007. The announcements described how to register and present at the meeting along with information on audio listening and a question and answer period for the meeting. Also, the announcements indicated written comments could be submitted to CMS on or before August 1, 2007.

Approximately 50 members of the public representing laboratories, manufacturers, medical societies and the press attended the public meeting. Sixteen members of the public utilized the opportunity to orally present payment recommendations for the new codes at the public meeting. Written comments were received during the comment period. After review of the public comments, CMS is providing summary charts of the comments, proposed payment determinations, and associated rationale as required by 42 CFR §414.506. The charts display for each new code, CMS' proposed determination to use a gap-fill method of local pricing by carriers or a cross-walk method and, if the latter, to which other code(s) the new test code will be cross-walked for a payment rate on the clinical laboratory fee schedule.

CMS' proposed determination for the hemoglobin A1C test is to continue using codes 83036 and 83037 rather than to replace them by a HCPCS alphanumeric code. CMS proposes to accept a comment from the American Medical Association's CPT Editorial Panel requesting that CMS postpone any action related to this issue pending discussion of these codes at the upcoming October 2007 CPT Editorial Panel meeting. CMS will consider any coding changes for these services as part of the process for developing the 2009 clinical laboratory fee schedule.

In addition, 42 CFR §414.506 requires that an additional written comment period on the proposed payment determinations be available to the public. Therefore, CMS is providing an additional comment period until September 21, 2007. Comments can be submitted on or before September 21, 2007 to the public meeting's coordinator Deborah Cooley at Mail Stop C4-03-06, 7500 Security Boulevard, Baltimore MD 21244-1850 or deborah.cooley@cms.hhs.gov. The 2008 clinical laboratory fee schedule will be developed taking into consideration all comments received.

The 2008 clinical laboratory fee schedule will be effective for services provided January 1 to December 31, 2008. CMS expects to issue instructions and fees to Medicare carriers/intermediaries for implementation of the 2008 clinical laboratory fee schedule on

or after the last week of October 2007. Internet access to the instructions will be available at www.cms.hhs.gov/manuals. The data file for the 2008 Medicare clinical laboratory fee schedule will be available on or after the third week of November 2007 at www.cms.hhs.gov/ClinicalLabFeeSched.

[illegible]

PUBLIC MEETING: PAYMENT FOR NEW CLINICAL LABORATORY TESTS FOR CY 2008

New Test Codes for CY 2008	College of American Pathologists	American Society for Clinical Pathology	American Clinical Laboratory Association	Clinical Laboratory Management Association	American Association for Clinical Chemistry	American Society for Microbiology	Abbott Laboratories	Dade Behring	PerkinElmer LAS	Roche Diagnostics	CMS Proposed Payment Determination	CMS Rationale
6. Code 86356 Mononuclear cell antigen, quantitative, (e.g., flow cytometry), not otherwise specified, each antigen	Crosswalk to Code 86355.	Crosswalk to Code 86355.	Crosswalk to Code 86586.	Crosswalk to Code 86355.	Crosswalk to Code 86586.	Crosswalk to Code 86355.					Crosswalk to Code 86361.	Code 86361 uses the same methodology and has the same clinical application as code 86356.
7. Code 86486 Skin test; unlisted antigen, each	Crosswalk to Code 86490; include on physician fee schedule.	Crosswalk to Code 86410; include on physician fee schedule.			Crosswalk to Code 86510; include on physician fee schedule.	Crosswalk to Code 86490.					Crosswalk to Code 86490; include on physician fee schedule.	This code will be paid under the physician fee schedule. It is appropriate to crosswalk it Code 86490, a similar test in the Skin test family of codes.
Microbiology												
8. Code 87500 Infectious agent detection by nucleic acid (DNA or RNA); vandomycin resistance, (e.g., enterococcus species van A, van B), amplified probe technique	Crosswalk to Code 87498.	Crosswalk to Code 87498.	Crosswalk to Code 87471.	Crosswalk to Code 87641.	Crosswalk to Code 87471.	Crosswalk to Code 87641.					Crosswalk to Code 87641.	A crosswalk to Code 87641 is appropriate as this is the first CPT code in the series of similar testing (i.e., infectious agent detection by nucleic acid (DNA or RNA). All codes in this series are priced the same.
9. Code 87809 Infectious agent antigen detection by immunoassay with direct optical observation; adenovirus	Crosswalk to Code 87899.	Crosswalk to Code 87899.	Crosswalk to Code 87802.	Crosswalk to Code 87810.	Crosswalk to Code 87802.	Crosswalk to Code 87802.					Crosswalk to Code 87802.	A crosswalk to Code 87802 is appropriate as this is the first CPT code in the series of similar testing (i.e., infectious agent antigen detection by immunoassay with direct optical observation.) All codes in this series are priced the same.

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Reproductive Medicine Procedures												
10. Code 89322 Semen analysis; volume, count, motility, and differential using strict morphologic criteria (e.g., Kruger)	Crosswalk to Code 89320 plus Code 85007.	Crosswalk to Code 89320 plus Code 85007.	Crosswalk to Code 89320 plus Code 85007.								Crosswalk to Code 89320 plus Code 85007.	Consistent with informaton reviewed and public recommendations.
11. Code 89331 Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)	Crosswalk to Code 89320 plus Code 87015.	Crosswalk to Code 89320 plus Code 87015.	Crosswalk to Code 89320 plus Code 87015.								Crosswalk to Code 89320 plus Code 87015.	Consistent with informaton reviewed and public recommendations.

Public Meeting: Payment for New Clinical Laboratory Tests for 2008					
New HCPCS Laboratory Code for 2008 (proposed)				Proposed Payment Determination	Rationale
1) Code Gxxxx Hemoglobin; glycosylated (A1C) For testing at all sites of service including, but not limited to, home, office, or facility.				Postpone action until after upcoming CPT meeting to review codes 83036 and 83037	CMS decision making on these issues should benefit from further detailed review by clinical experts.
Deleted or Inactive Codes for 2008 (proposed)					
2) 83036 Hemoglobin; glycosylated (A1C)				no change	CMS decision making on these issues should benefit from further detailed review by clinical experts.
3) 83037 Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use				no change	CMS decision making on these issues should benefit from further detailed review by clinical experts.
Commenters	Agree with proposed HCPCS code; crosswalk to 83036	Disagree with proposed HCPCS code; use CPT codes; crosswalk 83037 to 83036	Disagree with proposed HCPCS code Gxxxx Hemoglobin (A1C); use CPT codes	Disagree with proposed HCPCS code Gxxxx Hemoglobin (A1C); use CPT codes and fees for 83036 (\$13.56) and 83037 (\$21.06)	Request CMS postpone action until after CPT reviews codes 83036 and 83037 at upcoming CPT meeting
College of American Pathologists		X			
American Society for Clinical Pathology		X			
American Clinical Laboratory Association		X			
Clinical Laboratory Management Association	X				
American Association for Clinical Chemistry	X				
Roche Diagnostics	X				
Siemens Medical Solutions	X				
Reed Smith LLP				X	
Dr. Lon Lynn:Family Practitioner				X	
Bio-Rad Laboratories				X	
Metrika of Bayer Healthcare				X	
Indiana Congressman	X				
Indiana Senator	X				
American Diabetes Association			X		
American Ass. Clinical Endocrinologist				X	
American College of Physicians			X		
American Ass. of Diabetes Educ.				X	
American Academy Family Physicians				X	
Taking Control of Your Diabetes				X	
The Endocrine Society				X	
Diabetes Action Network			X		
Northern Virginia Endocrinologists				X	
H.M. Sung, MD				X	
Columbus Medical Physician Practice			X		
Anniston Clinic				X	
Family Medicine Specialists				X	
Pacific Medical Center				X	
Family Medicine Specialists				X	
Dallas Family Medicine				X	
Diabetes Coalition of California			X		
Grayson Valley Family Practice				X	
American Medical Association					X