Program Memorandum Intermediaries/Carriers

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal AB-01-162 **Date: NOVEMBER 5, 2001**

CHANGE REQUEST 1887

SUBJECT: 2002 Clinical Laboratory Fee Schedule and Laboratory Costs Subject to Reasonable Charge Payment Methodology

This Program Memorandum (PM) provides instructions for issuance of the calendar year (CY) 2002 clinical laboratory fee schedule and mapping for CY 2002 Current Procedural Terminology (CPT) codes for clinical diagnostic laboratory tests.

Update to Fees

In accordance with §1833(h)(2) of the Social Security Act, there is no annual update (economic index) to the local laboratory fees for 2002. Payment is the lesser of the actual charge, the local fee, or the national limitation amount (NLA) and the Part B deductible and coinsurance do not apply. For cervical or vaginal smear clinical laboratory tests, payment is the lesser of the local fee or the national limitation amount, but not less than the national minimum payment amount. However, in no case may payment for these tests exceed actual charges. The Part B deductible and coinsurance do not apply.

National Minimum Payment Amounts

A national minimum payment amount of $14.60 applies for cervical or vaginal smear clinical laboratory tests in accordance with §224 of the Balanced Budget Refinement Act (Public Law 106-113). As there is not an annual update (economic index) to the local laboratory fees for 2002, there is not an update to the national minimum payment amount for cervical or vaginal smear clinical laboratory tests. The affected CPT laboratory test codes for the national minimum payment amount are 88142, 88143, 88144, 88145, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, G0123, G0143, G 0144, G0145, G0147, G0148 and P3000.

National Limitation Amounts (Maximum)

For tests for which NLAs were established before January 1, 2001, the NLA calculation for 2002 remains at 74 percent of the median of the local fees. For tests for which NLAs are first established on or after January 1, 2001, under §1833(h)(4)(B)(viii) of the Act (amended by §531 of the Benefits Improvement and Protection Act of 2000), the NLA calculation for 2002 is 100 percent of the median of the local fees

Access to Data File

The 2002 laboratory fee schedule data file should be retrieved electronically through CMS' mainframe telecommunications system, formerly referred to as the National Data Mover. Attachment A depicts the filename and record layout for carriers who should retrieve the data file on or after November 1, 2001. Attachment B depicts the filename and record layout for intermediaries and the Railroad Retirement Board who should retrieve the data file on or after November 19, 2001. Instructions for intermediaries retrieving the 2002 laboratory fee data file are also incorporated in PM A-01-104, Change Request 1811, dated August 23, 2001. Notification of the 2002 laboratory fee schedule updates and code changes should be included in your next provider bulletins.

Internet access to the 2002 laboratory fee schedule data file should be available after November 21, 2001, at the Website www.hcfa.gov/audience/planprov.htm. Medicaid State agencies, the Indian Health Service, the United Mine Workers and other interested parties should use the Internet to retrieve the 2002 laboratory fee schedule which will be available in multiple formats: Excel, text, and comma delimited.

Data File Format

Attachment A depicts the record layout of the 2002 laboratory fee schedule data file for carriers. Attachment B depicts the record layout of the 2002 laboratory fee schedule data file for intermediaries. For each test code, if your system retains only the pricing amount, load the data from the field named '60% Pricing Amt'. For each test code, if your system has been developed to retain the local fee and the NLA, you may load the data from the fields named '60% Local Fee Amt' and '60% Natl Limit Amt' to use to determine payment. For clinical laboratory test codes for cervical or vaginal smear tests (listed above), you should load the data from the field named '60% Pricing Amt' to reflect the lower of the local fee or the NLA, but not less than the natiomal minimum payment amount. The fields named '62% Local Fee Amt', '62% Natl Limit Amt' and '62% Pricing Amt' should be used by intermediaries for payment of clinical laboratory tests performed by a sole community hospital's qualified laboratory.

Attachment C lists the clinical laboratory test codes that carriers should determine a gap-fill fee. The fee field for these codes contains a zero.

Code 81000 was erroneously left off of the data file MU00.@BF12394.CLAB.CY02.V1101, this code should added to the data file.

Comments

The mapping for new, deleted, and significantly revised American Medical Association's CPT codes for 2002 clinical laboratory tests represents a determination of the relationship between valid 2001 and 2002 codes. Attachment C lists new, deleted, and gap-fill codes that are included in the 2002 laboratory fee schedule data file. The 3-month grace period for deleted codes is defined in the Medicare Carriers Manual §4509.3 and begins January 1, 2002.

The mappings for new 2001 codes were revised for code 82373 to code 83789 and for code 87400 to code 87301. The revised mappings reflect further clinical recommendations and claims data.

On August 6, 2001, the CMS hosted a public meeting to discuss the payment relationship between valid 2001 codes and new 2002 CPT codes. The meeting information, registration, and agenda were published in the **Federal Register** on Friday June 29, 2001, pages 34693-34695. Over 70 members of the laboratory industry attended representing laboratories, manufacturers, and medical groups and societies. The meeting was productive in identifying determinations of the relationship between valid 2001 and 2002 codes. As stated in the **Federal Register** notice, a summary of the meeting was posted within one month of the meeting and can be viewed at the Website www.hcfa.gov/audience/planprov.htm. In response to requests to allow for further public input on payment determinations for new 2002 laboratory test codes, CMS also posted on this Website a summary of draft payment determinations and accepted further comments prior to the release of the 2002 laboratory fee schedule until October 24, 2001.

Additional comments after the release of the 2002 laboratory fee schedule can be submitted to the following address so that CMS may consider these comments for the development of the 2003 laboratory fee schedule. To be considered, comments should be in written format and include clinical, coding, and pricing information. To make it possible for CMS and its contractors to meet a January 1, 2001 implementation date, comments must be submitted by August 1, 2002.

Centers for Medicare & Medicaid Services (CMS)
Center for Medicare Management
Division of Acute Care
Mailstop: C4-07-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Pricing Information

The 2002 laboratory fee schedule includes separate fees for certain specimen collections (codes G0001, P9612, P9615). The fees have been established in accordance with §1833(h)(4)(B) of the Social Security Act. Instructions on separate fees for laboratory personnel to travel to perform a specimen collection for either a nursing home or homebound patient are provided in PM AB-99-49 Change Request 526, Medicare Travel Allowance Fees for Collection of Specimens, dated June 1999. The instructions describe how a separate travel fee can be computed on a per mileage basis (code P9603) or a flat rate per trip basis (code P9604). Each basis requires documentation of the number of specimens performed per trip (for both Medicare and non-Medicare patients) to calculate the Medicare prorated fee and uses $.44 per mile for personnel costs (updated in accordance with §1833(h)(4)(B) of the Act) the Federal standard mileage rate for transportation costs. For year 2002, there is no annual update for personnel costs. For dates of service January 1, 2002 through December 31, 2002, the updated Federal standard mileage rate is not yet available but when it becomes available you should utilize it for calculating the fee for the per mileage code (P9603) and the flat rate code (P9604). The flat rate code is calculated using (10 miles x Federal standard mileage rate) + $4.42 for labor and overhead based on data analyzed in the development of the PM). One source to verify the 2002 Federal standard mileage rate (available in late December) is http://www.irs.ustreas.gov, search for standard mileage rate, frequently asked questions.

The 2002 laboratory fee schedule also includes codes that have a "QW" modifier for laboratory services granted waived status under the Clinical Laboratory Improvement Amendments (CLIA) standards.

The CPT Editorial Panel created a new immunology code 86141 for C-reactive protein; high sensitivity (hsCRP) test. This test code was established with information identifying the use of the test as a preventive or 'screening test' for detection of cardiac risk rather than a diagnostic test for patient with symptoms. Medicare must differentiate between screening and diagnostic laboratory testing because there are statutory limitations on the frequency with which screening laboratory tests are allowed for payment. Thus, the billing of this new test code, 86141, for Medicare payment must reflect the diagnostic reason for the test.

Organ or Disease Oriented Panels

Similar to prior years, the 2002 pricing amount for each organ or disease panel was derived by summing the lower of the fee schedule amount or the NLA for each individual test included in the panel. The local fee amount field and the NLA field on the data file will be zero-filled.

Emerging Technology Codes

During 2001, the American Medical Association's CPT Editorial Panel has established a new category of CPT codes called Category III codes. They are a set of temporary codes intended for tracking emerging technologies. For laboratory tests, these codes represent emerging technologies that may not be performed by many laboratories and may not yet have been approved by the Food and Drug Administration. Review of emerging technology codes will be made by the CPT Editorial Panel as part of its procedures to annually update CPT codes. The CPT Editorial Panel will determine if a temporary emerging technology code should be converted to a permanent existing technology Category I CPT code or if a new emerging technology code should be established. The syntax of emerging technology codes is four digits followed by the letter "T". These codes are not included in the 2002 laboratory fee schedule data file because they can be covered and priced only at carrier discretion. More information on the use of emerging technology codes can be accessed

at the AMA's Website www.ama-assn.org. The new emerging technology codes relating to clinical laboratory tests are:

0010T Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response. An in vitro blood testing procedure for detecting tuberculosis infection rather than active disease (CPT code 87116). Used in conjunction with, or in place of the skin test (CPT code 86580).

0023T Infectious agent drug susceptibility phenotype prediction using genotypic comparison to know genotypic/phenotypic database, HIV 1. An add-on code to HIV genotype assay, which identifies mutations associated with drug resistance (CPT code 87901), to compare assay results to database and present comprehensive and color-coded results.

0026T Lipoprotein, direct measurement, intermediate density lipoproteins (IDL), remnant lipoproteins. Quantitative determination of remnant lipoproteins can be a risk factor for coronary heart disease for patients with familial type III hyperlipoproteinemia independent of very low density lipoproteins (CPT code 83719), low density lipoproteins (CPT code 83721), and high density lipoproteins (CPT code 83718).

Mapping Information

New code 82570QW is priced at the same rate as code 82570.

New code 83001QW is priced at the same rate as code 83001.

New code 83605QW is priced at the same rate as code 83605.

New code 83950 is priced at the same rate as 84233.

New code 84460QW is priced at the same rate as code 84460.

New code 86141 is priced at the same rate as 83520.

New code 86618QW is priced at the same rate as code 86618.

New code 87198 is priced at the same rate as code 87260.

New code 87199 is priced at the same rate as code 87260.

New code 87802 is priced at the same rate as code 87880.
New code 87803 is priced at the same rate as code 87810.

New code 87804 is priced at the same rate as code 87810.

New code 87902 is priced at the same rate as code 87901.

Gap-fill Codes

Codes for which carriers should determine a gap-fill fee are listed in Attachment C. Carriers may gap-fill on a flow basis as claims are received for the unpriced code. The code should have a gap-fill fee established by the carrier by March 31, 2002. Carriers should also communicate the gap-fill fees to corresponding intermediaries. Carriers can seek assistance from RO staff to facilitate communication of the gap-fill fees to intermediaries. Carriers should consider the charge for the clinical laboratory test in its area as well as the cost of performing the test in a laboratory with adequate volume to ensure cost efficiencies. A consideration of costs should reflect the costs of labor, supplies, and overhead for the test as appropriate. Carriers should also evaluate any information that may be submitted to the carrier by other interested parties in establishing the gap-fill fee. Carriers are to provide their ROs with these gap-fill fees by May 3, 2002. These gap-fill data

are needed for the development of the 2003 laboratory fee schedule. Attachment D depicts the record layout for the submittal of the 2002 gap-fill fees to the ROs.

Laboratory Costs Subject to Reasonable Charge Payment Methodology in 2002

When the following blood products, transfusion medicine and other procedures are performed for a hospital outpatient, payment is made under the hospital outpatient prospective payment system. However when the reasonable charge payment methodology applies (for example, nonpatients of the hospital), the inflation index update for 2002 is 3.2 percent. The following HCPCS codes relate to these services:

Blood Products

P9010 P9011 P9012 P9016 P9017 P9019 P9020 P9021 P9022 P9023 P9031 P9032 P9033 P9034 P9035 P9036 P9037 P9038 P9039 P9040 P9041 P9042 P9043 P9044 P9045 P9046 P9047 P9048 P9050

Transfusion Medicine and Other Procedures

86850 86860 86870 86880 86885 86886 86890 86891 86900 86901 86903 86904 86905 86906 86915 86920 86921 86922 86927 86930 86931 86932 86945 86950 86965 86970 86971 86972 86975 86976 86977 86978 86985 89250 89251 89252 89253 89254 89255 89256 89257 89258 89259 89260 89261 89264

The effective date for this PM is January 1, 2002.

The implementation date for this PM is January 1, 2002.

These instructions should be implemented within your current operating budget.

For questions regarding this document, contact Anita Greenberg on (410) 786-4601.

This PM may be discarded after December 31, 2002.

4 Attachments

ATTACHMENT A

CARRIER RECORD LAYOUT FOR DATA FILE

2002 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME: MU00.@BF12394.CLAB.CY02.V1101

Date Element Name	Picture	Location	Comment
HCPCS CODE	X(05)	1-5	
CARRIER NUMBER	X(05)	6-10	
LOCALITY	X(02)	11-12	00--Single State Carrier 01--North Dakota 02--South Dakota 20--Puerto Rico 40--New Hampshire 50--Vermont
60% LOCAL FEE	9(05)V99	13-19	
62% LOCAL FEE	9(05)V99	20-26	
60% NATL LIMIT AMT	9(05)V99	27-33	
62% NATL LIMIT AMT	9(05)V99	34-40	
60% PRICING AMT	9(05)V99	41-47	
62% PRICING AMT	9(05)V99	48-54	
GAP-FILL INDICATOR	X(01)	55-55	0--No Gap-fill Required 1--Carrier Gap-fill 2--Special Instructions Apply
MODIFIER	X(02)	56-57	Where modifier is shown, QW denotes a CLIA waiver test.
FILLER	X(03)	58-60	

ATTACHMENT B

INTERMEDIARY RECORD LAYOUT FOR DATA FILE

2002 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME:MU00.@BF12394.CLAB.CY02.V1119.FIRHHI

Date Element Name	Picture	Location	Comment
HCPCS	X(05)	1-5	
FILLLER	X(04)	6-9	
60% PRICING AMT	9(05)V99	10-16	
62% PRICING AMT	9(05)V99	17-23	
FILLER	X(07)	24-30	
CARRIER NUMBER	X(05)	31-35	
LOCALITY	X(02)	36-37	00--Single State Carrier 01--North Dakota 02--South Dakota 20--Puerto Rico 40--New Hampshire 50--Vermont
FILLER	X(23)	38-60	

ATTACHMENT C

2002 CLINICAL LABORATORY FEE SCHEDULE

I. New Codes

82274
82274QW
82570QW
83001QW
83605QW
83950
84460QW
86141
86336
86618QW
87198
87199
87802
87803
87804
87902

II. Deleted Codes

80072
85535
86683
86683QW
87076QW
87339QW

II. Codes That Require Gap-Fill Fees

82274 Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations. High sensitivity immunoassay to detect bleeding sources in gastrointestinal tract, colorectal carcinomas, and adenomas.

82274QW same as above for a laboratory registered with only a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

86336 Inhibin A. Quantitative enzyme immunoassay for prenatal assessment of reproductive disorders such as Down's syndrome, Turner syndrome, and Trisomy 18. Also limited use for tumor marker for gynecological cancers.

ATTACHMENT D

2002 CLINICAL LABORATORY FEE SCHEDULE

SUBMITTING 2002 GAP-FILL FEES

Similar to 2001, carriers may gap-fill on a flow basis as claims are received for the unpriced code. The codes to be carrier priced should have a gap-fill fee by March 31, 2002. Carriers should also communicate the gap-fill fees to corresponding intermediaries. Carriers can seek assistance from RO staff to facilitate communication of the gap-fill fees to intermediaries. The carrier should consider the charge for the clinical laboratory test in its area as well as the cost of performing the test in a laboratory with adequate volume to ensure cost efficiencies. A consideration of costs should reflect the costs of professional and clerical labor, supplies, and overhead for the test as appropriate. Carriers should also evaluate any information that may be submitted to the carrier by other interested parties in establishing the gap-fill fee.

Carriers are to provide their RO with the gap-fill fees by May 3, 2002, to be used by CMS-Central for the development of the 2003 laboratory fee schedule. Submit the gap-fill fees in a right-justified format. These gap-fill data should be transmitted in an ASCII file with the following file specifications to MStevenson@cms.hhs.gov with a copy to Agreenberg@cms.hhs.gov to assist with coordinated collection of the gap-fill fees.

DATA SET NAME: CLXXXXX.TXT* (ASCII File)
(*Denotes carrier 5-digit number)

Data Element Name	Picture	Location	Comment
YEAR	X(4)	1-4	Set to 2002
HCPCS CODE	X(5)	5-9	
MODIFIER	X(2)	10-11	
CARRIER NUMBER	X(5)	12-16	
LOCALITY	X(2)	17-18	00--Single State Carrier 01--North Dakota 02--South Dakota 20--Puerto Rico 40--New Hampshire 50--Vermont
60% LOCAL FEE	(5)V99	19-25	