Program Memorandum Intermediaries/Carriers

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

Transmittal AB-02-163 **Date: NOVEMBER 8, 2002**

CHANGE REQUEST 2420

SUBJECT: 2003 Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment Method

Scope

This Program Memorandum (PM) provides instructions for the calendar year 2003 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests and update for laboratory costs subject to the reasonable charge payment method.

Update to Fees

In accordance with §1833(h)(2)(A)(i) of the Social Security Act (the Act), the annual update to the local clinical laboratory fees for 2003 is 1.1 percent. Section 1833(a)(1)(D) of the Act provides that payment for a clinical laboratory test is the lesser of the actual charge billed for the test, the local fee, or the national limitation amount (NLA). For a cervical or vaginal smear test (pap smear), §1833(h)(7) of the Act requires payment to be the lesser of the local fee or the NLA, but not less than a national minimum payment amount (described below). However, for a cervical or vaginal smear test (pap smear), payment may also not exceed the actual charge. The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

National Minimum Payment Amounts

For a cervical or vaginal smear test (pap smear), §1833(h)(7) of the Act requires payment to be the lesser of the local fee or the NLA, but not less than a national minimum payment amount. Also, payment may not exceed the actual charge. The 2003 national minimum payment amount is $14.76 ($14.60 plus 1.1 percent update for 2003). The affected codes for the national minimum payment amount are 88142, 88143, 88144, 88145, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, and P3000.

National Limitation Amounts (Maximum)

For tests for which NLAs were established before January 1, 2001, the NLA is 74 percent of the median of the local fees. For tests for which NLAs are first established on or after January 1, 2001, the NLA is 100 percent of the median of the local fees in accordance with §1833(h)(4)(B)(viii) of the Act.

Access to Data File

The 2003 clinical laboratory fee schedule data file should be retrieved electronically through CMS' mainframe telecommunications system, formerly referred to as the National Data Mover. Carriers should retrieve the data file on or after November 4, 2002. Intermediaries and the Railroad Retirement Board should retrieve the data file on or after November 18, 2002.

Internet access to the 2003 clinical laboratory fee schedule data file should be available after November 18, 2002, at http://www.cms.hhs.gov/paymentsystems. Medicaid State agencies, the Indian Health Service, the United Mine Workers and other interested parties should use the Internet to retrieve the 2003 laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.

Data File Format

Attachment A depicts the record layout of the 2003 laboratory fee schedule data file for carriers. Attachment B depicts the record layout of the 2003 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 determine payment. For test codes for cervical or vaginal smears (pap smears), you should load the data from the field named '60% Pricing Amt' which reflects the lower of the local fee or the NLA, but not less than the natiomal minimum payment amount. Intermediaries should use the field '62% Pricing Amt' for payment to qualified laboratories of sole community hospitals.

Attachment C lists new, deleted, and gap-fill codes that are included in the 2003 clinical laboratory fee schedule data file. The data fields for gap-filled codes are zero-filled. The 3-month grace period for deleted codes is described in the Medicare Carriers Manual §4509.3 and begins January 1, 2003.

Public Comments

On August 5, 2002, CMS hosted a public meeting to solicit input on the payment relationship between valid 2002 codes and new 2003 CPT codes. The meeting announcement was published in the **Federal Register** on Friday November 23, 2001, pages 58743-58745. Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted a summary of the meeting and the tentative payment determinations on its web site at http://www.cms.hhs.gov/paymentsystems. Additional written comments from the public were accepted until September 30, 2002.

Comments after the release of the 2003 laboratory fee schedule can be submitted to the following address so that CMS may consider them for the development of the 2004 laboratory fee schedule. A comment should be in written format and include clinical, coding, and costing information. To make it possible for CMS and its contractors to meet a January 1, 2004 implementation date, comments must be submitted by August 1, 2003.

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

Pricing Information

The 2003 laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes G0001, P9612, and P9615). The fees have been established in accordance with §1833(h)(4)(B) of the Act.

Instructions on separately payable fees for traveling to perform a specimen collection for either a nursing home or homebound patient were issued in June 1999. There are two codes: P9603 for a per mileage trip basis or code P9604 for a flat rate trip basis where the average round trip is generally less than 20 miles (or an average of 10 miles per leg of the trip). To bill either code requires documentation of the number of specimens performed per trip (for both Medicare and non-Medicare patients) to compute the Medicare prorated fee. Code P9604 requires the laboratory to determine the appropriateness of billing on an average round trip basis for all trips during a one-year time period. Thus, payment for travel under code P9604 is made to reasonably pay on average for a varying range of trip miles so that the laboratory should not also require payment with another basis. The payment for codes P9603 and P9604 reflects personnel and transportation costs. For dates of service January 1, 2003 through December 31, 2003, the personnel payment is $.45 per mile updated in accordance with §1833(h)(4)(B) of the Act. For dates of service January 1, 2003 through December 31, 2003,

the standard mileage rate for transportation costs is $0.36 (decreased from year 2002). More explanation of the development of the 2003 standard mileage rate will be available by late December at the Web site www.gsa.gov, search for privately owned vehicle reimbursement rates.

The 2003 laboratory fee schedule also includes codes that have a 'QW' modifier to both identify codes and determine payment for tests performed by a laboratory registered with only a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

For 2003, the CPT Editorial Panel revised specimen collection code 36415 to represent *Collection of venous blood by venipuncture* and added code 36416 *Collection of capillary blood specimen (e.g., finger, heel, ear stick)*. However, CMS must undertake further efforts before implementing codes 36415 and 36416. For 2003, the clinical laboratory fee schedule will continue to include code G0001 *Routine venipuncture for collection of specimen(s*) and laboratories should continue to bill code G0001 for Medicare payment of venous blood collection by venipuncture.

For 2003, the CPT Editorial Panel developed 12 new codes 38204 through 38215 for bone marrow or stem cell services and procedures. These codes describe numerous steps in the harvesting and transplantation of cells. However, due to concerns about beneficiary liability and implications for the Medicare physician fee schedule, new codes 38207 through 38215 will be invalid for Medicare purposes. Instead, the 2003 laboratory fee schedule will retain codes 88240 and 88241 related to the harvesting and transplantation of cells for diagnostic purposes and will include two new codes G0265 and G0266 for therapeutic purposes. Code 86915 is deleted and replaced by code G0267 for Medicare billing. G0267 is subject to laboratory reasonable charge payment methodology.

G0265 *Cryopreservation, freezing and storage of cells for therapeutic use, each cell line*
G0266 *Thawing and expansion of frozen cells for therapeutic use, each cell line*
G0267 *Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (e.g., T-cells, metastatic, carcinoma)*

For 2003, the CPT Editorial Panel made changes in the reporting of automated complete blood count (CBC) parameters. Laboratories should review the coding changes to ensure claims accurately reflect automated CBC testing that was ordered and performed. CMS will monitor claims to detect potential misuse of these codes and may reevaluate these services in the future.

Based on comments regarding codes 87800 and 87801, the mappings were revised. Code 87800 has been mapped to two times code 87797 and code 87801 has been mapped to two times code 87798.

Organ or Disease Oriented Panels

Similar to prior years, the 2003 pricing amounts for certain organ or disease panel codes and evocative/suppression test codes were derived by summing the lower of the fee schedule amount or the NLA for each individual test code included in the panel code. The national limitation amount field on the data file is zero-filled.

Cervical or Vaginal Smear Tests (Pap smears)

For 2003, the CPT Editorial Panel created new codes 88174 and 88175 (and deleted codes 88144 and 88145) for cervical or vaginal smear tests performed for diagnostic purposes by automated testing systems with thin layer preparation. For the same tests performed for preventive or 'screening purposes', alpha-numeric HCPCS codes G0144 and G0145 are billed. For 2003, CMS revised the descriptor of codes G0144 and G0145 to match new codes 88174 and 88175.

Mapping Information for New and Revised Codes

New code 83880 is priced at the same rate as code 84588.

New code 84302 is priced at the same rate as code 84300.

New code 85004 is priced at the same rate as code 85027.

New code 85032 is priced at the same rate as deleted code 85590.

New code 85049 is priced at the same rate as deleted code 85595.

New code 85380 is priced at the same rate as code 85379.

New code 87255 is priced at the same rate as one-half code 87253 and code 87252.

New code 87267 is priced at the same rate as deleted code 87199.

New code 87271 is priced at the same rate as deleted code 87198.

New code 88174 is priced at the same rate as code 88142 and 8% of code 88147.

New code 88175 is priced at the same rate as code 88142 and 44% of code 88148.

New code 89055 is priced at the same rate as deleted code G0026.

Revised code G0144 is priced at the same rate as new code 88174.

Revised code G0145 is priced at the same rate as new code 88175.

New code G0265 is priced at the same rate as code 88240.

New code G0266 is priced at the same rate as code 88241.

Gap-fill Payments for New Laboratory Tests

In accordance with §531(b) of the Benefits Improvement and Protection Act of 2000 (BIPA), CMS solicits public comments on determining payment amounts for new laboratory tests. As described earlier, CMS hosts an annual public meeting to allow parties the opportunity to provide input to the payment determination process. The CMS employs one of two approaches to establishing payment amounts for new laboratory test codes, crosswalking and gap-filling. After considering public input regarding the new test codes, CMS determines which approach is most appropriate for each new test code.

If the new test is comparable to an existing test, the new test is "crosswalked" to the existing test, and it is assigned the local fee for the existing test and the corresponding NLA. The new test code and payment amounts are included in the updated laboratory fee schedule. Thus, payment amounts for new tests in 2003 that CMS has determined are to be crosswalked are established by this PM.

If CMS determines that the laboratory fee schedule includes no sufficiently comparable test to permit crosswalking, CMS instructs carriers to "gap-fill" the payment amount for the new test code Gap-filling is an empirical process of determining a payment amount in a locality using available information sources. Usually the period during which gap-filled payment amounts are instructed is the year following the introduction of a new code. During this period, carriers establish and use these payment amounts; they may be revised in the course of the year. Also during this period, carriers must report the gap-fill amounts to their ROs which are then forwarded to CMS. CMS considers the gap-fill amounts and uses them to establish the fees for the new test code in the next update of the laboratory fee schedule. Thus, the final fees for the tests gap-filled pursuant to this PM will take effect in January 2004.

Because questions have arisen on gap-fill payments for new laboratory test codes, CMS is here providing more instructions to carriers. In determining gap-fill amounts, the sources of information carriers should examine, if available, include: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. Carriers may consider other sources of information as appropriate, including clinical studies and information provided by clinicians practicing in the area, manufacturers, or other

interested parties. To assist each carrier in establishing a gap-fill amount, carriers' Medical Directors may meet and share information regarding the new test, though without reaching a formal consensus.

Establishing payment amounts for new laboratory tests is inherently difficult, precisely because these tests are new and as a result the types and extent of information available about them may be limited. Because the circumstances of different tests may vary significantly, specifying in detail a method of using the various information sources outlined above does not appear appropriate at this time. However, CMS designates a new test code for gap-filling in instances where no test code seems sufficiently similar to make a crosswalk approach appropriate. Accordingly, carriers should not determine a gap-fill amount by crosswalking to the payment amount for another test code.

In reviewing the 2002 gap-fill amounts for code 82274 and 82274QW, it appears some carriers may have crosswalked to code 82270. The gap-fill period for codes 82274 and 82274QW is extended in 2003 so that carriers can reexamine their gap-fill payment determinations for these codes in light of the discussion above.

After determining a gap-fill amount, a carrier may consider if a least costly alternative to a new test exists (see PIM Chapter 13, §5.4). If a carrier determines a least costly alternative test exists, the carrier may adopt the payment amount of the least costly alternative test as the gap-fill amount for the new test code. The least costly alternative amount will be considered the local fee, and CMS will use this payment amount in establishing the NLA. However in this case, the carrier must report two payment amounts, the gap-fill amount prior to determination of a least costly alternative and the payment amount that the carrier has determined to be the least costly alternative. Attachment D contains the record layout to report both amounts to better support the carriers' determinations.

For 2003, the gap-fill payment determinations are effective for services rendered from January 1, 2003 to December 31, 2003. Carriers are required to establish an initial gap-fill amount and provide this information to their RO on or before April 1, 2003. Carriers may revise this initial gap-fill amount and must report any revisions to their RO no later than September 1, 2003. The local fees will be established based on the gap-fill amounts reported as of September 1, 2003, and CMS will set the NLA for the new test code at 100 percent of the median of all local fees.

Carriers should also communicate the gap-fill amounts to corresponding intermediaries. Carriers can seek assistance from RO staff to facilitate communication of the gap-fill amounts to intermediaries. The list of codes which carriers are required to gap-fill for 2003 can be found in Attachment C. Attachment D contains the record layout for the submittal of the 2003 gap-fill amounts.

<u>Laboratory Costs Subject to Reasonable Charge Payment in 2003</u>

The following codes relate to services subject to laboratory reasonable charge payment method. When these services are performed for a hospital outpatient, payment is made under the hospital outpatient bundled prospective payment system. Sections MIM 3628C and MCM 5114.1B provide reasonable charge payment instructions for other outpatient settings. When the reasonable charge payment method applies (for example, a service rendered for a nonpatient of a hospital), the inflation-indexed update is 1.1 percent for year 2003. The inflation-indexed update is calculated in accordance with §1842(b)(3) of the Act and Section 42 CFR 405.509(b)(1).

Blood Products

P9010 P9011 P9012 P9016 P9017 P9019 P9020 P9021 P9022 P9023 P9031 P9032 P9033 P9034 P9035 P9036 P9037 P9038 P9039 P9040 P9041 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 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 G0267

Education

Include this information on the 2003 clinical laboratory fee schedule and laboratory services subject to reasonable charge payment in your next bulletins and/or post it on your Web site to notify laboratories of these changes.

The effective date for this PM is January 1, 2003.

The implementation date for this PM is January 1, 2003.

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, 2003.

4 Attachments

ATTACHMENT A

CARRIER RECORD LAYOUT FOR DATA FILE

2003 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME: MU00.@BF12394.CLAB.CY03.V1104

Data 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

2003 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME:MU00.@BF12394.CLAB.CY03.V1118.FIRHHI

Data 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

2003 CLINICAL LABORATORY FEE SCHEDULE

I. New Codes

83880
84302
85004
85032
85049
85380
87255
87267
87271
88174
88175
89055
G0265
G0266
G0267

II. Deleted Codes

80090
85021
85022
85023
85024
85031
85585
85590
85595
86915
87198
87199
88144
88145
G0026

III. Codes That Require Gap-Fill Amounts

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. The test method differs from the guaiac method fecal occult blood test. The test method eliminates medicinal and dietary restrictions before testing. Code 82274 encompasses one to three stool specimens which are self-collected by the patient at home on a single day or over several days. The patient uses kit brush on toilet water from around surface of stool, applies to specimen collection card, and mails or returns card to the laboratory for testing. All three specimens are used to complete a single immunoassay test billed with code 82274. Whether the stool specimen collection is self-performed in the home setting or is performed as part of a rectal examination, the specimen collection is not separately payable.

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

ATTACHMENT D

2003 CLINICAL LABORATORY FEE SCHEDULE

SUBMITTING 2003 GAP-FILL AMOUNTS

On or before April 1, 2003, carriers are required to establish initial gap-fill amounts and submit this information to their ROs and the ROs should transmit this information to MStevenson@cms.hhs.gov, and AGreenberg@cms.hhs.gov at CMS-Co. Carriers may revise initial gap-fill amounts and must report any revisions to their ROs, MStevenson@cms.hhs.gov, and AGreenberg@cms.hhs.gov no later than September 1, 2003. Carriers should also communicate the gap-fill amounts to corresponding intermediaries. Carriers can seek assistance from ROs to facilitate communication of the gap-fill amounts to intermediaries.

Submit the gap-fill amounts in a right-justified format. Carriers should transmit these gap-fill data in an ASCII file with the following file specifications.

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 2003
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
GAP-FILL AMOUNT	9(5)V99	19-25	Prior to any determination of a least costly alternative
LEAST COSTLY ALTERNATIVE AMOUNT	9(5)V99	26-32	
LEAST COSTLY ALTERNATIVE CODE	X(5)	33-37	