Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-00-109 **Date: NOVEMBER 29, 2000**

CHANGE REQUEST 1377

SUBJECT: 2001 Clinical Laboratory Fee Schedule and Laboratory Costs Subject to Reasonable Charge Payment Methodology

This Program Memorandum (PM) provides instructions for implementing the calendar year 2001 clinical laboratory fee schedule and the mapping for year 2001 Current Procedural Terminology (CPT) codes for clinical diagnostic laboratory tests.

Fees and National Limitation Amounts

In accordance with §4553 of the Balanced Budget Act of 1997 (which amended §1833(h)(4)(B) of the Social Security Act), there will be no annual update (economic index) to the local laboratory fees for 2001, and the national limitation amount (NLA) calculation for 2001 remains at 74 percent of the median.

Data File Format

Attachment A depicts the record layout of the 2001 clinical laboratory fee schedule data file. If your system retains only the pricing amount (lower of the local fee amount or the NLA, load the data from the 60 percent pricing amount field. If your system retains both the local fee amounts and the NLAs, load the data from the 60 percent local fee amount and the 60 percent NLA field in order to determine the lowest price. The 62 percent pricing amount field is used by intermediaries to process claims for services in a sole community hospital's qualified laboratory.

Access to Data File and Program Memoranda

The CY 2001 clinical laboratory fee schedule data file will be issued electronically by HCFA's Center for Health Plans and Providers via the software package for mainframe-to-mainframe communications, formerly referred to as the National Data Mover. The file was issued to carriers on November 1, 2000. The file will be issued to intermediaries and the Railroad Retirement Board on November 21, 2000. A diskette with the file will be sent to the Indian Health Service and the United Mine Workers on November 21, 2000. You should issue bulletins to the provider community advising providers of the new and deleted 2001 laboratory codes and mapping by December 1, 2000.

Internet access to the 2001 clinical laboratory fee schedule data file should be available on November 21, 2000, at the web site http://www.hcfa.gov/stats/pufiles.htm under the heading "Payment Rates--Non-Institutional Providers." HCFA's Center for Medicaid and State Operations will use the Internet to issue the CY 2001 clinical laboratory fee schedule to Medicaid State Agencies. Other interested parties can also download the file which will be available in multiple formats: Excel, text, and comma delimited. The web site http://www.hcfa.gov/pubforms/transmit/pmemos.htm provides efficient access to PMs.

Comments

Comments on the laboratory fee schedule can be submitted to the following address so that HCFA may consider these comments for the development of the calendar year 2002 laboratory fee schedule. Comments should be in written format, include clinical, coding, and pricing information, and submitted in advance of August 1, 2001. Comments submitted in any other manner, incomplete comments and comments submitted after August 1, 2001, may not be considered for the 2002 laboratory fee schedule due to deadlines both HCFA and its contractors must meet for a January 1, 2002, implementation date.

Health Care Financing Administration
Division of Acute Care
Center for Health Plans and Providers
Mailstop: C4-07-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Pricing and Billing Information

The mapping for new, deleted, and significantly revised American Medical Association's CPT codes for 2001 clinical diagnostic laboratory tests represents HCFA's determination of the relationship between valid 2000 and 2001 codes. Attachment B is a listing of new, deleted, and gap-fill codes that are included in the 2001 laboratory fee schedule data file. The 3-month grace period for deleted codes is defined in the Medicare Carriers Manual (MCM) §4509.3 and begins January 1, 2001.

The 2001 laboratory fee schedule includes fees for the codes related to specimen collection (G0001, P9615, P9612). Section 1833(h)(4)(B) of the Social Security Act limits the payment levels of specimen collection services for Medicare clinical diagnostic laboratory purposes. Questions on how to code specimen collections in other or atypical circumstances should be directed to the CPT Editorial Panel. PM AB-99-49 Change Request 526, Medicare Travel Allowance Fees for Collection of Specimens, dated June 1999, provides further instructions on specimen collection travel fees (codes P9603 and P9604). The standard Federal mileage rate for year 2000 is $.325. The updated standard Federal mileage rate for year 2001 is not yet available but can be verified beginning in late December 2000 at the web site http://www.irs.ustreas.gov/prod/forms_pubs/pubs/p4630401.htm

The 2001 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.

New code 84152 for prostate specific antigen; complexed (direct measurement) requires an instrument analysis of the result for billing.

The CPT Editorial Panel created new codes 86294, 86300, 86301, 86304 and revised code 86316 which provide more specificity for billing tumor marker testing.

The CPT Editorial Panel coding changes for microbiology culture testing (codes 87040 - 87163) also are more complex.

The CPT contains codes for urea breath testing to detect Helicobacter pylori in the stomach. Codes 83013 and 83014 are to be utilized for billing breath tests performed using the Carbon 13 isotope method. Code 83014 was established to report the drug administration and sample collection. Code 83013 reflect the breath test analysis. Effective the year 2000, new codes 78267 and 78268 are to be utilized for the Carbon 14 isotope method of testing. Code 78267 (Urea breath test, C-14; acquisition for analysis) is priced at the same rate as code 83014, and code 78268 (Urea breath test,

analysis) is priced at the same rate as code 83013. In addition for year 2001, the CPT Editorial Panel has created new code 87339 enzyme immunoassay for Helicobacter pylori.

Questions have arisen regarding the billing for a microbial identification test kit for three organisms: Candida, (code 87480) Gardnerella (code 87510), and Trichomonas (code 87797). When all three organisms are tested using one specimen for the test kit, regardless of the number of medically necessary tests performed, payment should reflect one unit of service using code 87797 and should not be billed individually.

Fetal fibronectin, cervicovaginal secretions, semi-quantitative (code 82731) is a test used to aid in treating obstetric patients to assess the risk of preterm delivery. Medicare seldom receives claims for this test; however, Medicaid State Agencies should note a year 2001 price adjustment to the Medicare national limitation amount for the code because the amount establishes an upper limit on the Medicaid payment amount.

Organ or Disease Oriented Panels

Similar to prior years, the 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.

Cervical or Vaginal Smear Tests (Pap Smears)

Carriers should again gap-fill code 88142 (Cytopathology, cervical or vaginal, collected in preservative fluid, automated thin layer preparation) and carriers should again gap-fill codes 88143, 88144, 88145, 88147, and 88148. Carriers should also gap-fill the corresponding screening Pap smear codes G0123, G0143, G0144, G0145, G0147, and G0148. Congressional legislative initiatives continue to warrant the delay of the establishment of NLAs for these codes; thus the gap-fill amounts established for the year 2000 continue to be effective. If evidence is presented to the carrier warranting a review of the gap-fill amounts for these codes in 2001, the carrier may proceed with the review. However, in accordance with the gap-fill process, the gap-fill amount should be established by March 31, 2001, reported to the RO by May 4, 2001, and provided to corresponding intermediaries as necessary.

PM AB-99-84 Change R 946, CY 2000 Clinical Diagnostic Laboratory Fee Schedule, dated November 1999, explained that HCFA has actively engaged in the numerous pricing and impact steps of an inherent reasonableness review for Pap smear payment during 1999 and intended to continue this review in the year 2000. The authority for HCFA to perform an inherent reasonableness review was granted by §4316 of the Balanced Budget Act of 1997 (which amended §1842(b)(8) of the Social Security Act) and is codified at §42 CFR 405.502(g) and (h). Steps of an inherent reasonableness review include a ***Federal Register*** notice and public comment time period. However, HCFA did not complete the review during year 2000 due to the enactment of sections 223 and 224 of the Balanced Budget Refinement Act on November 29, 1999 (P.L. 106-113). With this legislation, Congress suspended HCFA's authority to perform an inherent reasonableness review and established a minimum payment amount for the local fee schedule amount and the National Limitation Amount of not less than $14.60 for dates of service on or after January 1, 2000. As mentioned above, Congressional legislative initiatives continue to warrant the delay of a national application of pricing to the local fee schedule amounts for Pap smear codes so that a local review should be performed to determine the applicability of the minimum payment amount. In accordance with §4553 of the Balanced Budget Act of 1997 (which amended §1833(h)(4)(B) of the Social Security Act), an update to the minimum payment amount is not applicable for 2001. Payment is the lower of the submitted charge, the local fee schedule amount, or the National Limitation Amount. A further discussion of the establishment of minimum payment amount for Pap smears is contained in PM AB-99-99, Change Request 1081, Pap Smears Included in CY 2000 Clinical Diagnostic Laboratory Fee Schedule, dated December 1999.

Glucose Monitoring

During the past year, skilled nursing facility and home health providers requested a review of this service. During the course of this review we determined that a separate PM is warranted to discuss this service and provide instructions for coverage and payment with more precise effective dates. Two separate PMs were prepared, Change Request 1407, Glucose Monitoring Note, AB-00-99, which was issued on October 24, 2000, and Change Request 1362, Glucose Monitoring, AB-00-108. These PMs provide instructions for coverage and payment for glucose monitoring using a home-use device most often billed with CPT code 82962 *Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use*.

HIV Resistance Testing

For 2001 the CPT Editorial Panel created new codes 87901 for genotype and 87903 and 87904 for phenotype testing for Human Immunodeficiency Virus (HIV) type-1. The tests are referred to as HIV resistance testing because they help determine drug resistance or drug sensitivity for the patient. The tests can be useful for patients who are not improving on a specific drug regimen. Genotype analysis identifies mutations that are associated with drug resistance and phenotype analysis measures the ability of the virus to grow in the presence of drugs under consideration by the clinician. Regardless of the number of drugs analyzed, the new codes for phenotype testing reflect testing for up to only 15 drugs and additional drug testing is not separately payable. Note that §1862(a)(4) of the Act codified at §42 CFR 411.9 does not permit Medicare to pay for laboratory testing performed outside of the United States, except for very limited circumstances. There is a concern that not all HIV resistance testing for United States patients complies with §42 CFR 411.9 and program integrity efforts should be alert to this concern. Medical necessity guidelines are under development using International AIDS society and Department of Health and Human Services guidelines. Currently, most genotype and phenotype testing is being performed under the "homebrew" status and therefore are not subject to FDA approval. Some manufacturers are currently seeking FDA approval for genotype test kits. One manufacturer has a genotype kit that has received an FDA status of Investigational Device Exemption (IDE). The Part B clinical laboratory benefit does not encompass laboratory testing performed in conjunction with clinical trial protocols paid under another Medicare benefit. The FDA regulates how these non-FDA approved laboratory tests can be used, marketed, and distributed. HCFA examined all the comments that we received on these tests that were submitted in accordance with the instructions for commenting on the development on the 2001 laboratory fee schedule in PM AB-99-84 CR 946, CY 2000 Clinical Diagnostic Laboratory Fee Schedule, dated November 1999. The comments contained current cost and charge data as well as discussions of the rapid refinements and combinations of laboratory testing methods that have occurred in the past year for the treatment of HIV patients. Based on these comments, we believe reasonable prices can be established for these new codes using the addition of codes 87252, 87253, 83890, 83894, 83898, and 83904. We also believe the mapping is essential for consistent payment of these important tests. See the mapping information below. The new more specific codes represent both the performance of the test and interpretation and reporting the results so that codes representing the test components (e.g., 87252, 87253, 83890, 83894, 83898, 83902, 83912) may not be submitted in lieu or in addition to the new codes 87901, 87903, and 87904. Continued rapid refinements may warrant the CPT Editorial Panel to modify codes for the year 2002 and if necessary, we will revisit the mappings for the development of the 2002 laboratory fee schedule. We again are committed to examining all comments received on HIV resistance testing for the development of the year 2002 laboratory fee schedule that are submitted as described in this PM.

Mapping Information

New code 80157 is priced at three quarters of the rate of code 80185.

New code 80173 is priced at the same rate as code 80156.

New code 82373 is priced at the same rate as code 82977.

New code 82945 is priced at the same rate as code 82947.

New code 83090 is priced at the same rate as code 82131.

New code 83663 is priced at one half of the rate of code 83662.

New code 83664 is priced at one quarter of the rate of code 83662.

New code 83921 is priced at the same rate as code 83918.

New code 84152 is priced at the same rate as code 84153.

New code 84591 is priced at the same rate as code 84590.

New code 85307 is priced at the same rate as code 85306.

New code 85536 is priced at the same rate as code 85535.

New code 86001 is priced at the same rate as code 86003.

New code 86146 is priced at the same rate as code 86147.

New code 86294 should be priced as gap-filled amount.

New codes 86300, 86301, and 86304 are priced at the same rate as code 86316.

New codes 86611 and 86666 are priced at the same rate as code 86602.

New code 86683 is priced at the same rate as code 82270.

New codes 86696 and 86757 are priced at the same rate as code 86689.

New code 87046 is priced at one quarter of the rate of code 87045.

New codes 87071 and 87073 are priced one half of the rate as code 87045.

New code 87077 is priced at the same rate as code 87072.

New code 87107 is priced at the same rate as code 87106.

New code 87149 is priced at the same rate as code 87470.

New code 87152 is priced at the same rate as code 87158.

New codes 87168, 87169, and 87172 are priced at the same rate as 87210.

New code 87185 is priced at the same rate as code 87181.

New code 87254 is priced at one quarter of the rate of code 87250.

New code 87273 is priced at the same rate as code 87274.

New code 87275 is priced at the same rate as code 87276.

New codes 87277, 87279, 87281, and 87283 are priced at the same rate as code 87278.

New code 87300 is priced at one half of the rate of code 87301.

New codes 87327, 87336, and 87337 are priced at the same rate as code 87301.

New code 87339 is priced at the same rate as code 87449.

New code 87341 is priced at the same rate as code 87340.

New code 87400 is priced at one half of the rate of code 87301.

New code 87427 is priced at the same rate as code 87335.

New code 87451 is priced at the same rate as code 87450.

New code 87800 is priced at the same rate as code 87797.

New code 87801 is priced at the same rate as code 87798.

New code 87901 is priced at the same rate as the addition of codes 83890 (x2), 83894, 83898 (x4), 83902 (x2), 83904 (x8), and 83912.

New code 87903 is priced at the same rate as the addition of codes 83890 (x4), 83894 (x2), 83898 (x4), 83902 (x2), 83912, 87252 (x10), and 87253 (x3).

New code 87904 is priced at the same rate as code 87252.

New code 88400 is priced at one half of the rate as code 82247.

New code 89321 is priced at the same rate as code 89320.

Gap-fill Codes

Codes for which carriers should gap-fill are listed in Attachment B.

Similar to 2000, carriers may gap-fill on a flow basis as claims are received for the unpriced code. However, the code should have a gap-fill amount established by the carrier by March 31, 2001, and communicated to corresponding intermediaries as necessary. The carrier should consider the charge for the test in their area as well as the cost of performing the test in a laboratory with adequate volume to ensure cost efficiencies. Carriers are to provide their RO with these gap-fill fees by May 4, 2001. These data are needed for the development of the 2001 clinical diagnostic laboratory fee schedule. Attachment C depicts the record layout for the submittal of the 2001 gap-fill amounts to the ROs.

Laboratory Costs Subject to Reasonable Charge Payment Methodology in 2001

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), the inflation index update for 2001 is 3.7 percent. The following HCPCS codes relate to these services:

Blood Products

P9010 P9011 P9012 P9016 P9017 P9019 P9020 P9021 P9022 P9023

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

Institute of Medicine Study

HCFA has sponsored a Congressionally-mandated study by the Institute of Medicine to examine how Medicare pays for outpatient laboratory services. Over the past year the study committee has been gathering data, examining the issues and formulating their recommendations. This study describes the clinical laboratory industry and recent laboratory technology trends, documenting how it has changed since the early 1980's and what is expected in the future. The study assesses the strengths and weaknesses of the current Medicare payment system for outpatient laboratory tests as well as alternative Medicare payment methodologies and related administrative issues. The study report is expected to be released before the end of year 2000. The Institute of Medicine has posted further information on its web site for this study at http://www.iom.edu/iom/iomhome.nsf/pages/clinlab+home+page. When published, copies of the study report will be available for purchase from the National Academy Press by phone: toll-free (888) 624-7645 or 202-334-3313 or mail: 2101 Constitution Ave. NW, Washington, DC 20055. The complete text will be posted on the web site: www.nap.edu.

The effective date for this PM is January 1, 2001.

The implementation date for this PM is January 1, 2001.

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, 2001.

3 Attachments

ATTACHMENT A

RECORD LAYOUT FOR FILE

2001 CLINICAL DIAGNOSTIC LABORATORY FEE SCHEDULE
DATA SET NAME MU00.@AAA2394.CLAB2001.VER1101

FIELD NAME	PICTURE	START/ END POSITION	COMMENT
HCPCS CODE	X(5)	1-5	
CARRIER NUMBER	X(5)	6-10	
LOCALITY	X(2)	11-12	00-- Denotes Single State Carrier 01--North Dakota 02--South Dakota 20--Puerto Rico
60% LOCAL FEE AMT	9(5)V99	13-19	
62% LOCAL FEE AMT	9(5)V99	20-26	
60% NATL LIMIT AMT	9(5)V99	27-33	
62% NATL LIMIT AMT	9(5)V99	34-40	
60% PRICING AMT	9(5)V99	41-47	
62% PRICING AMT	9(5)V99	48-54	
GAP FILL INDICATOR	X(1)	55-55	0--No Gap Fill Required 1--Carrier Gap Fill 60% 2-- Special Instructions Apply
MODIFIER	X(2)	56-57	Where modifier is shown, QW denotes a CLIA waiver test.
FILLER	X(3)	58-60	

ATTACHMENT B

I. New Codes

80157	86683	87283
80173	86696	87300
82373	86757	87327
82945	87046	87336
83090	87071	87337
83663	87073	87339
83664	87077	87341
83921	87107	87400
84152	87149	87427
84591	87152	87451
85307	87168	87800
85536	87169	87801
86001	87172	87901
86146	87185	87903
86294	87254	87904
86300	87273	88400
86301	87275	89321
86304	87277	
86611	87279	
86666	87281	

II. Deleted Codes

82251
87060
87072
87082
87083
87085
87087
87117
87151
87155
87163
87174
87175
87192
87208
87211
P9013
P9018

III. Codes That Require Gap-Fill Amount

82962
86294
87338
88142
88143
88144
88145
88147
88148
G0123
G0143
G0144
G0145
G0147
G0148

ATTACHMENT C

PROCESS FOR SUBMITTING 2001 GAP-FILL AMOUNTS

Carriers are to provide their RO with the 2001 laboratory gap-fill amounts by May 4, 2001. Please submit the gap-fill amounts in a right justified format. The RO review should take into account whether the submitted amounts seemed in line with the amounts received from other carriers within the RO's jurisdiction. These data are needed for the development of the calendar year 2001 clinical diagnostic laboratory fee schedule. These data should be transmitted in an ASCII file with the following file specifications:

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

FIELD NAME	PICTURE	START-END POSITION	COMMENT
YEAR	X(4)	1-4	Set to 2001
HCPCS CODE	X(5)	5-9	
MODIFIER	X(2)	10-11	
CARRIER NUMBER	X(5)	12-16	
LOCALITY	X(2)	17-18	00--Denotes Single State Carrier 01--North Dakota 02--South Dakota 20--Puerto Rico
60% LOCAL FEE SCHEDULE	9(5)V99	19-25	

The ROs should review the files and then forward to HCFA by May 31, 2001. The address to send the files is: MStevenson@hcfa.gov.