CPT Coding Revisions

The new laboratory CPT codes for each of the three major areas of clinical genetic laboratory testing is available in the following report. The availability of these new codes will greatly facilitate billing for existing and new tests and technologies used in laboratories. They also provide the basis for addressing reimbursement issues. Without codes that accurately describe the services currently provided, discussions of appropriate reimbursement are difficult. Cost analysis information about tests from your laboratory is welcomed. This will allow the College to provide HCFA and other payers with information to allow them to make an educated decision regarding appropriate rates of reimbursement. Please provide this information to the fax number given below.

In order to stay abreast of the rapid evolution of tests and technologies, we encourage you to communicate with the Committee on the Economics of Genetic Services about anticipated needs for CPT coding. It can take from 6 months to years to fully develop the information and proposals for CPT modifications or additions.

Direct all comments and inquiries to the attention of "CPT Coding Revisions" and send via fax to 301-571-1895.

NEW LABORATORY CPT CODES

Major revisions to the CPT coding of genetic testing have been approved by the AMA CPT Editorial Panel and go into effect on January 1, 1999. The following will provide you with the revised CPT codes (new, modified, and deleted) and offer an overview of how they might be combined or "stacked" to describe particular tests. There is also a brief discussion of important considerations in incorporating these into your laboratory's or institution's billing and reimbursement systems.

As a point of reference to facilitate reviewing the individual lists of codes, note the following. The codes are presented in two columns. The first column shows the codes' 1998 status and language, while the second column shows this for 1999. Where a code did not exist in 1998, we have noted that in the 1998 column and inserted the language of the new code in the 1999 column. Deleted codes or modified codes have a line through the language being removed. When modified, the new language is underlined in the 1999 column. When a code description is indented, the first part of the code description is determined by the language of the code immediately preceding it. If that code is also indented, continue back through the codes to the first one which is not indented. The language preceding the semicolon applies to each of the indented codes following it. Where the code has not changed, "same" is noted in the 1999 column. The codes for each of the areas of genetic testing are appended.

Clinical Cytogenetics

Overview: There are several significant changes within the Cytogenetics codes. In general terms, the codes have been refocused to distinguish between testing for cancer versus constitutional abnormalities. The major changes include 1) the addition of CPT codes to describe FISH tests; 2) a new code for cancer cytogenetic analyses; 3) a new pair of codes to describe the freezing of viable cell lines and their subsequent thawing and reestablishment in cell culture to be used for tests (usually biochemical) requiring viable cells which are commonly sent to reference laboratories. These codes will likely be used by cytogenetics laboratories or biochemical genetics laboratories. 4) There is also a new CPT code for the reporting and interpretation of results of cytogenetic and molecular cytogenetic testing which is generally used when results and interpretation are abnormal and/or complex.

The CPT Codes: See Appendix 1 for CPT codes 88230-88299.

Example: A patient presents with an interrupted aortic arch and hypocalcemia. Your laboratory is asked to consider a diagnosis of DiGeorge syndrome by performing a complete chromosome analysis and fluorescence in situ hybridization (FISH) testing for a microdeletion in 22q11.2 from a blood sample.

The CPT codes that describe this test are:

88230 lymphocyte cell culture
88262 chromosome analysis; count 15–20 cells, 2 karyotypes, with banding
USE IF CHROMOSOME ANALYSIS IS INCLUDED IN STUDY
88271 molecular cytogenetics; DNA probe, each
USE ONCE FOR EACH PROBE USED
88271 see above
SECOND PROBE, IF USED
88273 molecular cytogenetics; chromosomal in situ hybridization, analyze 1–30 cells
88291 cytogenetic and molecular cytogenetics, interpretation and report
IF RESULT REQUIRES COMPLEX INTERPRETATION

Molecular Diagnostics

Overview: The primary changes to this area involve generalizing language to cover nucleic acids rather than DNA and the addition of several codes reflecting more recent technologies used in molecular diagnosis. Note that, for the most part, the codes discussed here have been developed to apply to the analysis of the human genome since a significant number of new codes exist for the molecular identification of infectious agents (see 87470-87799). However, the availability of codes for specific infectious agents does not necessarily preclude the use of codes within this area.

The CPT Codes: See Appendix 2 for CPT codes 83890-83912.

Example: A newborn presents with meconium ileus. From a blood sample, test for mutations in the CFTR gene associated with cystic fibrosis. Your laboratory does this test using DNA sequencing. You test for five mutations that lie within five independent stretches of DNA that are individually amplified by PCR.

The CPT codes that describe this test are:

83890 molecular isolation or extraction
83901 amplification of patient nucleic acid, (e.g., PCR), single primer pair, each primer pair
USE THIS CODE 5 TIMES FOR EACH PRIMER PAIR

USED TO AMPLIFY

3904 mutation identification by sequencing, single segment, each segment
USE THIS CODE 5 TIMES FOR EACH SEGMENT SEQUENCED

3912 interpretation and reporting

Biochemical Genetics

Overview: The goal for reworking the CPT coding for Biochemical Genetics was to move away from listing individual amino acids or organic acids, some of which have CPT codes already, to a more general approach. Furthermore, we wanted to provide for qualitative and quantitative assays, for single analytes, multiple analytes, and profiles, and to have the newer technologies more common to our field included. A few new analytes common to biochemical genetic testing have also been added. Note that new and modified codes are available in the cytogenetics section for cell culture. The language has been changed such that cell culture isn't specifically for the purpose of cytogenetic testing but, rather, is for testing for either nonneoplastic or neoplastic disorders. Furthermore, codes for cryopreservation as well as the thawing and reestablishment of cell lines, often needed for sequential distribution of cells to reference laboratories, are available.

Lastly, a code for interpretation and reporting was proposed but denied. The reasoning was that this activity is commonly a professional service component that is performed in the course of a consultation and, therefore, billable under that group of services.

The CPT Editorial Panel recently decided to incorporate all of our new codes into the chemistry section rather than have a subsection on Biochemical Genetics in order to accommodate others using these codes.

The CPT Codes: See Appendix 3 for the list of CPT codes in the Biochemical Genetics area. Note that this list is not all-inclusive due to the number of analytes in the existing CPT code book. Rather, the lists reflect codes that are new or modified only and applicable to this area of testing. For those codes for which the description of the code states "analyte not specified elsewhere," the existing analyte code description likely includes the analytical technique historically used for that test. You would stack the new codes in instances in which you apply a new analytical code. Lastly, the term "specimen" has been used to allow for the testing of multiple tissues in situations in which the ratio between tissues is important or multiple tissue assessments are clinically relevant.

Example: Your laboratory is asked to analyze a urine specimen for acylcarnitines. The test done in your laboratory involves profiling the carnitine esters using fast atom bombardment and electrospray ionization coupled with tandem mass spectrometry. The CPT codes that describe this test are:

82016 acylcarnitines; qualitative, each specimen

83788 mass spectrometry and tandem mass spectrometry

General

Important considerations: The availability of particular CPT codes does not necessarily guarantee their reimbursement. In most situations, diagnostic coding (ICD) must support the use of the test in any particular situation. Also, note that no relative value units (RVUs) have been assigned to the base code for reporting and interpretation of complex cytogenetic results. RVUs are assigned to professional services while the reimbursement for analytical codes is assigned by the Health Care Financing Administration (HCFA). In general terms, professional services are considered those reimbursable to an individual with a UPN, a number which identifies a physician within the Medicare system. Hence, only physicians can be reimbursed for the use of this code when Medicare is billed. This does not necessarily preclude their use being built into contracts with referral bases. We are beginning to pursue acquiring restricted licenses for Board-certified PhD lab directors, which would allow them to bill for professional services within their area of certification. This would parallel the actions in a few states in which this privilege already exists.

DISCLAIMERS IN REPORTS OF GENETIC TESTS USING ANALYTE SPECIFIC REAGENTS

Pursuant to a new FDA rule, effective November 23, 1998, laboratories reporting out results of tests using analyte specific reagents (ASRs), including molecular probes, that have not been approved by the FDA must include a specific disclaimer on the test report. ASRs are reagents composed of chemicals or antibodies that constitute the "active" ingredients of an in-house developed test. Manufacturers are required to label all such products as ASRs. The required disclaimer states as follows:

"This test was developed and its performance determined by (laboratory name). It has not been cleared or approved by the U.S. Food and Drug Administration."

Because this statement may cause confusion among physicians, patients, and payers regarding whether such tests are clinically necessary and reimbursable, laboratories may wish to add clarifying language after the disclaimer, such as the following:

"The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes."

Laboratories also may wish to add the following:

"Pursuant to the requirements of CLIA '88, this laboratory has established and verified the test's accuracy and precision."

Any clarifying language must be in addition to the exact language required in the FDA disclaimer.

Clinical laboratories using ASRs must verify or establish, for each use of an ASR, the performance characteristics, e.g., accuracy, precision, analytical sensitivity and specificity, etc. 42 CFR §493.1213.

Geneticists who provide interpretations of tests performed using ASRs, and laboratories that report out results of tests performed by other laboratories, also must include the FDA-required disclaimer on test reports. Although the disclaimer requirement does not apply to ASRs developed and used exclusively in-house (i.e., home-brew ASRs), which are not currently regulated by the FDA, some variation of the required disclaimer and clarifying language is recommended. The disclaimer also does not apply to ASRs that are sold and used as components of tests or kits (in vitro diagnostics) that have been cleared or approved by the FDA. Finally, the disclaimer is not required for tests using reagents that are labeled for "Research Use Only" (RUOs) or for "Investigational Use Only" (IUOs). Such reagents are subject to FDA approval but have not been approved for clinical use.

Appendix 1

Clinical Cytogenetics CPT Codes

1998 CPT Code(s)		1999 CPT Code(s)	
88230	tissue culture for chromosome analysis; lymphocytes	88230	tissue culture for non-neoplastic disorders; ~~chromosome analysis~~; lymphocyte
88233	skin or other solid tissue biopsy	88233	same; but now for non-neoplastic
88235	amniotic fluid or chorionic villus cells	88235	same; but now for non-neoplastic
88237	tissue culture for chromosome analysis; bone marrow (myeloid) cells	88237	tissue culture for neoplastic disorders; bone marrow (mycloid), blood cells
88239	other tissue	88239	other tissue solid tumor
	None; new code	88240	cryopreservation, freezing and storage of cells, each cell line
	None; new code	88241	thawing and expansion of frozen cells, each aliquot
88245	chromosome analysis for breakage syndromes; score 25 cells (SCE study), count 5 cells, 1 karyotype, with banding	88245	chromosome analysis for breakage syndromes; ~~score 25 cells (SCE study) count 5 cells, 1 karyotype, with banding (e.g., Bloom syndrome)~~ baseline Sister Chromatid Exchange (SCE), 20-25 cells
88248	score 100 cells, count 20 cells, 2 karyotypes, with banding (e.g., ataxia telangiectasia, Fanconi anemia)	88248	baseline breakage, score 50–100 cells, count 20 cells, 2 karyotypes, ~~with banding~~ (e.g., for ataxia telangiectasia, Fanconi anemia, fragile X)
	None; new code	88249	score 100 cells, clastogen stress, (e.g., diepoxybutane, mitomycin C, ionizing radiation, UV radiation)
88250	chromosome analysis for fragile X linked mental retardation, score 100 cells, count 20 cells, 2 karyotypes with banding	88250	~~chromosome analysis for fragile X linked mental retardation, score 100 cells, count 20 cells, 2 karyotypes, with banding~~ Code Deleted—See 88248
88260	chromosome analysis, count 5 cells, screening with banding	88260	~~chromosome analysis; count 5 cells, screening with banding~~ Code Deleted
88261	count 5 cells, 1 karyotype, with banding	88261	chromosome analysis, count 5 cells, 1 karyotype, with banding
88262	count 15-20 cells, 2 karyotypes, with banding	88262	Same
88263	count 45 cells for mosaicism, 2 karyotypes, with banding	88263	Same
88264	None; new code	88264	analyze 20-25 cells
88267	chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding	88267	Same
88269	chromosome analysis, in situ for amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding	88269	Same
	None; new code	88271	molecular cytogenetics; DNA probe, each (e.g., FISH) None; new code
	None; new code	88272	chromosomal in situ hybridization, analyze 3–5 cells, (e.g., for derivatives or markers)
	None; new code	88273	chromosomal in situ hybridization, analyze 10–30 cells (e.g., for microdeletions)
	None; new code	88274	interphase in situ hybridization, analyze 25–99 cells
	None; new code	88275	interphase in situ hybridization, analyze 100–300 cells
88280	chromosome analysis; additional karyotypes, each analysis	88280	Same
88283	additional specialized banding technique (e.g., NOR C-banding)	88283	Same
88285	additional cells counted, each study	88285	Same
88289	additional high resolution study	88289	Same
88291	None; new code	88291	cytogenetics and molecular cytogenetics, interpretation and reporting
88299	unlisted cytogenetics study	88299	Same

Crossed-out text has been deleted from 1999 codes, and underlined text has been added to 1999 codes.

Appendix 2

Molecular Diagnostics CPT Codes

1998 CPT Code(s)		1999 CPT Code(s)	
83890	molecular diagnostics; molecular isolation or extraction	83890	molecular diagnostics; molecular isolation or extraction
	None; new code	83891	isolation or extraction of highly purified nucleic acid
83892	enzymatic digestion	83892	enzymatic digestion
	None; new code	83893	dot/slot blot production
83894	separation (e.g., dot blot, electrophoresis)	83894	separation by gel electrophoresis (e.g. ~~dot blot, electrophoresis~~ agarose, polyacrylamide)
83896	nucleic acid probe, each	83896	Same
	None; new code	83897	nucleic acid transfer (e.g., Southern, Northern)
83898	molecular diagnostics; amplification, e.g., polymerase chain reaction (PCR)	83898	~~molecular diagnostics~~; amplification, e.g., polymerase chain reaction, each of patient nucleic acid (e.g., PCR, LCR, RT-PCR), single primer pair, each primer pair
	None; new code	83901	amplification of patient nucleic acid, multiplex, each multiplex reaction
83902	reverse transcription	83902	Same
	None; new code	83903	mutation scanning, by physical properties (e.g., single strand conformational polymorphisms (SSCP), heteroduplex, denaturing gradient gel electrophoresis (DGGE), RNA'ase A), single segment, each
	None; new code	83904	mutation identification by sequencing, single segment, each segment
	None; new code	83905	mutation identification by allele specific transcription, single segment, each segment
	None; new code	83906	mutation identification by allele specific translation, single segment, each segment
83912	interpretation and reporting	83912	Same

Crossed-out text has been deleted from 1999 codes, and underlined text has been added to 1999 codes.

Appendix 3

Clinical Biochemical Genetics CPT Codes

1998 CPT Code(s)		1999 CPT Code(s)	
	None; new code	82016	acylcarnitines, qualitative, each specimen
	None; new code	82017	quantitative, each specimen
	None; new code	82127	amino acids; single, qualitative, each specimen
82128	amino acids; qualitative	82128	~~amino acids, qualitative~~ multiple, qualitative, each specimen
82130	amino acids; urine or plasma, chromatographic fractionations	82130	~~amino acids, urine or plasma chromatographic fractionations~~ Deleted—see 82131, 82136, 82139
82131	amino acids, quantitation, each	82131	~~amino acids~~, single qualitative, each specimen
	None; new code	82136	amino acids, 2 to 5 amino acids, quantitative, each specimen
	None; new code	82139	amino acids, 6 or more amino acids, quantitative, each specimen
	None; new code	82261	biotinidase, each specimen
	None; new code	82379	carnitine (total and free), quantitative, each specimen
82486	chromatography, qualitative; column (e.g., gas liquid or high performance liquid chromatography), analyte not elsewhere specified	82486	chromatography, qualitative; column (e.g., gas liquid or HPLC ~~high performance liquid chromatography~~), analyte not elsewhere specified
82491	chromatography, quantitative, column (e.g., gas liquid or high performance, liquid chromatography) analyte not elsewhere specified, single stationary and mobile phase	82491	chromatography, quantitative, column (e.g., gas liquid or ~~high performance liquid chromatography~~ HPLC; single analyte not elsewhere specified, single stationary and mobile phase
	None; new code	82492	multiple analytes, single stationary and mobile phase
	None; new code	82541	column chromatography/mass spectrometry (e.g., GC/MS, or HPLC/MS), analyte not elsewhere specified, single stationary and mobile phase
	None; new code	82542	quantitative, single stationary and mobile phase
	None; new code	82543	stable isotope dilution, single analyte, quantitative, single stationary and mobile phase
	None; new code	82544	stable isotope dilution, multiple analytes, quantitative, single stationary and mobile phase
	None; new code	82657	enzyme activity in blood cells, cultured cells, or tissue, not elsewhere specified; nonradioactive substrate, each specimen
	None; new code	82658	radioactive substrate, each specimen
	None; new code	82726	very long chain fatty acids
	None; new code	83070	beta-hexosaminidase, each assay
	None; new code	83788	mass spectrometry and tandem mass spectrometry (MS, MS/MS), analyte not elsewhere specified; qualitative, each specimen
	None; new code	83789	quantitative, each specimen
	None; new code	83918	organic acids; quantitative, each specimen
	None; new code	83919	qualitative, each specimen
	None; new code	84376	sugars (mono-, di, and oligosaccharides); single qualitative, each specimen
	None; new code	84377	multiple qualitative, each specimen
	None; new code	84378	single quantitative, each specimen
	None; new code	84379	multiple quantitative, each specimen

Crossed-out text has been deleted from 1999 CPT codes, and underlined text has been added to 1999 codes.