



Association for Molecular Pathology (AMP) Proposal for CPT Coding Reform in Molecular Diagnostics

Introduction

During 2008-2009, aided by an unrestricted educational grant from Abbott Diagnostics, the Economic Affairs Committee of the Association for Molecular Pathology (AMP) has held discussions about current problems with CPT coding for molecular procedures which use CPT codes 83890 – 83914 that are applicable primarily in the areas of genetics and oncology. These discussions have involved monthly conference calls, e mails and three face to face daylong sessions. As a result of these efforts and in the context of informal contacts or feedback from a number of payers we have developed the following proposal for changes to CPT.

The intent of our proposal is to present new alternatives for CPT coding of molecular services that will be more intelligible to payers and promote uniformity of coding among laboratories. Although we feel that more uniform and transparent coding will assist payers and advisory groups in promulgating sound coverage policies and decisions and limit time expended on this area for payers and laboratories, we have consciously not addressed the many issues associated with appropriate reimbursement and coverage for procedures performed with these exciting new technologies.

Definitions

Molecular test, assay or procedure: A pathology or laboratory medicine service which involves diagnosis of the presence or absence of disease, prediction of disease behavior or predilection for developing disease based on the detection of nucleic acid (DNA or RNA) abnormalities.

Procedural codes: CPT codes 83890-83914 which describe the individual steps or components of a molecular service. These are often referred to colloquially as ‘stacking codes.’

Service specific CPT code: A code that defines a specific molecular genetic or molecular oncologic service. Many will apply to assessment of a single molecular analyte. These will generally be applied to the most common services provided.

Complexity codes: A series of proposed codes which incorporate varying levels of technical and interpretive work. These codes would be applied to less-frequently performed services which are not specifically identified. Complexity codes could be modeled on levels of complexity structure used for the Evaluation and Management codes and in the varying levels of service for surgical pathology. They are also known frequently called ‘level codes.’

Background and Current Problems

CPT codes for molecular testing have developed in steps over a period of ~15 years in two predominant directions, one for molecular microbiology assays, and the other for other assays directed primarily at inherited diseases and cancer.

Following the early adoption of two generic codes, CPT coding for molecular microbiology testing has pursued a mostly organism-specific approach. A number of microorganisms have each been provided three possible CPT codes depending on the method of testing (direct detection, detection after amplification, quantification); other codes have been developed for limited multiplex testing as well as genotyping of viruses and, more recently, bacteria. While some methodologies aren't applied to certain microorganisms and new tests and test formats present needs for the future, this approach has been reasonably transparent for laboratories and payers.

There is reasonable consensus among directors of molecular diagnostic laboratories that coding for molecular services for non-microbiology-related procedures is problematic. Early on it was appreciated that inherited and neoplastic disorders presented a large range of current and future services and a number of ways of performing them. CPT codes for such services were developed to document the individual steps of a procedure needed to produce a result. These procedural codes occupy the 83890 – 83914 series in the Pathology and Laboratory section of CPT. This approach offers specification of the steps involved in performing a diagnostic a molecular service. By the use of the Unit of Service (UOS) designation, the number of times a particular step is independently performed can also be designated. Take for example a service for an inherited disorder which is known to have potential mutations throughout the full length of a gene. While the sample to be analyzed requires a single extraction of DNA, the resulting DNA will require a number of independent PCR amplification steps to generate material for analysis of different regions of the gene; those amplification products in turn will undergo separate DNA sequence analysis and interpretation.

While such a system of procedural codes permits flexibility and precision reporting the technical services performed by the laboratory, a number of problems have emerged. Perhaps the most vexing is the fact that nowhere do the codes themselves provide information about the molecular target or disease state. Alphanumeric modifiers (Appendix I of CPT) were developed approximately five years ago to address this problem, but these have not been adopted by payers – and hence labs.

Another issue has been that correct coding for different methods of testing for the same target will generate different combinations of procedural CPT codes as well as units of service. A third problem is that multiple, albeit legitimate, units of service can reach large numbers (e.g. the neurofibromin gene associated with neurofibromatosis, type 1, has 59 exons). High units of service engender confusion and even suspicion of abuse by payers accustomed to single or low multiples of CPT codes for clinical chemistry assays. Finally, because procedural CPT codes are associated with steps that are essential for the performance of most molecular assays, narrowly-designed coverage policies for a particular application of molecular services

(e.g. hereditary breast/ovarian and colorectal cancer) which links these CPT codes with a limited number of ICD-9 codes, *de facto* exclude coverage of procedural codes in the 83890-83914 series for a huge number of molecular assays useful for other clinical conditions.

The major problems the AMP Economic Affairs Committee identified for resolution within existing constraints included those listed below.

1. Specificity of clinical (vs. procedural) services provided
2. Incorporation of methodologic complexity (laboratory and physician work) into molecular CPT codes
3. Issues raised by large numbers of units of service
4. Interpretation of complex molecular assays

Constraints included:

- a. Finite number of available CPT codes
- b. Rapidly growing list of analytes and technologies
- c. Dealing with 'multiplex' analyses
- d. Ability to accommodate innovation

Proposed Solution

Ideally for transparency and tracking, each molecular diagnostic service would have its own CPT code. However, because of limitations in the number of available CPT codes in the 8XXXX series, we propose a hybrid solution that permits two complementary approaches to coding and reporting of services (examples below):

- 1) The most common molecular genetic and molecular oncology services would each be indicated by a single service-specific CPT code. Information is being collected separately, but it is estimated from informal polling that these service-specific codes would encompass >80% of the total volume of molecular services performed. Note: because these would be predominantly for high volume services, they would NOT represent anywhere near 80% of the total volume of DIFFERENT molecular services performed.
- 2) The large and growing number of 'less common' services for which assignment of an individual CPT code is limited by specific code availability would be addressed by assigning a single complexity level code (of a small overall number) from a number of services which have a relatively narrow range of variation in resources required to perform, analyze and interpret such services. (such as the neurofibromin gene mentioned above). The complexity level codes would take into account the amount of professional work (measured as a factor of time and intensity of effort) and the laboratory technical costs reflecting a typical situation. This group of codes would be analogous to the complexity levels associated with Evaluation and Management codes or in the surgical pathology Level codes (88300-88309).
- 3) To maintain the single code per test concept we propose that nucleic acid preparation from a sample or treatments to preserve nucleic acid stability be no longer be freestanding, but be incorporated into the service-specific or complexity level code, acknowledging that more than one test can be run on nucleic acid extracted from a single sample. Nucleic acid extraction is typically a minor component of work and cost for most molecular assays.
- 4) Because the interpretation of assay data and construction of a medically meaningful report must be made in conjunction with the patient's medical history, clinical findings and the results of other diagnostic tests and procedures, the skills of a molecular pathologist are required. As such these codes properly belong on the Physician Fee Schedule. The level of such work effort varies among assays and can individually be reflected in the specific as well as complexity level codes.

These points are expanded upon in the sections below. We acknowledge that other more granular solutions may be possible (or even preferable). Our discussions have included consideration of alternative approaches for the concepts articulated above. Where appropriate these considerations and the reason they were not incorporated are discussed briefly in the detail section below.

Single unit of service for each molecular CPT code

Although multiple units of service have allowed precise description of procedural steps provided while performing a molecular service, these have created more confusion than value for payers and are a source of inconsistency among laboratories. Having stated that, it must be acknowledged that simultaneous analysis for several (or even multiple targets), often referred to as multiplex analysis, is the focus of many emerging applications which often provide cost-beneficial efficiencies in the management of outpatients or inpatients.

We propose that technical (laboratory or practice costs) and professional components (work=f(time+intensity)) of service each be coded as a single unit of service, acknowledging that laboratory resources vary by complexity of an assay as do interpretive (professional component) services. These do not necessarily rise in parallel fashion with increasing complexity of an assay, and at each level of complexity both the technical and professional components of the service need to be separately evaluated and valued (in the same fashion as other services on the Physician fee schedule are now evaluated by the RUC).

Reporting of interpretive and diagnostic services associated with molecular genetic and molecular oncology procedures

Molecular assays for inherited and neoplastic disorders are technically and clinically complex. Interpretation requires an understanding of molecular biology, familiarity with relevant medical literature as to therapeutic implications, and frequently correlation or integration with other laboratory and clinical features of the patient. For these reasons, it is appropriate to list CPT codes for molecular genetic and molecular oncology services on the Physician Fee Schedule. Currently there is a single CPT code (83912), reportable on both the Clinical Laboratory Fee Schedule and the Physician Fee Schedule (PFS) (RVU=0.37) to code for such services. The single PFS code will no longer be required in the new schema, as physician services will be the “-26” professional component of each code.

Examples of service-specific CPT codes for common molecular genetic and molecular oncology services.

As noted in the introduction, our purpose is to promote a system which will allow correct, consistent and transparent coding for both laboratories and payers of molecular services. We realize that the number of different services is destined to increase significantly as medicine moves forward in the pursuit of personalized healthcare decisions.

The following list represents (in decreasing rank order) the 14 most common molecular genetic and oncology services provided by a major US reference testing laboratory. It is presented as an example to demonstrate how service-specific CPT codes might be configured. As noted above, these are intended to be coded once for the service performed. There would not be stacked codes or multiple units of service. Additional individual CPT codes can be assigned for more complex (or easier) methods of doing targeted or expanded

gene analysis. To illustrate how service-specific codes might appear in CPT, we have chosen a currently available section within the Pathology and Laboratory Medicine section to which molecular genetic and oncology codes could potentially be moved.

Service-specific CPT codes

CPT Code	Molecular test/analyte
884X1	Factor V Leiden by PCR
884X2	Prothrombin 20210G>A mutation by PCR
884X3	MTHFR gene variant analysis by PCR
884X4	677T variant Other allele
884X5	Hereditary Hemochromatosis (<i>HFE</i> gene) Mutation Analysis by PCR
884X6	282Y mutation 63D mutation
884X7	<i>JAK2</i> Gene, V617F Mutation, Qualitative ^A
884X8	<i>BCR/ABL1</i> t(9;22) translocation assessment, quantitative ^B
884X9	<i>BCR/ABL1</i> t(9;22) Translocation Major breakpoint analysis
884X10	<i>BCR/ABL1</i> t(9;22) Translocation Minor breakpoint analysis <i>BCR/ABL1</i> t(9;22) Translocation Other breakpoint analysis
884X11	Cystic Fibrosis (<i>CFTR</i> gene)
884X12	<i>CFTR</i> gene, assessment of known familial mutation
884X13	<i>CFTR</i> gene, screening assay for multiple common variants (e.g. per ACMG/ACOG guidelines)
884X14	<i>CFTR</i> gene, full gene sequence analysis <i>CFTR</i> gene, assessment for duplication/deletion mutations
884X15	Fragile X syndrome
884X16	<i>FMRI</i> analysis for expansion via Southern blot
884X17	<i>FMRI</i> analysis for methylation sensitivity <i>FMRI</i> analysis, PCR sizing
884X18	<i>BCR/ABL1</i> t(9;22) Translocation assessment, Qualitative ^B
884X19	<i>BCR/ABL1</i> t(9;22) Translocation Major breakpoint analysis
884X20	<i>BCR/ABL1</i> t(9;22) Translocation Minor breakpoint analysis <i>BCR/ABL1</i> t(9;22) Translocation Other breakpoint analysis
884X21	APOE genotype for Cardiovascular Risk
884X22	<i>KRAS</i> Mutation Detection
884X23	PML/RAR alpha, t(15;17) by RT-PCR
884X24	Test for both common translocation breakpoints Test for known translocation breakpoint
884X25	HLA-B27 by PCR
884X26	<i>JAK2</i> Gene, V617F Mutation, Quantitative ^A

^A Presumably 884X7 and 884X26 would be grouped together, possibly with additional CPT codes for testing other sites within *JAK2* or perhaps mutation testing also of other genes which have been less commonly associated with myeloproliferative disorders

^B Presumably 884X8-10 and 884X18-20 would be grouped together reflecting *BCR/ABL1* transcript analysis may be done quantitatively or qualitatively

Application Example:

884X15 Global service, *FMR1* analysis for expansion via Southern blot

OR

884X15-TC Technical component, *FMR1* analysis for expansion via Southern blot884X15-PC Interpretive service, *FMR1* analysis for expansion via Southern blot

Currently this procedure might be coded as follows

83891 x 1 DNA preparation, high purity

83892 x 2 Digestion with EcoR1 and EagI restriction enzymes

83896 x 1 Nucleic acid probe (the probe for FMR1 must be labeled)

83897 x 1 Southern blot analysis

83912 x 1 Interpretation and Report

Alternatives considered, potential problematic areas:

- a. Services which employ combinations of different individual genetic analyses to define a single result or 'signature,' by means of computerized or other algorithms may, if the frequency warrants, require their own individual codes. The wide range and potential proprietary nature of such assays could be problematic.
- b. Specifically naming in the CPT code the disorder being tested, e.g. *KRAS* mutation testing for colorectal carcinoma, *KRAS* mutation testing for lung carcinoma was considered. Such an approach would further strain the availability of CPT codes and would not accommodate the rapid pace at which new applications become available. We felt the clinical application of testing should be apparent to payers from the associated ICD-9 or ICD-10 code(s).

Molecular Pathology Complexity Level codes

These are modeled on the current concept used to define surgical pathology services in category 'levels' (88300 – 88309). The number of levels could range from few to moderate in number. A given level would include multiple named assays and encompass the technical complexity of the assay including reagents, technologist cost and equipment as well as physician work (e.g. neurofibromin gene sequence analysis). Akin to surgical pathology level codes, if a particular procedure is not listed, it would be coded at the appropriate level for work/resources required. Brief hypothetical examples are provided in the Table below. The definition of levels and what services fall in which level could be determined by means of a consensus ballot of a number expert evaluators of both laboratory expenses and professional work, and initial decisions would provide useful guidelines for future classification of services. While this task of defining complexity levels is a daunting task, we feel it is not insurmountable.

CPT Code	Complexity level description
884X100	Level 1 e.g. identification of single nucleotide variant (SNP) by simple technique such as restriction digestion or melt curve analysis. examples: <i>CYP2D6</i> , <i>CYP2C19</i> , <i>CYP2C9</i> , <i>UGT1A1</i>
884X101	Level 2 e.g. small number of SNPs which define a single ‘haplotype’ (e.g. HLA or pharmacogenetic applications)
884X102	Level 3 e.g. multiple SNPs associated with population screening for mutations (such as cystic fibrosis screen for ACMG/ACOG-recommended mutations)
884X103	Level 4, e.g. Analysis of single exon by DNA sequence analysis, such as analysis for a known familial mutation previously identified; KRAS mutation analysis by sequencing.
884X104	Level 5 e.g. analysis of 2-5 exons by DNA sequence analysis, mutation ‘scanning’ of 2-10 exons. VHL mutation analysis by sequencing (see example below)
884X105	Level 6 e.g. Analysis of 5-10 exons by DNA sequence analysis, mutation ‘scanning’ of 10-25 exons
884X106	Level 7 e.g. Analysis of 10-25 exons by DNA sequence analysis, mutation ‘scanning of >25 exons, microarray analysis
884X107	Level 8 e.g. Analysis of >25 exons by DNA sequence analysis, sequence analysis of multiple genes on one platform (resequencing array, neurofibromin gene sequence analysis

Application Example:

884X104 Level 5 global service (in this case VHL gene sequence analysis); note the VHL gene contains 3 exons)

OR

884X104-TC technical component service, DNA sequence analysis (2-5 exons)

884X104-26 interpretive service, DNA sequence analysis (2-5 exons)

Currently VHL gene sequence analysis might be coded as follows:

83891 x 1 DNA purification, high purity
 83898 x 3 PCR amplification of each exon
 83894 x 3 separation (to prepare template for sequencing reaction)
 83904 x 3 mutation identification by sequence analysis
 83912 x 1 interpretation and report

Alternatives considered:

- a. Complexity level codes could accommodate timely incorporation of new and rare analytes and could be expanded to include higher complexity if needed in the future.
- b. Petition could be made to convert assays initially assigned to a complexity level code to a service-specific CPT by providers or payers.
- c. A major limitation of complexity level codes is these do NOT precisely specify the particular analytic target. The specific test(s) performed will not necessarily be apparent to payers or other non lab personnel, perhaps even in conjunction with ICD codes. This concedes that perhaps there can not be a 'transparent' CPT code for every assay.
- d. Defining properties of these codes might be modeled on evaluation and management codes (X of Y specific services provided plus typical work (time and intensity) for professional diagnostic and interpretive activities involved in this type of a procedure).
- e. The idea was entertained to retain existing procedural codes (83890 – 83914) for less commonly performed tests. Since the procedural codes are the nexus of current problems, that does not seem advisable, and the Committee felt new tests could be absorbed by the complexity level codes which would be more understandable to payers than technical codes with multiple units of service.
- f. While not a coding problem per se, varying work over many assay types under one level will require some sort of 'averaging' in valuing such codes. Initial categorization should be by a panel of experts (see above). While certain services will be modestly undervalued and others modestly overvalued within a given level, the overall result will be appropriate reimbursement for procedures within a level as a whole. While this may create mild inequities, it may also encourage the use of most efficient technologies to determine an analytic result.
- g. Miscellaneous codes will likely need to be retained for those services which cannot be well characterized at this time. Individual decisions will need to be made when it is best to use these, or apply to the CPT Panel for more definitive (and presumably more appropriately valued) codes.

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