

Clinical Laboratory Manager Association

May 12, 2006

WPS Response (internal copy)

1. How can an independent lab get reimbursement for a purchased cytogenetic interpretation (88291) when we do the technical components (88230-88285)?

Answer: 88291 has a PC/TC indicator of 2 on the Medicare Physician Fee Schedule Database. This indicator identifies stand-alone codes that describe the physician work portion of selected diagnostic tests for which there is an associated code that describes the technical component of the diagnostic test only and another associated code that describes the global test. Modifiers 26 and TC cannot be used with these codes. The total RVUs for professional component only codes include values for physician work, practice expense, and malpractice expense. If the independent lab is purchasing the test, you can bill for the global procedure and indicate the purchased amount.

2. Is WPS currently involved in any “Pay for Performance” projects? (Example: CMS / Premier Hospital Quality Incentive Demonstration) Do you have any plans to implement or have a demonstration project in the future using “Pay for Performance” measures?

Answer: As part of its overall quality improvement efforts, CMS launched the Physician Voluntary Reporting Program (PVRP) in January 2006. This new program builds on Medicare’s comprehensive efforts to substantially improve the health and function of our beneficiaries by preventing chronic disease complications, avoiding preventable hospitalizations, and improving the quality of care delivered. Under the voluntary reporting program, physicians who choose to participate will help capture data about the quality of care provided to Medicare beneficiaries, in order to identify the most effective ways to use the quality measures in routine practice and to support physicians in their efforts to improve quality of care. Voluntary reporting of quality data through the PVRP began in January 2006. CMS has begun the process of developing a comprehensive set of national consensus measures and indicators that will allow physicians to more efficiently report quality information on the health services provided to Medicare beneficiaries.

You can access more information on PVRP through CMS MLN Matters Article MM5036 at the Website below.

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5036.pdf>

There is also an Oncology Demonstration Project in place for 2006. This project also incorporates the use of self reporting G-codes. You can learn more about this project at the Website below.

3. The reference laboratory that we utilize screens for 32 Cystic Fibrosis mutations by PCR, oligonucleotide ligation assay (OLA), fluorescent hybridization probes, and capillary electrophoresis methods. The referenced CPT codes for this procedure are:

83890 – Molecular diagnostics; molecular isolation

83900 – Molecular diagnostics; amplification of patient nucleic acid, multiplex, first two nucleic acid sequences

83901 x30 – Molecular diagnostics; amplification of patient nucleic acid, multiplex, each additional nucleic acid sequence (use 83901 in conjunction with 83900)

83914 x 32 – Mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay)

83909 – Molecular diagnostics; separation and identification by high resolution technique (eg, capillary electrophoresis)

83912 – Molecular diagnostics; interpretation and report

Are the newly defined codes of 83901 and 83914 able to be quantity billed? Do we need to submit with a quantity modifier? (We are already submitting with the 90 modifier to indicate a purchased test).

Answer: 83901 and 83914 cannot be billed at a quantity greater than 1 on one line. You will have to bill each additional sequence on a separate claim line.

4. The Roche COBAS Amplicor HCV Test, V2.0 has FDA approval for the qualitative detection of Hepatitis C RNA in human serum or plasma from blood collected in EDTA. This same test kit can also provide quantitative HCV results to predict the likelihood of response to treatment, and to monitor treatment response. As this application of the kit falls outside the FDA approval criteria, all quantitative results provided to ordering physicians are labeled ‘Research Use Only’. We have a statement from Roche that we are using the kit as specified by the Roche Molecular Systems Research Use Certification Program for the COBAS Amplicor HCV MONITOR Test v2.0. Validation studies were completed as well as enrollment in proficiency testing. Can we submit claims to Medicare for the quantitative determination of HCV when the patient has active infection and physician orders to monitor treatment response? If initial HCV qualitative test is positive and subsequently the physician orders the quantitative

test for establishing a baseline, may both CPT's (87521 and 87522) be submitted with a 59 modifier to override the NCCI edits?

Answer: The hepatitis C qualitative test (87521) and the hepatitis quantitative test (87522) cannot be performed simultaneously and this would deny due to the CCI mutually exclusive edit. However, if the hepatitis C qualitative test came back positive, then the provider determined a quantitative test was necessary and gave a separate order for it to be done, then it would be appropriate to add the 59 modifier to 87522.

5. HCV Genotyping is being used as an integral part of decision making prior to initiating therapy for HCV infection. Guideline policies are written by various organizations including the American Association for the Study of Liver Diseases' (AASLD), the American Gastroenterological Association, and the Infectious Diseases Society of American specifying preferred approaches to the diagnostic, therapeutic and preventive aspects of care. These recommendations include determining HCV genotyping in all HCV-infected persons prior to treatment in order to determine the duration of therapy and likelihood of response. Test kits are not yet FDA approved, but are available for clinical use. Validation studies have been completed with the Bayer VERSANT HCV Genotype Assay (LiPa) and we are enrolled in proficiency testing. Can we submit claims to Medicare for HCV genotyping when the patient is diagnosed with HCV infection and the physician orders to determine treatment?

Answer currently being researched.

6. General questions regarding lab procedures that have not been approved through the FDA. As I understand the process, if a test has not gone through FDA approval, it may still be reimbursable if:
 1. The procedure uses ASR's (analyte specific reagents) and the performing lab has a high complexity CLIA license and follows all test validation procedures and is enrolled in proficiency testing.
 2. The test does not require FDA approval (some genetic procedures)What about tests that do not fall within these exceptions? If a test is considered research (RUO) or investigational (IUO), is it only reimbursable if a clinical trial exists? Who sets up the clinical trial - the test manufacturer, the performing lab, or the ordering physician? Is there a database for clinical trials? If the test is labeled as 'research' and no clinical trial exists, can it still be submitted for reimbursement if medical necessity can be documented? Must a beneficiary sign an ABN before being billed for a test not approved by FDA?

Answer currently being researched.

7. Flow cytometry testing is occasionally performed on multiple specimens collected from the same patient on the same day. Bone marrow is used for diagnosis of myelodysplasia, aplastic anemia, or acute leukemia, and peripheral blood is used as the specimen of choice for diagnosing Paroxysmal Nocturnal Hemoglobinuria (PNH). Example ICN 2205357371040

For PNH testing, the intensity of expression of the PNH-related antigens needs to be compared to "normal" or reference blood; laboratories do not use bone marrow for this testing due to the difficulty associated with availability of fresh "normal" or reference bone marrow.

The following article reviews the diagnosis of PNH using blood:

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=1751377&itool=iconabstr&query_hl=18&itool=pubmed_DocSum

Since different specimens from the same patient are tested for a variety of symptoms on the same day, which of the following coding approaches is appropriate:

1. Code each specimen separately and use a modifier to indicate unique specimens:
 - Bone Marrow testing: 88184, 88185x15, and 88188
 - Blood testing: 88184, 88185x3, and 88187
 - If this coding is appropriate, what modifier is needed on one set of codes?
2. Combine the markers from both specimens and report one set of codes (i.e. 88184x1, 88185x19, 88189).

Answer: The appropriate CPT code and add on code needs to be billed per the Current Procedural Terminology Manual. Each specimen should be billed separately with the appropriate modifier. If repeat testing is needed on the same day from the same specimen and anatomical site, modifier 91 would be appropriate. Modifier 59 would be used for the different specimen from a different anatomical site.