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*Washington Office*

October 10, 2008

Kerry Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Post Office Box 8013  
7500 Security Boulevard  
Baltimore, MD 21244-8013

Subject:       ASCP Comments on CMS' Initial Determinations of 2009 New Clinical  
Laboratory Fee Schedule Test Codes

Dear Administrator Weems:

On behalf of the American Society for Clinical Pathology (ASCP), I write to urge the Centers for Medicare and Medicaid Services (CMS) to reconsider its initial determinations for several of the new Current Procedural Terminology (CPT) codes being added to the clinical laboratory fee schedule in 2009. While we are concerned with almost all of CMS' initial determinations, our comments focus in the agency's proposed reimbursements for 83876, Myeloperoxidase (MPO); 83951, Oncoprotein; des-gamma-carboxy-prothrombin (DCP); and 85397, coagulation and fibrinolysis, functional activity, not otherwise specified (e.g., ADAMTS-13), each analyte.

The ASCP is a nonprofit medical specialty society representing 130,000 members. Our members are board certified pathologists, other physicians, clinical scientists, certified medical technologists and technicians, and educators. ASCP is one of our nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

To begin, ASCP is concerned that CMS' initial reimbursement determinations appear to ignore the agency's own policy requirements as well as the expert recommendations provided at the July 14<sup>th</sup> public meeting on the new Clinical Laboratory Fee Schedule codes. Moreover, we note that ignoring information provided as part of the public comment process, could undermine the agency's goal of gathering the charge, cost and clinically-detailed information it seeks to determine reimbursement for new clinical laboratory tests in the future.

For new CPT codes 83876, 83951, and 85397, CMS's assertion that reimbursement for these new tests should be crosswalked to the CPT codes initially used for billing purposes is fundamentally flawed. Per CPT coding conventions (See CPT Companion 2000), using a

methodologically-similar or miscellaneous code is required for initial billing when an analyte-specific CPT code is not available. It appears that CMS is assuming that the cost of new laboratory tests and procedures is equivalent to that of less specific CPT codes. In fact, methodologically-similar or generic tests can differ substantially in terms of their input costs, such as resources, reagents, testing platforms, staff time, processing requirements, etc.

Below are ASCP's comments regarding the specific crosswalks on which CMS is seeking input:

### **Myeloperoxidase**

CMS's initial determination that Myeloperoxidase (MPO) should be crosswalked to CPT code 83520 is flawed, contrary to public comments, and does not adequately value the test.

Clinical usefulness: MPO is a quantitative cardiac biochemical marker that is a useful predictor of ischemic heart disease, congestive heart failure, heart cancer, multiple sclerosis, and other conditions. MPO levels in plasma help assess whether a patient is at high risk for heart attack, in need of angioplasty or bypass surgery, or at an increased risk for cardiac death within six months. The New England Journal of Medicine reported that MPO has a 95 percent success rate in predicting cardiac arrest over a 30-day to 6-month period. In contrast, C-reactive protein, the industry standard in cardiac markers, has a 50 percent success rate as a predictor.

CMS states that CPT 83876 is similar in resource costs, testing technique and clinical outcomes identified to CPT code 83520, Immunoassay, quantitative, not otherwise specified, which many laboratories have been using to bill for MPO. CPT code 83520, however, is a generic code that is not affiliated with any particular technology or methodology. It does not describe any particular analyte. Since the crosswalking process requires that new codes be crosswalked to a similar analytic technology with the greatest degree of specificity, a generic code is, by definition, inappropriate. ASCP believes that for reimbursement purposes, the code best meeting this criteria is 83880 Natriuretic peptide.

### **Oncoprotein; des-gamma-carboxy-prothrombin**

CMS's initial determination that Oncoprotein; des-gamma-carboxy-prothrombin (DCP) should be crosswalked to CPT codes 82491 plus 83520 is flawed, contrary to public comments, and does not adequately value the test.

Clinical usefulness: DCP is an independent oncoprotein biomarker for hepatocellular carcinoma and is used for risk assessment, surveillance and detection of liver cancer in patients with chronic liver disease. The test is useful for its diagnostic sensitivity in detecting early stage liver cancer that may be missed by other methods. DCP is also useful for assessing disease progression and prognosis. This test's methodology is chromatography and immunoassay.

In the case of the CPT 83951, Oncoprotein; des-gamma-carboxy-prothrombin (DCP), we were surprised that CMS's initial determination was in sharp contrast to the unanimous recommendation from the laboratory community that this new CPT code be crosswalked to

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83950, Oncoprotein; HER-2/neu. Both codes (immunoassays) represent highly specific tumor markers for the analysis of oncoproteins and are diagnostically important analytes for the detection of cancer. This is not true of the immunoassay CMS used in its crosswalk—83520—which is not sufficiently specific for crosswalking purposes.

**Coagulation and Fibrinolysis, functional activity, not otherwise specified (e.g. ADAMTS-13), each analyte**

CMS's initial determination that Coagulation and Fibrinolysis, functional activity, not otherwise specified (e.g. ADAMTS-13), each analyte, should be crosswalked to CPT codes 85230 is flawed, incompatible with public comments, and does not adequately value the test.

Clinical Utility: This test is used to measure the functional activity of proteases, such as ADAMTS-13 (also known as von Willebrand factor cleaving protease), as well as other proteins participating in coagulation and fibrinolysis not currently specified in CPT. Mutations of the ADAMTS-13 gene (a disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13) reduce the activity of the ADAMTS-13 enzyme and may lead to abnormal clotting. The ADAMTS-13 assay may be used to identify chronic recurring thrombotic thrombocytopenic purpura (TTP), TTP secondary to the presence of ADAMTS-13 inhibitor, and hemolytic-uremic syndrome (HUS). Early diagnosis and prompt initiation of plasma exchange is critical to the clinical outcome in patients diagnosed with TTP.

Because of the level of analytical methodology involved, a crosswalk to CPT code 85246 Clotting Factor, VIII, VW Factor, multimetric antigen is more appropriate than 85230.

ASCP strongly urges CMS to reconsider its initial determinations. Basing reimbursement determinations largely on past billing actions—required by CMS coding conventions-- could adversely effect patient care and the development of new diagnostic technologies.

ASCP appreciates the opportunity to raise these concerns with the agency. If ASCP can be of further assistance, please do not hesitate to contact me or Matthew Schulze, ASCP's Senior Manager for Federal and State Affairs, at (202) 347-4450.

Sincerely,



Lee H. Hilborne, MD, MPH, FASCP,  
President, ASCP

cc: Liz Richter, CMS/CMM  
Glenn McGuirk, CMS