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This information is provided as a service to assist hospitals and other providers of blood products and blood services. Providers are responsible for accurately coding and billing for services rendered as appropriate to their situation and payer-specific requirements. Please contact your blood center with any questions pertaining to this newsletter.

CMS Publishes Proposed Changes to Medicare Hospital Inpatient Prospective Payment System

On April 13, 2007, the Centers for Medicare and Medicaid Services (CMS) published the fiscal year (FY) 2008 Hospital Inpatient Prospective Payment System (IPPS) proposed rule. The proposed rule includes changes to improve the accuracy of Medicare's payment under the IPPS as well as measures to provide additional incentives for hospitals to engage in quality improvement efforts.

CMS is continuing efforts from the FY 2007 IPPS final rule to restructure the inpatient diagnosis related groups (DRGs) to better account for the severity of a patient's condition. If implemented, the FY 2008 proposed rule would create 745 new severity-adjusted DRGs, called Medicare-Severity DRGs or MS-DRGs, to replace the current 538 CMS-DRGs. The new DRG system will be a budget-neutral change to Medicare's IPPS payments and will increase payment for some cases while decreasing payment for others.

Medicare also is continuing with the quality measure reporting started in the FY 2007 IPPS final rule. Part of this effort is the mandatory reporting of hospital-acquired conditions, including infections. Effective October 1, 2007, Section 5001(c) of the Deficit Reduction Act of 2005 (DRA) requires hospitals to begin reporting the secondary diagnoses that are present upon inpatient admission. Beginning October 1, 2008, cases with these conditions would not be assigned to a higher paying DRG unless they were present at admission. CMS worked extensively with the Centers for Disease Control (CDC) to identify six conditions that meet the inclusion criteria set forth in the DRA. The conditions identified for inclusion are catheter-associated urinary tract infections, pressure ulcers, staphylococcus aureus septicemia, objects left in surgery, air embolisms, and blood incompatibility.

CMS also is continuing the transition from charge-based to cost-based relative weights. For FY 2007, CMS used hospital data for 13 separate departments to determine cost-to-charge ratios (CCRs) to apply to charges on the Medicare claims to calculate the new cost weights. The FY 2007 final rule stated the weights would be adopted over a 3-year transition period in 1/3 increments between FY 2007 and FY 2009. Concerns were raised during the comment period about the methodology used to determine the CCRs. Specifically, the commenters expressed concern that the CCRs did not account for charge compression, the practice of applying a higher charge markup on lower cost items and services than on higher cost items and services.

CMS engaged a contractor, RTI International (RTI), to study several issues with respect to the cost weights, including charge compression. RTI's recommendations included the following:

- expanding from 13 to 19 hospital department CCRs to improve payment accuracy;
- disaggregating "Emergency Room" and "Blood and Blood Products" from the "Other Services" cost center;
- establishing regression-based estimates as a temporary or permanent method for disaggregating the Medical Supplies, Drugs, and Radiology cost centers; and
- reclassifying intermediate care charges from the intensive care unit cost center to the routine cost center.

However, CMS was unable to investigate how RTI's recommended changes may interact with other potential changes to the DRGs and to the method of calculating the DRG relative weights. Therefore, CMS is not proposing to adopt RTI's recommendations for FY 2008 but is seeking public comment on the recommendation of expanding from 13 to 19 CCRs.

How do policy analysts view recent Medicare changes? What are the implications of these changes for your products?

Covance's policy experts provide a perspective on new and revised Medicare policies by podcast:
<http://www.covance.com/marketaccess/podcasting.php>

Add-On Payments for IVIG Extended Through FY 2007

Due to problems with inadequate Medicare reimbursement for IVIG, CMS established a temporary \$70 per day payment for "pre-administration related services" in the FY 2006 hospital outpatient prospective payment system final rule and the physician fee schedule final rule. For FY 2007, Medicare will continue to make this temporary separate payment to physicians and hospital outpatient departments.

To receive the add-on payment, providers must bill the HCPCS code G0332 (*Preadministration-related services for intravenous infusion of immunoglobulin*) on the same claim form as the IVIG product and have the same date of service as the IVIG product and a drug administration service.

New HCPCS Codes for IVIG

Effective July 1, 2007, HCPCS code J1567 (*Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), 500 mg*) will no longer be payable by Medicare. In its place, CMS has established the following HCPCS codes:

- Q4087 (*Injection, immune globulin, (Octagam) intravenous, non-lyophilized (e.g. liquid), 500 mg*)
- Q4088 (*Injection, immune globulin, (Gammagard Liquid) intravenous, non-lyophilized (e.g. liquid), 500 mg*)
- Q4091 (*Injection, immune globulin, (Flebogamma) intravenous, non-lyophilized (e.g. liquid), 500 mg*)
- Q4092 (*Injection, immune globulin, (Gamunex) intravenous, non-lyophilized (e.g. liquid), 500 mg*)

CMS Proposes Restricted Coverage of Erythropoiesis Stimulating Agents (ESAs) for Non-Renal Uses

Emerging safety concerns on the use of ESAs have prompted CMS to review coverage of these products. The Food and Drug Administration (FDA) issued several alerts on the safety of ESAs, and on March 9, 2007, the FDA strengthened its warning about cardiovascular and thrombotic events in a variety of populations by requiring a black box warning. The FDA included black box warnings for tumor progression and decreased survival in cancer patients undergoing cancer treatment. They also warned that ESAs are not indicated for anemic cancer patients not undergoing treatment and that mortality is increased when ESAs are used by this population.

On May 14, 2007, CMS posted a proposed decision memorandum (PDM) on the use of ESAs for "non-renal" uses. CMS has stated that due to the preponderance of emerging data for ESA use in the oncology setting, the focus of the national coverage analysis (NCA) will be ESA use in cancer and related conditions. CMS expects to address other non-renal uses in future NCAs; however, in the interim, local Medicare contractors may continue to make reasonable and necessary determinations on all non-cancer and non-neoplastic conditions as well as other non-renal uses of ESAs.

In the PDM, CMS has proposed to deny coverage, based on the availability of sufficient evidence, to conclude that ESA treatment is not reasonable and necessary for certain conditions beneficiaries.

These conditions include:

- any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis,
- the anemia of myelodysplasia,
- the anemia of myeloid cancers,
- the anemia associated with the treatment of myeloid cancers or erythroid cancers,
- the anemia of cancer not related to cancer treatment,
- any anemia associated with radiotherapy,
- prophylactic use to prevent chemotherapy-induced anemia,
- prophylactic use to reduce tumor hypoxia,
- patients with erythropoietin-type resistance due to neutralizing antibodies,
- patients with treatment regimens including anti-angiogenic drugs such as bevacizumab,
- patients with treatment regimens including monoclonal/polyclonal antibodies directed against the epidermal growth factor (EGF) receptor,
- anemia due to cancer treatment if patients have uncontrolled hypertension, and
- patients with thrombotic episodes related to malignancy.

CMS expects the NCA to be completed in August 2007. The complete PDM can be found on CMS's website at: <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=203>