



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – September 27, 2007

CLINICAL PRACTICE COMMITTEE UPDATES: Thomas Gaddis, MD, Chairman

ICD 9 Updates – 10/1/07

Please see the List of ICD 9 Updates effective October 1, 2007, which are being sent to you with this fax blast.

FCSO Draft LCDs

A number of Draft LCDs are now available for comment. Please see the following website for additional information: http://www.floridamedicare.com/Part_B/Local_Medical_Coverage/Draft_LCDs/113096.asp

PROGRAM COMMITTEE: Gerardo Colon-Otero, MD, Chairman

Please plan to attend the November 9-10, 2007, FLASCO Fall Meeting at the Rosen Shingle Creek Hotel near Orlando. We really **need members to attend this meeting** and show the strength of FLASCO to the ASCO President, Dr. Nancy Davidson, who will speak at this meeting.

LEGISLATIVE UPDATES: Lowell Hart, MD, Chairman

US Senate approves drug safety legislation

The US Senate unanimously consented to approve legislation that would strengthen the FDA's safety oversight of prescription drugs. The bill, which [passed in the House](#) on Wednesday, will now go to President George W. Bush for signing.

The legislation would enable the agency to require drugmakers to conduct postmarketing safety studies and add warnings to drug labelling. Among other measures, the bill also calls for an increase in the fees that drugmakers pay to the FDA to speed product reviews. Additionally as part of the legislation, the US regulatory agency will be required to set up a computerised system to scan insurance and pharmacy records for patterns of adverse drug events.

CMS UPDATES:

SE0742 – Revised Payment System for Ambulatory Surgical Centers (ASC) in Calendar Year (CY) 2008

CMS has issued a final rule (available at http://www.cms.hhs.gov/ASCPayment/04_CMS-1517-F.asp#TopOfPage on the CMS website) that describes the revised payment system. Beginning in CY 2008, the revised ASC payment system will provide a transition to the revised rates for currently covered ASC services through three years of transitional payments that are based on a blend of the payment rates from the existing system and the revised payment rates calculated according to the methodology of the revised payment system. CMS also has issued a combined OPPS/ASC proposed rule (available at http://www.cms.hhs.gov/ASCPayment/05_CMS-1392-

Medicare Benefit Policy Manual:

On Sept. 21, 2007, CMS made a significant change to the Medicare Benefit Policy Manual regarding unlabeled use for anti-cancer drugs. Eleven new journals have been added to determine medically accepted indications for drugs and biologicals used in anti-cancer treatment. The journals are:

Annals of Oncology

Biology of Blood and Marrow Transplantation

Bone Marrow Transplantation

Gynecologic Oncology

Clinical Cancer Research

International Journal of Radiation, Oncology Biology and Physics

Journal of NCCN
Radiation Oncology
Annals of Surgical Oncology
Journal of Urology
Lancet Oncology

No journals are being deleted with this update.

In determining whether there is supportive clinical evidence for a particular use of a drug, carrier medical staff (in consultation with local medical specialty groups) will evaluate the quality of the evidence in published peer-reviewed medical literature. Now the carriers have 11 additional publications to use, for a total of 26.

DRUG UPDATES:

Genzyme Corp. and Bayer HealthCare Pharmaceuticals Inc. announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental biologics license application (sBLA) for Campath® (alemtuzumab) and granted regular approval for single-agent Campath for the treatment of B-cell chronic lymphocytic leukemia. Campath was initially approved in 2001 under accelerated approval regulations, and the FDA has determined that the study results submitted in the sBLA fulfill the post-marketing commitment to verify clinical benefit.

MEDLEARN MATTERS:

New:

MM5677 – Magnetic Resonance Imaging (MRI) Procedures

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5677.pdf>

Effective January 1, 2007, separate payment is made for the contrast media used in various imaging procedures. The cost of the contrast media is no longer included in the practice expense (PE) relative values units (RVUs) for the procedures. In addition to the Current Procedural Terminology (CPT) code representing the imaging procedure, the appropriate Healthcare Common Procedure Coding System (HCPCS) “Q” code (Q9945-Q9954; Q9958-Q9964) can be separately billed and paid for the contrast medium utilized in performing the service.

MLN Matters Number: MM5719 – Clinical Trials – Effective Date: October 9, 2007

This article is based on Change Request (CR) 5719, which implements two changes to the 2000 clinical trial policy by: (1) modifying for clarity the language describing coverage of an investigational item/service in the context of a clinical trial, and, (2) adopting coverage with evidence development (CED). The remainder of the 2000 clinical trials policy continues without change.

CR 5719 states that for items and services furnished on and after July 9, 2007, the routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial. The investigational item or service itself is excluded, *unless otherwise covered outside of the clinical trial*.

In addition, the National Coverage Determination (NCD) is revised to add coverage with evidence development (CED). CED is for items and services in clinical research trials for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination. CED is determined through the NCD process, and conditional upon meeting standards of patient safety and clinical evidence, items and services not otherwise covered would be considered “reasonable and necessary” in the context of a clinical trial. Coverage determined under CED is implemented via subsequent NCDs, CRs, and *MLN Matters* articles specific to the coverage issue.

MLN Matters Number: MM5718- October 2007 Update of the Hospital Outpatient Prospective Payment System (OPPS): Summary of Payment Policy Changes - Effective Date October 1, 2007 – Please view complete information at: <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5718.pdf>

New:

SE0743 – Clarification Concerning Provider Billing Procedures Related to the Transition of the Medigap claim-based Crossover Process to the Coordination of Benefits Contractor on October 1, 2007
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0743.pdf>

MM5724 – New Website for Approved Transplant Centers
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5724.pdf>

MM5729 – Unlabeled Use for Anti-Cancer Drugs: Medical Literature used to Determine Medically Accepted Indications for Drugs and Biologicals used in Anti-Cancer Treatment
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5729.pdf>

MM5723 – October 2007 Integrated Outpatient Code Editor (I/OCE) Specifications Version 8.3
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5723.pdf>

MM5730 – Revisions to 9-Digit ZIP Code List Provided in Change Request (CR) 5208
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5730.pdf>

Revised:

MM5452 – Stage 3 National Provider Identifier (NPI) Changes for Transaction 835, and Standard Paper Remittance Advice (RA) - <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5452.pdf>

CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2007)

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FLASCO EVENTS:

November 9-10, 2007 – FLASCO Fall Meeting – Rosen Shingle Creek – Orlando

March 7-8, 2008 – FLASCO Spring Meeting – Tampa Airport Marriott Hotel

November 7-8, 2008 – FLASCO Fall Meeting – Location TBD

OTHER EVENTS:

ACCC's 24th National Oncology Economics Conference – October 3-6, 2007 – Hyatt Regency, Dallas, TX

The Florida Association of Pediatric Tumor Programs will hold its 30th Anniversary Annual Seminar at the Hyatt Regency Grand Cypress in Orlando from November 15-17, 2007. To register please visit the following Web Site: www.faptp.org

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