



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – February 28, 2008

**MESSAGE FROM FLASCO PRESIDENT: Robert Cassell, MD**

FLASCO extends a big thanks to **PFIZER** for becoming a **GOLD** Member and to **IMCLONE** for becoming a **SILVER** Supporter for 2008.

**CLINICAL PRACTICE COMMITTEE: Thomas Gaddis, MD, Chairman**

**Meta-analysis: ESAs raise risk of death in patients with cancer – February 27, 2008**

A meta-analysis of 50 Phase III studies involving ESAs has been published in JAMA, (released February 27). The analysis concludes that patients receiving ESAs had a higher risk of death and venous thromboembolism. Both of these events have been previously reported and are reflected in the recently-revised ESA labeling. Expect the results of this analysis to be widely reported in the press. Articles will first appear in the Wall Street Journal, New York Times, USA Today, and Boston Globe, among other news outlets. This news exposure will likely generate patient inquiries. A link to the article is <http://jama.ama-assn.org/cgi/content/full/299/8/914> . (This is free if you are a member of AMA, otherwise cost is \$15 for a copy) – FLASCO will provide additional information as it is received from other sources.

**Below are several new articles that have been released by FCSO – recommend each be reviewed**

**J0881: Erythropoiesis Stimulating Agents (ESAs) - Revision to the LCD (IMPORTANT!)**

Last Modified: 2/25/2008 - FCSO has revised the epoetin alfa LCD by incorporating content of the darbepoetin alfa (Aranesp®) (novel erythropoiesis stimulating protein [NESP]) LCD into this new ESA LCD. With implementation of the ESA LCD, the Aranesp® LCD will be retired.

**[http://www.floridamedicare.com/Part\\_B/Local Medical Coverage/Local Medical Coverage Articles/121185.asp](http://www.floridamedicare.com/Part_B/Local_Medical_Coverage/Local_Medical_Coverage_Articles/121185.asp)**

**Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions**

Last Modified: 2/21/2008 - ESA treatment for the anemia secondary to a regimen of myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is reasonable and necessary only under specified conditions. [MM5818] **<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5818.pdf>**

**Reporting of Hematocrit or Hemoglobin Levels for the Administration of ESAs**

Last Modified: 2/21/2008 - CMS has revised this article on February 15, 2008, to add clarifying information to bullet points 1 and 3 on pages 3 and 4, respectively. All other information remains the same. [MM5699]

**<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5699.pdf>**

**Amending Medically-Accepted Indications for Off-Label Uses of Drugs/Biologicals**

Last Modified: 2/21/2008 - The 2008 Medicare physician fee schedule contains a new rule for revising the compendia list used to determine medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen. [MM5870] **<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5870.pdf>**

**Billing Laboratory Tests for Dialysis Patients**

Last Modified: 2/22/2008 - Certain end-stage renal disease (ESRD) laboratory tests provided to ESRD beneficiaries are included in the composite rate calculations. Therefore, these tests may not be billed separately to the Medicare program.

**[http://www.floridamedicare.com/Part\\_B/Local Medical Coverage/Local Medical Coverage Articles/120981.asp](http://www.floridamedicare.com/Part_B/Local_Medical_Coverage/Local_Medical_Coverage_Articles/120981.asp)**

**FCSO UPDATES: PART A**

**AIC Requirement for ALJ Hearings and Federal District Court Appeals**

*Last Modified: 2/26/2008* - For request made on or after January 1, 2008, the amount in controversy (AIC) requirement for Administrative Law Judge (ALJ) hearing requests is \$120. For Federal District Court review, the amount remaining in controversy goes to \$1,180. [MM5897] <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5897.pdf>

### **Full Recovery Audit Contractor Inpatient Denials**

*Last Modified: 2/27/2008* - CMS has amended previous instructions regarding inpatient denials identified by a recovery audit contractor to include type of bill 13x for any services provided on the inpatient bill that could be billed as outpatient. [JSM 08168] [http://www.floridamedicare.com/Part\\_A/Specialty/Hospitals/120709.asp](http://www.floridamedicare.com/Part_A/Specialty/Hospitals/120709.asp)

### **CMS MLM UPDATES:**

**New:** MM5946 - January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS) - Manualization <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5946.pdf>

### **FDA UPDATES:**

#### **Avastin: (Genentech)**

On February 22, 2008 it was announced that the U.S. Food and Drug Administration (FDA) granted accelerated approval for Avastin® (bevacizumab), in combination with paclitaxel chemotherapy, for the treatment of patients who have not received chemotherapy for their metastatic HER2-negative breast cancer. The approval is based on a Phase III study (E2100) that showed that Avastin in combination with paclitaxel chemotherapy resulted in a 52 percent reduction in the risk of disease progression or death compared to those treated with paclitaxel alone and a doubling in progression-free survival (PFS) (based on a hazard ratio of 0.48; p<0.0001). The safety profile of Avastin was consistent with our previous experience and no new safety signals were observed

### **MEMBERSHIP:**

FLASCO welcomes the following new 2008 Affiliate members from the Moffitt Cancer Center: Stephanie Andrews, ARNP; Erin Dean, PA; Leonard DeLorenzo, PA; Christine Ellis, ARNP; Richard Guyer, PA; Shawn Hartland, PA; Lorraine Hutson, ARNP; David Johnson, PA; Pamela Labadie, RN; Janell Lowe, PA; Aline Mierzejewski, ARNP; Michelle Mintz, ARNP; Karia Richards, PA; Christopher Salamanca, PA; Laurie Sullivan, ARNP; Susan Tan, ARNP; Sara Tinsley, ARNP; Ione Townsend, ARNP; Tiffany Valone, PA; and Michael Wilson, PA.

In addition, FLASCO welcomes Dr. Steven Fein, Advanced Medical Specialties in Miami, as a new Regular FLASCO member.

### **CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2008)**

FLASCO Members extends a big thanks to all of our 2008 Corporate Members/Sponsors

#### **PLATINUM**

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#### **GOLD**

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Genomic Health  
Novartis  
Pfizer

#### **SILVER**

MGI Pharma  
US Oncology Physician Services  
ImClone

#### **BRONZE**

Boehringer Ingelheim  
Pharmaceuticals, Inc.  
Alexion

### **FLASCO EVENTS:**

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

**November 7-8, 2008** – FLASCO Fall Meeting – Tampa Airport Marriott Hotel

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