



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – February 22, 2007

FLASCO 2007 ANNUAL MEETING AND SPRING SESSION:

The 2007 FLASCO Annual Meeting and Spring Session will be held on March 2-3, 2007, at the Tampa Airport Marriott Hotel. This is an outstanding meeting – Dr. Joe Bailes from ASCO will provide a Legislative Update and ASCO President, **Dr. Gabriel Hortobagyi** will speak at the Saturday session. **PLEASE MAKE EVERY EFFORT TO ATTEND THIS MEETING AND MEET AND HEAR THE ASCO PRESIDENT!**

CLINICAL PRACTICE COMMITTEE UPDATES: Gerald Robbins, MD

FCSO (Florida Medicare)

Healthcare Provider Taxonomy Code Update Effective April 1, 2007

Effective April 1 2007, the Healthcare Provider Taxonomy Codes (HPTC) will be updated. The HPTC is a national code set that allows medical providers to indicate their specialty. The latest version of the HPTC is available from the Washington Publishing Company website at: www.wpcedi.com/codes/taxonomy. If a HPTC is reported to Medicare, it should be a valid code or a batch and/or claim level rejection may occur.

To ensure you do not receive a claim or file level rejection, it is recommended that you verify the HPTC submitted is a valid code on the most recent HPTC listing. If you require assistance in updating the taxonomy code in your practice management system please contact your software support vendor.

CMS UPDATES:

2007 Physician Quality Reporting Initiative (PQRI) webpage is now available.

PQRI establishes a financial incentive for eligible professionals to participate in a voluntary quality reporting program. Eligible professionals who successfully report a designated set of quality measures on claims for dates of service from July 1 to December 31, 2007, may earn a bonus payment, subject to a cap, of 1.5% of total allowed charges for covered Medicare physician fee schedule services.

This newly established webpage will be updated regularly, so check it often for timely and reliable information from CMS. For more information on 2007 PQRI, visit

http://www.cms.hhs.gov/PQRI/01_Overview.asp#TopOfPage on the CMS website.

BLUE CROSS/BLUE SHIELD UPDATE:

Two new documents have been added to the Tips section of the Blue Cross/Blue Shield Physicians & Providers

USP DI DRUG UPDATES:

FDA UPDATES:

MLN MATTERS:

ASCO UPDATE:

In collaboration with the Food and Drug Administration (FDA), and as a service to members, ASCO will provide updates on recent FDA approvals and other important FDA actions (e.g., updated safety information, new prescribing information) pertaining to therapies for cancer patients. This will allow the agency to inform oncologists and professionals in oncology-related fields in a timely manner. Included in the email from the FDA will be a link to the product label or to other sites for additional relevant clinical information. The following is a message from the FDA's Office of Oncology Drug Products Director, Dr. Richard Pazdur:

FDA was recently notified of the results of a 989 patient, multicenter, double-blind, randomized, placebo-controlled study of Aranesp® (darbepoetin alfa, Amgen, Thousand Oaks, CA) in anemic cancer patients not receiving concurrent cytotoxic therapy. The study results demonstrated an increased mortality in patients receiving Aranesp® compared to those receiving placebo (hazard ratio 1.25; 95% confidence interval: 1.04, 1.51). In addition, Aranesp® did not reduce red blood cell transfusion requirements in these patients. The target hemoglobin in the Aranesp® treatment group was 12 g/dl. The findings in this study may be applicable to other erythropoiesis-stimulating agents (ESA). Additional information on this study is in Amgen's letter posted on FDA's MedWatch website at <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Aranesp>.

FDA also directs prescriber's attention to the interim results of the Danish Head and Neck Cancer Study Group trial (DAHANCA 10) comparing radiation therapy alone to radiation therapy plus Aranesp® in the treatment of advanced head and neck cancer. The data monitoring committee (DMC) recommended the trial's termination. This open-label, randomized trial was designed to test the hypothesis that use of Aranesp® to maintain a hemoglobin of 14.0-15.5 g/dL during radiotherapy would result in superior loco-regional disease control. The DMC reported an approximate 10% difference in 3-year loco-regional control (p=0.01) in favor of the control group. A statistically non-significant difference in overall survival (p=0.08) also favoring the control arm was observed. These results are consistent with findings by Henke et al that are described in the approved product labeling (under Precautions, Tumor Growth Factor Potential) and were presented at a May 4, 2004 Oncologic Drugs Advisory Committee (ODAC) meeting (transcript available at <http://www.fda.gov/ohrms/dockets/ac/cder04.html#Oncologic>). Additional information on the DAHANCA 10 study is available at <http://conman.au.dk/dahanca/>.

FDA has previously noted that increased mortality, possible tumor promotion and thromboembolic events have been observed in patients receiving ESAs when dosing has targeted hemoglobin levels >12 gm/dL. The recommended labeled target hemoglobin in current product labeling is 12 gm/dl. Please refer to the above 2004 ODAC transcript for further discussion.

FDA is planning to review and discuss the safety and efficacy of ESAs at an upcoming meeting of the ODAC.

Aranesp® was approved in July, 2002 for the treatment of anemia in patients with non-myeloid malignancies where anemia is attributed to the effects of concomitantly administered chemotherapy. Full prescribing information for Aranesp®, including clinical trial information, safety, dosing, drug-drug interactions, and contraindications is available at: <http://www.fda.gov/cder/foi/label/2006/103951s5097lbl.pdf> . A revised FDA Healthcare Professional Sheet regarding evolving safety issues with ESAs is posted at <http://www.fda.gov/cder/drug/infopage/RHE/default.htm>.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at <http://www.fda.gov/medwatch/report.htm>, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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

FLASCO Members extend a big thanks to the following companies who are 2007 Corporate Members/Sponsors:

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Oncology Supply/ION OSI Pharmaceuticals Millennium
Sanofi-Aventis GlaxoSmithKline
Bristol-Myers Squibb Roche
Eli Lilly

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EVENTS:

March 2-3, 2007 – FLASCO Spring & Annual Meeting – Tampa Airport Marriott Hotel

March 16-18, 2007 – Fourth Annual Winter Lung Cancer Conference – The Eden Roc Renaissance Resort & Spa, Miami Beach, FL

Sept. 13-16, 2007 – Joint Cancer Conference – The Breakers, Palm Beach

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

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