



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – March 19, 2008

MESSAGE FROM FLASCO PRESIDENT: Robert Cassell, MD

FLASCO extends a special thanks to the following companies for becoming Corporate Members/Supporters for 2008: **Roche (Gold); Imclone Systems, Inc. (Silver), Millennium Pharmaceuticals (Silver) and OSI Pharmaceuticals (Silver).**

CLINICAL PRACTICE COMMITTEE: Thomas Gaddis, MD, Chairman

ESA – ODAC

The Oncologic Drugs Advisory Committee to the FDA met last week to discuss the use of erythropoiesis stimulating agents (ESAs). The Committee addressed many different aspects of ESA use, including new studies that have been released since its last meeting in May of 2007. Below is a summary of the Committee's key recommendations. ASCO has also prepared a more in-depth summary including an outline of each question the Committee addressed. In summary, the ODAC recommended:

- Allowing ESAs to continue to be marketed for the chemotherapy-induced anemia (CIA) indication.
- Not to restrict use only to patients with small cell lung cancer.
- To modify the current indication to include a statement that ESA use is *not indicated* for patients receiving *potentially curative* treatments.
- To modify the current indication to include a statement that ESA use is *not indicated* for patients with *metastatic breast and/or head and neck cancers*.[\[1\]](#)
- That the FDA require the implementation of a signed informed consent/patient agreement for the treatment of CIA, but voted against the FDA mandating a restricted distribution system for oncology patients receiving ESAs.

A representative for ASCO and the American Society of Hematology (ASH) described the recent changes to the ASCO/ASH ESA guideline, and described plans for further updates focusing on providing tools for enhanced physician-patient communication regarding use of ESAs.

ODAC is an advisory committee to the FDA. We do not yet know which of these recommendations FDA will accept or when and how they will be implemented. ASCO will keep you apprised of additional developments.

BCBS of FL has changed its policy on ESAs to mirror the Medicare LCD, as below:

Anemia related to concomitant chemotherapy or previous chemotherapy within the past 12 months for non-myeloid malignancies

- The hemoglobin level immediately prior to initiation or maintenance of ESA treatment is <10 g/dL (or the hematocrit is <30%).
- The starting dose for ESA treatment is the recommended FDA label starting dose, no more than 150 U/kg/3 times weekly for epoetin and 2.25 mcg/kg/1 time weekly for darbepoetin alpha. Equivalent doses may be given over other approved time periods.
- Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10 g/dL (or hematocrit is <30%) 4 weeks after initiation of therapy and the rise in hemoglobin is >1g/dL (hematocrit >3%).
- For patients whose hemoglobin rises <1 g/dl (hematocrit rise <3%) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains <10 g/dL after the 4 weeks of treatment (or the hematocrit is <30%), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the hemoglobin rises <1 g/dl (hematocrit rise <3 %) compared to pretreatment baseline by 8 weeks of treatment.

- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in hemoglobin >1 g/dl (hematocrit >3%) over 2 weeks of treatment unless the hemoglobin remains below or subsequently falls to <10 g/dL (or the hematocrit is <30%). Continuation and reinstatement of ESA therapy must include a dose reduction of 25% from the previously administered dose.
- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

To read the policy, go to <http://www.bcbsfl.com> . Click on Physicians & Providers, then Medical Information. Select Medical Coverage Guidelines. Go down the page to the link Medical Coverage Guidelines. Choose Pharmacy in the Left column, then select Erythropoiesis Stimulating Agents from the drop down list

Blue Distinctin Centers for complex and Rare Cancers Program:

This week, the Blue Cross/Blue Shield Association (BCBSA) and many of its member plans announced the new Blue Distinction Centers for Complex and Rare Cancers program. This program designates approximately 80 facilities around the country as centers of excellence for “multidisciplinary treatment planning and complex, major surgical treatments” for 13 categories of malignancies. All FLASCO Members were faxed additional information on this Program earlier this week – If you desire additional information – please contact the FLASCO Executive Director.

FLASCO CLINICAL TRIALS NETWORK UPDATE:

Bayer/Onyx NSCLC Trial

On February 18, 2008, Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc announced that a Phase III trial evaluating sorafenib in patients with non-small cell lung cancer was stopped early following a planned interim analysis, when the independent Data Monitoring Committee concluded that the study would not meet its primary endpoint of improved overall survival. The Phase III ESCAPE trial evaluated sorafenib when administered in combination with carboplatin and paclitaxel in patients with NSCLC. Safety events were generally consistent with those previously reported. However, higher mortality was observed in the subset of patients with squamous cell carcinoma of the lung treated with sorafenib and carboplatin and paclitaxel versus those treated with carboplatin and paclitaxel alone.

After reviewing the results of the ESCAPE trial, Bayer/Onyx made the decision to suspend their sorafenib lung cancer program. This means that the first trial to be conducted by the FLASCO Cancer Trials Network (FCTN), “Randomized Phase II Trial of Chemotherapy (docetaxel) with or without Sorafenib in Elderly Patients with Advanced NSCLS”, will no longer be done.

This trial represented nearly 2 years of work by many people in FLASCO, and we are disappointed that it will not go forward. However, we understand the decision made by Bayer and Onyx. At this time, FLASCO is exploring opportunities for network trials with other pharmaceutical companies, as well as NCI-sponsored initiatives. We will keep you informed of our progress.

FCSO UPDATES:

Medicare B Update – Volume 6-Number 3 – March 2008

This Volume is now available at: http://www.floridamedicare.com/Part_B/Medicare_B_Update/Archive/122085.pdf

E&M service 99211

FYI: PLEASE BE SURE TO READ PAGE 46 OF THE MARCH MEDICARE UPDATE CONCERNING BILLING FOR 99211.

According to FCSO, there continues to be an issue with billing of 99211 specifically with PT Lab (85610). There are specific requirements when billing 99211, drawing blood and documenting results, along with recording level of medication to take does not necessarily meet the requirements of 99211.

Taken From The Update:" In cases where CPT code 99211 is billed in conjunction with CPT code 85610, it is not sufficient to simply document activities related to drawing a blood sample, recording the results, and, in some cases, changing the medication dosage.

When billing a 99211 E/M code, the presenting problem(s) is usually minimal, and, typically, five minutes is spent providing the service. Please note that there must be a presenting problem documented, and the documentation must demonstrate the reason for an E/M service on that particular date of service. The documentation must contain evidence of a

face-to-face encounter for the purpose of evaluating the patient". The presenting problem must be in addition to the encounter for PT draw. **Incidentally, 99211 must meet the "incident to" requirements. In other words, a physician is required to be on premises.**

Remittance Advice Remark Code and Claim Adjustment Reason Code Update

Last Modified: 3/11/2008 - This change reflects the latest update of Remittance Advice Remark Codes and Claim Adjustment Reason Codes, effective April 1, 2008. Both code lists are updated three times a year. [MM5942] - <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5942.pdf>

Payment for Inpatient Hospital Visits - General (Codes 99221 – 99239)

Last Modified: 3/11/2008 - When a hospital inpatient evaluation and management service (E/M) is furnished on a date the patient does not require critical care and the patient subsequently requires critical care, both the services may be paid. [MM5792] - <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5792.pdf>

Claim Status Category Code and Claim Status Code Update

Last Modified: 3/7/2008 - These updates are effective April 1, 2008, and are to be used in editing of all X12 276 transactions processed by Medicare contractors on or after April 7, 2008. [MM5947] <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5947.pdf>

PART B: Overpayment Refund Form

Last Modified: 3/6/2008 - Provider must select options. If none are checked, an overpayment letter will be issued. Mail the form to the appropriate address included at the bottom of the form. http://www.floridamedicare.com/Part_B/Forms/105650.pdf

Final/Active LCD List sorted by "FCSO LCD Number"

Last Modified: 3/11/2008 - This document is maintained on our Web site. The LCDs referenced are maintained on the CMS Web site - <http://www.floridamedicare.com/Home/license.asp>

IDE Coding and Cost Form

Last Modified: 3/5/2008 - The IDE Coding and Cost Form is required when submitting a request for an IDE or an IDE Extension. - http://www.floridamedicare.com/Part_B/Local_Medical_Coverage/Clinical_Trials/122080.asp

IDE Extension Request

Last Modified: 3/5/2008 - Medicare may provide extended coverage and reimbursement for certain investigational devices and services related to the use of those devices. Coverage is contingent upon meeting regulatory criteria and Florida medical director's approval. http://www.floridamedicare.com/Part_B/Local_Medical_Coverage/Clinical_Trials/122073.asp

Clarification on Billing for the Oral Three Drug Combination Anti-Emetic – Part A

Last Modified: 3/7/2008 - This article clarifies that hospital outpatient departments may bill the entire Tri-Pack of oral anti-emetic drugs to their FI or A/B MAC as part of a cancer chemotherapeutic regimen that includes the anti-emetic three drug combination. [MM5655] - <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5655.pdf>

Changes to the Long Term Care Hospital Prospective Payment System PRICER – Part A

Last Modified: 3/11/2008 - Effective for discharges occurring on or after April 1, 2008, through June 30, 2008, the federal rate for rate year 2008 will be \$38,086.04, and the revised high cost outlier fixed-loss amount is \$20,707. [MM5955] <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5955.pdf>

CMS UPDATES:

The Centers for Medicare & Medicaid Services (CMS) has made available the Medicare Part B Drug and Biological Average Sales Price (ASP) Payment Amounts for April 1, 2008 to June 30, 2008 on the CMS website at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2007aspfiles.asp - The files are located in the "Downloads" section of this web page.

ACADEMIC CENTERS/INSTITUTIONS NEWS & UPDATES:

Moffitt Cancer Center Hematology Active Clinical Trials

The Moffitt Cancer Center has provided FLASCO with a list of Active Hematology Clinical Trials currently being conducted at Moffitt. If you are interested in participating and would like to have a list of the Malignant Hematology Clinical Trials, please contact the FLASCO Executive Director.

EDUCATIONAL OPPORTUNITIES:

US Oncology CME/CE Accredited Webcast - Infection in Cancer Patients: Prevention and Management in the Community Care Setting Webcast Series - Join Oncology Today and the University of Texas Medical Branch at Galveston for a CME/CE webcast series offering expert presentations, case reviews and interactive question and answer sessions highlighting what you need to know to prevent and manage infections in cancer patients. To register please visit: <http://www.oncologytoday.com/programs/upcomingeventsreg.aspx>

New Directions in Quality Audio Conference

Thursday, April 10, 2008, 1:00 PM (EDT) - This educational series brought to you by Novartis Pharmaceuticals Corporation is a 45- minute session – the first in a series – it will address how employers are exploring alternative models of benefit design that promote shared decision making and gain more value from dollars spent on employee health benefits. The presentation will focus on trends in consumer-directed healthcare, disease management, prevention and wellness and value-based insurance design. **To register:** Copy and past the following into your browser: http://panastream.com/New_Directions_in_Quality/Registration.php

Onyx Pharmaceuticals To Present At Cowen And Company Health Care Conference

Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) announced that it will present at the Cowen and Company 28th Annual Health Care Conference on Tuesday, March 18, at 8:00 a.m. Eastern Time. Interested parties may access a live webcast of the presentation at: http://www.corporate-ir.net/ireye/conflobby.zhtml?ticker=ONXX&item_id=1779883. For those unable to participate during the live webcast, a recorded replay of the presentation will be available within 24 hours of the completion of the presentation through April 18, 2008.

DISCLAIMER: FLASCO has not reviewed these programs and “any views presented are not the views of FLASCO”

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

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

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FLASCO EVENTS:

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

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