



## FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – November 14, 2007

### FLASCO PRESIDENT REPORT: Robert Cassell, MD

This past weekend the FLASCO Executive Committee, Board Meeting and Fall Session were held at the Rosen Shingle Creek Resort near Orlando. A very special thanks is extended to Dr. Gerardo Colon-Otero, our Program Committee Chairman and his committee for the outstanding General Session. In addition, on behalf of FLASCO a big thanks is extended to all of the companies who supported and/or exhibited at this meeting. A complete report of the meeting is included with this fax blast.

### CLINICAL PRACTICE COMMITTEE UPDATES: Thomas Gaddis, MD, Chm.

#### ESA Update:

FDA has approved revised boxed warnings and other safety-related labeling changes for erythropoiesis-stimulating agents, which are used to treat certain types of anemia. The new statements address the risks that the drugs Aranesp, Epopgen, and Procrit pose to patients with cancer or with chronic kidney failure.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01740.html>

For patients with cancer, the new boxed warnings emphasize that ESAs caused tumor growth and shortened survival in patients with advanced breast, head and neck, lymphoid and non-small cell lung cancer when they received a dose that attempted to achieve a hemoglobin level of 12 grams per deciliter (g/dL) or greater. The boxed warnings also emphasize that no clinical data are available to determine whether there is a similar risk of shortened survival or increased tumor growth for patients with cancer who receive an ESA dose that attempts to achieve a hemoglobin level of less than 12 g/dL.

While we are thankful that the FDA has released this information for ESA labeling. However, major differences remain between the new FDA label and the CMS National Coverage Determination (NCD) on ESAs, and ASCO, ASH & ACCC remains concerned over these differences. As previously mentioned, we are all concerned that the CMS NCD will increase the number of blood transfusions for patients, causing a strain on hospitals and the nation's blood supply.

#### IVIG Payments Continue:

You can continue to bill G0332 (preadministered IV immune globulin, \$74.66 in 2007) for each day a patient receives an intravenous immune globulin (IVIG) infusion in your office. The code is billed in addition to the administration code and the relevant J-codes, which are J1566 (immune globulin, powder, \$51.44) or J1567 (immune globulin, liquid, \$61.14)

**Remember:** you can only bill G0332 once per day per patient, regardless of the number of IVIG infusions the patient receives.

### FCSO UPDATES:

#### Medicare Part A & B:

**Modifier GZ** must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny an item or service as not reasonable and necessary and they have not had an advance beneficiary notification (ABN) signed by the beneficiary.

**Modifier GA** must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny a service as not reasonable and necessary and they do have on file an ABN signed by the beneficiary.

All claims not meeting medical necessity of a local coverage determination must append the billed service with **modifier GA or GZ**. For more information concerning advance beneficiary notices, refer to [http://www.cms.hhs.gov/BNI/01\\_overview.asp](http://www.cms.hhs.gov/BNI/01_overview.asp)

## DRUG & INDUSTRY UPDATES

### **Tasigna® (nilotinib)**

The United States Food and Drug Administration (FDA) has approved the targeted agent Tasigna® (nilotinib) for the treatment of chronic and accelerated-phase chronic myeloid leukemia (CML) for patients who are not able to tolerate or who have stopped responding to Gleevec® (imatinib).

### **Dasatinib - (SPRYCEL, Bristol-Myers Squibb)**

On November 8, 2007, the U. S. Food and Drug Administration (FDA) granted accelerated approval of a new dosing regimen of dasatinib (SPRYCEL, Bristol-Myers Squibb) for the treatment of adults with chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy, including imatinib mesylate. The new dosing regimen is 100 mg taken orally once daily.

Submission of further follow-up data from ongoing studies will convert this accelerated approval to regular approval. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at [\\_www.fda.gov/cder/foi/label/2007/021986s0011bl.pdf\\_](http://www.fda.gov/cder/foi/label/2007/021986s0011bl.pdf).

### **Velcade - Millennium**

The FDA recently approved Millennium's supplemental new drug application, supporting the use of VELCADE® (bortezomib) for Injection in patients with renal insufficiency, including those on dialysis.

The VELCADE full Prescribing Information (PI) has been updated to reflect this important change. The new information can be found in the "Use in Special Populations" section of the new PI, as follows:

#### **8.6 Patients with Renal Impairment**

The pharmacokinetics of VELCADE are not influenced by the degree of renal impairment. Therefore, dosing adjustments are not necessary for patients with renal insufficiency. Since dialysis may reduce VELCADE concentrations, the drug should be administered after the dialysis procedure.

## ASCO UPDATES:

### **Adjuvant therapy for patients with non-small cell lung cancer (NSCLC)**

New guidelines on the use of adjuvant therapy for patients with non-small cell lung cancer (NSCLC) recommend the use of cisplatin-based chemotherapy in patients with tumors that have been successfully removed via surgery. The guidelines advise against the use of postoperative radiotherapy in stage I and stage II patients because its use has decreased survival compared to surgery alone.

The guidelines were developed by expert panels convened by the American Society of Clinical Oncology (ASCO) and Cancer Care Ontario. The guidelines recommend the use of adjuvant chemotherapy in patients with stages IIA, IIB, or IIIA NSCLC in which the tumors have been completely resected. In most of these cases, disease has spread to nearby lymph nodes. [A special report on these new guidelines appears in the November 7 NCI Cancer Bulletin.](#)

### **New Clinical Practice Guideline Details Measures for Anticoagulant Use**

A new ASCO Clinical Practice Guideline, "Recommendations for Venous Thromboembolism Prophylaxis and Treatment in Patients with Cancer," is now available, along with clinical tools and resources to help practicing oncologists and their colleagues implement the evidence-based recommendation in clinical settings.

An expert panel conducted a comprehensive and systematic review of medical literature (available through December 2006) about the prevention and treatment of venous thromboembolism (VTE). VTE, a leading cause of mortality and morbidity among people with cancer, affects 4% to 20% of patients, and the incidence appears to be increasing.

The panel made the following recommendations:

- Hospitalized patients with cancer should be considered candidates for vte prophylaxis in the absence of bleeding or other contraindications to anticoagulation.
- Ambulatory patients with cancer receiving thalidomide or lenalidomide with chemotherapy or dexamethasone warrant prophylaxis, specifically low molecular weight heparin (lmwh) or adjusted dose warfarin; otherwise, routine prophylaxis with an antithrombotic agent is not recommended.
- Patients with cancer undergoing surgery should receive (in the absence of bleeding or other contraindications to anticoagulation) prophylaxis with low-dose unfractionated heparin (ufh) or lmwh, or with mechanical methods for patients with contraindications to pharmacologic intervention.
- Patients with cancer with established vte should receive pharmacologic treatment for at least six months, with continued anticoagulation therapy considered beyond six months in those with active cancer.
- Neither medical prophylaxis nor treatment is recommended as a means of improving survival in patients with cancer without established vte.

The panel noted that special consideration should be given to women with gynecologic malignancies; elderly patients or patients with central nervous system malignancies; patients undergoing major abdominal or pelvic surgery for cancer who are at high risk of VTE, such as those with residual malignant disease; obese patients; patients with a history of VTE; and ambulatory patients with multiple myeloma who are receiving thalidomide or lenalidomide with chemotherapy or dexamethasone.

The guideline also includes a dosage guide for the various recommended anticoagulant regimens and a list of contraindications to anticoagulant therapy.

ASCO has developed several clinical tools to supplement the guideline, including an Executive Summary, summaries in PDF and PowerPoint formats, prophylaxis/recurrence algorithms, and a VTE Prophylaxis Orders and Flow Sheet. A Patient Guide is available on the People Living With Cancer website.

### CMS UPDATES:

The Centers for Medicare & Medicaid Services (CMS) has updated the following web-based (WBT) training course: ***Medicare Preventive Services Series: Part 2 Women's Health***. This WBT course provides information to help fee-for-services providers understand Medicare's coverage and billing guidelines for mammography services, pap tests, pelvic exams, colorectal cancer screenings, and bone mass measurements. CMS has been reviewed and approved as an Authorized provider by the International Association for Continuing Education and Training (IACET), (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. Participants who successfully complete this course may receive .2 IACET CEU. To register, free of charge for this course, please visit, [http://cms.meridianksi.com/kc/main/kc\\_frame.asp?kc\\_ident=kc0001&loc=5](http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5) on the CMS Website.

### **Hemoglobin Data Required for ESA Reimbursement - The Pink Sheet Daily. 2007 Nov 5**

The final PFS rule update requires providers to submit the most recent hemoglobin/hematocrit levels of all patients receiving erythropoiesis-stimulating agents. CMS is required by the Medicare Improvement and Extension Act of 2006 to enact regulations by Jan. 1, 2008, requiring that each request for payment of an ESA used in cancer patients be accompanied with hemoglobin/hematocrit data. The act does not address other indications, such as the treatment of HIV-AIDS and some surgical procedures, but CMS decided to expand the reporting requirements for all reimbursements for ESAs. The agency already collects this information for reimbursement of ESAs in the end-stage renal disease setting. CMS says it will use the change request process to issue implementing instructions to Medicare contractors.

### **2008 HOPPS**

With the release of the 2008 HOPPS final rule, hospitals face a decrease in drug payments to ASP+5 percent in 2008.

## QUESTION OF THE WEEK

Does anyone use a template for ESAs that assures the CMS criteria are met before the drug is given? If so, and you are willing to share it with other FLASCO members, please e-mail a copy to the FLASCO Executive Director and let her know if it is for a hospital based practice, community oncology practice or hospital. All examples will be shared with the membership.

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

FLASCO Members extends a big thanks to all of our 2007 Corporate Members/Sponsors

### PLATINUM

Astra Zeneca  
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### SILVER

Genomic Health, Inc.  
Talecris Biotherapeutics  
Millennium  
Celgene  
Novartis

### BRONZE

Oncology Pharmaceutical Services

### FLASCO EVENTS:

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

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

### OTHER EVENTS:

The Florida Association of Pediatric Tumor Programs will hold its 30<sup>th</sup> 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.fapt.org](http://www.fapt.org)

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