



**FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST –August 12, 2009**

**FLASCO WEBSITE: [www.flasco.org](http://www.flasco.org)**

**FLASCO CLINICAL TRIALS NETWORK WEBSITE: [www.fctn.org](http://www.fctn.org)**

**MESSAGE FROM THE PRESIDENT: Gerald Robbins, MD**

FLASCO would like to welcome the following new members:

<b>Carlos Castillo, MD</b>	<b>21<sup>st</sup> Century Oncology of Jacksonville</b>	<b>Regular Membership</b>
<b>Troy Guthrie, Jr., MD</b>	<b>21<sup>st</sup> Century Oncology of Jacksonville</b>	<b>Regular Membership</b>
<b>Zhen Hou, MD</b>	<b>21<sup>st</sup> Century Oncology of Jacksonville</b>	<b>Regular Membership</b>
<b>Robert Joyce, MD</b>	<b>21<sup>st</sup> Century Oncology of Jacksonville</b>	<b>Regular Membership</b>
<b>Joseph Mignone, MD</b>	<b>21<sup>st</sup> Century Oncology of Jacksonville</b>	<b>Regular Membership</b>
<b>Lynn Kuykendall</b>	<b>Palm Beach Institute of Hematology &amp; Oncology</b>	<b>Affiliate Membership</b>

We look forward to your involvement and contribution to our state society.

**CLINICAL PRACTICE COMMITTEE UPDATES (Thomas Gaddis, MD, Chairman):**

**ESA Clarification on Billing (Source: FCSO)**

Recently, FCSO acknowledged a "system error" causing incorrect denial of claims billed for administration of an ESA for CKD with the EC modifier, the correct dual diagnosis indicators (285.21 and either 585.1, 585.2, 585.3, 585.4, 585.5 or 585.9) along with any cancer diagnosis on the claim. The system did not have the ability to read only the detail line for J0885 or J0881 BUT, looked at the entire claims coding.

If you billed an EC modifier and there was a cancer diagnosis anywhere on the claim (including the header line), it would deny. When proceeding thru the appeals process the denial was upheld citing the NCD policy and hgb/hct limits for anemia due to chemotherapy.

You may treat patients having both a cancer diagnosis as well as an underlying diagnosis of CKD requiring treatment with an ESA, but you need to make certain that the coding is to the highest level of specificity for each detail line billed.

If you bill using the EC modifier and there is a cancer diagnosis **ON THIS DETAIL LINE WITH THE EC MODIFIER IT WILL BE DENIED**. Make certain that each service billed has the appropriate diagnosis (reason) for the test, visit etc.

FCSO is currently in the process of issuing checks for the incorrectly denied claims. **EVEN IF** you had begun the appeals process, (even thru the Q2 Administrator) **AND**, the denials were upheld.....If the claims were due to this system error, **YOU WILL RECEIVE PAYMENT FOR THESE**.and it will not be necessary to proceed any further with appeals.

**COA UPDATES:**

The Community Oncology Alliance (COA) is providing input on two topics that community oncology practices should be aware of in terms of their impact on practice operations.

**First**, the RAC audits have officially arrived. Connolly Healthcare, the contractor for Region C,(Florida, etc) has announced the initial set of issues that are eligible for RAC review. South Carolina is approved as the first target state within the region, with outpatient hospitals and physicians' practices eligible for audits. In terms of oncology-specific issues, they are blood transfusions, IV hydration therapy, and pegfilgrastim injections. Go to the Connolly website at [www.connollyhealthcare.com](http://www.connollyhealthcare.com) for more information. Connolly is our Florida RAC - it is recommend that you look at the issues and be prepared for possible action.

COA will be adding an interactive section to the *COA Administrators' Network* website that will allow practices to share appropriate information about RAC requests, audits, etc. Stay tuned.

**Second**, the Office of the Inspector General (OIG) has just issued a report on services performed by non-physicians under the “incident to” rule. Basically, OIG is recommending that the Centers for Medicare & Medicaid Services (CMS) make revisions to the “incident to” rule. Given that the report specifically cites a high use of non-physicians in the administration of chemotherapy, it is highly recommend that practices read the report. It is important to review the qualifications of non-physicians and the “incident to” rule.

COA will be monitoring this development. A copy of the OIG report is on the COA website at [www.communityoncology.org](http://www.communityoncology.org) under *Immediate Action Needed*.

## **DRUG AND INDUSTRY UPDATES:**

### **Avastin®**

The U.S. Food and Drug Administration (FDA) has approved **Avastin® (bevacizumab) plus interferon alfa** for people with metastatic renal cell carcinoma, the most common type of kidney cancer. The approval is based on data from a Phase III study that showed that patients who received the Avastin combo lived nearly twice as long without their disease getting worse compared to those on interferon alfa alone – 10.2 months versus 5.4 months. Patients in the bevacizumab group experienced a 30 percent decrease in tumor size compared with 12 percent in patients assigned interferon-alfa alone.

### **Erbitux® and Vectibix®**

New label information on the cancer treatment Erbitux will state there is no evidence the drug works on a minority of colon cancer patients with a specific genetic mutation. Eli Lilly & Co. and Bristol-Myers Squibb Company announced that the addition to the drug's label will state that studies have not shown that **Erbitux®** helps patients whose tumors have a mutated gene, or biomarker, called K-Ras. Amgen Inc. announced a similar label change for its cancer drug **Vectibix®**. Both Erbitux and Vectibix block the epidermal growth factor receptor, preventing cells from growing and expanding.

### **Alimta®**

Eli Lilly and Company (Indianapolis, Ind.) announced that the company received a fourth approval from the U.S. FDA for **Alimta® (pemetrexed for injection)**. The latest approval is for Alimta as a maintenance therapy for locally advanced or metastatic non-small cell lung cancer (NSCLC), specifically for patients with a nonsquamous histology whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. Alimta is not indicated for treatment of patients with squamous cell non-small cell lung cancer.

### **Vidaza®**

The National Comprehensive Cancer Network (NCCN) updated both its Clinical Practice Guidelines in Oncology for Myelodysplastic Syndromes (v.1.2010) and the *NCCN Drugs and Biologics Compendium*. The NCCN has upgraded **Vidaza® (azacitidine for injection)** to a Category 1, preferred status for patients with Intermediate-2 and High Risk myelodysplastic syndromes (MDS). Category 1 is the highest level of supporting evidence in the NCCN rating system. For more info on the NCCN guidelines and compendium, go to [www.NCCN.org](http://www.NCCN.org).

## **FDA UPDATES:**

### **New and Generic Drug Approvals - August 11, 2009**

- **Oxaliplatin** Injection, Mustafa Nevsat Ilac Sanayii A.S., Tentative Approval
- **Oxaliplatin** I.V. Injection, Fresenius Kabi Oncology Plc., Approval
- **Oxaliplatin** I.V. Injection, EBEWE Pharma, Approval
- **Oxaliplatin** I.V. Injection, Hospira Worldwide PTY, Tentative Approval
- **Oxaliplatin** I.V. Injection, Sun Pharma Global, Approval

## **CMS UPDATES:**

### **MEDICARE PROVIDER ENROLLMENT REMINDER (For Physicians, Non-Physician Practitioners and Group Practices)**

The Centers for Medicare & Medicaid Services reminds physicians and non-physician practitioners, and group practices that they are required to notify their designated Medicare contractor regarding (a) a change in ownership, (2) a change in practice location, including a change in reassignment of benefits, or (3) any final adverse action (e.g., license suspension/revocation or felony conviction) within 30 days of the reportable event. By reporting changes as soon as possible, but within 30 days of the reportable event, physicians, non-physician practitioners, and group practices will help to ensure that their claims are processed correctly.

Physicians, non-physician practitioners, and group practices are also encouraged to update their Medicare enrollment information on file with the Medicare contractor if the physician, non-physician practitioner, or group practice has not done so since November 2003.

Physicians, non-physicians practitioners, and group practices can use CMS' electronic enrollment process, known as Internet-based Provider Enrollment, Chain and Ownership System (PECOS), to enroll or make a change in an existing enrollment record.

Information regarding physician, non-physician practitioner, and group practice reporting responsibility and other informational material regarding provider enrollment can be found on the Medicare Provider/Supplier Enrollment web site, [www.cms.hhs.gov/MedicareProviderSupEnroll](http://www.cms.hhs.gov/MedicareProviderSupEnroll), and in the documents available for downloading in the Downloads section of each web page.

**The following ICD-10-CM/PCS publications are now available from the Centers for Medicare & Medicaid Services Medicare Learning Network:**

- *ICD-10-CM/PCS Myths & Facts* (June 2009), which presents correct information in response to some myths regarding the ICD-10-Clinical Modification/Procedure Coding System, is now available in print format. To place your order, visit <http://www.cms.hhs.gov/MLNGenInfo/>, scroll down to "Related Links Inside CMS" and select "MLN Product Ordering Page."

- *ICD-10-CM-PCS Bookmark* (revised August 2009), which provides information about the ICD-10-Clinical Modification/Procedure Coding System including the benefits of adopting the coding system, recommended steps to be taken in order to plan and prepare for implementation of the coding system, and where additional information about the coding system can be found, is now available in downloadable format at <http://www.cms.hhs.gov/MLNProducts/downloads/ICD-10ClinModBookmrk.pdf>.

**HEALTH AND HUMAN SERVICE UPDATES:**

**Expect stricter HIPAA enforcement under HHS consolidation**

The Department of Health and Human Services (HHS) announced that the Office for Civil Rights (OCR) will now be responsible for enforcing the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security rule in addition to the privacy rule. (The Centers for Medicare & Medicaid Services was previously responsible for the security rule). This consolidation of HIPAA enforcement activity highlights the Administration's heightened scrutiny of security and privacy of health information. In fact, the American Recovery and Reinvestment Act of 2009 mandates enhanced patient privacy rights and physician practice requirements, increased financial penalties for violations of the privacy rule and the security rules and allocated additional resources for enforcement. View the Federal Register notice of the delegation of authority to OCR. <http://www.hhs.gov/ocr/privacy/srdelegationofauthority2009.pdf>

**PROGRAM COMMITTEE UPDATES: Jose Lutzy, MD, Chairman**

**Business of Oncology Summit:**

FLASCO will be holding its 1<sup>st</sup> Annual Business of Oncology Summit on October 3, 2009, in Tampa. FLASCO has partnered with Abraxis BioScience to hold this very exciting and timely conference. Topics that will be presented by expert speakers are as follows: Financial Planning, Managed Care Contract Negotiations, Succession Planning, Clinical Pathway Development and Implementation, Utilizations and Responsibilities of the PA/ARNP, and Strategic Planning: What, Why and How.

JOIN US for this professional forum that explores what cancer care leaders are doing to achieve a future vision of successful cancer care delivery, focusing on innovative business practices, clinical integration, and patient-centric

approaches to providing care. For more information on the Business of Oncology Summit or to register, please go online to [www.flasco.org](http://www.flasco.org). The meeting announcement and registration form are available there.

**2010 PA/NP Conference:**

We are pleased to announce that FLASCO will sponsor its Second Annual Conference for PAs/NPs on March 26, 2010, in Miami. A special thanks is extended to Dayne Alonso, PA-C and Michele Taffaro Neskey, PA-C for agreeing to serve as Co-Chairmen of the Workgroup to plan this Conference.

**ASH UPDATES:**

The ASH annual State-of-the-Art Symposium is taking place on September 11-12 in Chicago, IL. This year's meeting is focused on advances in hematologic malignancies and platelet disorders. The direct link to the meeting site is <http://hematology.org/meetings/sas/index.cfm>.

**PA/NP UPDATES:**

**12<sup>th</sup> Annual APAO Conference**

The APAO National Conference is scheduled for September 10-13, 2009, in Boston. The meeting is for MidLevels and Physicians . There will be an ASCO highlights on 9/10/09. You may register on-line at: <http://www.focus-ed.net/apao/>

**BUSINESS Q & A: (Source: The Phipps Wealth Management Group)**

Q. I have heard there is going to be a new issue (IPO) that represents some of the “toxic” assets that US government is packaging. Do you anything about it?

A. Yes, it is the **Private Public Investment Partnership**, due out next week. We don't have the specific details but expect them later in the week. Merrill Lynch is an underwriter. For those of you with an interest, please contact us.

For more information you may contact: 561-276-1635 Direct - 877-276-1635 Toll Free – fax: 561-922-3275 - E-mail: [jeffrey\\_phippsr@ml.com](mailto:jeffrey_phippsr@ml.com) - <http://fa.ml.com/PhippsGroup/>

**CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2009)**

FLASCO Members extend a big thanks to all of our 2009 Corporate Members/Sponsors (Companies listed below have either paid 2009 dues or have submitted letters of intent)

**PLATINUM**

AMGEN  
Bayer/Onyx  
Cephalon Oncology  
Eli Lilly  
Oncology Supply/ION  
Sanofi-Aventis  
Celgene  
  
Eisai, Inc.  
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**GOLD**

Abraxis Oncology  
Bristol Myers Squibb  
Genomic Health  
Wyeth  
Roche  
Millennium  
Allos Therapeutics,  
Inc.  
ImClone

**SILVER**

OSI Pharmaceuticals  
US Oncology

**BRONZE**

Genzyme

**FLASCO 2009 MEETINGS:**

**October 3, 2009** – FLASCO Business of Oncology Summit - Tampa

**November 6-7, 2009** – FLASCO Fall Meeting – Tampa Airport Marriott Hotel

**March 5-6, 2010** – FLASCO Spring Meeting and Annual Session – Tampa Airport Marriott Hotel

**March 26, 2010** – PA/NP Conference - Miami

**OTHER MEETINGS/WEBCASTS**

**September 10-13, 2009** - APAO Annual meeting in Boston

**September 11-12, 2009** - ASH State of the Art Symposium – Chicago, IL – For more information:

<http://hematology.org/meetings/sas/index.cfm>.

**September 22-25, 2009** - ACCC's 26th National Oncology Economics Conference - - Hyatt Regency Minneapolis on Nicollet Mall, 1300 Nicollet Mall, Minneapolis, MN 55403 - 612.370.1234

**October 6-7, 2009** - ASCO Electronic Health Records Symposium - Harnessing the EHR: *From Incentives to Sustainability*- San Francisco Marriott Hotel - to register:

[www.asco.org/ehrsymposium](http://www.asco.org/ehrsymposium)

**Nov 1-5, 2009** - ASTRO's Annual Meeting – Chicago

**November 13 - 15, 2009** - Oncology Nursing Society Fall (ONS) – Tampa

**December 5-8, 2009** - ASH Annual Meeting – Ernest N. Morial Convention Center, New Orleans, LA – For more information: <http://hematology.org/meetings/2009/index.cfm>

**December 10 - 13, 2009** - San Antonio Breast Cancer Symposium (SABCS) San Antonio, TX

**Feb 25-27, 2010** - American College of Radiation Oncology Annual Meeting – Lake Buena Vista, FL

**March 17-20, 2010** - ACCC's 36th Annual National Meeting - -Baltimore Marriott Waterfront

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