



**FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST –May 7, 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**

This past week one of the major focuses for FLASCO was to actively support the “Pass the Buck Campaign”. Letters were sent to all Members of the Florida House of Representatives.

**CLINICAL PRACTICE COMMITTEE: Thomas Gaddis, MD, Chm.**

According to a recent press release, the Federal Trade Commission will delay enforcement of the new “Red Flags Rule” until August 1, 2009.

**Heads UP – 99245** – there seems to be a trend starting on this one – some MAC jurisdictions are auditing claims before payment.

**MEMBERSHIP COMMITTEE: Julio Hajdenberg, MD, Chairman**

We regret to announce that we have terminated 17 affiliate memberships and 32 regular memberships due to non-payment of FLASCO annual membership dues.

**DRUG AND INDUSTRY UPDATES:**

**Bevacizumab injection (Avastin®, Genentech, Inc)**

On May 5, 2009, the U.S. Food and Drug Administration granted accelerated approval to bevacizumab injection (Avastin®, Genentech, Inc.) as a single agent for patients with glioblastoma, with progressive disease following prior therapy. The approval was based on demonstration of durable objective response rates observed in two single-arm trials, AVF3708g and NCI 06-C-0064E.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/125085s0169lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/125085s0169lbl.pdf).

**FCSO UPDATES:**

**Billing for drugs usually administered orally**

According to Publication 100-02, the Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §50 - Drugs and Biologicals, the Medicare program provides limited benefits for outpatient drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals (see §50.1);
- They are of the type that are not usually self-administered (see §50.2);
- They meet all the general requirements for coverage of items as incident to a physician’s services (see §§50.1 and 50.3);
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (see §50.4);
- They are not excluded as noncovered immunizations (see §50.4.4.2); and
- They have not been determined by the FDA to be less than effective (see §50.4.4).

In order to meet all the general requirements for coverage under the incident-to provision, an **FDA approved** drug or biological must:

- Be of a form that is not usually self-administered;

- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the drug or biological must represent an expense to the physician. The program may pay for the use of an **FDA approved** drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration. Medicare Part B does not generally cover drugs that can be self-administered, such as those in pill form, or are used for self-injection.

However, First Coast Service Options has received claims for many medications that, in most circumstances, would be considered self-administered oral medications (examples include, but are not limited to, Ascorbic Acid, Tagamet, Lopressor, and Vasotec, among others). In many instances, these drugs have been billed with unlisted codes such as J3490, which requires that this contractor review the claim for medical necessity and manually price the drug.

Contractors will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient's condition, as well as to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.

Contractors will supplement these instructions as necessary, concerning appropriate use of specific injections in other situations. They will use these instructions to screen out questionable cases for special review, further development, or denial when the injection billed would not be reasonable and necessary. If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these instructions, the contractor excludes the entire charge (i.e., for both the drug and its administration). In addition, contractors exclude from payment any charges for other services (such as office visits), which were primarily for the purpose of administering a noncovered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury). **Contractors must provide notice 45 days prior to the date that these drugs will not be covered, and this article serves as that notice.** During the 45-day time period, contractors will maintain existing medical review and payment

### **Physician's order for clinical laboratory services and diagnostic procedures**

First Coast Service Options Inc. (FCSO) continues to see a large number of errors identified by the Comprehensive Error Rate Testing (CERT) contractor for clinical laboratory services and diagnostic procedures. The errors are largely due to the absence of a physician's order on file or for failure to provide a copy of the order when documentation is requested. It is inappropriate to bill the Medicare program for clinical laboratory services and diagnostic procedures without a physician's order. Many providers and facilities are being required to refund money to Medicare for not having a copy of the physician's order, or for not providing it when requested.

Medicare guidelines require that supporting documentation for laboratory and diagnostic services must include:

- A copy of the physician's/NPP's order
- Documentation that the test was performed
- Record of the result/report

It is imperative that complete records are submitted for review when requested. Without the appropriate physician's order, there is no way for Medicare or the CERT contractor to verify if a test was ordered or whether the exact test ordered was performed.

## **CMS UPDATES:**

**The General Equivalence Mappings – ICD-9-CM To and From ICD-10-CM and ICD-10-PCS (Fact Sheet) (March 2009)**, which provides information and resources regarding the General Equivalence Mappings that were developed as a tool to assist with the conversion of International Classification of Diseases, 9<sup>th</sup> Edition, Clinical Modification (ICD-9-CM) codes to International Classification of Diseases, 10<sup>th</sup> Edition (ICD-10) and the conversion of ICD-10 codes back to ICD-9-CM, is now available in print format from the Centers for Medicare & Medicaid Services **Medicare Learning Network**. To place your order, visit <http://www.cms.hhs.gov/MLNGenInfo/>, scroll down to “Related Links Inside CMS” and select “MLN Product Ordering Page

**The April 2009 quarterly Provider Specific Files (PSF) Text** data files have been revised and are now available on the CMS website at: [http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/03\\_psf\\_text.asp](http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/03_psf_text.asp) in the Downloads section. If you use the Provider Specific Text File data, please go to the page above and download the latest versions of the PSF Files. **Note:** These are the **quarterly** data sets for the Provider Specific Data for Public Use in **text** format.

## **The April 2009 quarterly Provider Specific Files (PSF) Statistical Analysis Software**

(SAS) data files have been revised and are now available on the CMS website at:

[http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/04\\_psf\\_SAS.asp](http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/04_psf_SAS.asp) in the Downloads section. If you use the Provider Specific SAS File data, please go to the page above and download the latest version of the PSF Files. **Note:** These are the **quarterly** data sets for the Provider Specific Data for Public Use in **SAS** Format.

## **MLM UPDATES:**

**New - SE0904 – An Introductory Overview of the HIPAA 5010**

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0904.pdf> **NOTE:** The implementation of HIPAA 5010 presents substantial changes in the content of the data that providers submit with their claims as well as the data available to them in response to their electronic inquiries. This Special Edition MLM Matters article alerts providers of these HIPAA changes and how they need to plan for their implementation

**New - MM6338 – Type of Bill (TOB) for Federally Qualified Health Centers (FQHCs) from 73x to 77x**

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6338.pdf>

**New - MM6417 – Expansion of the Current Scope of Editing for Ordering/Referring Providers for claims processed by Medicare Carriers and Part B Medicare Administrative Contractors (MACs)**

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6417.pdf>

**New - MM6458 – Update to List of Medicare Telehealth Services**

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6458.pdf>

**New - MM6455 – Ensuring Only Clinical Trial Services Receive Fee-for-Service (FFS) Payment on Claims Billed for Managed Care Beneficiaries -** <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6455.pdf>

## **Revised:**

**MM6330 – Clarification on Use of National Drug Codes (NDCs) in 837 I Billing**

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6330.pdf>

**MM6431 – Billing Routine Costs of Clinical Trials**

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6431.pdf>

**MM6386 – Revision to Processing Hospice Visit Charges on Remittance Advices and Medicare Summary Notices (MSNs) -** <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6386.pdf>

## **ACCC UPDATES:**

**DRUGDEX® Drug Compendium** Available to ACCC Members on Our Members-Only Website

In an agreement between the Association of Community Cancer Centers (ACCC) and Micromedex, Thomson Reuters (Healthcare), Inc., ACCC members have been granted access to *DRUGDEX*®. The agreement is in effect until May 31, 2009, and may at that time be renewed.

### **ASCO UPDATE:**

#### **ASCO State Affiliate Program**

In order to bring greater attention to and awareness of the important work being pursued on a local basis by ASCO State/Regional Affiliates, the State/Regional Affiliate Program and ASCO News & Forum have collaborated to create the online column “Spotlight on State Affiliates.” The quarterly column highlights the activities of a selected State Affiliate group. The fifth society to be featured in this series is the Florida Society of Clinical Oncology. Please visit either [www.asco.org/stateaffiliates](http://www.asco.org/stateaffiliates) or <http://www.asconews.org/anf/Online+Exclusives+Archive/Online+Exclusives+Archive+2009/Spotlight+On+State+Affiliates/Spotlight+on+State+Affiliates%3A+Florida+Society+of+Clinical+Oncology> to view the latest column.

**We are extremely pleased to announce that FLASCO was featured as a special state society affiliate and our FLASCO Clinical Trials Network was featured in this issue.** There is a link to the piece from the AN&F site homepage ([www.asconews.org](http://www.asconews.org)) (This article was also e-mailed to FLASCO members last week).

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

Q: A FLASCO member asked us “Is there any way I can suggest to my spouse a budgeting program to try to control discretionary expenses?”

A: Yes, there is a way. It is painful and is called Balance Sheet Management. We have a program designed for this. If interested, 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/>

### **EDUCATIONAL OPPORTUNITIES**

#### **Onyx Pharmaceuticals To Present At The Bank of America and Merrill Lynch 2009 Health Care Conference**

Onyx Pharmaceuticals will present at the Bank of America and Merrill Lynch 2009 Health Care Conference on Tuesday, May 12, at 10:40 a.m. Eastern Time. Interested parties may access a live webcast of the presentation on our website at: [http://www.onyx-pharm.com/wt/page/event\\_calendar](http://www.onyx-pharm.com/wt/page/event_calendar)

It is recommended that listeners log on 15 minutes early in order to register and download any necessary software. For those unable to participate during the live webcast, a recorded replay of the presentation will be available one hour following the conclusion of the presentation through June 12, 2009.

#### **Bristol Myers Squibb – Development in Chronic Leukemia – on demand conference**

This 24 hour a day on-demand conference features Michael J. Mauro, MD. To participate, please type in the following URL address: <http://developmentsincml.com> – please complete the registration page and when prompted, please enter the following password: **ondemand**.

**Roche** would like to extend the offer for FLASCO members to participate in an educational webcast series, updating you on current issues affecting the management of Colorectal Cancer (CRC). There is free CME course for physicians.

Information on the Webcasts as follows:

Educational Intervention 1

Webcast 1: Individualized Therapy for Colorectal Cancer: Ready for Prime Time?

Available NOW!!

Educational Interventions 2 and 3

Webcast 2: A pre-ASCO Webcast -*Available May 2009*

Webcast 3: A post-ASCO Webcast continuation - *Available July 2009*

Educational Intervention 4

Webcast 4: Performance Measures: Trying It All Together - *Available October 2009*

Educational Intervention 5 & 6

Webcasts: Reach the Experts Teleconference (An individualized question/answer session between learners and the experts)

Educational Intervention 7

Webcast: Publication and dissemination of an extensive, learner-stratified, Commitment-to-Change measured outcomes report.

**To register for these webcasts or to view the presentation, please go to [www.meddigest.com/CRC](http://www.meddigest.com/CRC)**

**US Oncology Live Webcast: “Cancer in the Elderly”**

US Oncology is hosting a live, CME accredited, webcast session on June 18, 2009, from 12:15pm to 1:00pm EST, on the following topic: “From life expectancy to chance of surviving in elderly patients: the concept of frailty.” This session will be hosted by expert Jean-Pierre Droz of Centre Leon-Berard, Lyon France.

**Celgene – Leukemia and Lymphoma Society Educational Opportunity**

Celgene is cosponsoring a telephone educational program with the Leukemia and Lymphoma Society and they would like to invite FLASCO members to participate. The guest speaker for this event is Dr. Seema Singhai. The objectives of the program are as follows: (1) Current and emerging treatment options for myeloma (2) The role of transplantation as a treatment option for myeloma (3) Possible symptom and side effect management (4) The role of clinical trials in the advancement of myeloma treatment.

**Date: May 14, 2009, 12:00pm to 1:30pm**

To register by phone, please call (866) 992-9950 x304. For more information on this program, go to <https://www.rmei.com/LLSmyeloma/index2.php>.

**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.  
Ortho Biotech  
Genentech  
GlaxoSmithKline  
The Phipps Wealth  
Management Group  
Novartis  
Astra Zeneca  
Pfizer

**GOLD**

Abraxis Oncology  
Bristol Myers Squibb  
Genomic Health  
Wyeth  
Roche  
Millennium

**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

## **OTHER MEETINGS/WEBCASTS**

**May 13, 2009** - American Cancer Society/Moffitt FREE Webinar for Nursing CEUs –  
Wednesday, May 6, 2009 / Noon – 1 p.m. - Why should I, as a Nurse, Talk to My Patients About Tobacco Prevention and Cessation? Wednesday, May 13, 2009 / Noon – 1 p.m. - Addressing Disparities in Tobacco Prevention and Cessation Interventions - Register by visiting [www.ahecregistration.org](http://www.ahecregistration.org) or email Susie Lloyd, CE Coordinator at Suwanee River AHEC at [slloyd@srahec.org](mailto:slloyd@srahec.org)

**May 30<sup>th</sup>, 2009:** SAVE THE DATE: “*Should Oncologists Shift Incentives from Drug Margins to Quality?*” – this innovative Physician Exchange Forum will be hosted by US Oncology in association with the Proceedings of the ASCO Annual Meeting in Orlando. The program will be held at 6:30 pm ET at the Westin Imagine Hotel near the Orange County Convention Center in Orlando. For more information contact Jim Gruber at [jim.gruber@usoncology.com](mailto:jim.gruber@usoncology.com) or call 770.356.1029.

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Email: [Dorothy.Green@cancer.org](mailto:Dorothy.Green@cancer.org)