



## FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – April 5, 2007

### **CLINICAL PRACTICE COMMITTEE:** Thomas Gaddis, MD, Chairman

### **ION Announces Update to Change in Medicare Coverage Policy For ESAs Practice Reimbursement Series:**

April 12, 2007 - 2:00 pm EST

To register: <https://www.iononline.com/index.aspx?id=PracticeReimbursementSeries>

### **FLASCO Website**

Please visit the FLASCO website and look under the Section Practice Issues and you will find LCD, Coding, USP DI, FDA, and other Updates & Issues.

Also contained on the website is a link to all patient assistance programs.

### **ACCC ANNUAL MEETING:**

Please see the attached report from Jeffrey Bubis, D.O., FLASCO Liaison to ACCC.

### **MEMBERSHIP:**

Everyone who has not paid their 2007 FLASCO dues have been notified their membership is terminated effective today unless the FLASCO Office is contacted.

### **AMERICAN CANCER SOCIETY:**

#### **American Cancer Society Guideline for Breast Screening with MRI**

The American Cancer Society's guideline for the use of magnetic resonance imaging (MRI) for women at increased risk for breast cancer recommends annual screening using MRI in addition to mammography for women with a 20-25 percent or greater lifetime risk of the disease. The guideline will be published in the March/April 2007 issue of *CA: A Cancer Journal for Clinicians*, a peer-reviewed journal of the American Cancer Society.

An expert panel convened by the Society reviewed new evidence that has become available since the Society last issued guidelines for the early detection of breast cancer in 2003, at which time there was insufficient evidence to justify a recommendation to use MRI to screen for breast cancer. Newer data provided the opportunity for the panel to make specific recommendations. The panel says in addition to mammography, annual screening using MRI is recommended for women who:

- have a BRCA 1 or 2 mutation
- have a first-degree relative with a BRCA 1 or 2 mutation and are untested
- have a lifetime risk of breast cancer of 20-25 percent or more using standard risk assessment models\*
- received radiation treatment to the chest between ages 10 and 30, such as for Hodgkin Disease
- carry or have a first-degree relative who carries a genetic mutation in the TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes).

The panel also identified several risk subgroups for which the available data are insufficient to recommend either for or against screening. They include women with a personal history of breast cancer, carcinoma in situ, atypical hyperplasia, and extremely dense breasts on mammography. The panel acknowledged that these clinical factors are relevant in making individualized decisions about MRI screening when family history alone does not predict a risk of approximately 20 to 25 percent.

## **FCSO UPDATES:**

### **Radioactive Tracer Fluorodeoxyglucose F-18 (FDG)**

Effective for services processed on or after March 16, 2007, First Coast Service Options (FCSO) will allow separate payment of \$220.80 per study dose for FDG. An article regarding FDG, Nitrogen N-13 ammonia and Rubidium Rb-82 has been posted to the Medicare website at [www.floridamedicare.com](http://www.floridamedicare.com) under Part B special release articles and will also be published in the April Part B provider update. Providers who have received denials may refile claims on or after March 16, 2007.

## **CMS UPDATES:**

### **PQRI:**

To access both the measures and measure specifications documents, visit the PQRI web page at [www.cms.hhs.gov/PQRI](http://www.cms.hhs.gov/PQRI), on the CMS website. Go to the Measures/Codes section of the page and scroll down to the Downloads section. Please note that the measure specifications document may be updated prior to the July 1, 2007 start date of the 2007 PQRI reporting period.

### **Important Note About Testing**

Providers may want to test their systems to be certain that claims containing the codes associated with the measures will be processed. Please note that many of the quality codes are new and will be rejected by Medicare claims processing systems prior to the July 1, 2007 HCPCS update. CMS will be issuing further information about which measures may be used for testing systems prior to the July 1 start date.

## **PHARMA/DRUG UPDATES:**

### **Celgene announces positive preliminary late-stage results for Revlimid**

Preliminary data from a Phase III study suggest a survival advantage for patients with newly-diagnosed multiple myeloma treated with Celgene's Revlimid (lenalidomide) plus a low dose of dexamethasone, compared to those administered a standard dose of dexamethasone plus Revlimid.

### **Erbitux meets primary endpoint in late-stage head and neck cancer study**

ImClone, Bristol-Myers Squibb and Merck KGaA stated that Phase III study results showed that Erbitux (cetuximab), in combination with platinum-based chemotherapy, increased overall survival as a first-line treatment in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck, compared to chemotherapy alone.

### **Campath submitted for expanded FDA approval**

Bayer and Genzyme submitted an application to the FDA to market Campath (alemtuzumab) for an expanded indication as a first-line treatment for patients with B-cell chronic lymphocytic leukaemia (B-CLL). A similar filing with EU regulators will be made in the coming week.

### **Cervarix®**

GlaxoSmithKline announced it has submitted a biologics license application for Cervarix®, (human papillomavirus vaccine, AS04 adjuvant-adsorbed), its cervical cancer candidate vaccine, to the U.S. FDA. If licensed, the vaccine will be indicated for the prevention of cervical cancer and precancerous lesions associated with the most common cancer-causing human papillomavirus types. For this candidate vaccine, the company selected a novel proprietary adjuvant system called AS04, intended to enhance immune response and increase duration of protection.

### **rNAPc2.**

Nuvelo, Inc., has been granted two separate fast track designations by the FDA for rNAPc2. The first fast track designation is for first-line treatment of metastatic colorectal cancer (mCRC) to improve progression-free survival and overall survival when added to Avastin®-containing 5-fluorouracil (5-FU)-based chemotherapy regimens. The other is for second-line treatment of mCRC to improve progression-free survival and overall survival when added to 5-FU-based chemotherapy regimens. rNAPc2 is currently being studied in a Phase 2 clinical trial in subjects with mCRC. Recombinant nematode anticoagulant protein c2 (rNAPc2) is a recombinant protein that interferes with the tissue factor/factor VIIa/factor Xa protease complex. This complex has been shown to play a role in activating the cellular signaling events leading to metastasis and angiogenesis in a variety of cancers.

### **Xeloda®**

Roche announced submission of a supplemental new drug application (sNDA) to the FDA for the use of Xeloda® (capecitabine) in combination with oxaliplatin—XELOX—with or without Avastin® (bevacizumab) in the treatment of metastatic colorectal cancer.

## **XL147**

Exelis, Inc., submitted an investigational new drug (IND) application to the FDA for XL147. XL147 is an orally available small molecule inhibitor of phosphoinositide-3 kinase (PI3K). Activation of PI3K is a frequent event in human tumors, promoting tumor cell growth, survival, and resistance to chemotherapy and radiotherapy. Inactivation of PI3K has been shown to inhibit growth and induce apoptosis in tumor cells.

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

A special thanks to **CELGENE** for renewing its Corporate Silver Membership for 2007!

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

### **PLATINUM**

Astra Zeneca  
Genentech  
Oncology Supply/ION  
Sanofi-Aventis  
Bristol-Myers Squibb  
Eli Lilly  
Bayer/Onyx  
Ortho Biotech  
Amgen

### **GOLD**

Cephalon Oncology  
Pharmion Corporation  
OSI Pharmaceuticals  
GlaxoSmithKline  
Roche  
Pfizer

### **SILVER**

Genomic Health, Inc.  
Talecris Biotherapeutics  
Millennium  
Celgene

### **BRONZE**

Abraxis Oncology  
Oncology Pharmaceutical Services

## **EVENTS:**

**April 21, 2007** – “Reality Hematology Oncology” Program – The Tradewinds Resort, St. Petersburg. FLASCO is co-sponsoring this program with The American School of Oncology

**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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