



**FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – December 30, 2008**

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

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

**MESSAGE FROM THE FLASCO PRESIDENT: Robert Cassell, MD**

As our FLASCO fiscal year comes to an end, on behalf of the entire FLASCO Membership, I want to take this opportunity to thank all of our 2008 Corporate Members/Supporters. Because of all of you, FLASCO has been able to become the “Voice of Oncology” in Florida.

In addition, I want to extend a special thanks to all of the FLASCO members for your continued help and support this year – we are so fortunate to have so many members who are very active and dedicated to our Mission. If you would like to become more involved in FLASCO in 2009, please contact our Executive Director.

Wishing everyone a Very Happy Holiday Season!

**PROGRAM COMMITTEE: Rogerio Lilenbaum, MD, Chairman**

**Save the date for Highlights of ASH®**

This year one of the Highlights of ASH is taking place in Miami, FL, on February 6-7, 2009. The following is a direct link to the Highlights information on the ASH Web site: <http://hematology.org/meetings/highlights/index.cfm#2>  
The FLASCO member code is FLH09 – FLASCO special registration fee - \$110. Let’s have a good showing of attendees from FLASCO! Early registration discount ends **December 31, 2008**. REGISTER TODAY

**Save the date for FLASCO Annual Meeting & Spring Session:**

The 2009 FLASCO Annual Meeting and Spring Session will be held on February 27 and 28, 2009, at the Marriott Sawgrass Resort near Jacksonville. The President of ASCO and the CEO of ASCO will both speak at the dinner on Friday, February 27. Please mark your calendars to attend this meeting. A meeting announcement and registration form is in the mail to you.

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

**Healthcare Clinic Establishment Permit Update**

Healthcare Clinic Establishment Permit (HCCE) information can be found on DOH (department of health) website @ [www.doh.state.fl.us/pharmacy](http://www.doh.state.fl.us/pharmacy). DOH has received over 650 applications to date. Processing of applications will take sometime and DOH staff has stated they will not be issuing their first permit until after January 5<sup>th</sup>, 2009. There will be a page on DOH website devoted to listing names of physicians whose applications have been finalized. Also, DOH is developing a website that will contain permit status information, [www.flhealthsource.com](http://www.flhealthsource.com), which will be available soon. If you have any questions concerning this application, you can contact DOH @ 850-245-4227.

**DRUG & INDUSTRY UPDATES:**

**J-code, for TORISEL® (temsirolimus) for Injection**

Wyeth Pharmaceuticals announced that the Centers for Medicare and Medicaid Services ("CMS") has established a product-specific billing code, or J-code, for TORISEL® (temsirolimus) for Injection. The J-code becomes effective on January 1, 2009. The new J-code, J9330 for 1 mg of TORISEL, replaces the miscellaneous J-code J9999 under which TORISEL is currently reimbursed. The J9330 (for 1 mg) code should be accepted by the Medicare contractors for all TORISEL claims for reimbursement submitted for Medicare beneficiaries for dates of service on or after January 1, 2009.

TORISEL is approved for the treatment of patients with advanced renal cell carcinoma (2009 ICD-9-CM code 189.0). To view a copy of the package insert: [http://www.wyeth.com/hcp/torisel/prescribing-information?WT.mc\\_ID=2EE82164-4B59-49C0-BDC7-8E5B70D62B56&WT.srch=1&WT.mc\\_ev=click](http://www.wyeth.com/hcp/torisel/prescribing-information?WT.mc_ID=2EE82164-4B59-49C0-BDC7-8E5B70D62B56&WT.srch=1&WT.mc_ev=click)

The standard patient administration of TORISEL is as an intravenous infusion over 30-60 minutes. The recommended dose is 25 mg administered weekly until disease progression or unacceptable toxicity. To bill this dosage, use 25 units of J9330 after 1/1/2009. If the drug is administered as per the aforementioned regimen, the code to use for administration will be 96413\*, if it is the initial or only infusion of the encounter.

To enroll in the TORISEL reimbursement program, please go to [this website](#):

[http://www.wyeth.com/products/prescription?product=/wyeth\\_html/home/products/prescription/Torisel%C2%AE%20%28t%20emsirolimus%29%20Injection/reimbursement\\_support\\_program.html](http://www.wyeth.com/products/prescription?product=/wyeth_html/home/products/prescription/Torisel%C2%AE%20%28t%20emsirolimus%29%20Injection/reimbursement_support_program.html) or call 866-993-8466.

### Herceptin – United Health Care:

Dr. Lee Newcomer from United Health Care stated that he is delighted to announce the policy change for Herceptin--the problem of patient's being treated without over-expression of the HER2 gene is resolved. He believes they should eliminate the reviews if the problem is solved. **The official announcement follows:**

“UnitedHealthcare is removing the requirement to submit a pathology report to obtain coverage for trastuzumab. **This change will be effective for claims submitted after 1/1/2009.**

Herceptin claims that were submitted in 2008 that are pending payment will require the submission of the pathology report showing over expression of the HER2 gene. The pathology reports should be faxed to 915-231-1970 and you should use the dedicated fax cover sheet.

Herceptin claims submitted after 1/1/2009 will continue to be subjected to two reimbursement policies that may impact the reimbursement. The National Comprehensive Cancer Network (NCCN) policy and the Maximum Dosage Edit policy both review Herceptin claims. Both of these policies are posted on the unitedhealthcareonline web site.

UnitedHealthcare launched the Herceptin policy in early 2006 based on an audit showing that 12 percent of the patients being treated with trastuzumab did not have over-expression of the HER2 gene. Our last audit in September 2008, demonstrated that less than 1 percent of the submissions failed to show over- expression.

Our medical policy hasn't changed – treatment of patients with under-expression is still inappropriate. We believe the recent audit demonstrates that this quality parameter is being followed and no longer requires the quality check.

There are other critical issues with HER2 gene expression testing. Studies show that concordance between local laboratories and a central laboratory with quality controls can be poor. The College of American Pathology has established accreditation for HER2 gene testing, but participation in the accreditation process is voluntary. UnitedHealthcare contracts with two national laboratories, Genezyme and Lab Corporation that meet the ASCO / CAP guideline recommendations and proficiency testing for HER2. We encourage the use of laboratories that meet these standards. If you don't know the accreditation status of your current lab for HER2, we would encourage retesting, or a second opinion, from either of these laboratories for your UnitedHealthcare patients. “

### **Orphan Drug Approval for Pancreatic Cancer Treatment (Mibefradil, trade-named Posicor™)**

The pancreatic cancer treatment for which Tau Therapeutics recently received FDA orphan drug status is the existing drug mibefradil, trade-named Posicor™. The T-channel-blocking drug was once marketed as a hypertension medication. Although it was withdrawn from the market due to drug-drug interactions with cholesterol-lowering medications, mibefradil has demonstrated efficacy in treating pancreatic cancer in animals and has also received FDA orphan drug status for the treatment of ovarian cancer. Further, because mibefradil is non-toxic, it could be an excellent alternative to existing cancer drugs.

In addition to pancreatic and ovarian cancer, mibefradil may also be effective in treating glioblastoma, considered the most lethal form of brain cancer, and metastatic melanoma cancer drugs.

### **Intravenous Emend® (Fosaprepitant) (Source: First Coast Service Options)**

Following is an article that has been posted to FCSO website outlining the coverage guidelines (per Medicare manual) for coverage of drug both in IV form as well as oral. This follows inquiries from providers for denials of IV Emend on day one

of chemotherapy followed by oral administration. At the end of the article, FCSO states they are reviewing claims for the IV administration on day one. It is suggested if you have received denials for IV administration and you believe you meet medical necessity in this situation, that you continue thru the appeals process.

**Emend® (aprepitant)** capsules for **oral (po)** administration and Emend® (fosaprepitant dimeglumine) for injection, when given in combination with other antiemetic agents is indicated for:

- the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, and
- the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Emend®, administered orally, is a covered benefit for a three dose oral pack as outlined in the Centers for Medicare & Medicaid Services (CMS) Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Section 110.18. The three dose oral regimen is covered and paid by the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). There is also a Part D or similar coverage in certain circumstances. For Medicare Part B to cover the IV product, the IV route of administration must meet the criteria for what is considered “reasonable and necessary” as outlined in the CMS Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50.4.3, which indicates medication given by injection is not covered if standard medical practice indicates that the oral administration of the medication is effective and is an accepted or preferred method of administration.

If the patient tolerates the subsequent oral doses of aprepitant, the medical necessity for the IV route of administration on the initial dose is uncertain. Regardless of whether the initial IV dose is covered under Medicare Part B, the subsequent oral doses may be covered under the patient’s Medicare Part D plan. *When the initial dose is administered intravenously, none of the doses are covered through the DME benefit.*

In the absence of a National Coverage Determination (NCD) or Local Coverage Determination (LCD), First Coast Service Options Inc. (FCSO) is currently reviewing claims in which Emend® is administered intravenously to determine if the IV administration of Emend® meets the medical necessity criteria as outlined in the Medicare Benefit Policy Manual.

### **FDA approves degarelix, a new gonadotropin releasing hormone (GnRH) receptor antagonist, for the treatment of patients with advanced prostate cancer**

On December 24, 2008, the U. S. Food and Drug Administration (FDA) approved degarelix for injection (Ferring Pharmaceuticals Inc., Parsippany, NJ), a new gonadotropin releasing hormone (GnRH) receptor antagonist, for the treatment of patients with advanced prostate cancer.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at <http://www.fda.gov/cder/foi/label/2008/022201lbl.pdf>.

### **FCSO UPDATES:**

FCSO has created a new J9 transition Web site ([www.fcso.com/transition](http://www.fcso.com/transition)) to offer providers additional assistance and information. We encourage you to visit the site often to view special monthly bulletins, learn about upcoming teleconferences and webcasts, and to subscribe to J9 e-mail updates.

### **CMS UPDATES:**

#### **News on the ICD-10-CM/PCS initiative**

Transcript from the national provider conference call for physicians now available

The transcript of the Centers for Medicare & Medicaid Services (CMS) International Classification of Diseases, 10th Edition, Clinical Modification/Procedure Coding System (ICD-10-CM/PCS) national provider conference call for physicians that was held on November 17, 2008, is now available at <http://www.cms.hhs.gov/ICD10/Downloads/November17calltranscript.pdf>.

ICD-10 2009 files

CMS has updated the ICD-10 download files by posting the 2009 version of the following documents at [http://www.cms.hhs.gov/ICD10/01m\\_2009\\_ICD-10-PCS.asp#TopOfPage](http://www.cms.hhs.gov/ICD10/01m_2009_ICD-10-PCS.asp#TopOfPage):

- ICD-10 General equivalence mappings (these refer to procedure codes)
- Reimbursement mappings and guides for the use of the mappings
- 2009 version of ICD-10-procedure coding system (PCS)
- ICD-10 version of the digestive Medicare severity-diagnosis related groups (MS-DRG)

The 2009 ICD-10-CM (diagnosis codes) general equivalence mappings have been posted at [http://www.cms.hhs.gov/ICD10/03\\_ICD\\_10\\_CM.asp](http://www.cms.hhs.gov/ICD10/03_ICD_10_CM.asp).

The 2009 version of ICD-10-Clinical Modifications (CM), diagnoses, will be posted by the end of December 2008 on the following sites:

- <http://www.cdc.gov/nchs/icd9.htm>
- [http://www.cms.hhs.gov/ICD10/03\\_ICD\\_10\\_CM.asp](http://www.cms.hhs.gov/ICD10/03_ICD_10_CM.asp)

### **BUSINESS AND FINANCE: (Source: Phipps Wealth Management Group)**

**Q** I have heard about the “January Effect” phenomenon and do not think it is related to the weather. What is it?

**A** It is whereby lower-quality small cap stocks tend to heat up during the first month of the year. Any rise in share price for these investments is generally short-lived....when lower quality assets outperform, they can temporarily depress the prices of higher quality stocks—creating some bargains among just the sort of investments Merrill Lynch Research recommends for today’s markets.

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

### **EDUCATIONAL OPPORTUNITIES:**

Genomic Health, Inc. sponsored Interactive Web Conferences  
Oncotype Dx Post San Antonio Breast Conference Data Review

Call in number for all: 1-888-504-7949

January 6<sup>th</sup>, 8PM EST Pass code 2170454

Meeting URL: <http://web.envisioncomm.net/OncotypeDX/Jan6.htm>

January 8<sup>th</sup>, 12PM EST Pass code 9330354

Meeting URL: <http://web.envisioncomm.net/OncotypeDX/Jan8.htm>

January 13<sup>th</sup>, 1PM EST Pass code 6052549

Meeting URL: <http://web.envisioncomm.net/OncotypeDX/Jan13.htm>

January 22<sup>nd</sup>, 3PM EST Pass code 9135429

Meeting URL: <http://web.envisioncomm.net/OncotypeDX/Jan22.htm>

Tech support 1 888 569 3848 - To pre register 1 866 984 5114

**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 2009 MEETINGS:**

**February 27 & 28, 2009** – FLASCO Spring Meeting – Marriott Sawgrass – Jacksonville  
**November 6-7, 2009** – FLASCO Fall Meeting – Tampa Airport Marriott Hotel

**FLASCO EVENTS:**

**FLASCO is co-sponsoring the following three Events:**

- (1) January 17-18, 2009** –Clinical Breakthroughs & Challenges in Hematologic Malignancies – Grand Floridian Resort – Lake Buena Vista - **For more information, call (813) 745-1247 or e-mail: [Melissa.Pearson@MOFFITT.org](mailto:Melissa.Pearson@MOFFITT.org)**
- (2) February 6 & 7, 2009** – Highlights of ASH – Miami - <http://hematology.org/meetings/highlights/index.cfm#2>.  
The FLASCO member code is FLH09
- (3) March 20, 2009** – Statewide PA & NP Conference, Moffitt Cancer Center – Tampa

**FLASCO Contact Information:** Dorothy Green Phillips, Executive Director -3709W. Jetton Ave., Tampa, Florida 33629 - Tel: 800.444.1410, Ext. 4410 - Cell Phone: 813.294.2620 - Fax: 813.349-4410 or 813.349.4472  
Email: [Dorothy.Green@cancer.org](mailto:Dorothy.Green@cancer.org)