



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – July 9th, 2008

MESSAGE FROM FLASCO PRESIDENT: Robert Cassell, MD

Contact Information

A number of important correspondences are being returned to the FLASCO office due to incorrect contact information. Please keep the FLASCO Office advised of any changes to your contact information (mailing address, telephone number, fax number and e-mail address). **If the office does not have your e-mail address, you are missing many important communications.**

PROGRAM COMMITTEE: Rogerio Lilenbaum, MD, Chairman

Mid-Level Statewide Oncology Conference

As part of the 2008 ASCO State Affiliate Grant, a Statewide Oncology Conference for Mid-Levels will be held in Tampa on March 20, 2009. Also, as part of this grant, a survey will be sent to all identified mid-levels working in the oncology field this week. All are encouraged to complete the survey – this is extremely important as it will help us identify how FLASCO can increase benefits to mid-level positions. In addition, if you have not provided contact information for mid-levels in your practices, please provide this info to the FLASCO Executive Director ASAP.

CLINICAL PRACTICE COMMITTEE: Tom Gaddis, MD, Chairman

Neupogen:

For those of you who have received denials when giving Neupogen on the same day as a Monoclonal Antibody (ex. Herceptin), First Coast Service Options has reviewed this issue following a face to face meeting in May between FLASCO, OMF, and SCOOP. I am happy to report that FCSO has adjusted their system on June 20, 2008 to allow Neupogen to be paid for on the same day as MABs. Listed below are the drugs that have been identified in this category.

The ones identified were:

J9010 (Campath), J9035 (Avastin), J9055 (Erbix), J9300 (Mylotarg), J9303 (Vectibix), J9310 (Rituxan) and J9355 (Herceptin).

FCSO stated there are other MABs that did not fall within the chemo drug range so they would not be affected. If anyone feels there are other drugs in the chemo range that should be included, please let me know and I will forward on to FCSO for their review.

DRUG/INDUSTRY UPDATES:

FDA Approves Velcade for Injection for Patients with Previously Untreated Multiple Myeloma

Millennium Pharmaceuticals, The Takeda Oncology Company, and Takeda Pharmaceutical Company Limited announced that the U.S. Food and Drug Administration (FDA) approved Velcade for patients with previously untreated multiple myeloma (MM).

The current approval was based on an international, multicenter, open label, active-control trial in previously untreated patients with symptomatic multiple myeloma. Patients were randomized to receive either nine 6 week cycles of oral melphalan (M) plus prednisone (P) or MP plus Velcade. Patients received M (9 mg/m²) plus P (60 mg/m²) daily for four days every 6 weeks or the same MP schedule with bortezomib (1.3 mg/m²) IV on days 1, 4, 8, 11, 22, 25, 29 and 32 of every 6 week cycle for 4 cycles then once weekly for 4 weeks on days 1, 8, 22 and 29 of every 6 week cycle for 5 additional cycles. Antiviral prophylaxis was recommended for patients on the Velcade study arm. Time-to-progression (TTP) was the primary efficacy endpoint. Overall survival (OS), progression-free survival (PFS) and response rate (RR) were secondary endpoints. A total of 682 patients were randomized: 338 to receive MP and 344 to receive the combination of bortezomib

plus MP. The median age of patients for both groups was 71 years. Demographics and baseline disease characteristics were similar between the two groups.

FDA Grants Approval to Bristol-Myers Squibb for new SPRYCEL (dasatinib) 100 mg Tablet

The U. S. Food and Drug Administration (FDA) has granted Bristol-Myers Squibb approval of a SPRYCEL 100 mg tablet. This new tablet supports the recently FDA approved SPRYCEL 100 mg starting dose for chronic phase CML treatment.

The FDA has approved new labeling for SPRYCEL to include a lower recommended starting dose of 100 mg once daily and safety and efficacy data in a greater number of patients with chronic-phase chronic myeloid leukemia (CML) resistant or intolerant to prior therapy including Gleevec. The product labeling now also includes data from the first randomized trial of SPRYCEL and Gleevec. SPRYCEL is indicated for the treatment of adults with chronic-, accelerated-, or myeloid or lymphoid blast-phase CML with resistance or intolerance to prior therapy including Gleevec. The effectiveness of SPRYCEL is based on hematologic and cytogenetic response rates.

The new 100 mg tablet will be available by the first week of July

Zometa Receives new AHFS-DI Compendium Indication

Zoledronic acid (Zometa) has been accepted by the *American Hospital Formulary Service Drug Information (AHFS-DI)* drug compendium as treatment for prevention of aromatase inhibitor-associated bone loss (AIBL) in postmenopausal women. The oncology determination table is available online. *AHFS-DI* is published by the American Society of Health-System Pharmacists (ASHP).

FCSO UPDATES:

July 2008 Update to the ASC Payment System and Summary of Payment Policy Changes

Effective Date: July 1, 2008 - **Implementation Date:** July 7, 2008

Summary

Key points in change request 6095 includes:

- Billing for and payment of drugs and biologicals
- Payment for brachytherapy sources
- Category III CPT codes added to the list of payable procedures

In addition, this change request amends the ASC fee schedule payment file for selected office-based procedures and radiology services subject to payment at the lesser of the nonfacility practice expense (PE) relative value units (RVU) amounts under the Medicare physician fee schedule (MPFS).

Here is the link to the MLN Matters article MM6095

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6095.pdf>

J9025: VIDAZA and administration code 96401 - clarification of correct billing

There has been recent discussion between First Coast Service Options Inc. (FCSO) and providers regarding VIDAZA® and chemotherapy administration code *96401 (Chemotherapy administration, subcutaneous or intramuscular; non-hormonal)*. VIDAZA® is indicated for treatment of patients with the following myelodysplastic syndrome subtypes:

- Refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusion)
- Refractory anemia with excess blasts
- Refractory anemia with excess blasts in transformation
- Chronic myelomonocytic leukemia (CMML)

VIDAZA® can be administered intravenously or subcutaneously. Discussion between FCSO and the provider community regarding VIDAZA® administration has focused on the subcutaneous route. For subcutaneous administrations of VIDAZA® where the dose is greater than 4 mL, the dose should be divided equally into two syringes and administered into two different sites. Oncology offices are paid extra for chemo administration (as opposed to other drug administration) given the risk and side effects associated with these drugs and the associated overhead to monitor. There is **not** a doubling of risk given the dose is split between two injections that are given one after the other. The additional cost for the syringe and nurse work is not a major factor since the code is weighted three times a therapeutic injection. Therefore, FCSO would not expect to see more than 1 unit of *96401* billed for the administration of VIDAZA®.

CMS UPDATES:

Medicare Adds Another Recognized Compendium

On July 2, 2008, CMS announced additional updates to the information it uses in determining which drugs may be covered under Medicare Part B when used to treat patients undergoing cancer treatment through chemotherapy. CMS will add **Elsevier Gold Standard's Clinical Pharmacology compendium** to the list of Medicare anti-cancer treatment compendia. Medicare local contractors, which process and pay Medicare claims and approve coverage for drugs under Medicare Part B, use compendia as one of several tools to determine whether an anti-cancer drug may be covered under Medicare Part B. This decision marks the completion of the CMS evaluation and comment period to supply contractors with up-to-date references for coverage inquiries.

Approved compendia now includes: **NCCN's Drugs & Biologics Compendium, Thomson Micromedex's DrugDex., The American Hospital Formulary Service Drug Information (AHFS-DI) and Elsevier Gold Standard's Clinical Pharmacology.**

AVAILABLE CLINICAL TRIALS:

UFPTI 0609-PC01: A Study Using Photon/Proton Beam Radiation Therapy and Chemotherapy for Unresectable Carcinoma of the Pancreas

Detailed Description:

Chemotherapy Capecitabine (Xeloda ®) 1,000 mg PO BID (approx. Q12 hrs) 5 days/week (M-F) starting day 1 of RT until end of RT, on radiation days only.*

Regional RT Gross tumor and regional lymph nodes at risk 45 Gy in 25 fractions at 1.8 Gy per fraction over 5 weeks.

Concomitant Boost Primary mass and gross disease 22.5 CGE in 15 p.m. fractions during the last 3 weeks of regional RT.

Consolidation Chemotherapy Gemcitabine (Gemzar ®) 1,000mg/m² IV over 30 min on days 1, 8, and 15 of each 28 day cycle for 4 total cycles (12 total doses)*. Starting 4 weeks after the completion of RT/Xeloda.

required PPI and Imodium per section 6.4.1

Photons via IMRT 45 Gy @ 1.8 Gy per a.m. fraction

Proton Boost 22.5 CGE @ 1.5 CGE per p.m. fraction during weeks 3-5 of RT At least 6 hrs after a.m. fraction

Contact Info: University of Florida **Proton** Therapy Institute
Jacksonville, Florida, United States, 32206
Contact: Amanda D Prince, RN 904-588-1298 aprince@floridaproton.org
Contact: Cindy L Carroll (904) 588-1288 ccarroll@floridaproton.org
Principal Investigator: Felicia E Snead, MD

LUNG CANCER GRANT OPPORTUNITY

The National Lung Cancer Partnership announces the opening of the application period for two award programs:

National Lung Cancer Partnership/ LUNgevity Foundation Research Grants for the promotion of understanding lung cancer risk, biology, and response to treatment. This grant program, administered by the National Lung Cancer Partnership and co-funded with the LUNgevity Foundation, is designed to provide seed money for promising novel research in lung cancer for faculty members at any point in their careers, performing research at any institution world-wide.

Two grants are available:

- One is specifically for research in the area of sex differences in lung cancer.
- One is for research pertaining to any facet of lung cancer.

Research Grants will be awarded for one or two years, for up to \$50,000 per year (\$100,000 maximum over 2 years).

National Lung Cancer Partnership Career Development Award for junior clinical and basic investigators involved in lung cancer etiology, prevention, and treatment at any U.S. or Canadian research institution. The National Lung Cancer Partnership's goal is to create a critical mass of lung cancer researchers to ensure that basic and behavioral research discoveries are effectively translated into patient therapies to reduce lung cancer incidence, morbidity and mortality. Applicants will be judged on the merits of their research proposal, career development plan, and research environment, among other factors. Applicants must be post-doctoral fellows, or within the first five years of a faculty appointment. Career Development Awards will be awarded for one or two years, for up to \$50,000 per year (\$100,000 maximum over 2 years).

For application eligibility and instructions for these Grant & Award competitions, please visit the National Lung Cancer Partnership website at www.NationalLungCancerPartnership.org. Application deadline is **September 2, 2008**.

EDUCATIONAL OPPORTUNITIES:

JOIN A LIVE, INTERACTIVE WEBCAST: - Nexavar in the Treatment of Patients with Unresectable Hepatocellular Carcinoma (HCC)

Bayer HealthCare Pharmaceuticals Inc. and Onyx Pharmaceuticals Inc. welcome your participation in a live, online event. This is a unique, interactive opportunity to learn more about exciting developments in the treatment of patients with unresectable HCC. This educational opportunity is available commencing June 17, 2008 – through August 13, 2008.

EDUCATIONAL OBJECTIVES

- Learn about the incidence, prevalence, and risk factors for HCC
- Discuss the Sorafenib HCC Assessment Randomized Protocol (SHARP) study design
- Review the final SHARP study data for Nexavar—the first and only systemic treatment approved for patients with unresectable HCC

To register for this promotional event, contact your Bayer or Onyx Oncology Specialist or log on to <http://www.pharmethod.com/bayeronyx/register> and follow the instructions on the link. Please feel free to direct any questions to the Bayer/Onyx PharmaCAST Program Manager at **1-866-606-0768**.

ImClone Systems Incorporated

Web based reimbursement updates available.

1. "2008 Washington Update" authored by Dr. Joseph Bailes, M.D.
2. "2008 Reimbursement and Coding Changes" authored by Bobbi Buell

If you are interested in having an ImClone representative visit your office and present one or both of these programs, please contact Bob Bexley at Bob.Bexley@imclone.com or call 770-331-4453.

DISCLAIMER: FLASCO has not reviewed these programs and “any views presented are not the views of FLASCO”

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 EVENTS:

August 8-9, 2008 – FLASCO Executive Committee Retreat – Marriott World Center Hotel - Orlando

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

January 17-18, 2009 – Clinical Breakthroughs & Challenges in Hematologic Malignancies – Grand Floridian Resort – Lake Buena Vista

February 6 & 7, 2009 – Highlights of ASH - Miami

February 27 & 28, 2009 – FLASCO Spring Meeting – Marriott Sawgrass – Jacksonville

March 20, 2009 – Statewide PA & NP Conference, Moffitt Cancer Center - Tampa

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Email: Dorothy.Green@cancer.org

OTHER EVENTS:

September 17-20, 2008 – ACCC 25th National Oncology Economic Conference – San Francisco, California

September 19-20, 2008 - Annual ASCO/ASH/SGO Meeting of the Hematology/Oncology CAC Network

September 25-28, 2008 - Oncology Congress - the Hilton San Francisco

October 19-22, 2008 – MGMA 2008 Annual Conference – San Diego

December 6-9, 2008 – ASH Annual meeting – San Francisco

February 26-28, 2009 – ASCO - GU Symposium, Orlando World Center Marriott

March 22-24.2009 - 2009 AOHA Assembly Conference – Los Angeles, California