



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST –August 20, 2009

FLASCO WEBSITE: www.flasco.org

FLASCO CLINICAL TRIALS NETWORK WEBSITE: www.fctn.org

MESSAGE FROM THE PRESIDENT: Gerald Robbins, MD

The Executive Committee Retreat was held this past weekend. In the next few weeks a summary of the recommendations from this Retreat will be distributed to all FLASCO members. There are many new exciting opportunities for FLASCO members and their staff. Thanks to all members who participated in this Retreat.

CLINICAL PRACTICE COMMITTEE: Thomas Gaddis, MD, Chairman

Blue Cross Blue Shield Update:

July 29, 2009, FLASCO sent a letter to the Medical Director offering several suggestions and changes to the Medical Coverage Guidelines issued by Blue Cross Blue Shield of Florida for the benefit of our cancer patients. Several of our physicians have dedicated a significant amount of time and effort to review and analyze these guidelines and their effects on patient care. A copy of the letter which contained recommendations is included with this fax blast. To-date, we have not received a written response from BCBS.

Payer Provider Ad Hoc Committee Update: (Thomas Marsland, MD, Chairman

The Payer Provider Ad Hoc Committee met last Friday with representatives from three groups, name and contact information listed below, to discuss their approach to controlling cancer costs. All three had a number of key components which included: pathway development, direct patient interactions (disease management), and end of life care. They had some compelling information to suggest that programs that included these components could result in significant cost savings without compromising quality care. FLASCO will be reviewing this concept and putting out a position paper sometime soon. In addition we hope to develop a presentation which would include some of these concepts and begin to take this to payers prospectively.

UPMC (University of Pittsburgh Medical Center)

The University of Pittsburgh Medical Center (UPMC) has a pathway program and will negotiate with payers. They have a computer module that is web based and are currently working on crosstalk with other medical records and payment systems. Their program includes end of life issues, and is easy to implement as it is only a single component. Program cost was not discussed. Patient information remains under practice and not for sale. Back up can be local at site or distant through web.

Contact Information:

Kathy Lokay, Senior Vice President
UPMC Commercial Oncology Services
Phone: 412-623-1634
E-mail: lokaykg@upmc.edu
Website: www.upmc.com

Innovent Oncology

Innovent Oncology has a three-component system. Part 1: Clinical Pathways system, physician developed and updated on a regular basis through open committee and general voting system. Level 1 data is included in decision-making first, then toxicity and patient issues and then if two regimens are considered equivalent, cost can be considered. Negotiating ASP plus higher % for compliance/use of generics. Part 2: Oncology Management Program that is nursing based. Several thousand scripts provided for local nurses to utilize or can use a bank of central nurses that they provide. System is composed of follow phone contacts to monitor any

toxicity or symptoms aggressively to prevent hospitalization and reduce costs. Part 3: End of Life Care including documentation of discussions and reimbursement.

Innovent program is a web-based portal. Innovent Oncology will not sell the data and also negotiates directly with payers. Payment is based upon tiered system of usage, compliance and level of US Oncology affiliation. It is a transparent system of fee schedule on a per-patient per-month on treatment basis with pre-determined split with practice and US Oncology.

Contact Information:

Website: www.innoventoncology.com

Note: If you need additional contact information, please contact the FLASCO Office.

P4 Pathways

P4 has clinical pathways but rather than national, will adjust to local market. P4 will negotiate an incentive for generic drug use by adding fixed fee and will negotiate ASP plus higher % for compliance. They also negotiate with payors. They did not disclose what discounts they are negotiating (i.e. how much they keep), just how much we would keep. End of life care also a component. Patient info is not for sale.

Contact Information:

Jeff Hawes PharmD, RPh

Senior Director of Managed Care

Office: (574) 243-3811

Cell phone: (574) 286-4011

E-mail: jhawes@p4healthcare.com

Website: <http://www.p4pathways.com/go/program>

UNITED HEALTH CARE UPDATES:

BRCA Testing

BRCA Genetic Testing Notification and Expanded Access to Genetic Counseling

Effective August 16, 2009 – for complete information please go to:

<https://www.unitedhealthcareonline.com/b2c/CmaAction.do?channelId=f3478c10d2152210VgnVCM1000002f10b10a>

DRUG UPDATES:

US court suspends approvals of generic Eloxatin

A US appeals court suspended FDA approvals of generic versions of sanofi-aventis' Eloxatin (oxaliplatin). The suspension is related to litigation initiated by sanofi-aventis against the FDA and a court order issued as part of the case, noted Hospira, which said it will temporarily stop shipments of generic Eloxatin after having received regulatory approval for its product last week.

LEGISLATIVE UPDATES:

Legislators need to hear from Patient & Caregivers during the legislator break though Labor Day.

Consider providing this existing information to your patients:

- Print the 1 page information page from the Community Oncology Alliance (COA) regarding how patients & caregivers can get involved in health care reform and provide in your waiting room (+/- patient rooms).
 - To print, see <http://www.communityoncology.org/coa-patient-advocacy-network/>
- Print the 1 page sign from COA notifying patients & caregivers of what the future of healthcare may look like and hang in your waiting room (+/- patient rooms). This sign can be individualized.
 - To obtain, contact FLASCO
- Print the list of other recourses and links for patients and caregivers to get involved and learn more and provide in your waiting room (+/- patient rooms)
 - <http://www.acponline.org/advocacy/>
 - http://www.cancer.org/docroot/ADV/ADV_0.asp

- <http://www.patientsactionnetwork.org/index.aspx>
- <http://www.communityoncology.org/coa-patient-advocacy-network/>
- http://www.aarp.org/about_aarp/contact/a2003-01-27-contact-aarpissues.html

Legislators need to hear from each FLASCO member about health care reform by Labor Day. Please provide the FLASCO Office with the name, title and contact information of your Office Manager/Office Administrator (Thanks to the FLASCO members who have already provided this information to the FLASCO Office) . FLASCO will provide them with:

- TEMPLATE LETTERS for easy cut/paste
- ADDRESSES and FAX NUMBERS for all legislators for easy cut/paste
- INDIVIDUALIZED HELP

Legislators need to hear from each FLASCO member about preventing devastating CMS payment cuts by August 31st. Please provide the FLASCO Office with the name, title and contact information of your Office Manager/Office Administrator. (Thanks to the FLASCO members who have already provided this information to the FLASCO Office) FLASCO will provide them with:

- TEMPLATE LETTERS for easy cut/paste
- ADDRESSES and FAX NUMBERS for all legislators for easy cut/paste
- INDIVIDUALIZED HELP

NOTE: Template Letters and instructions have already been e-mailed to all of the practice administrators whose e-mail info has been provided to FLASCO. In addition, a special thanks to Michelle Smith Flowers for distributing our template letters and info to all of the OMF members.

CMS UPDATES:

Proposed Decision Memo for Positron Emission Tomography (FDG) for Cervical Cancer (CAG-00181R2)

CMS was asked to reconsider Section 220.6 of the National Coverage Determinations Manual to end the prospective data collection requirements for FDG PET for initial staging of cervical cancer. CMS proposes that the evidence is adequate to determine that the results of FDG PET imaging for cervical cancer staging of beneficiaries diagnosed with cervical cancer are used by the treating physician to make meaningful changes in therapeutic management and improve health outcomes, and thus are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act.

Therefore, CMS proposes to **cover only one FDG PET** for staging in beneficiaries who have biopsy proven cervical cancer when the beneficiary's treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial treatment strategy:

- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

The requestor also noted that "CMS may find it appropriate to exclude coverage for diagnosis of cervical cancer since this disorder is initially diagnosed by biopsy. CMS agrees and proposes that there is no credible evidence that the results of FDG PET imaging are useful to make the initial diagnosis of cervical cancer, and therefore do not improve health outcomes, and thus are not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act. Therefore CMS proposes to noncover FDG PET for this indication.

CMS is soliciting public comments on this proposed decision pursuant to §1862(l) of the Social Security Act. For more information, you can view the complete proposed decision memo at <https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=232>.

MEDICAID UPDATES:

Billing Change for CMS-1500 Claims with Modifier 24

Effective 09/01/2009, and after, CMS-1500 claims submitted with modifier 24 (unrelated evaluation and management service by the same physician during a postoperative period) will no longer be subject to Medicaid medical review. Therefore, documentation will no longer be required for submission of claims billed with modifier 24.

While the Physician Services Coverage and Limitations Handbook policy on modifier 24 still reflects the need for documentation and medical review, that requirement becomes obsolete on and after 09/01/2009. The old policy will be removed from the handbook.

CMS MLM UPDATES

New:

MM6228 – Reporting Non-Tax Withholding Due to Federal Payment Levy Program (FPLP)

<http://www.cms.hhs.gov/MLNMArticles/downloads/MM6228.pdf>

MM6585 – October 2009 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

<http://www.cms.hhs.gov/MLNMArticles/downloads/MM6585.pdf>

MM6524 – Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens

<http://www.cms.hhs.gov/MLNMArticles/downloads/MM6524.pdf>

PROGRAM COMMITTEE UPDATES: Jose Lutzy, MD, Chairman

Business of Oncology Summit:

FLASCO will be holding its 1st 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. 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:

12th 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. Is there research available that presents an unbiased review of the oncology industry? I am most interested in future predictions.

A. Yes, Bank of America/ Merrill Lynch has a specialized research group dedicated to health care and a sub group focused on oncology. If you wish to see this research, 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 - <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.
Ortho Biotech
Genentech
GlaxoSmithKline
The Phipps Wealth
Management Group
Novartis
Astra Zeneca
Pfizer

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

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

FLASCO Contact Info:

Dorothy Green Phillips, Executive Director - Phone: 1.813.349.4410 – Dorothy.Green@cancer.org

July 29, 2009

Jonathan Gavras, MD
Vice President of Medical Operations
Blue Cross Blue Shield of Florida
4800 Deerwood Campus Parkway
Jacksonville, FL 32246

Dear Dr. Gavras:

The Florida Society of Clinical Oncology (FLASCO) is committed to improving patient care by serving as a resource to other organizations that interact with the Florida cancer care community, disseminating information and providing an opportunity for oncologists to network and exchange information on cancer care, and assisting the cancer practitioners in providing the most cost effective quality care for their patients.

FLASCO would like to offer several suggestions and changes to the Medical Coverage Guidelines issued by Blue Cross Blue Shield of Florida for the benefit of our cancer patients. Several of our physicians have dedicated a significant amount of time and effort to review and analyze these guidelines and their effects on patient care. We have subsequently discussed the following proposed modifications in committee and would recommend the following:

1. Blue Cross Blue Shield of Florida has established review of coverage guidelines on an annual basis. We believe that this frequency is insufficient, as oncology practices change very quickly, and suggest at minimum a quarterly review. It would be inappropriate, for example, to have patients wait the better part of a year before they could have access to potentially life saving treatments.

2. Dosing limitations on bevacizumab (Avastin) and trastuzumab (Herceptin) should be removed. Avastin and Herceptin dosages are based on patients' weights; thus making dosing limitations unfounded and unsubstantiated. Also, to further validate, neither package insert for Avastin nor Herceptin, indicate dosing limitations. There could be an issue of subtherapeutic dosing in large framed individuals.

3. For Avastin, we suggest usage in colorectal cancer with a FU based combination in first, second, and third line protocols. Also, we recommend Avastin usage in the treatment of breast cancer in conjunction with any taxane or epothilone (Taxol, Taxotere, and Abraxane, Ixabepilone) or capecitabine. Finally, for Avastin in lung cancer, we suggest usage in non-squamous, non-small cell for the first line of treatment on combination with Carboplatin, Cisplatin, Taxol, Abraxane, and gemcitabine (Gemzar).

4. For Herceptin usage in breast cancer, we suggest usage as part of a treatment regimen consisting of Cyclophosphamide, Doxorubicin, and either Paclitaxel or Docetaxel; with Docetaxel and Carboplatin; with Abraxane; with liposomal doxorubicin or with navelbine or as a single agent.

5. The time restriction placed upon Neulasta should be changed to 13 days instead of the 14 day restriction in the drug protocol. In dose dense protocols, chemotherapy is administered every 14 days, making the 14 day restrictions imposed problematic. Even FCSO has revised the LCD to include 13 day dosing for "dose dense" regimens.

6. For Aloxi usage, we feel that most combination chemotherapy regimens would fall into the highly emetogenic category when one considers the emetogenic potential of each drug. It is also the only drug in its class that has duration of activity lasting more than 1 day saving repeated administration of intravenous antiemetic therapy of other 5-HT3 blockers.

7. Lastly, the language on Her2 testing is unclear and we recommend that the requirement for trastuzumab therapy be changed to read “Her2 positive (as defined by any reference laboratory)”. Current testing is variable and frequently not reproducible. Limiting of FISH values of 2.2 or higher for positive results is not necessary in keeping with the literature and the positive range of values in some laboratories.

FLASCO and its members are committed to decreasing total cancer drug expenditures, disease management (symptom control to reduce the incidence of ER visits and hospitalizations), and advanced care planning (the earlier introduction of the concepts of palliative as opposed to active care). We all recognize that to make progress in these areas we need to partner with our patients and with payers as advocates.

Thank you very much for your time in reviewing these suggestions. FLASCO recognizes that while we may vary on our perspectives, in order for patients to receive optimum care, we need to maintain clinical efficacy as well as operate in a cost conscientious environment. We look forward to continued collaboration and communication with Blue Cross Blue Shield of Florida.

Sincerely,

A handwritten signature in cursive script that reads "Gerald Robbins".

Gerald Robbins, MD
FLASCO President