



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – December 11, 2008

FLASCO WEBSITE: www.flasco.org

FLASCO CLINICAL TRIALS NETWORK WEBSITE: www.fctn.org

MESSAGE FROM THE FLASCO PRESIDENT: Robert Cassell, MD

We want to call your attention to an article by former FLASCO President Dr. Robert Kane in the November 2008 issue of The Oncologist, entitled "**The Clinical Significance of Statistical Significance**," located on-line at <http://theoncologist.alphamedpress.org/cgi/content>.

YOUR E-MAIL ADDRESS: - there are times extremely important information becomes available before our next weekly fax blast and it is e-mailed to our membership - therefore, it is extremely important that you provide your e-mail address to dorothy.green@cancer.org so you won't miss out on these important announcements and news -

REMINDER: All 2008 Corporate Memberships/Sponsorships expire on December 31, 2008. It will be greatly appreciated if all companies who plan to renew their Corporate Membership/Sponsorship for 2009 will notify the FLASCO Office.

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! This same opportunity is being offered to the physicians from Puerto Rico.

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.

MEMBERSHIP COMMITTEE: Julio Hajdenberg, MD, Chairman

Keep your eye out for your 2009 FLASCO dues notices in the mail. We sincerely hope that you will continue your membership and involvement with FLASCO for 2009.

CLINICAL PRACTICE COMMITTEE: Thomas Gaddis, MD, Chairman

Health Care Clinic Establishment permit

NOTE: We still don't know all of the details of the permit or the process for the HealthCare Clinic Establishment Permit. It appears that every practice will need a permit for every location - the only exception being a (unincorporated) single practitioner with only one location.

Please see the info below from DOH:

On May 1, 2008, the Florida Legislature passed HB 7049. In addition to substantially reorganizing Chapter 499, Part I, Florida Statutes, the bill created two new permits under Drugs, Devices, and Cosmetics Program. One of the new permits is called a "Health Care Clinic Establishment Permit."

Effective January 1, 2009, a health care clinic establishment permit will be required for the purchase of prescription drugs by a group practice (place of business at one general physical location owned and operated by a professional corporation or professional limited liability company described in chapter 621 F.S., or a corporation that employs a veterinarian as a qualifying practitioner) that wishes to purchase and own prescription. Under current law, health care practitioners in a

group practice setting must individually order their own prescription drugs for dispensing or administering to their own patients under their own license number.

As part of the application required under section 499.012, F.S., the establishment will be required to designate a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. For the purposes of this section, a “qualifying practitioner” is a licensed health care practitioner defined in s. 456.001 or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

Additionally, the designated qualifying practitioner must be the practitioner whose name, establishment address, and license number is used on all distribution documents for the prescription drugs purchased or returned by the health care clinic establishment.

The qualifying practitioner and health care clinic establishment are responsible for notifying the department within 10 days of any changes to their designated qualifying practitioner.

Please follow the links below for the Health Care Clinic Establishment permit application, application instruction / reference, and the Change Qualifying Practitioner form .

Link to Application: http://www.doh.state.fl.us/pharmacy/ap_HCCE.pdf

Link to Instructions: http://www.doh.state.fl.us/pharmacy/info_HCCEGuide.pdf

Link to Health Care Clinic Establishment Law Summary: http://www.doh.state.fl.us/pharmacy/info_HCCELaw.pdf

Link to Qualifying Practitioner Change form Change of Designated Practitioner Form:
http://www.doh.state.fl.us/pharmacy/info_practitioner.pdf

The FLASCO Office has received many calls regarding this issue - in general practices are asking the following questions:

“Do we need a separate permit for each location to which drugs are sent and used? Also, are infusable drugs included in this mandate or are they pegging practices that purchase, dispense and bill oral prescription drugs?”

Here is the understanding of some of the members of our Committee -

Agreed that the answer to the first question above is YES - any site that administers drugs needs a permit. A designated physician needs to be on the permit and preferably a backup for group practice. Each physician does not need a permit, but each site needs a physician designated on the permit and it is assumed they need to attend the site on some regular schedule. Second Question: They are definitely including infusions & injections, as well as dispensing of oral meds.

As additional information becomes available to FLASCO it will be provided to the membership by e-mail and/or in our fax blast.

Leucovorin Shortage

Please see the attached sheet regarding the Leucovorin Shortage and Alternatives

Insurance Company Issues – Is your practice having this issue?

The FLASCO Office has received the following from a member – if your practice is having this same issue please e-mail dorothy.green@cancer.org and advise her of your situation, including any pattern to the type of claims they are requesting records for and any specific carrier. If enough practices have this problem, the FLASCO Clinical Practice Committee will contact the Insurance Commissioner.

“Although we have a prompt pay law for clean claims it appears that managed care companies (Blue Cross, Cigna, Aetna, United Health Care, etc.) try to get around this by not paying claims, but asking for records. We will fax them the records and then have to wait 30 days. When we don’t get paid we call them and they state they have not received the records. Sometimes they will pay on part of the claim that they did not pay originally. We have to call again and again and again. I do not know if this is legal or not. I am sure that there is in the agreement that they have the right to ask for documentation of medical records to verify medical necessity as well as document that the service was provided. In any event, this is getting to be quite burdensome and I think they are abusing the system. Do we have any options through FLASCO to appeal to the insurance commissioner or the insurance companies themselves? “

2009 HCPCS Changes

Here are the new HCPCS changes for Hematology-Oncology for 2009. Do not use these codes for service dates before 1/1/09.

New Codes

J0641 INJECTION, LEVOLEUCOVORIN CALCIUM, 0.5 MG
J1453 INJECTION, FOSAPREPITANT, 1 MG
J1459 INJECTION, IMMUNE GLOBULIN (PRIVIGEN), INTRAVENOUS, NON-LYOPHILIZED (E.G.)
J8705 TOPOTECAN, ORAL, 0.25 MG
J9033 INJECTION, BENDAMUSTINE HCL, 1 MG
J9207 INJECTION, IXABEPILONE, 1 MG
J9330 INJECTION, TEMSIROLIMUS, 1 MG

Changed Code Descriptors

- J1572 INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA/FLEBOGAMMA DIF), INTRAVENOUS,
- J2788 INJECTION, RHO D IMMUNE GLOBULIN, HUMAN, MINIDOSE, 50 MICROGRAMS (250 I.U.)
- J2790 INJECTION, RHO D IMMUNE GLOBULIN, HUMAN, FULL DOSE, 300 MICROGRAMS (1500 I.U.)

Deleted Codes

- Q4096 INJECTION, VON WILLEBRAND FACTOR COMPLEX, HUMAN, RISTOCETIN COFACTOR (NOT
- Q4097 INJECTION, IMMUNE GLOBULIN (PRIVIGEN), INTRAVENOUS, NON-LYOPHILIZED (E.G.)
- Q4098 INJECTION, IRON DEXTRAN, 50 MG

Reinstated Code

- J1750 INJECTION, IRON DEXTRAN, 50 MG

These are only a preliminary list of codes that apply to Hem-Onc. To see the total list, check it out in EXCEL.
<http://www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/>

FCSO UPDATES:

FL Part B (General Information) eNews: J9 transition information

First Coast Service Options (FCSO) will assume its new role as the Medicare administrative contractor for Jurisdiction 9 (MAC J9) on February 1, 2009 (Florida Part B), and February 13, 2009 (Florida Part A). This news means FCSSO will maintain its long-standing relationships with Medicare beneficiaries and providers in Florida. Our existing Florida providers can expect business as usual with minimal impacts as we transition to the new MAC J9.

FCSSO’s top priority over the next few months is to communicate with all stakeholders on the J9 transition and any changes resulting from the new contract. In support of this goal, FCSSO is launching today the first in a three-part series of J9 special edition bulletins for Florida providers. The November edition bulletin covers the following topics:

- Resources for staying informed about the J9 transition
- Consolidation of MAC J9 local coverage determinations
- Tips for preparing for a transition from an FI/Carrier to a Medicare administrative contactor
- Upcoming J9 educational events for Florida providers

For the latest J9 transition news, go to www.fcso.com and select "J9 Transition." Don't forget to also subscribe to FCSO's [J9 e-mail listserv](#) to receive automatic e-mail notifications whenever urgent or critical J9 information is posted to the FCSO Web site.

ASCO UPDATES:

FDA Issues Q&A on Medication Guides for ESAs

The Food and Drug Administration (FDA) issued a [document](http://www.fda.gov/Cder/drug/infopage/RHE/qa2008.htm) (<http://www.fda.gov/Cder/drug/infopage/RHE/qa2008.htm>) answering a series of questions related to its medication guides for erythropoiesis-stimulating agents (ESAs).

FDA developed this [medication guide](http://www.fda.gov/cder/drug/infopage/RHE/default.htm) (<http://www.fda.gov/cder/drug/infopage/RHE/default.htm>) to provide patients with information on the risks of taking ESAs. FDA states that the medication guide should be distributed when ESAs are "dispensed" to patients. ASCO continues to seek clarification from the FDA on the extent to which this requirement applies outside of the pharmacy setting.

The document also notes that the FDA is working with drug manufacturers to develop additional regulatory requirements in the form of a Risk Evaluation and Mitigation Strategy (REMS) for ESAs.

Contact ASCO's Cancer Policy & Clinical Affairs Department with any questions, at 571-483-1670 or practice@asco.org

DRUG & INDUSTRY UPDATES:

The TORISEL Reimbursement Support Program (Wyeth)

This is a one-stop resource for your reimbursement and patient access needs.

<http://www.wyeth.com/hcp/torisel/billing-reimbursement> Here is some additional contact information on the Wyeth support program: One call connects you to your dedicated Regional Reimbursement Consultant (RRC), who is ready to handle your reimbursement questions about TORISEL.

Contact Information

Phone: 1-866-WYETH-ONC (1-866-993-8466)

Fax: 1-866-993-8411

Monday – Friday, 9am – 6pm, Eastern Time

TORISEL Reimbursement Support Program

P.O. Box 220907

Charlotte, NC 28222-0907

CMS UPDATES:

Advanced Practice Nursing & Physician Assistants Web Page

The Medicare Learning Network (MLN) is pleased to announce the availability of the **Advanced Practice Nursing & Physician Assistants (APN/PA)** web page. This dedicated web page is for Medicare fee-for-service (FFS) advanced practice nurses and physician assistants who provide services to Medicare beneficiaries.

From this web page, you will be able to access and peruse the Medicare FFS program topics in order to keep abreast of policy and operational updates specific to Advanced Practice Nurses and Physician Assistants.

One of the educational resources featured on this webpage is the "**Advanced Practice Nurse/Physician Assistant Web-Based Training Program**" – this interactive web-based training program provides definitions of the Advanced Practice Nursing/Physician Assistant provider types; outlines the qualifications of the Advanced Practice Nursing/Physician Assistant provider types; describes collaboration/supervision requirements for Advanced Practice Nursing/Physician Assistant Medicare reimbursements; lists the Medicare billing requirements for Advanced Practice Nursing and Physician Assistants; and identifies links to Medicare manuals and other resources.

This web page is updated on a regular basis, so check it often for timely and reliable information from MLN.

For more information, visit the web page at http://www.cms.hhs.gov/MLNProducts/70_APNPA.asp#TopOfPage on the CMS website.

PQRI Conference Call December 16, 2008

The conference call will take place from 3:30 p.m. - 5:00 p.m. (EST) on December 16, 2008. Following a brief presentation on the final PQRI 2007 reporting experience and a discussion of results from 2007, CMS will allow participants to ask questions of CMS PQRI subject matter experts. **To participate in the conference call, registration is required. Registration will close at 3:30 p.m. (EST) on December 15, 2008 or when available space has been filed.** To register, go to . <http://www2.eventsvc.com/palmettogba/register/d2066cc9-e313-4ca3-b594-b7fef8626b30>

CMS will also make an audio recording of the conference call available from 4:00 p.m. (EST) on December 16, 2008 until 11:59 p.m. (EST) on December 23, 2008. To access the audio recording, one must call (800) 642-1687 and use passcode 76618434.

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

Q: Does the Section 529 College Savings Plan account grow and compound tax free?

A: Yes and as long as any withdrawals are used for qualified post secondary educational expenses, they are non taxable, too.

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 - <http://fa.ml.com/PhippsGroup/>

EDUCATIONAL OPPORTUNITIES:

Sanofi-Aventis: Live Satellite Program: Evolving Paradigms in the Adjuvant Treatment of HER2 Overexpressing Breast Cancer: The Role of Anthracyclines

Date: Wednesday, January 14th, 2009

Faculty: Dr. Dennis Slamon, Dr. Stephen Jones, and Dr. Michael Ewer

Locations: Choose from one of the restaurants below

Morton's 5050 Town Center Circle - Boca Raton

Morton's 2333 Ponce de Leon Blvd.- Coral Gables

Maggiano's 10367 Midtown Parkway – St. John's Towne Center - Jacksonville

Morton's 1200 Brickell Avenue- Miami, FL

Morton's Dr. Phillips Market Place – 7600 D. Phillips Blvd-, Orlando, FL

Morton's 777 S. Flagler Drive W.- Palm Beach, FL

Maggiano's 203 West Shore Plaza -Tampa, FL

Contact your local Sanofi-Aventis Sales Representative with any questions and additional information.

CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2008)

FLASCO Members extends a big thanks to all of our 2008 Corporate Members/Sponsors

PLATINUM

Astra Zeneca

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Eli Lilly
Oncology Supply/ION
Sanofi-Aventis
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OSI Pharmaceuticals
Millennium Pharmaceuticals, Inc.

BRONZE

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Alexion
Genzyme

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**
- (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 2009 MEETINGS:

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

OTHER EVENTS:

February 26-28, 2009 – ASCO - GU Symposium, Orlando World Center Marriott
March 22-24, 2009 - 2009 AOHA Assembly Conference – Los Angeles, California
June 13-17, 2009 – AMA Annual Meeting – Chicago, IL
July 23-26, 2009 – FMA Annual Meeting – Boca Raton, FL

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

Leucovorin shortage

Treatment Guide of Colorectal Cancer

| Adjuvant Treatment (curative intent) | Metastatic Disease |
|---|--|
| Prioritized by preference | Prioritized by preference |
| New Patients | New Patients |
| 1. Initiate FOLFOX regimen, substituting Levoleucovorin (Fusilev) for Leucovorin at ½ dose. (subject to precert approval) | 1. Do not initiate patients with new regimens containing Leucovorin or Levoleucovorin. |
| 2. Consider XELOX or single agent Xeloda if unable to obtain Leucovorin | 2. Consider XELOX or single agent Xeloda. |
| 3. Initiate FOLFOX regimen, omitting Leucovorin | 3. Initiate FOLFOX, or FOLFIRI like regimen, but omit LV |
| | 4. Consider single agent 5-FU |
| | |
| Current Patients | Current Patients |
| 1. Continue therapy if patient on FOLFOX, but substitute L-LV (if approved by precert) | 1. Continue current regimen, but omit LV |
| 2. Omit LV for precert denials | 2. If on LV containing regimen, and cannot omit LV, switch to CAPOX, Xeloda, or 5-FU |
| 3. Switch to Xeloda | |
| | |

- Use of Fusilev (levoleucovorin) is subject to precert approval, and availability.
- Do not use Leucovorin or Levoleucovorin in metastatic patients until supply is restored. Reserve for adjuvant treatment, or treatment with curative intent.
- Treatment guide is applicable to colorectal cancer treatment, and any regimens containing leucovorin with 5-FU
- High dose methotrexate-containing protocols for sarcoma and lymphoma requiring leucovorin rescue should be given in inpatient setting