



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST –July 9, 2009

FLASCO WEBSITE: www.flasco.org

FLASCO CLINICAL TRIALS NETWORK WEBSITE: www.fctn.org

MESSAGE FROM THE PRESIDENT: Gerald Robbins, MD

This week on behalf of FLASCO, I faxed a letter to all Florida Congressmen and to Senators Martinez and Nelson asking them to co-sign H.R. 1392 and S 1221, which is legislation that would remove the prompt-pay discounts extended to wholesalers from the ASP calculation. All FLASCO Members are encouraged to write your Congressman and Senators Nelson and Martinez.

CLINICAL PRACTICE COMMITTEE UPDATE: Thomas Gaddis, MD, Chm.

The Florida Drugs, Devices and Cosmetics Program website address has changed. The new website address is <http://www.doh.state.fl.us/mqa/ddc>. Please update your records. You can visit the website for information regarding meetings, new rules/legislation and listings of application status.

LCD UPDATES:

LCD Oncotype DX Test Breast Cancer Prognosis (L28287) – Genomic Health

Revision #4, effective for dates of service on or after 06/25/2009

Revisions made: This LCD was updated to make clarification of coverage and to expand coverage.

Under "Indications and Limitations of Coverage and/or Medical Necessity" added the statement that clinical data supports its use for micrometastases and for 1-3 positive nodes. Also added the statement the gene expression yields a Recurrence Score which correlates with the recurrence of breast cancer and "may be used in the decision making for the type of chemotherapy used ". Removed the statement that CMS ALJ has consistently determined that Oncotype DX test is covered by Medicare.

Under subheading 'Characteristics of the Disease' added 'for patient with estrogen receptor positive micrometastases of carcinoma of the breast, and for patients with estrogen positive breast carcinoma with 1-3 positive nodes'.

Under subheading 'Timeliness of the Test' added the statement 'for patients with micrometastases and/or 1-3 positive nodes'. Also added the statement "Breast cancer that is ER negative or has 4 or more positive lymph nodes is not covered for this test because clinical tests show the test cannot be used for prognosis or determination of clinical course.

Under "Documentation Requirements" added node negative, micrometastases present and three or less positive nodes.

Under "Utilization Guidelines" added the test is covered for Estrogen receptor (RE) positive, lymph node negative breast cancer, Estrogen receptor (ER) positive breast cancer with micrometastases and Estrogen receptor (ER) positive breast cancer with no more than 3 positive lymph nodes (ER) - positive. Also added the statement that one would not perform this test more than once in a lifetime; but there are rare conditions where breast cancer can occur in a contralateral breast that is of a different cell type or different gene expression. In these cases a second test will be covered. Chart documentation should support the second test.

LEGISLATIVE UPDATE:

Washington Update – Dr. Thomas Marsland, FLASCO CAC Member

Earlier this week I had an opportunity to participate in a call wherein Dr. Joe Bailes provided a Washington Review. Here are some of the main points from the call:

- Lots of noise on “proposed” physician fee schedule. CMS took the most negative view and put out the worse case scenario which assumes no fix for SGR. If there is NOT a fix then that does result in a 20% decrease in the conversion factor as of Jan '10. MOST folks believe Congress will act to address this but obviously with all the other health legislation that will most likely be coming there are no promises of a fix.
- The other factor floated in the proposed fee schedule is the use of the “cost of care” (practice expense) survey done by the AMA last year and forwarded to CMS for them to use in setting new fees..... Problem here is that it is a “0” sum game... no additional money is being put into the budget so if one group wins another loses..... what happens is that costs increased for all groups including oncology BUT the increase in cost for primary care (IM FP, GYN, Peds) was astronomical.... (more than 20% increase) so dollars were shifted to primary care codes at the expense of the specialists.... ALL specialties lost money Med onc down 6% Rad onc and imaging down 12% cardiology down 11% rheumatology down 7%....
- Obviously organized specialty groups (ASCO) will be sending in comments to CMS..... urge all of you to respond also..... talking points being... that the methodology of the survey is flawed, since very limited data set (70 oncology practices ???) the increase seen in primary care expenses is unprecedented never before such a large increase in practice costs,... and the SGR needs to be fixed and tied to a national index like GDP or Medical economic index....
- As for Congress and legislative initiatives Global reform is primary.. objective is to have universal coverage so far many white papers and plans being floated but no actual legislation out yet.... Coming this month.... Biggest problem will be the “pay for” how much and how to get the \$\$\$\$ (\$\$\$\$\$\$\$\$\$\$\$\$\$) need to cover it. House will probably pass something a little more problematic in Senate reported even some Dems concerned about a Government sponsored program.... Sen Dodd who is leading charge said that if no bill by November all bets are off if gets to '10 probably nothing will happen because it is election yr.... even if no global bill many expect a “medicare” bill to fix SGR....
- Unclear how fee schedule issue may get caught up in all the legislative wrangling.... Several cancer specific bills being floated elimination of prompt pay discount from ASP (Davis), end of life demo project (Crowley) chemotherapy treatment plan (Capps) and bill to automatically add uninsured cancer patient to Medicare at the time of diagnosis.... Each of which have a fair chance of passage but again unclear how they may play into a broader Global bill....
- SO..... fasten your seat belts it is going to be a bumpy ride for the rest of the year.....

Invite your US House Member and US Senator to your practice:

It is extremely important for all FLASCO Members to be actively involved in Healthcare Reform. We need to let our voices be heard. Please invite your US Congressman and our two US Senators to visit your practice – let them see what you are facing each day in your practice (whether it be a private practice or academic practice). Let them know what you believe is needed to provide quality healthcare to our cancer patients in Florida. Congress will be in recess during the month of August – a great time to invite them to your practice. **Please start inviting them to visit your practice NOW.**

PROGRAM COMMITTEE UPDATES:

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.

FCSO UPDATES:

Revised national correct coding initiative edits for physicians from July 1

Modified: 7/7/2009 Business: Part B Location: FL, PR, USVI

If you downloaded the national correct coding initiative (NCCI) edits for physicians (version number 15.2) on July 5 or 6, please download the files again. [PERL 200907-03]

CMS UPDATES:

Healthcare Common Procedure Coding System (HCPCS) Quarterly Update

The Centers for Medicare & Medicaid Services is pleased to announce the scheduled release of modifications to the Healthcare Common Procedure Coding System (HCPCS) code set. These changes have been posted to the HCPCS website - Changes are effective on the date indicated on the update.

http://www.cms.hhs.gov/HCPCSReleaseCodeSets/02_HCPCS_Quarterly_Update.asp.

Revised National Correct Coding Initiative (NCCI) Edits for Physicians from July 1st

If you downloaded the National Correct Coding Initiative (NCCI) Edits for Physicians (version number 15.2, effective 7/1/09 – 9/30/09) yesterday or today, **please download the files again**. Incorrect files were posted for the NCCI Edits for Physicians. The files have been corrected, and can be found at

<http://www.cms.hhs.gov/NationalCorrectCodInitEd/NCCIEP/list.asp> on the CMS website.

The publication titled ICD-10-CM/PCS Myths & Facts (June 2009), which presents correct information in response to some myths regarding the ICD-10-Clinical Modification/Procedure Coding System, is now available in downloadable format from the Centers for Medicare & Medicaid Services **Medicare Learning Network** at <http://www.cms.hhs.gov/MLNProducts/downloads/ICD-10Mappingfctst.pdf> .

The Second in Series: General Equivalence Mappings – ICD-9-CM to and from ICD-10-CM and ICD-10-PCS Fact Sheet (May 2009), which provides basic information about the General Equivalence Mappings (GEM) including possible users of the GEMs, why the GEMs are needed, and how the GEMs files are formatted as well as Reimbursement Mappings information, is now available in print format from the Centers for Medicare & Medicaid Services **Medicare Learning Network**. To place your order, visit <http://www.cms.hhs.gov/MLNGenInfo/> , scroll down to “Related Links Inside CMS” and select “MLN Product Ordering Page.”

MLN MATTERS UPDATES:

New:

MM6452 – **Method of Payment for Extended Stay Services Under the Frontier Extended Stay Clinic (FESC) Demonstration, Authorized by Section 434 of the Medicare Modernization Act (MMA) - CR6452 provides additional information to CR 6057** <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6452.pdf>

MM6491 – **Revisions to Certain Items in CMS Change Request 6310**
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6491.pdf>

MM6525 – **Claim Status Category Code and Claim Status Code Update**
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6525.pdf>

Revised:

MM6417 – **Expansion of the Current Scope of Editing for Ordering/Referring Providers for claims processed by Medicare Carriers and Part B Medicare Administrative Contractors (MACs)**
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6417.pdf>

MM6426 – Instructions on utilizing 837 Institutional Claim Adjustment Segments (CAS) for Medicare Secondary Payer (MSP) Part A Claims. (This CR Rescinds and Fully Replaces CR 6275)

<http://www.cms.hhs.gov/MLNMArticles/downloads/MM6426.pdf>

MM6431 – Billing Routine Costs of Clinical Trials

<http://www.cms.hhs.gov/MLNMArticles/downloads/MM6431.pdf>

MM6330 – Clarification on Use of National Drug Codes (NDCs) in 837 I Billing

<http://www.cms.hhs.gov/MLNMArticles/downloads/MM6330.pdf>

FDA UPDATES:

Pemetrexed injection (Alimta® Injection –(Eli Lilly and Company)

On July 2, 2009, the U. S. Food and Drug Administration (FDA) approved pemetrexed injection (Alimta® Injection, Eli Lilly and Company) for maintenance treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. This approval is the third approved indication for pemetrexed in locally advanced or metastatic nonsquamous non-small cell lung cancer. Pemetrexed is not indicated for the treatment of patients with squamous cell non-small cell lung cancer

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021462s0211bl.pdf

FDA approves ferumoxytol (Feraheme Injection)

On June 30, 2009, the United States Food and Drug Administration (FDA) approved ferumoxytol (Feraheme™ Injection, AMAG Pharmaceuticals, Inc.) for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD). Ferumoxytol is an iron-containing product for intravenous (IV) administration. Full prescribing information is available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/0221801bl.pdf.

AMA UPDATES:

AMA CPT Department

The listing of Category III codes and the short and medium descriptors were updated July 1, 2009. These updates have been posted to the AMA Web site and can be viewed by going to <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/about-cpt/category-iii-codes.shtml>

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/>

DRUG AND INDUSTRY UPDATES

New Genentech BioOncology Access Solutions Service: Genentech Access to Care Foundation (GATCF)

Eligibility ScreeningTES:

1) The Launch of GATCF Eligibility Screening: Genentech BioOncology Access Solutions now offers GATCF Eligibility Screening to assess whether a patient meets GATCF medical and financial criteria before insurance coverage is established. In the event that your patient's insurance coverage is denied, he or she may be eligible for free product from GATCF.

2) Revised Forms: To help facilitate patient access to GATCF, the current GATCF and Access Solutions Enrollment forms have been combined into a single, new Statement of Medical Necessity (SMN). To initiate a GATCF Eligibility Screening request, check the appropriate box in the new Services Requested section on the SMN (upper left corner). Please note that the physician's signature is now required on the SMN, and the patient financial information for GATCF has been moved to the Patient Authorization and Notice of Release of Information (PAN) form.

To access the most current forms, please visit www.BioOncologyAccessSolutions.com or contact **Denise Capo**, BioOncology Field Reimbursement Manager |(C 305.439.4746 |(F 305.499.4378) - dcapo@gene.com, or additional assistance is available through Genentech BioOncology Access Solutions at (888) 249-4918.

EDUCATIONAL OPPORTUNITIES

US Oncology HIT Incentives Webinar

US Oncology Physician Services will sponsor a **FREE Webinar: “Medicare HIT Incentives for the Community Oncology Practice” on Friday, July 10th at 2pm Eastern Time.** With the signing of the American Recovery and Reinvestment Act this spring, allocating approximately \$20 Billion toward Electronic Health Record (EHR) adoptions, physicians who demonstrate meaningful use of certified EHRs could be eligible for up to \$44,000 in incentives over five years. This interactive webinar will be presented by Matt Brow, Vice President of Government Relations and Public Policy with US Oncology, and by Cindy Chavez, Vice President of I KnowMed – an oncology-specific EMR offering. The program will feature:

- A review of standards for qualified EHRs and “meaningful use” requirements
- Information on how standards should be set and what standards should apply to oncology-specific EHRs

To register for this program email cecilia.rosales@usoncology.com or call (866) 216-5053

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)

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The Phipps Wealth
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Novartis
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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

OTHER MEETINGS/WEBCASTS

September 10-13, 2009 APAO Annual meeting in Boston

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

March 17-20, 2010 - ACCC's 36th Annual National Meeting - -Baltimore Marriott Waterfront

December 5-8, 2009 – ASH Annual Meeting – Ernest N, Morial Convention Center, New Orleans, LA