



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – October 3, 2007

CLINICAL PRACTICE COMMITTEE UPDATES: Thomas Gaddis, MD, Chairman

Recent Drug Updates - |

Please see separate document with this fax blast that provides a complete listing of recent drug updates.

PROGRAM COMMITTEE: Gerardo Colon-Otero, MD, Chairman

Please plan to attend the November 9-10, 2007, FLASCO Fall Meeting at the Rosen Shingle Creek Hotel near Orlando. We really **need members to attend this meeting** and show the strength of FLASCO to the ASCO President, Dr. Nancy Davidson, who will speak at this meeting.

FCSO UPDATES:

Payment Adjustment for CPT Code 85025

First Coast Service Options, Inc. (FCSO) has identified an overpayment in the Medicare allowances for CPT code 85025. This overpayment affects claims for dates of service on or after January 1, 2007, with a processed date of June 30, 2007, through August 2, 2007.

The correct allowance for CPT code 85025 is based on the 2007 clinical laboratory service fee schedule of \$10.86 (60% rate) and \$11.22 (62% rate). Claims with receipt date on or after August 3, 2007, were not affected and were paid correctly.

NO ACTION REQUIRED BY PROVIDERS

FCSO initiated the claim adjustments to correct the affected claims on September 17, 2007. Adjustments to all affected claims will be completed by October 5, 2007.

New Extended Service Telephone Line starts Monday - http://www.floridamedicare.com/Part_A/Articles/111513.asp - please visit this website for complete information.

FCSO is announcing a new extended service line to its providers starting Monday. The extended service line will deliver comprehensive service specific to inquiries related to provider enrollment and debt collection activities. Representatives delivering service on this line receive extensive training and certification to ensure they can provide comprehensive support for non-general enrollment and debt collection inquiries.

HOW DOES IT WORK?

- Call the FCSO customer service toll-free line for assistance on all inquiries.
- Part A – 1-888-664-4112
- Part B – 1-866-454-9007
- When the FCSO representative determines your provider enrollment or debt collection issue requires more in-depth research and assistance, he or she will provide the new toll-free number for the extended service line and assign a referral number.
- Call the toll-free number and supply the assigned referral number.
- You work directly with a representative from the appropriate operational area within FCSO to resolve your issue.
- Hours of operation for the new extended service line are Monday – Friday (excluding holidays), 9 a.m. – 4 p.m. ET, closed for lunch from noon - 1 p.m.

Revised Medicare Physician Fee Scheduled - http://www.floridamedicare.com/Part_A/Articles/113921.asp

Notification of the 2008 Physician Election Period for the Part B Drug CAP

Last Modified: 10/1/2007

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5675.pdf>

Part B Advanced Beneficiary Notice

Modifier GZ must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny an item or service as not reasonable and necessary and they **have not had** an advance beneficiary notification (ABN) signed by the beneficiary.

- **Modifier GA** must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny a service as not reasonable and necessary and they **do have on** file an ABN signed by the beneficiary.
- All claims not meeting medical necessity of a local coverage determination must append the billed service with **modifier GA or GZ**.

For more information concerning advance beneficiary notices, refer to http://www.cms.hhs.gov/BNI/01_overview.asp

FDA UPDATES:

Serious Side Effects with Cancer Pain Drug Fentora

FDA is alerting consumers and health care professionals to concerns about Fentora (fentanyl buccal) tablets after reports of deaths and other serious side effects. <http://www.fda.gov/consumer/updates/fentanyl092807.html>

CMS UPDATES:

President Signs Bill Delaying Tamper-Resistant Prescription Pad Requirement

On Saturday, September 29, 2007, President George W. Bush signed the "Extenders Law," delaying the implementation date for all paper Medicaid prescriptions to be written on tamper-resistant paper.

Under the new law, all written Medicaid prescriptions must be on tamper-resistant prescription pads as of April 1, 2008. CMS will issue additional guidance on this implementation delay as it becomes available.

DRUG RECALLS RECALLS:

Baxter Healthcare Corporation has recalled certain COLLEAGUE and FLO-GARD infusion pumps that were sent back to the company for service. These pumps may have been returned to users without the service being performed on them.

The recall initially involved over 500 COLLEAGUE and FLO-GARD pumps, but it has been expanded to include approximately 2000 more pumps with certain model and serial numbers (see link for additional information:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#pumps>

MEDLEARN MATTERS:

Magnetic Resonance Imaging (MRI) Procedures MLN Matters Number: MM5677

Implementation Date: October 22, 2007

Effective July 1, 2007, separate payment is made for the contrast media used in various imaging procedures. The cost of the contrast media is no longer included in the practice expense (PE) relative values units (RVUs) for the procedures.

In addition to the Current Procedural Terminology (CPT) code representing the imaging procedure, the appropriate Healthcare Common Procedure Coding System (HCPCS) "Q" code (Q9945-Q9954; Q9958-Q9964) can be separately billed and paid for the contrast medium utilized in performing the service.

Make certain that your billing staffs are aware of these changes. Please see <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5677.pdf> for additional information.

CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2007)

FLASCO Members extends a big thanks to all of our 2007 Corporate Members/Sponsors

PLATINUM

Astra Zeneca
Genentech
Oncology Supply/ION
Sanofi-Aventis
Bristol-Myers Squibb
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Pfizer
Amgen

SILVER

Genomic Health, Inc.
Talecris Biotherapeutics
Millennium
Celgene
Novartis

BRONZE

Oncology Pharmaceutical Services

FLASCO EVENTS:

November 9-10, 2007 – FLASCO Fall Meeting – Rosen Shingle Creek – Orlando

March 7-8, 2008 – FLASCO Spring Meeting – Tampa Airport Marriott Hotel

November 7-8, 2008 – FLASCO Fall Meeting – Location TBD

OTHER EVENTS:

The Florida Association of Pediatric Tumor Programs will hold its 30th Anniversary Annual Seminar at the Hyatt Regency Grand Cypress in Orlando from November 15-17, 2007. To register please visit the following Web Site: www.fapt.org

FLASCO Contact Information:

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FLORIDA SOCIETY OF CLINICAL ONCOLOGY – OCTOBER 3, 2007 – RECENT DRUG UPDATES

Taxotere:

Sanofi-aventis announced October 1 that the U.S. Food and Drug Administration (FDA) has approved Taxotere® (docetaxel) Injection Concentrate in combination with cisplatin and 5-fluorouracil for induction therapy of locally advanced squamous cell carcinoma of the head and neck before patients undergo chemoradiotherapy and surgery. The FDA based its approval on the results of the phase III randomized, open-label, international trial, TAX 324, which established the efficacy and safety of the Taxotere-based regimen in significantly improving survival\\

Evista:

The U.S. FDA has approved Eli Lilly and Company's (Indianapolis, Ind.) osteoporosis drug Evista® (raloxifene HCl) for a new use to reduce the risk of invasive breast cancer in two populations: postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer. Evista, a selective estrogen receptor modulator or SERM (recently classified by the FDA as an estrogen agonist/antagonist), is already approved for the prevention and treatment of osteoporosis in postmenopausal women

Campath:

Genzyme Corp. and Bayer HealthCare Pharmaceuticals Inc. (Cambridge, Mass. and Wayne, N.J.) announced that the U.S. FDA has approved a supplemental biologics license application (sBLA) for Campath® (alemtuzumab) and granted regular approval for single-agent Campath for the treatment of B-cell chronic lymphocytic leukemia (B-CLL). Campath was initially approved in 2001 under accelerated approval regulations and the FDA has determined that the study results submitted in the sBLA fulfill the post-marketing commitment to verify clinical benefit. Campath is the first and only monoclonal antibody approved by the FDA for the treatment of B-CLL.

Eloxatin:

Sanofi-aventis (Bridgewater, N.J.) has launched a new 200 mg single-use vial of its chemotherapy treatment Eloxatin® (oxaliplatin injection) for patients who have adjuvant stage III colon cancer and advanced colorectal cancer, which is expected to offer more convenience, efficiency, and safety in the preparation of the injectable cancer drug. Previously, Eloxatin had been available in 50 mg and 100 mg single-use vials. According to the company, the 200 mg vial would be available for order by cancer treatment clinics and hospitals nationwide starting in the last week of August 2007 (NDC number: NCD 0024-0592-40).

Revlimid:

DrugPoints, the successor publication to the *USP DI* compendia, has updated its monograph for Revlimid (lenalidomide) (Celgene Corporation, Summit, N.J.) to include: multiple myeloma, in combination with dexamethasone, first-line therapy. Evidence favors efficacy, Class IIa recommendation

Aloxi:

MGI Pharma, Inc., (Minneapolis, Minn.) and its partner Helsinn Healthcare SA, announced approval of a supplemental new drug application (sNDA) for Aloxi® (palonosetron hydrochloride) Injection by the U.S. FDA allowing for repeated dosing for cancer patients receiving multiple day chemotherapy regimens. This sNDA includes the removal of a dosing recommendation, which limited Aloxi use to once per seven day interval, from the product's label. Data from several safety and efficacy trials that evaluated multiple day dosing of Aloxi were included in the sNDA. Aloxi is approved by the FDA for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy

IPI-504:

Infinity Pharmaceuticals, Inc., and MedImmune, Inc., (Cambridge, Mass. and Gaithersburg, Md.) announced that the FDA has granted orphan drug designation to IPI-504 for the treatment of gastrointestinal stromal tumors (GIST). IPI-504, the companies' heat shock protein 90 (Hsp90) inhibitor, is currently being evaluated in two separate multi-center clinical trials in patients with GIST and other soft tissue sarcomas, and in patients with non-small cell lung cancer

ALS-357:

Advanced Life Sciences Holdings, Inc. (Woodridge, Ill.) announced that the U.S. FDA has granted orphan drug designation to the company's oncology product, ALS-357, for the topical treatment of metastatic melanoma. ALS-357 is a novel drug entering phase I/II clinical development that has demonstrated potent anti-tumor activity against malignant melanoma. ALS-357 operates by inducing apoptosis in tumor cells.

Treanda:

Cephalon Inc. (Frazer, Pa.) has submitted a new drug application (NDA) to the U.S. FDA requesting approval of Treanda® (bendamustine HCl) for the treatment of patients with chronic lymphocytic leukemia (CLL). In August 2007, the FDA granted orphan drug designation to Treanda for this indication. The NDA is based on a large, international multi-center Phase III clinical trial that evaluated the safety and efficacy of bendamustine HCl, the active ingredient in Treanda, compared to chlorambucil in patients who were not previously treated for their disease. In the pivotal trial, bendamustine HCl met both primary endpoints, overall response and progression-free survival and demonstrated an acceptable tolerability profile. The company is also studying Treanda for treatment of patients with indolent non-Hodgkin's lymphoma (NHL), who are refractory to the monoclonal antibody rituximab.