



**FLORIDA SOCIETY OF CLINICAL ONCOLOGY**  
**FLASCO BLAST –April 21, 2010**  
**FLASCO WEBSITE: [www.flasco.org](http://www.flasco.org)**  
**FLASCO CLINICAL TRIALS NETWORK WEBSITE: [www.fctn.org](http://www.fctn.org)**

**MESSAGE FROM FLASCO PRESIDENT: Gerald Robbins, MD**

**New e-mail address for FLASCO Executive Director**

Effective April 15, 2010, the new email address for Dorothy Green Phillips, FLASCO Executive Director, will be: **[Dorothy.Green@flasco.org](mailto:Dorothy.Green@flasco.org)**

**CLINICAL PRACTICE COMMITTEE: Thomas Gaddis, MD, Chairman**

**Ferrlecit**

Recently FLASCO sent a question to FCSO asking if a dual diagnosis was required for the injection of Ferrlecit.

**Response from FCSO:** According to our Local Coverage Determination (LCD) Number L29174, a dual diagnosis is required for the possible payment of this type of service. You can refer to the LCD by accessing the link, [http://www.cms.gov/MCD/viewlcd.asp?lcd\\_id=29174&lcd\\_version=3&show=all](http://www.cms.gov/MCD/viewlcd.asp?lcd_id=29174&lcd_version=3&show=all).

**DRUG AND INDUSTRY UPDATES:**

**FDA Approved Tarceva® (erlotinib) for maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer**

On April 16, 2010, the U. S. Food and Drug Administration (FDA) approved Tarceva® (erlotinib) for maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. This approval is erlotinib's second indication in locally advanced or metastatic NSCLC. Erlotinib was originally approved in November, 2004 for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available on the [FDA website](#)

**Abraxis BioScience Second Payer+Coinsurance Assistance Program**

Abraxis BioScience is happy to introduce the Second Payer+ coinsurance assistance program for Abraxane. The program is an extension of our current patient assistance program, APAP, assisting patients who have coverage for Abraxane through their primary private insurance, but need assistance with their Abraxane coinsurance.

**Eligibility is the same as the APAP program:**

- Gross family household income of  $\leq$  100K
- Permanently residing in the US or US territories
- Any diagnosis deemed medically necessary by the patient's oncologist
- Private or commercial insurance** with Abraxane coverage **through the medical benefit**

**Program Exclusions:**

- Patients residing in CO or MA**
- Patients with coverage through traditional Medicare, Medicaid, VA, DoD, or Tricare
- Patients currently receiving coinsurance assistance for Abraxane through a foundation or other organization

**Enrollment is simple:**

- ARC of Support Reimbursement services (ARC, (800) 564-0216, option 3) is accepting patient applications for **DOS on or after April 1, 2010**
- *There are no new forms, applications, credit cards or phone numbers*
- Once enrolled, the patient will be assigned an ID number along with two copies of the enrollment letter. The patient should provide one copy of the letter to the provider.

### **FIRST COAST SERVICE OPTIONS UPDATES:**

#### **Zero percent update extended through May 31**

President Obama on Thursday signed into law the “Continuing Extension Act of 2010.” This law extends through May 31, 2010, the zero percent update to the Medicare physician's fee schedule that was in effect for claims with dates of service January 1-March 31. The law is retroactive to April 1.

As a result, effective immediately, claims with dates of service April 1 and later, which are being held by Medicare contractors, are being released for processing and payment. Please keep in mind that the statutory payment floors still apply and, therefore, clean electronic claims cannot be paid before 14 calendar days after the date they are received by Medicare contractors (29 calendar days for clean paper claims).

Given the uncertainty regarding MPFS claims with dates of service June 1, 2010, and later, please watch your listserves and your contractor’s Web site for more information.

#### **Florida Vendor List**

Modified: 4/19/2010 Location: FL Line of Business: Part A, Part B

This is a list of electronic billing vendors who have passed X12N 837 (4010A1) testing with First Coast Service Options Inc. - [http://medicare.fcso.com/Getting\\_started/137473.pdf](http://medicare.fcso.com/Getting_started/137473.pdf)

#### **ZEVALIN: Ibritumomab tiuxetan (Zevalin™) therapy - revision to the LCD**

##### **LCD ID Number: L29193 (Florida)**

##### **LCD ID Number: L29348 (Puerto Rico/U.S. Virgin Islands)**

The local coverage determination (LCD) for ibritumomab tiuxetan (Zevalin™) therapy was most recently revised on February 2, 2009, for Florida and March 2, 2009, for Puerto Rico and the U.S. Virgin Islands. A reconsideration request was received asking First Coast Service Options Inc. (FCSO) to revise the LCD to include the new Food and Drug Administration (FDA) indication approved on September 3, 2009. The new indication allows Zevalin™ to be administered for patients with previously untreated follicular non-Hodgkin’s lymphoma (NHL) who achieve a partial or complete response to first-line chemotherapy. The LCD has been revised to include this new FDA indication under the “Indications and Limitations of Coverage and LCD ID Number: L29193 (Florida)/or Medical Necessity” section of the LCD.

##### **Effective date**

This LCD revision is effective for services rendered **on or after September 3, 2009, for claims processed on or after April 6, 2010**. First Coast Service Options Inc. LCDs are available through the CMS Medicare Coverage Database at <http://www.cms.gov/mcd/overview.asp>.

#### **J3420: Vitamin B12 injections - revision to the LCD**

##### **LCD ID Number: L29309 (Florida)**

##### **LCD ID Number: L29488 (Puerto Rico/U.S. Virgin Islands)**

The local coverage determination (LCD) for vitamin B12 injections was most recently revised on February 2, 2009, for Florida and March 2, 2009, for Puerto Rico and the U.S. Virgin Islands. A reconsideration request was received asking First Coast Service Options Inc. (FCSO) to revise the indications to allow for coverage of Folutyn™ in addition to the already covered drug Alimta®. In addition the request asked for a revision to the documentation requirements to include the use of Folutyn™. The “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD has been revised to include coverage criteria for vitamin B12 injections when administering Folutyn™. Also, the “Documentation Requirements” section of the LCD has been revised to include Folutyn™ within the requirements listed.

**Effective date**

This LCD revision is effective for services rendered **on or after April 06, 2010**. First Coast Service Options Inc. LCDs are available through the CMS Medicare Coverage Database at <http://www.cms.gov/mcd/overview.asp>.

**J9310: Rituximab (Rituxan®) - revision to the LCD**

**LCD ID number: L29271 (Florida)**

**LCD ID number: L29472 (Puerto Rico/U.S. Virgin Islands)**

The local coverage determination (LCD) for rituximab (Rituxan®) was most recently revised on February 2, 2009, for Florida and March 2, 2009, for Puerto Rico and the U.S. Virgin Islands. A reconsideration request was received asking First Coast Service Options Inc. (FCSO) to revise the LCD to include the new Food and Drug Administration (FDA) indication approved on February 18, 2010. The new indication allows Rituxan® to be administered for chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide (Fc), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. Previously FCSO covered the CLL as an off-label indication. The LCD has been revised to include CLL as an FDA approved indication and has removed CLL from the off-label list of covered indications, under the “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD.

**Effective date**

This revision to the LCD is effective for services rendered **on or after February 18, 2010 for claims processed on or after April 6, 2010**. First Coast Service Options Inc. LCDs are available through the CMS Medicare Coverage Database at <http://www.cms.gov/mcd/overview.asp>

**J2796: Romiplostim (Nplate™) - new LCD**

**LCD ID Number: L30878 (Florida/Puerto Rico/U.S. Virgin Islands)**

Romiplostim (Nplate™) is an injectable thrombopoietin (TPO) receptor agonist that stimulates bone marrow megakaryocytes to produce platelets. It is used in patients with (idiopathic) thrombocytopenic purpura (ITP), whose degree of thrombocytopenia (i.e., bleeding condition in which the blood doesn't clot as it should due to low platelet counts) and clinical condition increase the risk for bleeding.

Romiplostim (Nplate™) is available only through a restricted distribution program called Nplate™ NEXUS (Network of Experts Understanding and Supporting Nplate™ and Patients) Program. Under this program, only prescribers and patients registered with the Nplate™ NEXUS Program are able to prescribe, administer, and receive romiplostim (Nplate™).

This local coverage determination (LCD) is based upon the U.S. Food and Drug Administration (FDA) approved indication for patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP), ICD-9-CM code 287.31, who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and are registered (including the prescriber) with the Nplate™ NEXUS Program.

The LCD has been developed to outline indications and limitations of coverage, documentation requirements, and utilization guidelines. In addition, a “Coding Guidelines” LCD attachment has been developed for this service.

**Effective date**

This new LCD is effective for services rendered **on or after June 7, 2010**. First Coast Service Options, Inc. LCDs are available through the CMS Medicare Coverage Database at <http://www.cms.gov/mcd/overview.asp>.

Coding Guidelines for an LCD (when present) may be found by selecting “LCD Attachments” in the “Jump to Section...” drop-down menu at the top of the LCD page

**J2562: Plerixafor (Mozobil®) - new LCD**

**LCD ID Number: L30874 (Florida/Puerto Rico/U.S. Virgin Islands)**

The availability of stem cell growth factors has led to the treatment of certain types of cancers by performing peripheral blood stem cell transplants (PBSCT). Performing PBSCT allows a patient to be treated with higher doses of drugs such as chemotherapy or with radiation therapy. PBSCT is a process by which blood-forming cells that have been destroyed by cancer treatment are replaced after the patient has been treated with chemotherapy or radiation therapy.

Two types of cancers commonly treated with PBSCT are non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM). NHL is a type of cancer that forms in the cells that make up the immune system and is either fast or slow growing. MM is a type of cancer that forms in the plasma cells (white blood cells). In order to proceed to the process of performing a PBSCT, the stem cells must be collected through a process called apheresis. To increase the number of stem cells released into the blood stream for collection, the patient may be given a drug called a growth factor (colony stimulating factor).

Plerixafor (Mozobil®) is not a growth factor. It is a reversible inhibitor of the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell-derived factor-1 $\alpha$  (SDF-1 $\alpha$ ). SDF-1 $\alpha$  and CXCR4 are recognized to play a role in the trafficking and homing of human hematopoietic stem cells (HSCs) to the marrow compartment. Plerixafor (Mozobil®) is a hematopoietic stem cell mobilizer approved by the Food and Drug Administration (FDA) to be used for the following indication:

Mozobil® is indicated to be used in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma.

This local coverage determination (LCD) has been developed to provide indications and limitations, documentation requirements and utilization guidelines. In addition, a "Coding Guidelines" LCD attachment has been developed for this service, which includes information regarding proper coding of diagnosis codes and an outline of a typical treatment regimen since this drug must be given in conjunction with Neupogen®.

#### **Effective date**

This new LCD is effective for services rendered **on or after June 7, 2010**. First Coast Service Options Inc. LCDs are available through the CMS Medicare Coverage Database at <http://www.cms.gov/mcd/overview.asp>. Coding Guidelines for an LCD (when present) may be found by selecting "LCD Attachments" in the "Jump to Section..." drop-down menu at the top of the LCD page.

### **EDUCATIONAL OPPORTUNITY: Health 2.0 in the Doctor's Office – COMP REGISTRATION FOR FLASCO MEMBERS - Co-Sponsored by FLASCO**

Event: April 24, 2010

Location: Marriott Sawgrass Resort – Ponte Vedre, FL

To book room - <http://www.marriott.com/hotels/travel/jaxsw-sawgrass-marriott-golf-resort-and-spa/?groupCode=FROFROA&app=resvlink>

With the passage of the HITECH and ARRA acts of 2009 which stipulated bonus payments of up to \$44,000 per physician for those who used certified electronic health care programs that meet "meaningful use" criteria, physicians and healthcare providers have become a catalytic force for change in the EMR landscape.

We'll explain how Health 2.0 tools are revolutionizing medical practices today and how the new concept of Clinical Groupware fits in with the HITECH/ARRA stimulus dollars for meaningful use. We'll be demonstrating the very latest innovations in technology for the physicians' office, revealing the keys to meaningful use and showing physicians the practical next steps to receive HITECH funding.

This special regional event will be in partnership with **ICON, (Integrated Community Oncology Network)**. ICON is a leading multidisciplinary group of Radiation Oncologists, Medical Oncologists, Urologists and Radiologists that specializes in cancer treatment, research, and education.

For complete information: <http://www.health2con.com/florida-2010/>

**If you need assistance in registering for a complimentary registration, please contact the FLASCO Office.**

### **20th Annual Mayo Clinic Hematology/Oncology Reviews**

**Thursday July 29th – Saturday July 31st, 2010**

The Ritz-Carlton Amelia Island, Amelia Island, Florida

Get Updated and Connected

**11th Annual Fellows' Research Presentations**

**Register online:** [www.mayo.edu/cme/hematology-oncology/index.html](http://www.mayo.edu/cme/hematology-oncology/index.html)

## **Course Description**

Mayo Clinic Hematology/Oncology Reviews is a comprehensive postgraduate course designed to provide the busy practicing hematologist/oncologist with practical new developments. Didactic presentations will be case-based. Attendees will leave with up-to-date, practical information which will have immediate clinical application.

## **CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2010)**

FLASCO Members extend a big thanks to all of our 2010 Corporate Members/Sponsors (Companies listed below have either paid 2010 dues or have submitted letters of intent)

<b><u>DIAMOND</u></b>	<b><u>PLATINUM</u></b>	<b><u>GOLD</u></b>	<b><u>SILVER</u></b>	<b><u>BRONZE</u></b>
Celgene	Abraxis	Allos Therapeutics	Genzyme	Alexion Pharmaceuticals
Cephalon	AMGEN	Bristol Myers Squibb	Meda Pharmaceutical	Biogen Idec
Eli Lilly	AstraZeneca	Genomic Health		The France Foundation
Genentech	Bayer Onyx	Millennium Pharmaceuticals		
Novartis	Eisai, Inc.	US Oncology		
Sanofi-Aventis	GlaxoSmithKline	OSI Pharmaceutical		
	Oncology Supply/ION			
	Pfizer			
	Ortho Biotech			

### **FLASCO MEETINGS:**

**October 2, 2010** – FLASCO Business of Oncology Summit – Tampa

**November 5-6, 2010** – FLASCO Fall Meeting – Miami

**April 15-16, 2011** – FLASCO Annual Meeting & Spring Session - Tampa

### **OTHER MEETINGS/WEBCASTS**

**May 7 and 8, 2010** – **early registration on May 6** - Moffitt Cancer Center “Florida Oncology Symposium” – The Ritz-Carlton Hotel, Naples, FL. Register on line at: <http://www.moffitt.org/continuinged/floncs>. For additional information please contact [Claire.modarelli@moffitt.org](mailto:Claire.modarelli@moffitt.org) – 813.745.7252.

**October 7-10, 2010** – The Association of Physician Assistants in Oncology (APAO), 13<sup>th</sup> Annual APAO Conference, The Ritz Carlton – Amelia Island, Florida **For more information, please visit [www.focus-ed.net/apao](http://www.focus-ed.net/apao)**

### **FLASCO Contact Info:**

Dorothy Green Phillips, Executive Director - Phone: 1.813.349.4410 – **NEW E-MAIL ADDRESS**  
**EFFECTIVE APTIL 15, 2010 – [Dorothy.Green@flasco.org](mailto:Dorothy.Green@flasco.org)**