

# ASCO CAC Network E-News

## November 2007 Issue

### Local Coverage News

#### ***New A/B MAC contract awarded to Palmetto GBA (Palmetto)***

On October 25, 2007, CMS awarded the contract for the Jurisdiction 1 (J1) A/B MAC to [Palmetto GBA](#) (Palmetto). Palmetto will be responsible for the workload in American Samoa, California, Guam, Hawaii, Nevada, and the Northern Mariana Islands. As the J1 A/B MAC, Palmetto will immediately begin implementation activities, and will assume full responsibility for the work no later than June 2008.

For more information, refer to CMS's [Background Sheet](#) and [Q & A](#) related to the award.

#### ***New A/B MAC contract awarded to Highmark Medicare Services, Inc. (HMS)***

On October 24, 2007, CMS awarded the contract for the Jurisdiction 12 (J12) A/B MAC to [Highmark Medicare Services, Inc.](#) (HMS). HMS will be responsible for the workload in Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania. As the J12 A/B MAC, HMS will immediately begin implementation activities, and will assume full responsibility for the work no later than September 2008.

For more information, refer to CMS's [Background Sheet](#) and [Q & A](#) related to the award.

### National News

#### ***2008 Medicare Physician Fee Schedule (Overview)***

On November 1, 2007, the Centers for Medicare & Medicaid Services (CMS) issued the Medicare Physician Fee Schedule [Final Rule](#) for 2008. It will be published in the Federal Register on November 27, 2007.

For more information, refer to ASCO's [summary](#) of the provisions of greatest interest to oncologists.

#### ***CMS Maintains Coverage for Clinical Trials***

Last month, the Centers for Medicare & Medicaid Services (CMS) stated that it would NOT change its clinical trials coverage policy.

CMS had issued a draft proposal July 17 that would have rescinded automatic Medicare coverage for clinical trials funded by the federal government, or conducted under Food and Drug Administration (FDA) review. The proposal would have required that sponsors or principal investigators self-certify that the clinical trial meets 13 scientific and technical standards set forth by CMS before the agency would approve coverage. However, in a Decision Memo issued this morning, CMS stated that "after careful consideration, the Agency has decided that no change ...is appropriate at this time, and therefore, we are not imposing any additional conditions of coverage." CMS decided to

maintain coverage that has been in place since 2000, with [two clarifications made July 9](#).

CMS has developed a [Q & A document](#) that explains the implications of its decision to maintain coverage. For more information, contact ASCO's Cancer Policy & Clinical Affairs Department at 703-299-1050 or [researchpolicy@asco.org](mailto:researchpolicy@asco.org).

### ***ASCO Requests CMS To Issue Instructions on DrugPoints Compendium***

On October 5, ASCO sent a [letter](#) to Kerry Weems, CMS Acting Administrator, requesting that CMS issue instructions to its Medicare contractors, state Medicaid programs, and Medicare Part D plans regarding coverage of off-label drug uses listed in the compendium, DrugPoints.

Drug Points has been named by its publisher, [Thomson Healthcare](#), as the successor for the United States Pharmacopoeia Drug Information (USP-DI), the specified compendia for Medicare and Medicaid coverage purposes, which is currently being phased out.

To alleviate confusion, and ensure that cancer patients have access to medically appropriate therapies, ASCO has requested that CMS immediately issue contractor instructions to:

- Recognize DrugPoints as the successor publication to USP-DI with the same authoritative status as USP-DI, and
- Require coverage of all FDA-approved and off-label uses listed in DrugPoints under the respective programs involved.

## **Other CMS News**

### ***New CMS Contractor to Audit RACs***

CMS has hired AdvanceMed (A division of [DynCorp](#)) to randomly review RAC demands on physicians and other providers. AdvanceMed has also worked as the CMS contractor for the Comprehensive Error Rate Testing (CERT) program. Unlike the RAC contractors themselves, AdvanceMed is paid per claim reviewed, not on a contingency payment system.

### ***2008 Current Procedural Technology (CPT) Updates***

Several new CPT codes were added for infusions and pushes (90769-90776). Please note, however, that these updates might be more applicable to a clinic or hospital outpatient department than to a private physician office. CPT 90776, in particular, is designed for use in a facility.

## **New FDA Approvals**

### ***FDA Approves New Boxed Warnings for ESAs***

On November 8, the Food and Drug Administration (FDA) approved new [Boxed Warnings](#), and other safety-related product labeling changes, for Erythropoietin Stimulating Agents (ESAs) to treat chemotherapy-related anemia in patients with cancer.

The new labeling stresses that clinical studies have not been conducted to exclude ESA-associated tumor progression, or shortened survival, when ESAs are dosed to achieve lower hemoglobin levels.

The new labeling also states that, for cancer patients, ESAs have not been demonstrated in controlled clinical trials to improve symptoms of anemia, quality of life, fatigue, or patient well being.

FDA developed a [podcast](#) to clarify how to safely and effectively use these products, and to strengthen the information about risks from using ESAs.

ASCO is currently examining how these changes will affect the joint updated [clinical practice guideline](#) on the use of Epoetin and Darbepoetin that was recently released with the American Society of Hematology.

For more information, contact ASCO's Cancer Policy & Clinical Affairs Department at 703-299-1050 or [publicpolicy@asco.org](mailto:publicpolicy@asco.org).

### ***FDA Approves IXEMPRA™ for Injection for Two Indications***

On October 16, 2007, the U.S. Food and Drug Administration approved Ixabepilone for injection (IXEMPRA™, Bristol-Myers Squibb) for the following two indications:

- Ixempra™ is indicated in combination with Capecitabine for the treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an Anthracycline and a Taxane, or whose cancer is Taxane-resistant, and for whom further anthracycline therapy is contraindicated.
- Ixempra™ is indicated as monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine.

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

### ***FDA Granted Accelerated Approval for TASIGNA®***

On October 29, 2007, the U. S. Food and Drug Administration granted accelerated approval to Nilotinib (TASIGNA® Capsules, Novartis Pharmaceuticals Corporation) for use in the treatment of Chronic Phase (CP) and Accelerated Phase (AP) Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML) in adult patients resistant or intolerant to prior therapy that included Imatinib.

The effectiveness of Tasigna<sup>®</sup> is based on hematologic and cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival. Submission of further follow-up data from an ongoing study is required to convert this accelerated approval to regular approval.

Full [prescribing information](#), including clinical trial information, safety, dosing, drug-drug interactions, and contraindications is available at.

***FDA Grants Accelerated Approval for Sprycel<sup>™</sup> for Treatment of Adults w/Chronic Phase (CP) Chronic Myeloid Leukemia (CML)***

On November 8, 2007, the U. S. Food and Drug Administration (FDA) granted accelerated approval of a new dosing regimen of Dasatinib (SPRYCEL<sup>™</sup>, Bristol-Myers Squibb) for the treatment of adults with Chronic Phase (CP) Chronic Myeloid Leukemia (CML) with resistance or intolerance to prior therapy, including Imatinib Mesylate. The new dosing regimen is 100 mg, taken orally once daily.

FDA had previously granted accelerated approval to Dasatinib, in June, 2006, for the treatment of adults with CP, accelerated-phase, or Myeloid or Lymphoid Blast phases of CML with resistance to, or intolerance to prior therapy, including Imatinib Mesylate. In June 2006, the FDA also granted regular approval for the treatment of patients with Philadelphia Positive Acute Lymphoblastic Leukemia. The recommended dosing regimen in the 2006 approval was 70 mg twice daily.

Submission of further follow-up data from ongoing studies will convert this accelerated approval to regular approval.

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

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ASCO sends periodic e-mails to its Carrier Advisory Committee (CAC) Network as a means of disseminating information and increasing awareness about Carrier/LCD issues around the country. You have received this e-mail as an identified interested party in the LCD process (e.g. State Society President, Oncology/Hematology/Gynecology CAC Representative/Alternate, CPC Member, CPC State Affiliate). More information is available at [ASCO's website](#). To submit corrections to ASCO's CAC website, or to obtain further information about any items included in this e-mail or CAC issues in general, please contact:

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