

ASCO CAC Network E-News

October 2007 Issue

CAC Updates

ASCO has completed updating the current [State Contacts](#) information located on our CAC website. Please let us know if any additional changes need to be made. Thank you!

Local Coverage News

Erythropoietin Stimulating Agents (ESA) LCDs Open For Comments:

- [First Coast](#) – Due by 11/3/2007
- [Noridian](#) – Due by 12/3/2007
- [Trailblazer](#) – Due by 12/3/2007

National Coverage News

CMS Responds to ASCO's ESA Reconsideration Request Letter

On August 30, ASCO [formally requested](#) that CMS reconsider its NCD on the use of ESAs in cancer and related neoplastic conditions, based on the fact that the policy materially mis-interpreted existing clinical evidence. [CMS responded to ASCO](#) on September 24, asking for new evidence. At this point, CMS has neither accepted nor rejected ASCO's formal request for reconsideration. ASCO is currently developing a response to CMS's additional request for information.

Because Michael Leavitt, the Secretary of Health and Human Services (HHS), has oversight of both the FDA and CMS, and the CMS ESA NCD is in direct conflict with FDA policy, ASCO also sent a [letter](#) on September 28 to Secretary Leavitt expressing concern about the NCD, and outlining the conflicts between the CMS coverage decision and the FDA-approved label for ESAs.

Representatives Introduce Legislation on ESA Coverage

On September 27, Congress representatives Anna Eshoo (D-CA) and Mike Rogers (R-MI) introduced [H.J.RES.54](#), a Joint Resolution disapproving CMS's [National Coverage Decision \(NCD\)](#) on the use of ESAs in cancer and related neoplastic conditions. If passed by both the House and Senate, and signed by the President, this Joint Resolution would have the force of law and would prohibit CMS from implementing the coverage change.

Read more in ASCO's [10/3/2007](#) issue of Cancer Policy Today.

Off-Label Updates

CMS Expands List of Peer-Reviewed Journals Used for Off-Label Coverage

On September 21, CMS announced it had updated the [list of peer-reviewed journals](#) that

Medicare contractor medical directors may use as references for off-label use of anti-cancer drugs.

ASCO submitted two requests, one in 2003 and another in 2006, urging CMS to update the original list of 15 journals established in 1993. Last year, CMS opened a public comment period and conducted a review of the recommended journals. Based on this review, CMS will accept the following journals as of October 22:

- *Annals of Oncology*
- *Biology of Blood and Marrow Transplantation*
- *Bone Marrow Transplantation*
- *Gynecologic Oncology*
- *Clinical Cancer Research*
- *International Journal of Radiation, Oncology, Biology, and Physics*
- *Journal of NCCN*
- *Radiation Oncology*
- *Annals of Surgical Oncology*
- *Journal of Urology*
- *Lancet Oncology*

The full transmittal, which includes the complete list of journals recognized for purposes of off-label coverage review, can be accessed at the [CMS website](#).

Other CMS News

ASP Part B Changes – October 2007 Quarterly Update

CMS has recently issued their [October 2007 Average Sales Price \(ASP\) Quarterly Update](#). The ASP methodology is based on quarterly data submitted to the Centers for Medicare & Medicaid Services (CMS) by manufacturers, and CMS supplies Medicare contractors (carriers, DME MACs, FIs, A/B MACs, and/or RHHIs) with the [ASP drug pricing files](#) for Medicare Part B drugs on a quarterly basis.

CMS Awards Contract for ICD-10-CM Impact Analysis

On [October 2, 2007](#), the CMS Office of Public Affairs announced a contract to the American Health Information Management Association (AHIMA) to begin assessing the impact on CMS of replacing the ICD-9 code sets now used in reporting health care transactions with the ICD-10 versions.

The AHIMA will analyze CMS' systems, policies and operations to determine potential impacts of transitioning from the ICD-9 to the ICD-10, including the ICD-10's ability to support more accurate payment for new procedures, efficient claims processing, and improved disease management.

Medicare Part B Drug Competitive Acquisition Program (CAP) 2008 Election

The 2008 Physician Election Period for the [Medicare Part B Drug Competitive Acquisition Program \(CAP\)](#) will begin on October 1, 2007 and concludes on November 15, 2007. The CAP is a voluntary program that offers physicians the option to acquire many drugs they use in their practice from an [approved CAP vendor](#), thus reducing the

time they spend buying and billing for drugs. The 2008 CAP program period will run from January 1 to December 31, 2008.

Physicians are instructed to submit their [CAP election forms](#) to their local carrier. As per Change Request (CR) 4064, local carriers are required to forward a list to the CAP designated carrier of all physicians and practitioners who have elected to participate in the CAP. This list is due on November 22, 2007.

New FDA Approval

FDA Approves EVISTA® for Reduction in Risk of Invasive Breast Cancer in Postmenopausal Women w/ Osteoporosis & at High Risk for Invasive Breast Cancer

On September 13, 2007, the U. S. Food and Drug Administration approved Raloxifene Hydrochloride tablets (EVISTA ®, Eli Lilly and Company) for reduction in the risk of Invasive Breast Cancer in postmenopausal women with Osteoporosis and in postmenopausal women at high risk for Invasive Breast Cancer. Safety and efficacy for reduction in the risk of Invasive Breast Cancer in postmenopausal women with Osteoporosis were demonstrated in three clinical trials (RUTH, MORE and CORE).

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

FDA Expands Labeling & Grants Regular Approval for Campath ® for B-cell Chronic Lymphocytic Leukemia

On September 19, 2007, the U.S. Food and Drug Administration expanded labeling and granted regular approval for single-agent Alemtuzumab (Campath ®, Genzyme Corporation) for the treatment of B-cell Chronic Lymphocytic Leukemia (B-CLL). Campath ® was initially approved in 2001 under accelerated approval regulations. The safety profile observed in this trial was consistent with the previously described safety profile provided in the product label.

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

FDA Changes in Avastin® Package Insert re: Warning and Dose and Administration for Non-Gastrointestinal Fistula Formation

On March, 2007 the FDA was informed of the occurrence of two confirmed and one suspected cases of Tracheoesophageal Fistula in an investigator-sponsored trial using Bevacizumab (Avastin ®, Genentech Corporation) concurrently with chemo-radiation in the treatment of limited-stage small cell lung cancer. Three cases were fatal. The trial was closed and a “Dear Healthcare Provider” letter was issued.

At the FDA's request, Genentech performed a search in the safety database of all events of "fistula" occurring with Avastin ®. Results of this search serve as the basis for this safety labeling update. The occurrence of fistula associated with Bevacizumab treatment

is currently labeled in the Avastin® U.S. Package Insert under “Gastrointestinal Perforations”, along with “Intra-Abdominal Abscess Formation”.

New sub-sections were added to the "WARNINGS" section of the Avastin® label:

- "Non-Gastrointestinal Fistula Formation

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

FDA approves Taxotere ® for use in combination with Cisplatin and Fluorouracil (5-FU) for the induction treatment of patients with locally advanced SCCHN

On September 28, 2007, the U. S. Food and Drug Administration (FDA) approved Docetaxel (Taxotere ® Injection Concentrate, Sanofi-Aventis) for use in combination with Cisplatin and Fluorouracil (5-FU) for the induction treatment of patients with locally advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN).

The safety and efficacy of Taxotere® for the above indication were evaluated in a multi-center, open-label, randomized trial.

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

FDA Expands Labeling and Approves Erbitux for tx of pts with EGFR-expressing metastatic colorectal cancer

On October 2, 2007, FDA expanded labeling and granted regular approval for single-agent Cetuximab (Erbitux ®, ImClone Systems, Inc.) for the treatment of patients with EGFR-expressing Metastatic Colorectal Cancer (mCRC) after failure of both Irinotecan- and Oxaliplatin-based chemotherapy regimens. Erbitux ® was initially approved in 2004 under accelerated approval regulations.

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

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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