



NNECOS News

an email publication of Northern New England Clinical Oncology Society

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The ASCO Clinical Practice Committee met in Washington, DC on January 28, 2005. NNECOS was well represented with Doctors Steve Larmon, Steve Grunberg, Dan Hayes and Denis Hammond all in attendance. Complete minutes of this meeting are posted on www.nnecoss.org. Here are some highlights and areas for immediate action.

DRUG PRICING SURVEY

ASCO is collecting data from practices nationwide on drug acquisition costs. They have prepared a spreadsheet that can be accessed on the ASCO website at www.asco.org or using this link http://www.asco.org/ac/1,1003,12-002860-00_18-0035930-00_19-0035931-00_20-001,00.asp. This data is essential to ASCO's efforts on behalf of oncologists. This spreadsheet is not only important data for ASCO but also a valuable exercise for your practice. The bottom line calculation will show your practice's current margin on drugs. You may have completed this spreadsheet at the end of 2004, but please consider completing it again with 2005 data and sharing it with ASCO as soon as possible.

If completing the entire spreadsheet is not possible, ASCO will accept information on your drug acquisition costs in other formats, including spreadsheets from your practice, invoices, or "scraps of paper." Email your data to ASPs spreadsheet@asco.org. If you have questions, call the Public Policy staff at 703-299-1050.

CARRIER ISSUES

ASCO is also collecting information about claims processing issues that Medicare carriers are having with the new G codes. CMS has been incredibly responsive to issues that have been identified thus far. If you are experiencing problems with NHIC, please share your experiences with Elaine Towle, NNECOS Executive Director, at etowle@oncomet.com and Dr. Dan Hayes, President-Elect, at hayesd@mmc.org. We will pass your concerns along to ASCO for resolution with CMS.

MMA IMPACT ON HOSPITALS, ACADEMIC CENTERS

ASCO is interested in the effects of MMA changes on hospital-based oncology programs and programs at academic medical centers. They realize it may be a little early to determine these effects, but if you are in the hospital or academic environment please consider this issue and share your findings with ASCO over the next weeks and months.

OIG STUDY

As you know, the Medicare Modernization Act mandated a drug pricing study by the Office of Inspector General (OIG). ASCO reports that this study has begun. Apparently the OIG is calling offices to schedule appointments for this study. If you are called, you should participate and you should report all problems your

practice is having purchasing drugs for less than ASP. This is the official report that will go back to MedPAC and Congress.

SAVE THE DATE!

You won't want to miss NNECOS' 2005 Annual Meeting at the elegant Sheraton Harborside in beautiful Portsmouth, New Hampshire November 4-5, 2005.

Sheraton Harborside Portsmouth
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MEDICARE LAUNCHES EFFORTS TO IMPROVE CARE FOR CANCER PATIENTS

CMS issued two national coverage decisions on Friday, January 28, for improving care for cancer patients by expanding coverage for diagnostic tests and chemotherapy treatments for Medicare beneficiaries. The full text of the CMS announcement follows:

The Centers for Medicare & Medicaid Services (CMS) issued two national coverage decisions on Friday for improving care for cancer patients by expanding coverage for diagnostic tests and chemotherapy treatments for Medicare beneficiaries. "We are working with the National Cancer Institute (NCI), the oncology community and cancer patient advocates to ensure that patients get the care they need and to develop the evidence needed by doctors and patients to make informed decisions about their treatment" said CMS Administrator Mark B. McClellan, M.D., Ph.D. "NCI-sponsored clinical trials offer patients safeguards ensuring appropriate evaluation, selection, and use of cancer chemotherapy." The actions announced today include coverage expansions for:

- * Additional "off-label" uses in CMS selected clinical studies for new cancer drugs that are already approved for colorectal cancer, including oxaliplatin, irinotecan, bevacizumab, and cetuximab.

- * Positron emission tomography (PET) scans for certain uses in evaluation of patients with of brain, cervical, ovarian, pancreatic, ovarian, and testicular cancers, as well as for a broad range of other cancers. These two coverage decisions reflect Medicare's emphasis on ensuring that patients receive high quality, medically necessary care and on developing better evidence by linking coverage to the collection of clinical data. The cancer drug policy will ensure that all Medicare contractors pay for the four anti-cancer drugs in selected clinical trials sponsored in part by the National Cancer Institute (NCI). This coverage is an expansion of current CMS coverage for off-label treatments.

Off-label uses mentioned in certain drug compendia will continue to be covered, and contractors will continue to have the authority to pay for off-label use of the drugs for patients not enrolled in these trials. The CMS policy will also ensure funding for certain routine costs of clinical items and services provided to patients enrolled in these trials, where funding for the drugs services was not previously available. "Our final decision reflects input from the oncology community, cancer patient advocates, and experts at the National Cancer Institute to add to the evidence needed by doctors and seniors to get the most out of increasingly innovative and personalized cancer therapies," McClellan said. "NCI-sponsored clinical trials offer patients safeguards ensuring appropriate evaluation, selection, and use of cancer chemotherapy." McClellan added. "It's particularly important for these studies to close the knowledge gaps for seniors and people with disabilities, who have been less likely to participate in such studies." "Our partnership with CMS will enhance clinical evaluation of new medicines to improve decision making regarding drug approval," said Andrew von Eschenbach, MD, NCI Director. "Ultimately, our working relationship with the CMS is about improving the quality of and access to cancer care for cancer patients everywhere." Medicare currently provides coverage for physician-administered cancer drugs for FDA-approved indications or indications listed in certain drug compendia. Medicare does not

routinely pay for drug costs for off-label indications that are not listed in these compendia, although Medicare does pay for the routine services provided to beneficiaries in federally funded trials. "Expanding coverage for the experimental and routine services provided to Medicare beneficiaries enrolled in these NCI sponsored trials is an important first step in getting better evidence for decisions," said Dr. Sean Tunis, the chief medical officer for CMS. "We will also be initiating an extensive dialog with patient advocates, clinical oncologists, the pharmaceutical and biotech industry, commercial payers and other stakeholders to ensure that the most important questions are identified and answered." In addition to the positive coverage decisions, CMS will shortly announce a proposed decision that will maintain current policies for the use of ibritumomab tiuxetan and tositumomab. This decision will propose to maintain the existing requirement for coverage of these agents as outlined in current law and regulations. Under current policy coverage of off-label use is based on local coverage policy. Federal law requires that all off-label uses listed in specific compendia must be covered, and other unlisted uses are at contractor discretion. CMS also announced new coverage for PET scanning for a range of cancers. PET is a diagnostic imaging procedure that has the ability to differentiate cancer from normal tissue, and may add important information beyond conventional imaging studies in diagnosing and staging cancer and monitoring a patient's progress during treatment.

The expansion in PET scan benefits makes this test available to patients when the patient and doctor participate in high quality clinical studies or submit information to a PET database. The data collected as part of this policy will help ensure that the PET information is used accurately and appropriately in patient management and will also help doctors and Medicare beneficiaries make better-informed choices about their health care. The PET database is being developed by a working group that includes representatives from clinical oncologists, imaging organizations, academic institutions, and industry. Medicare coverage will become effective when the database is fully established within the next several months. The CMS Council on Technology and Innovation will now begin to develop a draft guidance document on this policy approach in order to make the process more systematic, predictable and transparent. An open door forum on this topic will be held on Feb 14, 2005, to obtain public input on linking coverage to practical trials and databases.

In addition, comments on this approach can be submitted to the CTI website (www.cms.hhs.gov/providers/cti). An initial draft guidance will be issued in by March 31, 2005, at which time additional public feedback will be solicited.

More information on CMS coverage decisions is located at <http://cms.hhs.gov/coverage>.