

# NATIONAL

# PATIENT ADVOCATE FOUNDATION

A National Network for Healthcare Reform

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Press Release: "Medicare Launches Efforts to Improve  
Care for Cancer Patients"

CMS Office of External Affairs • November 1, 2004

"Demonstration of Improved Quality of Care for Cancer Patients Undergoing  
Chemotherapy"

CMS Office of External Affairs • November 1, 2004

November 2, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
314-G Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Administrator McClellan:

National Patient Advocate Foundation would like to take this opportunity to commend the Centers for Medicare and Medicaid Services for its actions announced on November 1, 2004 to expand and improve cancer care services furnished to Medicare patients.

We are supportive of the decision to provide Medicare coverage for additional "off-label" uses in clinical studies for new targeted cancer therapeutics for colorectal cancer. For many cancer patients, an "off-label" use of an approved drug is the only beneficial form of therapy, and therefore it becomes the standard of care. We believe this new coverage decision will provide meaningful benefit to those patients for whom an "off-label" use of an approved drug is recommended by their oncologist. We encourage the agency to continue its review of existing policies regarding coverage for "off-label" uses of approved drugs, including coverage for beneficiaries who are unable to participate in a clinical trial, and to make additional coverage determinations where there are credible data to support such coverage. NPAF commends the collaboration between CMS and NCI through the use of nine NCI approved clinical trials as locations through which Medicare beneficiaries can access these expanded trials.

NPAF appreciates the opportunity to provide additional comment during the formal comment period to address the process through which industry trials may also be considered for this program with support from the local carriers. The Agency's foresight in this matter is appreciated and recognizes that for many Seniors, access will be more readily available with industry trials included.

We are also supportive of the decision to establish new codes and provide additional reimbursement to oncologists who participate in the nationwide demonstration program to measure and improve the quality of care provided to Medicare patients in the community oncology setting. Cancer patients undergoing chemotherapy frequently experience pain, nausea and vomiting and fatigue during their course of treatment. We believe this demonstration program will result in a greater understanding about the frequency of these symptoms as well as the best means to treat them. National Patient Advocate Foundation recognizes the value in restoring \$300 million in oncology reimbursement in the community setting to physicians who will participate in this program as a process to assure patients will more likely maintain access to community oncologists.

Thank you and your dedicated professional staff who have listened to the concerns of the patient community relative to maintaining access to oncology care in the local communities of this nation. Again, we commend the Centers for Medicare and Medicaid Services for these important actions that will improve the quality of life for Medicare beneficiaries with cancer.

Sincerely,

A handwritten signature in black ink, appearing to read "Nancy Davenport-Ennis". The signature is written in a cursive style and is positioned above the printed name and title.

Nancy Davenport-Ennis  
Chief Executive Officer

**View Press Releases**

[Press Release: "Medicare Launches Efforts to Improve Care for Cancer Patients"](#)  
CMS Office of External Affairs • November 1, 2004

["Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy"](#)  
CMS Office of External Affairs • November 1, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
Room 303-D  
200 Independence Avenue, SW  
Washington, DC 20201



**Office of External Affairs**

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## **MEDICARE NEWS**

**FOR IMMEDIATE RELEASE**  
November 1, 2004

Contact: CMS Public Affairs  
(202) 690-6145

### **MEDICARE LAUNCHES EFFORTS TO IMPROVE CARE FOR CANCER PATIENTS**

#### **New Coverage, Better Evidence, and New Support for Improving Quality of Care**

The Centers for Medicare & Medicaid Services (CMS) today announced a set of new steps to improve care for cancer patients, by expanding coverage for screening tests and treatments, developing better evidence on which treatments work best for beneficiaries with cancer, and implementing a demonstration program to measure and improve quality of care.

“We are moving aggressively to provide more up-to-date, higher quality care for cancer patients on Medicare,” said CMS Administrator Mark B. McClellan, M.D., Ph.D. “Seniors will have faster access to innovative cancer treatments that clearly work, and they will have better support for care that addresses the pain, nausea, and fatigue that cancer patients too often face.”

The actions announced today include proposed coverage expansions for:

- Additional “off-label” uses in clinical studies for new “targeted” cancer drugs that are already approved for colorectal cancer, including oxaliplatin (Eloxatin), irinotecan (Camptosar), bevacizumab (Avastin), and cetuximab (Erbix).
- Positron emission tomography (PET) scans for cervical cancer, and for studies of PET for diagnosis and staging involving a broad range of additional types of cancer.

CMS also announced a \$300 million nationwide demonstration program open to all oncologists to measure and improve the quality of care provided Medicare patients.

“We are working with the National Cancer Institute, oncologists, and the cancer community to develop better evidence to support the best possible treatment decisions for our beneficiaries,” Dr. McClellan said. “There are too many unanswered questions in cancer care today for seniors and people with disabilities, and Medicare will help develop more practical evidence to improve care.”

“The National Cancer Institute's goal of eliminating death and suffering due to cancer will require improvements in how the nation's health care delivery system works to provide quality care to patients,” said Andrew C. von Eschenbach, M.D., Director of the National Cancer Institute. “Consequently, NCI is working with CMS to help provide the data that would serve to demonstrate efficacy of off-label chemotherapeutic drug usage and to expand the availability of advanced imaging, such as Position

Emission Tomography, where such services can improve the management and overall quality of care of cancer patients.”

The coverage expansions announced today reflect new procedures CMS is implementing to review scientific evidence for coverage decisions more rapidly. CMS also will include funding of the clinical and experimental costs of these drugs in nine clinical trials to learn more about the benefits and risks of certain “off-label” use of these treatments in Medicare beneficiaries. The trials are sponsored in part by the National Cancer Institute (NCI), and the more rapid coverage decisions and expanded efforts to develop better evidence on cancer treatment in seniors are the result of the new CMS collaboration with NCI.

Medicare currently provides coverage for office-administered cancer drugs for FDA-approved indications or indications listed in certain drug compendia. Medicare does not routinely reimburse for drug costs for off-label indications that are not listed in these compendia, although Medicare does pay the routine costs of care for beneficiaries in federally funded trials.

CMS is also seeking public comment on the processes used by the private contractors that pay Medicare claims and set local drug coverage policies. CMS expects to collaborate with NCI, the American Society of Clinical Oncology, patient advocacy organizations and other stakeholders in this process.

PET is a diagnostic imaging procedure that has the ability to differentiate cancer from normal tissue in some patients, and thus can help in diagnosing and staging cancer and monitoring a patient’s progress. Medicare already covers PET scanning in many cancers for this purpose. The proposed expansion in coverage for PET scans would make this test available for certain uses in patients with cervical cancer, because the available evidence indicates that PET can provide more reliable guidance than existing imaging methods on whether the patient’s cancer has spread.

It also would make PET scans available to patients with other cancers where the PET scan is not currently covered, if the provider and patient are participating in certain PET clinical trials, or if the provider and patient are participating in a high quality PET registry. Data collected as part of clinical studies will help doctors and Medicare beneficiaries make better-informed decisions about the effective use of PET.

CMS also announced a national oncology demonstration to evaluate measures of patient well-being in office-based oncology practice, as a basis for addressing quality of life concerns for Medicare beneficiaries with cancer.

“We want to work with oncologists to make sure we are addressing what should be our shared goal: improving the well-being of our beneficiaries with cancer,” said Dr. McClellan. “We want to provide the most effective support possible for our beneficiaries to get better outcomes from their cancer care, and this national demonstration program will provide useful information to help us work with cancer providers and patients to achieve this goal.”

This one-year demonstration will focus on three major areas of concern for cancer patients: pain, nausea and vomiting, and fatigue.

Practitioners participating in the project must provide three new codes describing a chemotherapy patient’s status with respect to pain, nausea and vomiting, and fatigue. To make it easier to collect this information, CMS has established 12 new temporary codes to be used by oncologists in billing for the

administration of chemotherapy drugs, based on well-established scales used to assess a cancer patient's status in these important dimensions of quality of life.

Oncologists can participate in the demonstration simply by providing the three relevant codes for a patient, in conjunction with billing for the patient's chemotherapy services. Providers will receive a payment of \$130 per patient per day for participating in the demonstration.

More information on the CMS proposed coverage decision for cancer drugs is at <http://cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=90>, and the decision for expanded PET scan coverage is at <http://cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=92>. CMS expects to hold open-door forums and other opportunities for public discussion and comment of these new proposals on improving cancer care in the next few weeks.

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**Office of External Affairs**

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# MEDICARE FACTS

## Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy

In order to assess and provide new support for the quality of care for cancer patients undergoing chemotherapy, Medicare will initiate a one-year demonstration project during CY 2005.

Quality cancer treatment includes determining patient status and preferences; outlining appropriate chemotherapy regimens; assessing patient symptoms, complaints, and quality of life; and supporting and educating caregivers. In addition to reducing cancer burden or providing cures, effective cancer care also results in managing pain, minimizing nausea and vomiting, and limiting fatigue. These steps may also help reduce the overall costs of cancer care, by avoiding hospitalizations with complications. In particular, clinicians armed with appropriate assessments can intervene to reduce some of the unpleasant and frequent side effects that often accompany cancer and chemotherapy treatment.

While CMS seeks to encourage quality care in all facets of cancer treatment, the demonstration will focus on measuring patient outcomes in three areas of concern often cited by patients undergoing chemotherapy: controlling pain, minimizing nausea and vomiting, and reducing fatigue. Standardized assessment scales will be used to measure the condition of chemotherapy patients, and CMS will collect data based on these assessments and on subsequent treatments to trace improvement in outcomes, such as trends and variations in these measures of patient function as well as reduced hospitalizations or emergency department visits.

To facilitate the collection of information on these areas, we have established new billing codes to be reported by practitioners in the demonstration. The codes correspond to four patient assessment levels for each of the patient status factors: nausea and/or vomiting; pain; and fatigue. These levels, based on the Rotterdam scale, have already proved effective in cancer care, are easily understood by patients, and have been in widespread use.

Any office-based physician or nonphysician practitioner operating within the State scope-of-practice laws who takes care of oncology patients and administers chemotherapy to them in an office setting is eligible to participate in this demonstration.

Receiving payment in the demonstration requires entering three new codes in conjunction with each chemotherapy encounter (i.e., one code for each patient status factor). For this purpose, a patient encounter is defined as a day when chemotherapy is administered through intravenous infusion or push. The severity scale for each of these three aspects of patient status has four levels, ranging from no impairment to severe impairment.

A participating practitioner will determine the patient's status by directly asking the patient about each of the three factors, preferably at the start of each chemotherapy session. The resulting data will be used by the oncology practice to appropriately tailor treatment of the factors.

Practices reporting data on all three factors to Medicare will qualify for an additional payment of \$130 per encounter. By billing the designated codes, the practitioner will self-enroll in the project.

Practitioners participating in the project must provide and document specified services related to pain control management and minimization of nausea and vomiting, and the reduction of fatigue. To facilitate the collection of this information, we have established 12 new G-codes to be reported by program participants.

#### **G-codes for Assessment of Nausea and/or Vomiting**

**G9021:** Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level one: not at all (for use in a Medicare-approved demonstration project)

**G9022:** Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level two: a little (for use in a Medicare-approved demonstration project)

**G9023:** Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level three: quite a bit (for use in a Medicare-approved demonstration project)

**G9024:** Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level four: very much (for use in a Medicare-approved demonstration project)

#### **G-Codes for Assessment for Pain**

**G9025:** Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level one: not at all (for use in a Medicare-approved demonstration project)

**G9026:** Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level two: a little (for use in a Medicare-approved demonstration project)

**G9027:** Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment level three: quite a bit (for use in a Medicare-approved demonstration project)

**G9028:** Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level four: very much (for use in a Medicare-approved demonstration project)

**G-Codes for Assessment for Lack of Energy (Fatigue)**

**G9029:** Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level one: not at all. (For use in a Medicare approved demonstration project).

**G9030:** Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level two: a little. (For use in a Medicare approved demonstration project).

**G9031:** Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level three: quite a bit. (For use in a Medicare approved demonstration project).

**G9032:** Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level four: very much. (For use in a Medicare - approved demonstration project).

The codes correspond to four patient assessment levels ('not at all', 'a little', 'quite a bit', or 'very much') for each of the following patient status factors: nausea and/or vomiting; pain; and lack of energy (fatigue). These levels, based on the Rotterdam scale, have already proved effective in cancer care, are easily understood by patients, and have been in widespread use.