CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

February 3, 2005

Mark A. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 314-G – HHH Building
Washington, D.C. 20201

RE: Draft Decision Memo for Aprepitant for Chemotherapy-Induced Emesis (CAG-00248N)

Dear Dr. McClellan:

The undersigned patient advocates, providers and cancer research organizations appreciate the recent decision by the Centers for Medicare & Medicaid Services (CMS) to cover a new class of oral anti-emetic drugs under Part B of Medicare as part of a "full replacement" regimen instead of intravenous anti-emetic therapy. This decision by CMS is a fitting complement to your recent initiation of a demonstration project to measure and assess quality of life during cancer chemotherapy.

While this coverage is a step in the right direction, the limits imposed by the decision memorandum are troubling and may undermine the otherwise beneficial impact of your action. According to the memorandum, coverage will be available only for those patients who "have demonstrated unresponsiveness to other anti-emetic regimens."

The Food and Drug Administration (FDA) approved this new class of drug for the prevention of nausea and vomiting associated with initial and repeat courses of chemotherapy with a high emetic risk, including high-dose cisplatin. If the new drug is relegated essentially to second-line treatment by omitting it from "initial" chemotherapy, it will be much less likely to control nausea and vomiting.

Chemotherapy-induced nausea and vomiting are among the most dreaded aspects of treatment for cancer. Prevention of this significant side effect will encourage compliance with therapy and greatly improve quality of life for cancer patients. We urge you to reconsider the CMS decision that would restrict coverage for this important preventative only to those patients who have previously failed anti-emetic therapy. Instead the drug should be covered in accordance with the

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FDA approval and with clinical practice guidelines that recognize it to be most effective when administered with the initial dose of chemotherapy as a means of preventing chemotherapy-induced nausea and vomiting.

As noted in a 2003 Editorial in the ***Journal of Clinical Oncology*** (JCO), the clinical trials studying this new drug make its inclusion in anti-emetic regimens "a standard of care for individuals receiving cisplatin," and a drug that "should be added to the antiemetic regimens of all patients receiving highly emetogenic chemotherapy."

Thank you for your continuing interest in quality of life issues for Medicare beneficiaries dealing with the consequences of cancer care.

Sincerely,

Cancer Leadership Council

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American Psychosocial Oncology Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology, Inc.
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Cancer Research and Prevention Foundation
Coalition of National Cancer Cooperative Groups
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