



**VIA EMAIL: CAGinquiries@cms.hhs.gov**

November 20, 2006

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Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Medical Literature for Local Medicare Contractors to Determine Medically Accepted Indications for Drugs and Biologicals Used in Anticancer Treatment**

Schering-Plough Corporation appreciates the opportunity to provide comments on the list of publications used by Medicare contractors to determine whether off-label uses of anticancer drugs and biologicals should be allowed in the Medicare program.

Schering-Plough is a global science-based health care company with leading prescription, consumer and animal health products headquartered in Kenilworth, NJ. Oncology is an important therapy area for Schering-Plough, given the serious unmet medical need. Schering-Plough currently markets two anticancer drugs: temozolomide (Temodar®), for certain types of brain tumors, including glioblastoma multiforme, which is the most prevalent form of brain cancer; and interferon alfa-2b, recombinant (Intron-A®), for malignant melanoma, clinically aggressive follicular non-Hodgkin's Lymphoma, and hairy cell leukemia. Schering-Plough also is actively engaged in researching new advances in cancer therapy.

As stated by CMS, under section 1861 (t)(2)(B)(ii)(II) of the Social Security Act, Medicare recognizes a “medically accepted indication” for the off-label use of a drug or biological used in an anticancer treatment regimen if the carrier involved determines that the use is “medically accepted based on supportive clinical evidence in peer-reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.” CMS has specified 15 publications for this purpose the Medicare Benefit Policy Manual (Chapter 15, section 50.4.5). This list has not been updated since CMS first published the publications list in 1993.

As a career oncologist, and Schering-Plough’s Chief Medical Officer, I feel it is important to regularly update the list of publications used to provide evidence to support coverage of off-label cancer treatment to ensure these publications reflect the best

available clinical evidence regarding new uses of anticancer treatments. As the clinical information regarding cancer treatment has progressed, a number of new publications have been introduced, which reflect the state-of-the-art in terms of new uses of cancer drugs. Other journals have evolved over time to provide more rigorous, peer-reviewed research results in key areas of cancer treatment. Schering-Plough is supportive of CMS's initiative to review and update this list to reflect changes in the state of the art of medical evidence that have occurred in the last thirteen years.

The most effective way for CMS to ensure that its list of oncology publications encompasses the best available clinical evidence is to receive input from thought-leader physicians in the oncology community. We understand you have received this kind of input from the American Society of Clinical Oncology (ASCO), and we support the recommendations provided in their letter to CMS dated May 4, 2006<sup>1</sup>. The eight journals recommended by ASCO meet the criteria of interest specified by CMS (rigorous impartial peer review process, lack of publication bias, full and timely public disclosure of potential conflicts of interest of authors, reviewers and editorial staff, reputation for scientific integrity and authoritative stature in the field of cancer treatment). In combination with the existing 15 approved publications, these additional journals would provide Medicare contractors with the best evidence possible in terms of clinically valid new uses of anticancer drugs and biologicals.

Again, we appreciate the opportunity to comment on this important issue. Please do not hesitate to contact me at 908-740-2700 if you have questions or if you would like additional information.

Sincerely,



Robert J. Spiegel, M.D. FACP  
Senior Vice President and  
Chief Medical Officer

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<sup>1</sup> ASCO recommends adding the following eight journals to the existing list of 15: *Annals of Oncology*; *Biology of Blood and Marrow Transplantation*; *Clinical Cancer Research*; *Gynecologic Oncology*; *Journal of the National Comprehensive Cancer Network*; *Journal of Thoracic Oncology*; *Breast Cancer Research and Treatment*; and the *International Journal of Radiation Oncology, Biology, Physics*.