

August 23, 2007

The Honorable Pete Domenici  
United States Senate  
328 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Domenici,

We believe that the current CMS policies governing medical oncology cancer treatment reimbursement, and the current CMS NCD regarding the use of ESA's require legislative input. There is no question that we are now seeing an adverse effect on our New Mexico seniors, as it relates to their ability to receive all of the appropriate care they deserve relative to their cancer diagnoses.

On the legislative front, please support S1750 Community Cancer Care Preservation Act of 2007 introduced by Senator Arlin Specter. This bill addresses three major areas that were deficient in the 2003 MMA.

The Average Sales Price methodology needs to be modified so that all oncology practices are reimbursed at least 6% more than they pay for the drugs. CMS assumes that the "underwater drugs" do not comprise the majority of drugs used in any given practice and therefore "it all evens out". It doesn't and failure to fix this methodology will doom outpatient cancer chemotherapy, as we know it. Fifty-six percent of the drugs we use day in and day out are "underwater" when we use our purchase price + 6% to determine the threshold.

The 2003 MMA established appropriate reimbursement for the administration of chemotherapy; however, the reimbursement has plummeted since and negates the rationale of that provision in the original 2003 MMA, which was very appropriate at the time for 2004.

It is essential that all healthcare providers pay for professional pharmacy services within our offices. This should be obvious, but difficult to change old ways in CMS. It is essential that healthcare providers should pay for treatment planning, which is the foundation of quality cancer care.

The Centers for Medicare and Medicaid Services (CMS) have recently issued a National Coverage Decision (NCD) which will impose significant restrictions on the use of erythrocyte stimulating agents (ESAs) in patients with cancer, and will eliminate its use in patients with chronic leukemias. These guidelines, which have gone into effect July 30, 2007, are contrary to current FDA labeling and the consensus of expert opinion as summarized in the American Society of Clinical Oncology (ASCO) and the American Society of Hematology (ASH) guidelines on the use of ESAs. This policy established a new treatment paradigm for the ESAs that has never been tested clinically, and that physicians have never used. As your constituents, we and the patients we serve will, in our opinion, be adversely impacted by the proposal as currently written.

Specifically, these points need to be addressed:

1. CMS has essentially rewritten the FDA label by establishing an initiation level of 10 g/dL, and a new upper limit of 10 g/dL rather than an upper limit of 12 g/dL as in current FDA, ASCO and ASH guidelines. CMS is assuming the authority to usurp the medical expertise of the FDA and contradict the current consensus of expert medical opinion.
2. In our opinion, this policy will eventually lead to increasing the transfusion requirement for patients and may adversely impact cancer care delivery, as we know it today. At this time we are only in the first full month of implementing these guidelines.
3. The decision to eliminate coverage of chronic myelogenous leukemia patients will adversely affect management of these patients.

Physicians must make decisions about when and how to manage anemia with ESAs to prevent transfusions, and to treat patient's symptoms. This policy undermines clinical judgment and undermines physician decision making.

We would appreciate your signing onto S1750. We believe a letter from your office emphasizing the above points to CMS regarding ESA's would be helpful. This may need to be dealt with legislatively.

Sincerely yours,

Paul R. Duncan, MD, FACP and James Lin M.D.