

United States Senate
WASHINGTON, DC 20510

August 20, 2010

Dr. Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Mailstop 314G
Washington, DC 20201

Dear Administrator Berwick:

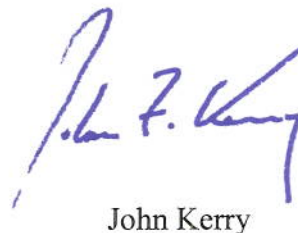
We are writing you regarding a National Coverage Analysis that the Centers for Medicare and Medicaid Services (CMS) issued on June 30, 2010, for autologous cellular immunotherapy treatment for prostate cancer. We are informed that this action was taken based on internal concerns regarding a new FDA-approved treatment regimen.

Only three times in the past has CMS issued a National Coverage Assessment on a new treatment for cancer, each time focusing on the need to restrict potential off-label usage of such drugs. These assessments have not focused on whether or not to cover appropriate on-label use of such a therapy as this latest review appears to be.

There is great concern from the prostate cancer community that this assessment could limit access to appropriate care for Medicare beneficiaries with prostate cancer. We would appreciate an explanation as to why CMS decided to proceed with a National Coverage Assessment for on-label use of an FDA-approved cancer treatment. We look forward to your timely response.

Sincerely,


Arlen Specter


John Kerry