

July 27, 2010

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BY ELECTRONIC DELIVERY

Louis B. Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C1-09-06
Baltimore, Maryland 21244

Re: National Coverage Analysis Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Jacques:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) opening of a national coverage analysis (NCA) for autologous cellular immunotherapy of treatment of metastatic prostate cancer.¹ ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 900 member institutions and organizations, when combined with our physician membership, treat 60 percent of all U.S. cancer patients.

ACCC is deeply concerned that CMS has opened this NCA regarding an autologous cellular immunotherapeutic agent for its Food and Drug Administration (FDA)-approved indication to treat certain forms of prostate cancer.² Not only is CMS's action contrary to Congress' intent to ensure beneficiary access to drugs and biologicals used in an anticancer chemotherapeutic regimen, but it threatens to

¹ NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.

² FDA Approval Letter for Provenge, April 29, 2010, <http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm210215.htm>.

stifle future innovation and cancer research for years to come. Accordingly, ACCC urges CMS to withdraw this NCA immediately.

Opening an NCA to question coverage of a cancer drug for its FDA-approved indication is inconsistent with the law as well as the intent of Congress to provide Medicare beneficiaries with comprehensive access to agents used in their battle against this deadly disease. Within the statutory definition of drugs that must be covered by Medicare, Congress specifically included “any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication.”³ A “medically accepted indication” includes not only indications approved by the FDA, but also certain uses supported by one or more citations in certain authoritative compendia.⁴ The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium is one of these compendia.⁵ Provenge®, the autologous cellular immunotherapy that is the subject of the NCA, is listed in the NCCN Compendium with category 1 support for use in asymptomatic or minimally symptomatic patients with ECOG performance status 0-1, and who do not have visceral disease and a life expectancy less than six months. Category 1 is the highest level of consensus that exists and means that the recommendation is “based on high level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus.”⁶ Thus, there should be no question that Provenge® should be covered by Medicare for its FDA-approved indication. To fail to do so would violate the law and needlessly would deny Medicare beneficiaries access to this exciting new advance.

ACCC also is concerned that CMS’s decision to initiate this NCA will be detrimental to cancer research for years to come. Cancer is a deadly disease, and patients often require treatment with the most innovative and cutting-edge therapies to win their battles against it. Bringing new therapies to market is costly, however, and investors will be more hesitant to fund new research if CMS threatens to restrict coverage for medically accepted indications of cancer drugs. Again, we urge CMS to withdraw this NCA right away and not to restrict coverage for this or any other cancer drug for its medically accepted indication either now or in the future. Indeed, this protection is precisely what Congress intended. If CMS does move forward with the NCA, we urge the agency to issue a National Coverage Determination (NCD) as soon as possible, covering Provenge nationally under the same standards as other drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication.

³ Social Security Act (SSA) § 1861(t)(2)(A).

⁴ SSA § 1861(t)(2)(B).

⁵ Medicare Benefit Policy Manual, ch 15, § 50.4.5.

⁶ NCCN Categories of Evidence and Consensus,
http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp.

Louis B. Jacques, MD
July 27, 2010
Page 3 of 3

ACCC appreciates the opportunity to submit these comments. We would be pleased to answer any questions. Please contact Matt Farber at 301-984-9496, ext. 221 if ACCC can be of any assistance.

Sincerely,

A handwritten signature in black ink that reads "Al B. Benson III". The signature is written in a cursive style with a large, prominent "A" and "B".

Al B. Benson III, MD, FACP
President

Association of Community Cancer Centers