

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
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**Office of Communications**

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## MEDICARE NEWS

**FOR IMMEDIATE RELEASE**

June 30, 2011

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**Medicare expands treatment options for patients with advanced prostate cancer**  
*Medicare now covers first FDA-approved immunotherapy for prostate cancer treatment*

Medicare patients with metastatic prostate cancer can get a first-of-its kind treatment just approved by the Food and Drug Administration, under a final coverage decision issued today by the Centers for Medicare & Medicaid Services (CMS).

Autologous cellular immunotherapy, known clinically as sipuleucel-T, is marketed in the United States as Provenge, for treating some forms of prostate cancer in seriously ill patients. Today's decision is effective immediately.

Provenge activates a patient's own immune system to defend him against prostate cancer. The treatment consists of a multi-day regimen in which the patient's white blood cells are collected and exposed to proteins that direct the white blood cells to fight prostate cancer cells. After the patient's cells are treated, the patient receives his own cells back into his body in order to stimulate his immune system to fight the prostate cancer. This regimen is repeated over several weeks for a total of three treatments.

"We are optimistic that innovative strategies may improve the experience of care for our beneficiaries who have cancer," said CMS Administrator Donald M. Berwick, M.D. "CMS is dedicated to assuring that these patients can seek the treatments they need in accordance with their wishes."

Prostate cancer is the most common non-skin cancer in men in the United States. The cancer forms in the prostate, a gland in the male reproductive system, which can spread to other parts of the body and threaten life. In 2009, an estimated 192,280 new cases of prostate cancer were diagnosed and an estimated 27,360 men died. According to the National Cancer Institute, prostate cancer is most commonly a cancer of older men, with most men diagnosed after 65 and the median age at diagnosis of 72.

CMS internally initiated the national coverage determination process for Provenge for multiple reasons, including: variations in local coverage; questions about the appropriate benefit

category for Provenge; and inquiries from Congress. There was no prior NCD on this technology, and local contractors were generally making case by case determinations.

CMS convened the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), a group of nationally recognized independent medical and scientific experts, on November 17, 2010 to make recommendations about the evidence. The MEDCAC votes supported coverage of Provenge for the FDA labeled indication and did not support coverage for unlabeled uses.

Today's coverage decision includes coverage of Provenge for the uses approved by the FDA: for treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

More information for patients and health professionals about FDA's approved uses of Provenge is online at <http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm210037.htm>.

"CMS is covering Provenge nationally only for those indications supported by evidence and consistent with the FDA label," said Patrick Conway, MD, MSc, CMS Chief Medical Officer and Director of the Agency's Office of Clinical Standards & Quality. "Similar to other treatment decisions, individual patients should discuss the risks and benefits with their physician to make an individual decision."

The final coverage decision is available on the CMS website at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Autologous%20Cellular%20Immunotherapy%20Treatment%20of%20Metastatic%20Prostate%20Cancer&bc=ACAAAAAIAAA&NCAId=247&>.

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