Medicare confirms payment for prostate cancer drug

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(AP) -- Medicare officials confirmed Thursday that the program will cover the $93,000 price tag for prostate cancer drug Provenge, an innovative therapy that typically gives men suffering from an incurable stage of the disease an extra four months to live.

The decision from the Centers for Medicare and Medicaid essentially reiterates an earlier proposed ruling that the biotech drug, made by Dendreon Corp., is a "reasonable and necessary" medicine. As expected, the government will cover the cost for men who meet the drug's approved criteria: those with prostate disease that has spread throughout the body and has not responded to hormone therapy or radiation. The government will not pay for alternate, or so called "off-label," use.

"We do not believe there is any persuasive evidence for the off-label use," of Provenge, the agency concluded in the ruling, posted online late Thursday.

About 240,000 new cases of prostate cancer are diagnosed each year in the U.S. and the disease claims over 33,000 lives annually, according to the American Cancer Society. The decision ensures that tens of thousands of men will be able to take the drug through the government-backed health care plan that covers seniors. With government reimbursement, analysts estimate Provenge could rack up $1 billion in sales next year. The decision is important for Dendreon because most prostate cancer patients are 65 or older.

The infused drug is a first-of-a-kind treatment in that each dose is customized to work with each individual patient's immune system. The drug is given in three infusions over the course of one month.

Medicare is legally prohibited from considering price when deciding whether to pay for a new treatment. But Provenge's steep price tag had generated debate about the cost of new drugs and the government's role in paying for them, especially against the political backdrop of health care reform and the rising cost of Medicare given the large number of baby boomers.

Seattle-based Dendreon says Provenge's price reflects the more than $1 billion spent researching and developing the drug. And prostate cancer patients point out that the median survival time with Provenge is double that of chemotherapy, which is about two months and is marked by painful side effects.

Each regimen of Provenge must be tailored to the immune system of the individual patient using a time-consuming formulation process. Doctors collect special blood cells from each patient that help the immune system recognize cancer as a threat. The cells are mixed with a protein found on most prostate cancer cells and another substance to rev up the immune system, and then given back to the patient as three infusions two weeks apart.

Provenge is the first federally-approved cancer drug that uses the body's own immune system to fight the disease, offering an alternative to chemotherapy drugs that attack cancerous and healthy cells at the same time.

On Wednesday, Dendreon announced it received federal regulatory approval to open a second manufacturing facility in Los Angeles, in addition to its primary facility in New Jersey. The company hopes to

open a third facility in Atlanta by the end of August.

Shares of Dendreon rose 96 cents, or 2.4 percent, to $40.40 in afterhours trading. The stock had closed the regular session down $1.06, or 2.6 percent, at $39.44.