MEDICARE ANNOUNCES FINAL NATIONAL COVERAGE DECISION FOR PROVENGE

On June 30, 2011, the Centers for Medicare and Medicaid Services (CMS) released a National Coverage Determination (NCD) that reaffirms coverage of PROVENGE for on-label uses in Medicare beneficiaries.

PROVENGE has FDA-approved labeling for the treatment of patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

Once this NCD is implemented, coverage for patients meeting these criteria will be available to all Medicare beneficiaries in all regions of the country.

The NCD issued by CMS for PROVENGE is binding on Medicare payers only. Please confirm coverage of PROVENGE by non-Medicare payers before prescribing by contacting Dendreon ON Call at 1-877-336-3736.

PROVENGE GRANTED A Q-CODE

For service dates on or after July 1, 2011, Medicare recognizes a new code for billing for PROVENGE use in the physician's office and hospital outpatient settings:

Q2043 — Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion

Although coding requirements of other payers may vary, many non-Medicare payers recognize Q2043 as well.

You can access the NCD and locate your local Medicare contractor on the CMS Web site: www.cms.gov

INDICATION: PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

IMPORTANT SAFETY INFORMATION: PROVENGE is intended solely for autologous use and is not routinely tested for transmissible infectious diseases.

In controlled clinical trials, serious adverse events reported in the PROVENGE group include acute infusion reactions (occurring within 1 day of infusion) and cerebrovascular events. Severe (Grade 3) acute infusion reactions were reported in 3.5% of patients in the PROVENGE group. Reactions included chills, fever, fatigue, asthenia, dyspnea, hypotension, bronchospasm, diarrhea, headache, hypertension, muscle ache, nausea, and vomiting. No Grade 4 or 5 acute infusion reactions were reported in patients in the PROVENGE group.

The most common adverse events (incidence ≥15%) reported in the PROVENGE group are chills, fatigue, fever, back pain, nausea, joint ache, and headache.

Please click here for full Prescribing Information for PROVENGE.

www.PROVENGE.com