Provenge (sipuleucel-T)

Line(s) of Business: HMO; PPO; QUEST Integration
Akamai Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 03/01/2017

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
• Provenge is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

Compendial Use
• Appropriate therapy for castration-recurrent metastatic disease for asymptomatic or minimally symptomatic patients with performance status 0-1, life expectancy greater than 6 months, and no hepatic metastases

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
• Cancer type/location, tumor histology and grade, staging, new cancer/recurrence, metastases, prior treatments, treatment intent (e.g., initial chemotherapy, neoadjuvant, adjuvant, or palliative), and pertinent pathology and imagine reports
• Treatment plan with treatment regimen including dose, frequency, length of each cycle, number of cycles, and additional therapies (e.g., other medications, radiation)

C. PRESCRIBER RESTRICTION
The medication must be prescribed by, or in consultation with, an oncologist

D. EXCLUSIONS
• Members who have received Provenge previously
• Members requesting greater than 3 doses

E. CRITERIA FOR APPROVAL
Prostate Cancer
a. Authorization of 6 months may be granted for members prescribed Provenge for metastatic, castration-resistant prostate cancer who meet the following criteria:
• Member is asymptomatic or minimally symptomatic
F. **DOSING AND ADMINISTRATION**
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. **PROGRAM EXCEPTION – AKAMAI ADVANTAGE**
   For Akamai Advantage members, the following National Coverage Determination (NCD) applies:
   - Autologous Cellular Immunotherapy Treatment (110.22).

H. **ADMINISTRATIVE GUIDELINES**
   Precertification is required. Please refer to the [HMSA medical policy web site](http://www.hmsa.com) for the fax form.

I. **IMPORTANT REMINDER**
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

   Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

   This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

J. **REFERENCES**

Revised: May 2016.