

Title: sipuleucil-T (Provenge)

Origination: 05/25/11	Revised: 09/07/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Sipuleucel-T is an autologous cellular immunotherapy used for the treatment of asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone refractory) prostate cancer. The vaccine is composed of autologous peripheral blood mononuclear cells, including antigen presenting cells (APCs), cultured with a fusion protein. The Member's peripheral blood mononuclear cells are obtained via standard leukapheresis approximately three (3) days prior to the sipuleucel-T infusion date. Each dose of sipuleucel-T contains a minimum of 50 million autologous CD54⁺ cells activated with PAP-GM-CSF.

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Member is receiving concurrent administration of chemotherapy or other immunosuppressant therapies.
- Member diagnosed with pathological long bone fractures or spinal cord compression.
- Members whose gender is woman.

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Procedure:

- 1.0 Request for *initiation of therapy* of Provenge for **Prostate Cancer** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Provider is medical oncologist; **AND**
 - 1.2 Member's diagnosis is **asymptomatic** or minimally symptomatic metastatic, castrate resistant (hormone refractory) prostate cancer as evidenced by the following:
 - 1.2.1 No current opioid use for cancer-related pain within the past three (3) months; **AND**
 - 1.2.2 Progression of metastasis despite prior regimen with leuprolide **OR** removal of testes; **AND**
 - 1.3 Member has life expectancy greater than six (6) months; **AND**
 - 1.4 Member shows an inadequate response to androgen deprivation therapy including
 - 1.4.1 LHRH analogs; **OR**
 - 1.4.1 LHRH antagonists; **OR**
 - 1.4.1 Anti-androgens excluding abiraterone (Zytiga); **AND**
 - 1.5 Current testosterone is < 50 ng/mL; **AND**
 - 1.6 Serum prostate-specific antigen (PSA) \geq 5 ng/mL; **AND**
 - 1.7 Member is not currently receiving chemotherapy, or if previously administered, chemotherapy has been discontinued for at least three (3) months and systemic corticosteroids or radiation have been discontinued for at least one (1) month;
 - 1.8 If the Member meets the above criteria, therapy may be approved one-time per lifetime for a maximum of three (3) infusions, each of which includes harvest and re-infusion of activated leucocytes.

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References:

1. PROVENGE [package insert]. Seattle, WA; Dendreon Corporation; 2010.
2. Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. *J Clin Oncol* 2006;24:3089-3094.
3. Small EJ, Fratesi P, Reese DM, et al. Immunotherapy of hormone-refractory prostate cancer with antigen-loaded dendritic cells. *J Clin Oncol* 2000;18:3894-3903.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.