DESCRIPTION: Sipuleucel-T is an autologous cellular immunotherapy, which contains a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF. PROVENGE is designed to induce an immune response targeted against PAP, an antigen expressed in most prostate cancers. During ex vivo culture with PAP-GM-CSF, APCs take up and process the recombinant target antigen into small peptides that are then displayed on the APC surface.

INDICATION(S): Sipuleucel-T indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

The recommended course of therapy for PROVENGE is 3 complete doses, given at approximately 2-week intervals.

For Intravenous Use Only. Do Not Use a Cell Filter

REASONS FOR PA: ☒ Cost ☒ Potential for misuse ☒ Toxicity

CRITERIA for APPROVAL:
1. Patient is diagnosed with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer?
   AND
2. Patient had a trial of a docetaxel-containing regimen?
3. Will Sipuleucel-T be given as a series of 3 complete doses of 50 million cells, given at 2-week intervals?

REASONS for DENIAL of BENEFIT:
1. Patient has a known history of sensitivity to medication or to any component of the product.
2. Patient does not meet above criteria

RENEWAL CRITERIA: Review of past demonstrates a reduced frequency of clinical exacerbations and improved health-related quality of life

BENEFIT APPROVAL: Initial approval for a period of 3 months. Renewal approval period: 3 months

References: Product Information, Dendreon Corporation 3005 First Avenue Seattle, Washington 98121