Sipuleucel-T (Provenge®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 10/4/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of sipuleucel-T. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

Sipuleucel-T is classified as an autologous cellular immunotherapy. While the precise mechanism of action is unknown, sipuleucel-T is designed to induce an immune response targeted against prostatic acid phosphatase (PAP), an antigen expressed in most prostate cancers. During ex vivo culture with PAP linked to granulocyte-macrophage colony stimulating factor (GM-CSF), antigen presenting cells (APC) take up and process the recombinant target antigen into small peptides that are then displayed on the APC surface.

FDA Indications[1]

Sipuleucel-T is FDA indicated for the following:

- Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer

Coverage Determinations[1,2]

Sipuleucel-T (Provenge®) will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Prostate Cancer

- The member must have a diagnosis of metastatic castrate-resistant (hormone refractory) prostate cancer (CRPC), as evidenced by disease progression despite bilateral orchiectomy or other androgen deprivation therapy **AND**
- The member must be ≥18 years of age **AND**
- The member exhibits asymptomatic or minimally symptomatic disease with an Eastern Cooperative Oncology Group performance score of 0-1 **AND**
- The member has a life expectancy of at least six months **AND**
- The member does not have hepatic or other visceral metastases **AND**
- The member has not received ≥ 3 doses of sipuleucel-T **AND**
- The member will receive sipuleucel-T as monotherapy

Recommended dosage: Each dose of sipuleucel-T contains a minimum of 50 million autologous CD54 cells activated with PAP-GM-CSF. A leukapheresis collection procedure occurs at approximately 3 days prior to each infusion of sipuleucel-T. Recommended course of therapy is to complete 3 doses, given at approximately 2-week intervals.

All indications:

- Sipuleucel-T will be approved through clinical review for up to a 3-month duration.

Coverage Limitations

Treatment with sipuleucel-T is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on sipuleucel-T
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:
    - Acute infusion reactions
    - Syncope and hypotension
    - Used in caution in members with risk factors for thromboembolic events

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: sipuleucel-T billing unit: 1
  - Q2043

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Provenge [package insert]. Dendreon Pharmaceuticals LLC, Seal Beach, CA. Available at: https://www.provenge.com/Portals/_default/Skins/ProvengeDTC/downloads/PRV.0039.USA.18-%20Provenge%20Prescribing%20Information.pdf
2. Sipuleucel-T. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/