Reference number(s)
2409-A

Standard Medicare Part B Management Provenge

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-Counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Provenge	sipuleucel-T

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[1,2]

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

Compendial Use[3]

Biochemical relapse of nonmetastatic androgen-dependent (castration-naïve) prostate cancer

CMS Nationally Covered Use[4]

The following NCD policy applies to these criteria: Autologous Cellular Immunotherapy Treatment (110.22).

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Coverage Criteria

Prostate cancer[1-4]

Authorization of 6 months may be granted when the requested medication is prescribed for a maximum of 3 doses for either of the following indications:

- Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.
- Biochemical relapse of nonmetastatic androgen-dependent (castration-naïve) prostate cancer.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

The requested medication is administered every 2 weeks for a total of 3 doses. Authorization for 3 months to complete the 3-dose treatment may be granted when all of the following criteria are met:

- The member is currently receiving treatment with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member has not yet completed treatment with all 3 doses.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Provenge.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Prostate cancer
- NCD 110.22- Autologous Cellular Immunotherapy Treatment

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Provenge are covered in addition to biochemically-relapsed, androgen-dependent prostate cancer.

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Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Provenge to treat biochemically-relapsed, androgen-dependent prostate cancer can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer is covered according to the conditions outlined in National Coverage Determination Manual section 110.22- Autologous Cellular Immunotherapy Treatment.

References

1. Provenge [package insert]. Seal Beach, CA: Dendreon Pharmaceuticals LLC; July 2017.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 15, 2025.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 15, 2025.
4. National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22). Version 1. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=344&ncdver=1&bc=0. Accessed July 15, 2025.

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