Molina Clinical Policy
Provenge™ (sipuleucel-T): Policy No. 105

Last Approval: 02/12/2025
Next Review Due By: February 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

POLICY DESCRIPTION

To define and describe the accepted indications for Provenge (sipuleucel-T) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS and/or LIMITATIONS OF COVERAGE

A. Continuation requests for a not-approvable medication shall be exempt from this policy provided:

1. The requested medication was used within the last year; **AND**
2. The member has not experienced disease progression and/or no intolerance to the medication; **AND**
3. Additional medications are not being added to the continuation request.

B. Prostate Cancer

1. NOTE: Provenge (sipuleucel-T) is not supported by policy for metastatic castrate-resistant prostate cancer. This policy position is based on the lack of Level 1 evidence (randomized clinical trials and or meta-analyses) to show that Provenge (sipuleucel-T) is superior in terms of PFS or OS when compared to the recommended alternative agents/regimens, including but not limited to regimens at http://evolent.com/pathways

EXCLUSION CRITERIA

A. Disease progression while taking Provenge (sipuleucel-T).

B. Concurrent use with other anticancer therapies.

C. Dosing exceeds 3 doses, given at approximately 2-week intervals.

D. Investigational use of Provenge (sipuleucel-T) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.

2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer- reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

APPLICABLE CPT / HCPCS PROCEDURE CODES

CPT (Current Procedural Terminology)

Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
Q2043	Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion

AVAILABLE DOSAGE FORMS: Each dose of Provenge is suspended in 250 mL of Lactated Ringer's Injection, USP in a sealed, patient-specific infusion bag

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

02/12/2025	Included disease progression, dosing, and concurrent use with other anticancer therapies in exclusion criteria.
02/14/2024	Updated references.
06/14/2023	Entire inclusions section rewritten. Pathway reference removed from exclusions.
08/10/2022	Adopted NCH policy and retired MCP.

REFERENCES

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3. Ellis LM, Bernstein DS, Voest EE, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80. doi: 10.1200/JCO.2013.53.8009. Epub 2014 Mar 17. PMID: 24638016.
4. Holko P, Kawalec P. Economic evaluation of sipuleucel-T immunotherapy in castration-resistant prostate cancer. Expert Rev Anticancer Ther. 2014 Jan;14(1):63-73. doi: 10.1586/14737140.2014.856270. PMID: 24224852.
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6. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.
7. National Comprehensive Cancer Network.Cancer Guidelines and Drugs and Biologics Compendium 2024.
8. Provenge prescribing information 2017. Dendreon Pharmaceuticals LLC, Seal Beach, CA