Medical Necessity Guidelines
Medical Benefit Drugs

# Provenge® (sipuleucel-T)

*Effective: January 1, 2025*

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| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration - Approved Indications**

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

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of Provenge for Members when all the following criteria are met:

1. Documented diagnosis of asymptomatic or minimally symptomatic castrate-resistant prostate cancer

## Limitations

None

## Codes

The following code(s) require prior authorization:

**Table 1: HCPCS Codes**

| HCPCS Codes | Description |
|---|---|
| Q2043 | Provenge (sipuleucel-T) |

## References

1. Provenge (sipuleucel-T) [package insert]; Seattle, WA; Dendreon Corporation: 2017 July.

## Approval And Revision History

February 14, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

February 15, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Removed age requirements. Minor wording updates. Removed the Limitation The Plan may cover up to 3 doses when all criteria is met (eff 12/1/23).
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- November 12, 2024: No changes (eff 1/1/25)
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).

## Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.