

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

## Provenge (sipuleucel-T)

Override(s)	Approval Duration
Prior Authorization	90 days

Medications
Provenge (sipuleucel-T)

### APPROVAL CRITERIA

Requests for Provenge (sipuleucel-T) may be approved if the following criteria are met:

- I. Individual has a diagnosis of prostate cancer; **AND**
- II. Individual has metastatic castrate-resistant or hormone refractory disease; **AND**
- III. Individual meets all of the following (Kantoff 2010):
  - A. Asymptomatic or minimally symptomatic; **AND**
  - B. ECOG (Eastern Cooperative Oncology Group) performance status 0-1; **AND**
  - C. No visceral metastasis; **AND**
  - D. No pathologic long bone fracture, or spinal cord compression within the last 3 months; **AND**
  - E. Life expectancy of greater than 6 months; **AND**
  - F. No treatment within the previous 28 days with systemic glucocorticoids, external-beam radiation (EBRT), surgery, or systemic therapy for prostate cancer (except medical or surgical castration); **AND**
  - G. Progressive disease documented by either of the following:
    1. Serum prostate-specific antigen (PSA) level increasing; **OR**
    2. Osseous metastases on imaging with objective evidence of progression regardless of PSA levels

Requests for Provenge (sipuleucel-T) may not be approved for the following:

- I. Small cell/neuroendocrine prostate cancer (NCCN Prostate Cancer Guidelines); **OR**
- II. When the above criteria are not met and for all other indications.

### Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL:

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 17, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Kantoff PW, Higano CS, Shore ND, et al.; IMPACT Study Investigators. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. N Engl J Med. 2010; 363(5):411-422.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 17, 2020.
  - a. Prostate Cancer. V1.2020. Revised March 16, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.