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CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Provenge (sipuleucel-T)
BILLING CODE	Q2043
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 1 doses per 2 weeks, up to 3 doses total
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Provenge (sipuleucel-T) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PROSTATE CANCER

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by an oncologist, a hematologist, or a urologist; AND
3. Member must have a diagnosis of metastatic castrate resistant prostate cancer (CRPC) and is asymptomatic or minimally symptomatic (Gleason score of 7 or less documented in chart notes); AND
4. Member has level of testosterone (< 50 ng/dL) achieved via medical or surgical castration; AND
5. Members had **not** received ANY of the following treatments within the previous 28 days:
   a) External beam radiation therapy or major surgery requiring general anesthetic;
   b) Systemic corticosteroids;
   c) Non-steroidal anti-androgens (e.g., bicalutamide, flutamide, or nilutamide);
   d) Any other systemic therapy for prostate cancer including secondary hormonal therapies, such as megestrol acetate (Megace®), diethylstilbestrol (DES), and ketoconazole; AND
6. Member must have a life expectancy of 3 months or greater; AND
7. Member does **not** have any of the following:
   a) Visceral metastases (liver, lung, or brain);
   b) Moderate to severe prostate cancer-related pain;
   c) Use of narcotics for cancer-related pain.
8. **Dosage allowed:** 3 doses, 1 dose every 2 weeks.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Provenge will not be reauthorized for continued therapy.

CareSource considers Provenge (sipuleucel-T) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/29/2017	New policy for Provenge created.

References:

1. Kantoff PW, Higano CS, Shore ND, et al. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. N Engl J Med 2010;363:411-422.
2. Provenge [package insert]. Seattle, WA; Valeant Pharmaceuticals.; Revised October 2014.
3. Wolters Kluwer. Lexi-Comp. www.online.lexi.com. 2016.
4. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT00901342. Open Label Study of Sipuleucel-T in Metastatic Prostate Cancer; May 23, 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT00901342?term=sipuleucel&recrs=e&draw=1&rank=1.

Effective date: 11/29/2017
Revised date: 11/15/2017