Clinical Oversight Review Board (CORB) Criteria for Prescribing

Sipuleucel-T (Provenge)

Non-Formulary **sipuleucel-T (Provenge)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **sipuleucel-T (Provenge)** will be covered on the prescription drug benefit when the following criteria are met:

- Histological documentation of adenocarcinoma of the prostate
- No evidence of neuroendocrine or small cell features
- Metastatic disease as evidenced by either:
  - Soft tissue metastases on CT abdomen/pelvis within 2 months **OR**
    Bony metastases on bone scan within 2 months
- No known lung, liver, or brain metastases, malignant pleural effusions, or malignant Ascites.
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Serum PSA greater than 5.0 ng/mL.
- Testosterone less than 50 ng/dL achieved via medical or surgical castration.
- Life expectancy of at least 6 months.
- Has progressive androgen independent prostate cancer, defined as:
  - Rising PSA on two consecutive rises at least 14 days apart **OR**
    Progression of measurable disease **OR**
    Progression of non-measurable disease such as 2 or more new areas of abnormal uptake on bone scan (increased uptake of pre-existing lesions on bone scan does not constitute progression)
- The patient meets all of the following laboratory criteria:
  - White blood cell (WBC) greater than 2,500 cells/uL
  - Neutrophils greater than 1,000 cells/uL
  - Platelets greater than 100,000/uL
  - Hemoglobin (HgB) greater than 9.0 g/dL
  - Creatinine less than 2.0 mg/dL
  - Total Bilirubin less than 2x upper limit of normal (ULN)
  - Aspartate transferase (AST) less than 2.5x ULN
  - Alanine transferase (ALT) less than 2.5x ULN
- No opioid analgesics for any reason within 21 days prior to planned sipuleucel-T treatment
- Average weekly pain score of 0-3 within 14 days prior to planned sipuleucel-T treatment

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- No non-steroidal antiandrogens (e.g., flutamide, nilutamide or bicalutamide) within past 6 weeks of planned sipuleucel-T treatment
- No anti-androgen withdrawal response, defined as a greater than 25% drop in PSA following discontinuation of a non-steroidal antiandrogen.
- No treatment with chemotherapy within 3 months of planned sipuleucel-T treatment
- No more than 2 chemotherapy regimens for catration-resistent disease prior to planned sipuleucel-T treatment
- Not planning initiation of bisphosphonate therapy within 28 days prior to planned sipuleucel-T treatment
- No external beam radiation therapy within 28 days of planned sipuleucel-T treatment
- No surgery within 28 days of planned sipuleucel-T treatment
- No treatment with enzalutamide, abiraterone, ketoconazole, apalutamide, darolutamide within 28 days?
- No requirement for >10 mg of prednisone (or its equivalent) daily within the last two weeks prior to planned sipuleucel-T treatment
- No other systemic therapy for prostate cancer (except for medical castration leuprolide (LUPRON), goserelin acetate (ZOLADEX) within 28 days of planned sipuleucel-T treatment
- No treatment with any investigational vaccine within 2 years of planned sipuleucel-T treatment
- No known pathologic long-bone fractures, imminent pathologic long-bone fracture (cortical erosion on radiography greater than 50%) or spinal cord compression.
- No requirement for systemic immunosuppressive therapy for any reason
- No history of allergic reactions attributed to compounds of similar chemical or biologic composition to sipuleucel-T (PROVENGE) or GM-CSF
- No infections requiring parenteral antibiotic therapy or causing fever (temp greater than 100.5°F or greater than 38.1°C) within 1 week prior to planned sipuleucel-T treatment