I. PURPOSE
To define and describe the accepted indications for Jevtana (cabazitaxel) usage in the treatment of cancer.

II. DEFINITIONS

**Jevtana (cabazitaxel):** is a taxane derivative of the natural taxoid 10-deacetylbaccatin III prepared semi-synthetically with a precursor extracted from yew needles. Jevtana (cabazitaxel) binds to tubulin and promotes its assembly into microtubules. Simultaneously, Jevtana (cabazitaxel) inhibits microtubule disassembly by stabilizing tubulin. This results in inhibition of microtubule depolymerization and cell division, cell cycle arrest (G2/M phase), and the inhibition of tumor cell proliferation. Unlike other taxanes, Jevtana (cabazitaxel) is a poor substrate for the multidrug resistance P-glycoprotein efflux pump and may be useful for treating multidrug-resistant tumors. In addition, Jevtana (cabazitaxel) penetrates the blood-brain barrier, where Pgp efflux pumps may serve as barriers.

Jevtana (cabazitaxel) is a microtubule inhibitor indicated in combination with prednisone for the treatment of members with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Jevtana (cabazitaxel) is available for IV solution in a 60mg/1.5ml vial.

III. POLICY

New Century Health is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century Health may be deemed as not approvable and therefore not reimbursable. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

**Inclusion Criteria:** Jevtana (cabazitaxel) may be considered medically necessary when any of the following selection criteria is met:

1. **Hormone Refractory Prostate Cancer (HRPC)**
   a. The member has evidence of HRPC and treated previously with a docetaxel – based regimen **AND**
The member will also take prednisone 10mg daily in combination with Jevtana (given IV every 3 weeks) AND

No prior history of hypersensitivity to Jevtana or to drugs formulated with polysorbate 80 AND

The ANC (absolute neutrophil count) is >1500 AND

Premedicate each dose of Jevtana with IV doses of an antihistamine, a corticosteroid, and a H2-antagonist.

Exclusion Criteria: Jevtana (cabazitaxel) is not considered medically necessary when any of the following selection criteria is met:

1. Jevtana (cabazitaxel) is being used concurrently with other chemotherapy.
2. The member has a total bilirubin greater than 3 times the ULN.
3. Dosing exceeds single dose limit of Jevtana (cabazitaxel) 25 mg/m².
4. Treatment exceeds a maximum duration of 10 cycles of Jevtana (cabazitaxel).
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Jevtana (cabazitaxel) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. Dosage and Administration:
   a. Premedication
      i. To reduce the risk and/or severity of hypersensitivity, members should be premedicated with the following recommended intravenous regimen: diphenhydramine 25 mg, dexamethasone 8 mg, and ranitidine 50 mg (or equivalents) at least 30 minutes prior to each dose of Jevtana (cabazitaxel).
   b. Dose
      i. The recommended dosage is cabazitaxel 20 mg/m² intravenously over 1 hour (using a 0.22 micrometer nominal pore size in-line filter) every 3 weeks in combination with prednisone 10 mg orally daily throughout Jevtana (cabazitaxel) treatment. A dose of 25 mg/m² can be used in select patients at the discretion of the treating healthcare provider.

2. Dosage Adjustments:
   a. Diarrhea (grade 3 or higher or persisting despite medication, fluid, and electrolyte replacement): delay treatment until improved or resolved, then reduce cabazitaxel to 20 mg/m² or from 20 mg/m² to 15 mg/m².
   b. Febrile neutropenia: delay treatment until improvement or resolution and neutrophil count is greater than 1500 cells/cubic millimeter, then reduce Jevtana (cabazitaxel) to 20 mg/m² or from 20 mg/m² to 15 mg/m² and use granulocyte-colony stimulating factor (G-CSF) for secondary prophylaxis.
c. Neutropenia - prolonged (greater than 1 wk), grade 3 or higher despite the use of granulocyte-colony stimulating factor (G-CSF): delay treatment until neutrophil count is greater than 1500 cells/cubic millimeter, then reduce Jevtana (cabazitaxel) to 20 mg/m² or from 20 mg/m² to 15 mg/m² and use granulocyte-colony stimulating factor (G-CSF) for secondary prophylaxis.

d. Hepatic, mild impairment (total bilirubin greater than 1 up to 1.5 times the ULN or AST greater than 1.5 the ULN): 20 mg/m²

e. Hepatic, moderate impairment (total bilirubin greater than 1.5 up to 3 times the ULN and any AST): Reduce starting dose to 15 mg/m²; dose efficacy unknown.

f. Hepatic, severe impairment (total bilirubin greater than 3 times the ULN): Use contraindicated.

g. Concomitant strong CYP3A inhibitors: If coadministration cannot be avoided, consider reducing cabazitaxel dose by 25%.

h. Peripheral neuropathy, Grade 2: Delay treatment until improvement or resolution, and reduce cabazitaxel from 25 mg/m² to 20 mg/m² or from 20 mg/m² to 15 mg/m².

i. Peripheral neuropathy, Grade 3: Discontinue cabazitaxel.

3. Monitoring

a. Prostate cancer: tumor response may indicate efficacy

b. CBC with differential; weekly during cycle 1 and before each cycle thereafter

c. Signs of hypersensitivity reaction (especially rash/erythema, hypotension, and bronchospasm); especially during the first and second infusions

d. Signs or symptoms of cystitis: During therapy in patients who have previously received pelvic radiation

e. Respiratory disorders

f. Patients with mild or moderate hepatic impairment

g. Patients with ESRD.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES


