

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP
2

Diagnosis	<input type="checkbox"/> Metastatic, castrate-resistant (hormone-refractory) prostate cancer	<input type="checkbox"/> Other (please state): _____
Clinical Consideration	<input type="checkbox"/> Patient has been treated previously with docetaxel <input type="checkbox"/> Patient has experienced disease progression during or after docetaxel therapy	
Physician Specialty	Diagnosis made by: <input type="checkbox"/> Oncology <input type="checkbox"/> Other (please state): _____	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription order below: Jevtana [®] (cabazitaxel) Strength _____ Sig _____ Qty _____ Refills _____	
	<i>*Please attach all relevant medical records and test results*</i> We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.	

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

 Prescriber Signature

 Date

STEP
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
 970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/05/11

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Jevtana (cabazitaxel)

CLASSIFICATION

- Antineoplastic, mitotic inhibitor

DESCRIPTION

- Cabazitaxel is a microtubule inhibitor, of the taxane class, indicated (in combination with prednisone) for the treatment of hormone-refractory metastatic prostate cancer, previously treated with a docetaxel-containing regimen
- Cabazitaxel binds to tubulin and simultaneously promotes assembly and inhibits disassembly of microtubules. This stabilization of microtubules inhibits mitotic and interphase cellular functions
- In an international, multicenter, randomized, open-label study (n=755), cabazitaxel in combination with prednisone provided superior overall survival (15.1 months) compared with mitoxantrone plus prednisone (12.7 months) in hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen

FORMULARY COVERAGE

Prior authorization:	Required for Good Health and Commercial only
Good Health Formulary:	T6
Commercial Formulary:	T6
Medicare Part D coverage:	T5 at a pharmacy; Part B if incident to a physician's service

COVERAGE CRITERIA

Jevtana (cabazitaxel) meets the definition of **medical necessity** for the following:

- Hormone refractory prostate cancer, Metastatic, in combination with prednisone, after failure of a prior docetaxel-containing regimen

Jevtana (cabazitaxel) is considered **experimental** for the following:

- Any use or indication outside of FDA approval

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION:

Adult Dosing

- 25 mg/m² IV over 1 hr every 3 wks; administer continuous ORAL prednisone 10 mg daily; premedicate with dexchlorpheniramine 5 mg or diphenhydramine 25 mg, dexamethasone 8 mg, and ranitidine 50 mg or equivalents IV at least 30 min prior to each administration

Pediatric dosing

- Safety and efficacy has not been established in pediatric patients

Dosing adjustments

- Diarrhea, grade 3 or higher or persisting despite medication, fluid, and electrolyte replacement; delay treatment until improved or resolved, then reduce cabazitaxel to 20 milligrams/square meter
- Febrile neutropenia; delay treatment until improvement or resolution and neutrophil count is greater than 1500 cells/cubic millimeter, then reduce cabazitaxel to 20 milligrams/square meter and use granulocyte-colony stimulating factor (G-CSF) for secondary prophylaxis
- 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 cabazitaxel to 20 milligrams/square meter and use granulocyte-colony stimulating factor (G-CSF) for secondary prophylaxis

PRECAUTIONS:

- Black Box Warning
 - Neutropenic deaths have been reported. In order to monitor the occurrence of neutropenia, frequent blood cell counts should be performed on all patients receiving cabazitaxel. Cabazitaxel should not be given to patients with neutrophil counts of 1,500 cells/mm³ or less.
 - Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the cabazitaxel infusion and administration of appropriate therapy. Patients should receive premedication. Cabazitaxel must not be given to patients who have a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80
- Age 65 yr or older; increased risk of adverse reactions including neutropenia and febrile neutropenia
- Concomitant use of strong CYP3A inducers (eg, phenytoin, rifampin, phenobarbital, St. John's wort) or strong CYP3A inhibitors (e.g. ketoconazole, clarithromycin, ritonavir) should be avoided
- Hepatic impairment; use not recommended due to increased risk of severe and life-threatening complications with drugs in the same class
- Nausea, vomiting, and diarrhea leading to electrolyte imbalance and death have occurred; treatment delay, dosage reduction, and management may be required pregnancy; potential for fetal harm
- Renal failure, sometimes fatal, has been reported

Billing/Coding information

Associated HCPCS Codes:

C9276	Injection, cabazitaxel, 1mg
J9043	Injection, cabazitaxel, 1mg
J9999	Not otherwise classified, antineoplastic drugs

Associated CPT Coding:

Associated ICD-9 Coding:

185	Malignant neoplasm of the prostate

COST

- AWP (September 2010) – 60mg/1.5ml vial (1): \$9,600
- AWP (December 2011) – 60mg/1.5ml vial (1): \$9,696

COMMITTEE APPROVAL:

- September 22, 2010

GUIDELINE UPDATE INFORMATION:

Sep 2010	Policy created

REFERENCES:

- DRUGDEX®, accessed 09/13/2010
- Product Information: JEVTANA(R) IV infusion, cabazitaxel IV infusion. Sanofi-Aventis US LLC, Bridgewater, NJ, 2010.