



Medication Policy Manual

Policy No: dru232

Topic: Jevtana®, cabazitaxel

Date of Origin: January 14, 2011

Committee Approval Date: January 13, 2017

Next Review Date: January 2018

Effective Date: February 1, 2017

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Cabazitaxel (Jevtana) is an intravenous chemotherapy medication used in the treatment of metastatic hormone-refractory prostate cancer when docetaxel (Taxotere) has not been effective.

Policy/Criteria

- I.** Most contracts require prior authorization approval of cabazitaxel prior to coverage. Cabazitaxel (Jevtana) may be considered medically necessary when both criteria A and B below are met.
 - A.** A diagnosis of metastatic castration-resistant prostate cancer (mCRPC).

AND

 - B.** Prior treatment with docetaxel (Taxotere) has been ineffective or not tolerated.

- II.** Administration and Authorization Period
 - A.** OmedaRx does not consider cabazitaxel (Jevtana) to be a self-administered medication.
 - B.** Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

- III.** Cabazitaxel (Jevtana) is considered investigational when used for all other conditions, including but not limited to:
 - A.** Breast cancer.
 - B.** Central nervous system tumors.
 - C.** Head and neck cancers.
 - D.** Gastric cancer.
 - E.** Non-small cell lung cancer.
 - F.** Other Solid tumors.
 - G.** Urothelial carcinoma.

Position Statement

- Cabazitaxel (Jevtana) is a taxane chemotherapy medication used in the treatment of metastatic castration-resistant prostate cancer (mCRPC). It is given in conjunction with a low dose of prednisone.
- Docetaxel (Taxotere) plus prednisone is considered the gold-standard therapy in men with mCRPC because it was shown to improve overall survival relative to palliative care with mitoxantrone (Novantrone) plus prednisone.
- Cabazitaxel (Jevtana) was studied in the second-line setting (after docetaxel) and demonstrated a similar survival benefit.
- There is currently no published data that evaluates the safety and efficacy of cabazitaxel (Jevtana) in any other cancer setting.

Summary

Clinical Efficacy

- The effectiveness of cabazitaxel (Jevtana) has been evaluated in a study of 755 men with metastatic castration-resistant prostate cancer (mCRPC) in a single, unreliable, randomized controlled trial. ^[1,2]
 - * The study was not blinded (open-label).
 - * A high proportion of men (~20%) withdrew from the trial prior to its completion.
 - * Crossover to other therapies after disease progression may have confounded the study.
- The men enrolled in the trial had disease progression after an orchiectomy and/or luteinizing hormone-releasing hormone agonists (LH-RH agonist) with or without an antiandrogen (i.e. they had castration-resistant disease). ^[1]
- All men had prior treatment for mCRPC with docetaxel plus prednisone. ^[1]
- The study evaluated the overall survival of men treated with cabazitaxel (Jevtana) plus prednisone versus those treated with palliative therapy consisting of mitoxantrone plus prednisone. ^[1]
- Second-line salvage chemotherapy with cabazitaxel (Jevtana) plus prednisone demonstrated a survival benefit over palliative care. ^[1]
- The National Comprehensive Cancer Network (NCCN) prostate cancer guideline lists cabazitaxel (Jevtana) with prednisone as a category 1 recommendation (highest recommendation) for men with mCRPC who have progressed after docetaxel. ^[3]
- Cabazitaxel (Jevtana) is being studied in metastatic solid tumors, advanced non-small cell lung cancer, and mCRPC in patients without previous chemotherapy; however, no information evaluating its safety and efficacy in these settings is publically available at this time. ^[4]

OmedaRx performs independent analyses of oncology medications. The OmedaRx analysis and coverage policy may differ from NCCN guidelines.

Safety ^[5]

- The most common adverse events ($\geq 20\%$) include neutropenia, anemia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, and asthenia.
- Box warnings include severe neutropenia and hypersensitivity reactions.

Dosing considerations ^[5]

- Cabazitaxel (Jevtana) is administered intravenously over one hour once every three weeks. It is given along with daily prednisone.
- Dose modifications may be necessary for severe neutropenia.

Cross References
Provenge®, sipuleucel-T, Medication Policy Manual, Policy No. dru216
Xtandi®, enzalutamide, Medication Policy Manual, Policy No. dru280
Zytiga®, abiraterone acetate, Medication Policy Manual, Policy No. dru252

Codes	Number	Description
HCPCS	J9043	Injection, cabazitaxel, 1 mg
HCPCS	J9171	Injection, docetaxel, 1 mg
ICD-9	185	Malignant neoplasm of the prostate
ICD-9	V 10.46	Personal history of malignant neoplasm of the prostate
ICD-10	C61	Malignant neoplasm of the prostate.
ICD-10	Z85.46	Personal history of malignant neoplasm of the prostate.

References

- de Bono, JS, Oudard, S, Ozguroglu, M, et al. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. *Lancet*. Oct 2;376(9747):1147-54. PMID: 20888992
- Center for Drug Evaluation and Research; U.S. Food and Drug Administration Medical Review; NDA 201-023; Jevtana (cabazitaxel). [cited 12/10/2012]; Available from: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/201023s000MedR.pdf.
- NCCN Clinical Practice Guidelines in Oncology™. Prostate Cancer v1.2016. [cited 12/16/2015]; Available from: http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
- Clinicaltrials.gov. [cited 12/16/2015]; Available from: <http://clinicaltrials.gov>.
- Jevtana® [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; June 2015.

Revision History

Revision Date	Revision Summary
1/13/2017	No criteria changes.
1/8/2016	No criteria changes.