Drug Reimbursement Coding and Pricing Advisory™

JEVTANA® (cabazitaxel) Injection – by SANOFI U.S.


Effective January 1, 2012 JEVTANA® has been assigned a HCPCS J-Code:

J9043 Injection, cabazitaxel, 1 mg

by CMS (Centers for Medicare and Medicaid Services).

See detailed information for JEVTANA® using the CMS 1500 Form below.

Indication

JEVTANA® is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Important Safety Information for JEVTANA® (cabazitaxel) Injection

WARNING1

• Neutropenic deaths have been reported. Obtain frequent blood counts to monitor for neutropenia. Do not give JEVTANA® if neutrophil counts are ≤1,500 cells/mm³.

• Severe hypersensitivity can occur and may include generalized rash/erythema, hypotension and bronchospasm. Discontinue JEVTANA® immediately if severe reactions occur and administer appropriate therapy.

• Contraindicated if history of severe hypersensitivity reactions to JEVTANA® or to drugs formulated with polysorbate 80.

Please see additional important safety information on pages 3-4 and click here for full prescribing information including boxed WARNING.
Please note: This document is an abbreviated reference. Providers should select and use the codes which most accurately describe the procedure performed and which are consistent with the requirements of any applicable health insurers. To support compliance with insurer requirements, providers should contact local, public or private health insurers to determine the appropriate codes for the services provided. Sanofi U.S. cannot and does not guarantee that use of any code(s) will assure coverage or payment at any level.

Box 21 - Diagnosis Code

Enter the appropriate ICD-9-CM code for JEVTANA® in Box 21. Possible ICD-9 code(s) include:

Box 21  185  Malignant neoplasm of prostate
         Excludes seminal vesicles (187.8)

Column 24D and Box 19 - Medication Information

Column 24D  Indicate the appropriate HCPCS code for JEVTANA®:

   J9043  Injection, cabazitaxel, 1 mg

Box 19  Optional: Indicate the full name of the medication administered including strength (if applicable) (e.g., Jevtana 60 mg/1.5 mL) as well as the NDC (National Drug Code) on the package used (e.g., 00024-5824-11).

Column 24D - Administration Code

Since JEVTANA® is administered as a 1 hour intravenous infusion, you need to include, on a separate line in Column 24D, the appropriate administration code (e.g., 96413)

Column 24D  96413:  Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

Column 24G - Medication Quantity

Column 24G  1 mg of JEVTANA® is equal to 1 unit of J9043 and 1 vial (60 mg/1.5 mL) of JEVTANA® is equal to 60 units of J9043.

Please see important safety information on pages 3-4 and click here for full prescribing information including boxed WARNING.
Important Safety Information for JEVTANA® (cabazitaxel) Injection

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 JEVTANA®, JEVTANA® should not be given to patients with neutrophil counts of ≤1,500 cells/mm³.

• Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the JEVTANA® infusion and administration of appropriate therapy. Patients should receive premedication.

• JEVTANA® must not be given to patients who have a history of severe hypersensitivity reactions to JEVTANA or to other drugs formulated with polysorbate 80.

CONTRAINDICATIONS

• JEVTANA® should not be used in patients with neutrophil counts of ≤1,500/mm³.

• JEVTANA® is contraindicated in patients who have a history of severe hypersensitivity reactions to JEVTANA® or to other drugs formulated with polysorbate 80.

WARNINGS AND PRECAUTIONS

• Neutropenic deaths have been reported.
  — Monitoring of complete blood counts is essential on a weekly basis during cycle 1 and before each treatment cycle thereafter so that the dose can be adjusted, if needed.
  — Monitor blood counts frequently to determine if initiation of G-CSF and/or dosage modification is needed.
  — Primary prophylaxis with G-CSF should be considered in patients with high-risk clinical features.

• Severe hypersensitivity reactions can occur.
  — Premedicate with antihistamines, corticosteroids and H₂ antagonists.
  — Patients should be observed closely for hypersensitivity reactions, especially during the first and second infusions.
  — Discontinue infusion immediately if hypersensitivity is observed and treat as indicated.

Please see additional important safety information on page 4 and click here for full prescribing information including boxed WARNING.
• Mortality related to diarrhea has been reported
  — Rehydrate and treat with anti-emetics and anti-diarrheals as needed
  — If experiencing grade ≥3 diarrhea, dosage should be modified

• Nausea, vomiting and severe diarrhea, at times, may occur. Death related to diarrhea and electrolyte imbalance occurred in the randomized clinical trial. Intensive measures may be required for severe diarrhea and electrolyte imbalance

• Renal failure, including cases with fatal outcomes, has been reported. Identify cause and manage aggressively

• Patients ≥65 years of age were more likely to experience fatal outcomes not related to disease progression and certain adverse reactions, including neutropenia and febrile neutropenia. Monitor closely

• Patients with impaired hepatic function were excluded from the randomized clinical trial
  — Hepatic impairment is likely to increase the JEVTANA® concentrations
  — JEVTANA® should not be given to patients with hepatic impairment

• JEVTANA® can cause fetal harm when administered to a pregnant woman
  — There are no adequate and well-controlled studies in pregnant women using JEVTANA®
  — Women of childbearing potential should be advised to avoid becoming pregnant during treatment with JEVTANA®

ADVERSE REACTIONS

• Deaths due to causes other than disease progression within 30 days of last study drug dose were reported in 18 (5%) JEVTANA®-treated patients. The most common fatal adverse reactions in JEVTANA®-treated patients were infections (n=5) and renal failure (n=4)

• The most common (≥10%) grade 1–4 adverse reactions were anemia, leukopenia, neutropenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysgeusia, cough, arthralgia, and alopecia

• The most common (≥5%) grade 3–4 adverse reactions in patients who received JEVTANA® were neutropenia, leukopenia, anemia, febrile neutropenia, diarrhea, fatigue, and asthenia

Please click here for full prescribing information including boxed WARNING