Medical Policy:

Jevtana® (cabazitaxel) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.87	February 15, 2024	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

60 billable units per 21 days

Guideline

I. Initial Approval Criteria

Coverage is provided in the following conditions:

1. Prostate Cancer †

A. Patient is 18 years or older; **AND**

B. Must be used in combination with a steroid (e.g. prednisone or dexamethasone); **AND**

C. Patient has castration-resistant metastatic disease; **AND**

i. Used as a single agent **†; AND**

a. Patient must have been previously treated with docetaxel unless contraindicated or intolerant to docetaxel; **OR**

ii. Used in combination with carboplatin ‡; **AND**

b. Used for fit patients with aggressive variant disease (e.g., visceral metastases, low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (e.g., defects in at least two of the following: PTEN, TP53, and RB1); **AND**

1) Patient has received prior docetaxel and no prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, apalutamide, etc.); **OR**

2) Patient has received prior novel hormone therapy and no prior docetaxel; **OR**

3) Patient has received prior docetaxel and prior novel hormone therapy; **AND**

a) Patient does not have visceral metastases; **OR**

D. Patient has castration-resistant metastatic small cell/neuroendocrine prostate cancer; **AND**

i. Used in combination with carboplatin; **AND**

ii. Used for fit patients with aggressive variant disease (e.g., visceral metastases, low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (e.g., defects in at least two of the following: PTEN, TP53, and RB1)

† FDA Approved Indication(s) ‡ Compendia recommended indication(s)

II. Renewal Criteria

Coverage can be renewed based upon the following criteria:

1. Patient continues to meet criteria identified above; **AND**
2. Disease response as defined by lack of disease progression, improvement in tumor size and/or improvement in patient symptoms; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: neutropenia, anemia, leukopenia, thrombocytopenia, severe hypersensitivity reactions, severe diarrhea, nausea, vomiting, severe hemorrhagic cystitis, renal or hepatic toxicity, interstitial lung disorders, etc.

Limitations/Exclusions

1. Jevtana is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.
2. Contraindicated when neutrophil counts of ≤1,500/mm3
3. Contraindicated in severe hepatic impairment (total bilirubin >3 × ULN)

Dosing and Administration

Administer 20-25 mg/m², intravenously, every 3 weeks in combination with an oral corticosteroid

Applicable Procedure Codes

Code	Description
J9043	Injection, cabazitaxel, 1 mg: 1 billable unit= 1 mg
J9064	Injection, cabazitaxel (sandoz), not therapeutically equivalent to j9043, 1 mg

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Applicable NDCs

Code	Description
00024-5824-11	Jevtana 60 mg/1.5 mL solution for injection, single-dose vial
00024-5823-15	Jevtana 10 mg/mL

ICD-10 Diagnoses

Code	Description
C61	Malignant neoplasm of prostate
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/15/2024	Annual Review: Formatting updates, no criteria changes
EmblemHealth & ConnectiCare	9/11/2023	Added J Code Injection, cabazitaxel (sandoz), not therapeutically equivalent to j9043, 1 mg
EmblemHealth & ConnectiCare	6/22/2023	Annual Review: Prostate Cancer: Initial Criteria: removed "Patient must have been previously treated with docetaxel; AND • May not be used with other chemotherapy agents" added "• Used as a single agent †; AND O Patient must have been previously treated with docetaxel unless contraindicated or intolerant to docetaxel; OR • Used in combination with carboplatin ‡; AND O Used for fit patients with aggressive variant disease (e.g., visceral metastases, low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (e.g., defects in at least two of the following: PTEN, TP53, and RB1); AND □ Patient has received prior docetaxel and no prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, apalutamide, etc.); OR □ Patient has received prior novel hormone therapy and no prior docetaxel; OR □ Patient has received prior docetaxel and prior novel hormone therapy; AND • Patient does not have visceral metastases; OR

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		• Patient has castration-resistant metastatic small cell/neuroendocrine prostate cancer; AND O Used in combination with carboplatin; AND O Used for fit patients with aggressive variant disease (e.g., visceral metastases, low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (e.g., defects in at least two of the following: PTEN, TP53, and RB1)" Added code: J9043, added NDC: 00024-5824-xx, ICD-10 codes C61, C7A.1 and C7A.8
EmblemHealth & ConnectiCare	07/25/2022	Transferred policy to new template, updated billing codes

References

1. Jevtana [package insert]. Bridgewater, NJ; Sanofi-Aventis U.S. LLC; February 2021. Accessed February 2022

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