Jevtana® (Cabazitaxel)

Guideline Number: MPG182.06
Approval Date: September 9, 2020

➲ Terms and Conditions

Table of Contents Page

Related Medicare Advantage Policy Guideline

- Coverage of Drugs and Biologicals for Label and Off-Label Uses

Related Medicare Advantage Reimbursement Policy

- Discarded Drugs and Biologicals Policy, Professional

Related Medicare Advantage Coverage Summary

- Chemotherapy and Associated Drugs and Treatments

Policy Summary

➲ See Purpose

Overview

Jevtana is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

Jevtana (cabazitaxel) injection is an antineoplastic agent belonging to the taxane class that is for intravenous use. It is prepared by semi-synthesis with a precursor extracted from yew needles. The recommended dose of Jevtana is based on calculation of the Body Surface Area (BSA) and is administered as a one-hour intravenous infusion every three weeks in combination with oral prednisone administered daily throughout Jevtana treatment.

Guidelines

Note: This policy does not describe drug and biological coverage under the Medicare Part D benefit.

It is not appropriate to bill UnitedHealthcare for services that are not covered (as described by this entire reimbursement policy) as if they are covered. When billing for non-covered services, use the appropriate modifier (see “Coding Guidelines” section in this policy).

This policy explains the coverage criteria for drugs and biologicals used in the treatment of cancer. The policy has been promulgated to establish the clinical conditions for which the included chemotherapeutic drug is considered to be medically reasonable and necessary and thus, covered by Medicare.

As published in CMS IOM 100-08, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary.

Drugs and biologicals must be determined to meet the statutory definition. Under the statue 1861(t) (1) Drugs and Biologicals.

There are many reasons to consider an unlabeled use for a cancer chemotherapy agent. Some of these are:

- Drugs may be effective for many other cancers in addition to the ones that were considered in the primary labeling of the drug.
- Many chemotherapeutic agents are given in combinations. Any one of the drugs in the combination may not have been approved in the initial labeling of the products. In addition the combination of effective chemotherapeutic agents changes over time.
- Cancer chemotherapeutic agents are always changing and improving over time.
- Oncologists are often left with few approved treatment options if initial treatment regimens have failed.

Several cancer chemotherapeutic agents and regimes have been developed and approved by the Food and Drug Administration (FDA) to treat various types of cancer. The intended mechanism of action is to interfere with or prevent the growth of malignant (cancerous) cells.

Generally, cancer chemotherapeutic agents are covered only if all of the following requirements are met:
- Documentation is present to support that the drug is safe and effective and is being administered for an approved indication.
- Documentation in the patient's medical record supports the medical necessity of administering the chemotherapy drug to that individual patient.
- Documentation in the patient's medical record supports that the chemotherapy drug was administered as billed.

Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.

Coverage for medication is based on the patient's condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition. The drug must be used according to the indication and protocol listed in the accepted compendia ratings listed below.
- National Comprehensive Cancer Network (NCCN) Drugs and Biologies Compendium
- Thomson Micromedex DrugDex
- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Clinical Pharmacology

The compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as medically accepted if the:
- Indication is a Category 1 or 2A in NCCN
- Class I, Class IIa, or Class IIb in DrugDex; or,
- Narrative text in AHFS or Clinical Pharmacology is supportive.

Cabazitaxel should be billed using chemotherapy administration codes and is payable in the following places of service: office (11), skilled nursing home for patients in a Part A stay (31) [if the drug is supplied by the facility, no claims for the drug should be submitted to the Part B carrier.], nursing facility for patients not in a Part A stay (32) and independent clinic (49) only when supplied as an "incident to" service by the physician.

Chemotherapy Administration

Chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumab, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal antineoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes.

The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients are not considered chemotherapy administration.

If performed to facilitate the chemotherapy infusion or injection, the following services and items are included and are not separately billable:

- Use of local anesthesia;
- IV access;
- Access to indwelling IV, subcutaneous catheter or port;
- Flush at conclusion of infusion;
- Standard tubing, syringes and supplies; and
- Preparation of chemotherapy agent(s).

Payment for the above is included in the payment for the chemotherapy administration service. If a significant separately identifiable evaluation and management service is performed, the appropriate E & M code should be reported utilizing modifier 25 in addition to the chemotherapy code. For an evaluation and management service provided on the same day, a different diagnosis is not required.

Refer to the Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50.4.5.

Applicable Codes

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J9043	Injection, Cabazitaxel, 1 MG

Diagnosis Code	Description
C61	Malignant neoplasm of prostate

References

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A52953 Billing and Coding: Chemotherapy Administration	Noridian	AS, CA (Northern and Southern), GU, HI, MP, NV	AS, CA (Entire State), GU, HI, MP, NV
N/A	A52991 Billing and Coding: Chemotherapy Administration	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

CMS Benefit Policy Manual

Chapter 15; § 50 Drugs and Biologicals

CMS Claims Processing Manuals

Chapter 12; § 30.5 Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions
Chapter 17; § 40 Discarded Drugs and Biologicals, § 90 Claims Processing Rules for Hospital Outpatient Billing and Payment
Chapter 32 Billing Requirements for Special Services

Other(s)

CGS Coding, CMS Website
Medicare Program Integrity Manual Chapter 13, § 13.5.1 Reasonable and Necessary Provisions in LCDs
NCCN Guidelines® & Clinical Resources, CCN Drugs & Biologics Compendium, National Comprehensive Cancer Network Website
Prescribing information
Social Security Act (Title XVIII) Standard References, Sections:

- 1862(a)(1)(A) Medically Reasonable & Necessary
- 1862(a)(1)(D) Investigational or Experimental
- 1833(e) Incomplete Claim
- 1861(t) (1) Drugs and Biologicals

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	**Template Update** • Reformatted policy; transferred content to new template
09/09/2020	**Related Policies** • Added reference link to the Medicare Advantage Reimbursement Policy titled Discarded Drugs and Biologicals Policy, Professional • Removed reference link to the Medicare Advantage Policy Guideline titled *Self-Administered Drug(s) (SAD)* **Policy Summary** *Guidelines* • Removed language pertaining to self-administered drugs **Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version MPG182.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.