UnitedHealthcare®

Reimbursement Policy

Jevtana (Cabazitaxel)

Policy Number	JEV02282012RP	**Approved By**	UnitedHealthcare Medicare Reimbursement Policy Committee	**Current Approval Date**	09/24/2014

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies 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.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Summary

Overview

This reimbursement policy supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for chemotherapeutic drug and biological services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this policy. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for chemotherapeutic drug and biological services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies regarding chemotherapeutic drug and biological services are found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50.
- National Coverage Determinations (NCD) Manual - Pub. 100-03 **...**
- Medicare Claims Processing Manual – Pub. 100-04, Chapter 17, Section 40.
- Correct Coding Initiative - *Medicare Contractor Beneficiary and Provider Communications Manual* - Pub. 100-09, Chapter 5.
- 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

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals;
- They are of the type that are not usually self-administered by the patients who take them;
- They meet all the general requirements for coverage of items as incident to a physician's services;
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
- They are not excluded as immunizations; and
- They have not been determined by the FDA to be less than effective.

In reading this document, please note that there is a difference between the section of the statute which defines the overall Medicare benefit for coverage of drugs and biologicals, and the section of the statute which states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury. This policy gives information about the overall Medicare

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benefit for coverage of drugs and biologicals.

Jevtana (cabazitaxel) is an antineoplastic taxane class agent extracted from yew needles. It is indicated as a treatment for hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. The medication binds with the tubulin and disrupts the function and reproduction of the cell.

June 17, 2010 FDA approved Cabazitaxel injection in combination with prednisone for the treatment of patients previously treated with a docetazel-containing treatment regimen. Cabazitaxel demonstrated an improved overall survival compared with mitoxantrone. Cabazitaxel also showed improvement equally palliative as mitoxantrone.

Recommended dose is based on body surface area and is administered by IV infusion over the course of one hour. Jevtana is supplied as a solution for intravenous administration. Patients should be premedicated at least 30 minutes prior to each dose of Jevtana with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: antihistamine, corticosteroid or H2 antagonist. The individual dosage of Jevatana is based on calculation of the Body Surface Area and is 25 mg/m2 administered as a one-hour intravenous infusion every three weeks in combination with oral prednisone 10 mg administered daily throughout Jevtana treatment. The Jevtana dose should be reduced to 20 mg/m2 if one of the following adverse reactions occurs: prolonged grade >3 neutropenia for more than one week despite medication; febrile neutropenia or Grade >3 diarrhea or persisting diarrhea despite appropriate medication. Jevtana should be discontinued if a patient continues to experience any of these reactions at 20 mg/m2.

Reimbursement Guidelines

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

It is not appropriate to bill UHC 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.

Unless certain specified conditions are met, UHC will not reimburse for unlabeled use of non-self-administered drugs, since unlabeled use of the drug is considered an investigational use. Medicare is not allowed to pay for investigational treatments. However, FDA-approved drugs used for indications other than what is indicated on the official label may be covered by UHC when Medicare determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of unlabeled use for anti-cancer drugs, the conditions for Medicare coverage and reimbursement have been especially well outlined.

Notice: This reimbursement policy imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

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. UHC shall consider a service to be reasonable and necessary if we determine that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
  - Furnished in a setting appropriate to the patient's medical needs and condition.
  - Ordered and furnished by qualified personnel.

- One that meets, but does not exceed, the patient's medical needs.
- At least as beneficial as an existing and available medically appropriate alternative.

Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t) (1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USD-DI), or the American Dental Association (ADA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.

Drugs that are usually self-administered by the patient, such as those in pill form, or are used for self-injection, are generally not covered by Part B. However, there are a limited number of self-administered drugs that are covered because the Medicare statute explicitly provides coverage. Examples of drugs that are usually self-administered by the patient and are covered include: blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, and osteoporosis drugs for certain homebound patients. (See Self Administered Drug(s))

Generally, when a physician gives a patient pills or other oral medication, these drugs are excluded from coverage since the form of the drug is self-administered. Similarly, if a physician gives a patient an injection that is usually self-injected this drug is excluded from coverage, unless administered to the patient in an emergency situation.

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must be of a form that cannot be self-administered and must be administered by a physician or by auxiliary personnel employed by him/her under his/her personal supervision. To be covered, drugs and biologicals must be an expense to the physician billing for the service. For example, if a patient purchases a drug and the physician administers it, the drug is not covered. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals and cancer chemotherapeutic agents approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling.

Therefore, payment may be made for an FDA-approved chemotherapeutic drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the contractor determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. The following guidelines identify three categories in which medications would not be reasonable and necessary according to accepted standards of medical practice.

- Not for Particular Illness – – Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations).
- Injection Method Not Indicated – – Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.
- Excessive Medications – – Medications administered for treatment of a disease which exceed the frequency

or duration of injections indicated by accepted standards of medical practice are not covered.

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.

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge will be excluded (i.e., for both the drug and its administration). Also excluded from payment is any charge for other services (such as office visits) which are primarily for the purpose of administering a non–covered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).

A drug that is less than effective is not eligible for reimbursement, i.e., one that the Food and Drug Administration has determined to lack substantial evidence of effectiveness for all labeled indications. Any other drug product that is identical, similar, or related, will also be ineligible.

If a use is identified as not indicated by CMS or the FDA or if a use is specifically identified as not indicated (in one or more of the three compendia mentioned) or if it is determined (based on peer reviewed medical literature) that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, **the drug is not covered**. In this instance, the administration is also not covered.

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.

Self-administered drugs are not covered and should not be submitted to UHC unless requested to do so by the beneficiary. (See Self Administered Drug(s))

The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug

Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. An invoice may be requested if pricing is not available on the ASP pricing file. This file contains lists for NOC and true codes. This file can be located using the following web link http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice.

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, alemtuzumb, 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:

1. Use of local anesthesia;
2. IV access;
3. Access to indwelling IV, subcutaneous catheter or port;
4. Flush at conclusion of infusion;
5. Standard tubing, syringes and supplies; and
6. 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.

Drug Wastage:

Medicare provides payment for the discarded drug/biological remaining in a single-use drug product after administering what is reasonable and necessary for the patient's condition. If the physician has made good faith efforts to minimize the unused portion of the drug/biological in how patients are scheduled and how he ordered, accepted, stored and used the drug, and made good faith efforts to minimize the unused portion of the drug in how it is supplied, the program will cover the amount of drug discarded along with the amount administered. Documentation requirements are given below. Refer to national policy: Medicare Claims Processing Manual – Pub. 100-04, Chapter 17, Section 40.

Note: The JW modifier is not used on claims for drugs or biologicals provided under the Competitive Acquisition Program (CAP). Reference to national policy: Medicare Claims Processing Manual, Pub. 100-04, Chapter 17, Section 100.2.9.

Documentation Requirements:

Medical record documentation maintained by the ordering/referring physician must substantiate the medical need for the use of these chemotherapy drugs by clearly indicating the condition for which these drugs are being used. This might include the type of cancer, staging, if applicable, prior therapy and the patient's response to that therapy. This documentation is usually found in the history and physical or in the office/progress notes.

If the provider of the service is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician's order for the chemotherapy drug. The physician must state the clinical indication/medical need for using the chemotherapy drug in the order.

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this reimbursement policy. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

The medical record must include the following information:

- The name of the drug or biological administered;
- The route of administration;
- The dosage (e.g., mgs, mcgs, cc's or IU's);
- The duration of the administration (for CPT codes that are time based); and
- When a portion of the drug or biological is discarded, from single use vials, the medical record must clearly document the amount administered and the amount wasted or discarded.

Coding Guidelines:

1. Anti-cancer drugs may be billed with the specified ICD-9 codes diagnosis codes only. Guidelines for coverage of anti-cancer drugs include FDA approval for specific indications and citation in the USPDI (United States Pharmacopeia Drug Information) and/or AHFS (American Hospital Formulary Service Drug Information) providing support for the drug.
2. 12/20/2011-Per 2012 HCPCS Code Update, replaced HCPCS Code C9276 with J9043 effective 01/01/2012.
3. HCPCS codes and associated ICD-9 codes will be placed on an active audit for verification of appropriate drug/diagnosis. Claims for anti-cancer drugs billed without a specified allowable diagnosis will be denied. Approved ICD-9 codes will be updated to reflect changes in indications and approval as noted by the FDA, AFHS, and/or USPDI.

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

CPT / HCPCS Codes

Code	Description
C9276	Injection, Cabazitaxel, 1 MG (code deleted 1-1-2012)
J9043	Injection, Cabazitaxel, 1 MG

Modifiers

Code	Description
JW	Drug amount discarded/not administered to any patient
KX	Requirements specified in the medical policy have been met

References Included (but not limited to):

CMS LCD(s)

Numerous LCDs

CMS Article(s)

Numerous Articles

CMS Benefit Policy Manual

Chapter 15;§ 50 Drugs and Biologicals

CMS Claims Processing Manual

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

CMS Transmittals

Transmittal 2378, Change Request 7682, Dated 12/29/2011 (January 2012 Update of the Ambulatory Surgery Center Payment System (ASC))

Transmittal 2386, Change Request 7672, Dated 01/13/2012 (January 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS))

UnitedHealthcare Medicare Advantage Coverage Summaries

Chemotherapy, and Associated Drugs and Treatments

UnitedHealthcare Reimbursement Policies

Self Administered Drug(s)

MLN Matters

Article MM7672, January 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)

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Article MM7682, January 2012 Update of the Ambulatory Surgery Center (ASC) Payment System

Others

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

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

History

Date	Revisions
09/24/2014	• Annual review • Administrative updates
10/09/2013	Re-review completed with no changes
06/13/2012	Administrative updates
02/29/2012	Policy approved by committee
02/23/2012	Policy created

