Billing and Coding Guideline for HONC-010 Chemotherapy Drugs and their Adjuncts

Medicare Regulation Excerpts:
PUB.100-20 One time Notification (OTN); Change Request (CR) 3818, 3631, 3028)

> *For services furnished on or after January 1, 2005, chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs and also to anti-neoplastic agents provided for the treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents and other biologic response modifiers. Administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration.*

Excerpts from CMS internet only Manual (IOM):

Publications 100-02 Medicare Benefit Policy Manual: Chapter 15 Section 50.4.5 - Unlabeled Use for Anti-Cancer Drugs

*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.*

Publications 100-02 Medicare Benefit Policy Manual: Chapter 15 Section 60.1 Incident to Physician Professional Services

To be covered, supplies, including drugs and biologicals, must be an expense to the physician or legal entity billing for the services or supplies. For example, where 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.

Publications 100-04 Medicare Claims Processing Manual Chapter 12 Section 30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions

D. 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. Local carriers may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare.

The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is 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.

Publications 100-04 Medicare Claims Processing Manual Chapter 17 Section 90.2

90.2 - Drugs, Biologicals, and Radiopharmaceuticals
(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

A. ***General Billing and Coding for Hospital Outpatient Drugs, Biologicals, and radiopharmaceuticals***
Hospitals should report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.

Payment for drugs, biologicals and radiopharmaceuticals under the OPPS is inclusive of both the acquisition cost and the associated pharmacy overhead or nuclear medicine handling cost. Hospitals should include these costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals.

Under the OPPS, if commercially available products are being mixed together to facilitate their concurrent administration, the hospital should report the quantity of each product (reported by HCPCS code) used in the care of the patient. Alternatively, if the hospital is compounding drugs that are not a mixture of commercially available products, but are a different product that has no applicable HCPCS code, then the hospital should report an appropriate unlisted drug code (J9999 or J3490). In these situations, it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned.
The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPPS is published quarterly via Recurring Update Notifications. The latest payment rates associated with each APC and HCPCS code may be found in the most current Addendum A and Addendum B, respectively, that can be found under the CMS quarterly provider updates on the CMS Web site at: ***http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp***

Publications 100-04 Medicare Claims Processing Manual Chapter 14 Section 10 Ambulatory Surgery Center

Billing for Drugs and Biologicals

ASCs are strongly encouraged to report charges for all separately payable drugs and biologicals, using the correct HCPCS codes for the items used. ASCs billing for these products must make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of the drug or biological that was used in the care of the patient. ASCs should not report HCPCS codes and separate charges for drugs and biologicals that receive packaged payment through the payment for the associated covered surgical procedure.

We remind ASCs that under the ASCPPS, if two or more drugs or biologicals are mixed together to facilitate administration, the correct HCPCS codes should be reported separately for each product used in the care of the patient. The mixing together of two or more products does not constitute a "new" drug as regulated by the Food and Drug Administration (FDA) under the New Drug Application (NDA) process. In these situations, ASCs are reminded that it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which a HCPCS code has not been assigned.

Unless otherwise specified in the long description, HCPCS descriptions refer to the non-compounded, FDA-approved final product. If a product is compounded and a specific HCPCS code does not exist for the compounded product, the ASC should report an appropriate unlisted code such as J9999 or J3490.

Publication 100-02 Chapter 15 Excerpt
50.4.5 - Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen (Rev.96, Issued: 10-24-08, Effective: 06-05-08 NCCN/06-10-08 Thomson Micromedex/07-02-08 Clinical Pharmacology, Implementation: 11-25-08)
A. *Overview*
Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration-(FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified under the conditions described below. A regimen is a combination of anti-cancer agents clinically recognized for the treatment of a specific type of cancer. Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature. The contractor may maintain its own subscriptions to the listed compendia or peer-reviewed publications to determine the medically accepted indication of drugs or biologicals used off-label in an anti-cancer chemotherapeutic regimen. Compendia documentation or peer-reviewed literature supporting off-label use by the treating physician may also be requested of the physician by the contractor.
Current compendia:
American Hospital Formulary Service-Drug Information (AHFS-DI)
Effective June 5, 2008 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
Effective June 10, 2008 - Thomson Micromedex DrugDex
Effective July 2, 2008 - Clinical Pharmacology

In general, a use is identified by a compendium as medically accepted if the indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or, narrative text in AHFS or Clinical Pharmacology is supportive.
Publication 100-03 Medicare NCD Manual, *Section 110.22 – Autologous Cellular Immunotherapy Treatment (Effective June 30, 2011)(CR 7431-Transmittal 133)*

A. General

Prostate cancer is the most common non-cutaneous cancer in men in the United States. In 2009, an estimated 192,280 new cases of prostate cancer were diagnosed and an estimated 27,360 deaths were reported. The National Cancer Institute states that prostate cancer is predominantly a cancer of older men; the median age at diagnosis is 72 years. Once the patient has castration-resistant, metastatic prostate cancer the median survival is generally less than two years.

In 2010 the Food and Drug Administration (FDA) approved sipuleucel-T (PROVENGE®; APC8015), for patients with castration-resistant, metastatic prostate cancer. The posited mechanism of action, immunotherapy, is different from that of anti-cancer chemotherapy such as docetaxel. This is the first immunotherapy for prostate cancer to receive FDA approval.

The goal of immunotherapy is to stimulate the body's natural defenses (such as the white blood cells called dendritic cells, T-lymphocytes and mononuclear cells) in a specific manner so that they attack and destroy, or at least prevent, the proliferation of cancer cells. Specificity is attained by intentionally exposing a patient's white blood cells to a particular protein (called an antigen) associated with the prostate cancer. This exposure "trains" the white blood cells to target and attack the prostate cancer cells. Clinically, this is expected to result in a decrease in the size and/or number of cancer sites, an increase in the time to cancer progression, and/or an increase in survival of the patient.

Sipuleucel-T differs from other infused anti-cancer therapies. Most such anti-cancer therapies are manufactured and sold by a biopharmaceutical company and then purchased by and dispensed from a pharmacy. In contrast, once the decision is made to treat with sipuleucel-T, a multi-step process is used to produce sipuleucel-T. Sipuleucel-T is made individually for each patient with his own white blood cells. The patient's white blood cells are removed via a procedure called leukapheresis. In a laboratory the white blood cells are exposed to PA2024, which is a molecule created by linking prostatic acid phosphatase (PAP) with granulocyte/macrophage-colony stimulating factor (GM-CSF). PAP is an antigen specifically associated with prostate cancer cells; GM-CSF is a protein that targets a receptor on the surface of white blood cells. Hence, PAP serves to externally manipulate the immunological functioning of the patient's white blood cells while GM-CSF serves to stimulate the white blood cells into action. As noted in the FDA's clinical review, each dose of sipuleucel-T contains a minimum of 40 million treated white blood cells, however there is "high inherent variability" in the yield of sipuleucel-T from leukapheresis to leukapheresis in the same patient as well as from patient to patient. The treated white blood cells are then infused back into the same patient. The FDA-approved dosing regimen is three doses with each dose administered two weeks apart. The total treatment period is four weeks.

Nationally Covered Indications

Effective for services performed on or after June 30, 2011, The Centers for Medicare and Medicaid Services (CMS) proposes that the evidence is adequate to conclude that the use of autologous cellular immunotherapy treatment - sipuleucel-T; PROVENGE® improves health outcomes for Medicare beneficiaries with asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer, and thus is reasonable and necessary for this on-label indication under 1862(a)(1)(A) of the Social Security Act.

Effective for services performed on or after June 30, 2011, coverage of all off-label uses of autologous cellular immunotherapy treatment – sipuleucel-T; PROVENGE® for the treatment of prostate cancer is left to the discretion of the local Medicare Administrative Contractors.

Publication 100-04 Medicare Claims Processing Manual -*Chapter 32 – Billing Requirements for Special Services (CR 7431-transmital 2339, CR 7431-transmittal 2254) Excerpts:*

280 – Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer
280.1 - Policy
280.2 – Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding
280.3 - Types of Bill (TOB) and Revenue Codes

Coverage for PROVENGE®, Q2043, for asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer is limited to one (1) treatment regimen in a patient's lifetime, consisting of three (3) doses with each dose administered approximately two (2) weeks apart for a total treatment period not to exceed 30 weeks from the first administration.

280.1 – Policy
(Rev. 2339, Issued: 11-02-11, Effective: 06-30-11, Implementation: 08-08-11)
Effective for services furnished on or after June 30, 2011, a National Coverage Determination (NCD) provides coverage of sipuleucel-T (PROVENGE®) for patients with asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone refractory) prostate cancer. Conditions of Medicare Part A and Medicare Part B coverage for sipuleucel-T are located in the Medicare NCD Manual, Publication 100-3, section 110.22.

280.2 – Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding
(Rev. 2339, Issued: 11-02-11, Effective: 06-30-11, Implementation: 08-08-11)

Effective for claims with dates of service on and after July 1, 2011, Medicare providers shall report the following HCPCS code:

Q2043 – Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion; short descriptor, Sipuleucel-T auto CD54+.

ICD-9 Diagnosis Coding : *For claims with dates of service on and after July 1, 2011, for PROVENGE®, the on-label indication of asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone refractory) prostate cancer, must be billed using ICD-9 code 185 (malignant neoplasm of prostate) and at least* ***one*** *of the following ICD-9 codes:*

ICD-9 code	***Description***
196.1	*Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes*
196.2	*Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes*
196.5	*Secondary and unspecified malignant neoplasm of lymph nodes of inguinal region and lower limb*
196.6	*Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes*
196.8	*Secondary and unspecified malignant neoplasm of lymph nodes of multiple sites*
196.9	*Secondary and unspecified malignant neoplasm of lymph node site unspecified -* *The spread of cancer to and establishment in the lymph nodes.*
197.0	*Secondary malignant neoplasm of lung –* *Cancer that has spread from the original (primary) tumor to the lung. The spread of cancer to the lung. This may be from a primary lung cancer, or from a cancer at a distant site.*
197.7	*Malignant neoplasm of liver secondary -* *Cancer that has spread from the original (primary) tumor to the liver. A malignant neoplasm that has spread to the liver from another (primary) anatomic site. Such malignant neoplasms may be carcinomas (e.g., breast, colon), lymphomas, melanomas, or sarcomas.*

198.0	*Secondary malignant neoplasm of kidney -* *The spread of the cancer to the kidney.* *This may be from a primary kidney cancer involving the opposite kidney, or from a cancer at a distant site.*
198.1	*Secondary malignant neoplasm of other urinary organs*
198.5	*Secondary malignant neoplasm of bone and bone marrow – Cancer that has spread from the original (primary) tumor to the bone. The spread of a malignant neoplasm from a primary site to the skeletal system. The majority of metastatic neoplasms to the bone are carcinomas.*
198.7	*Secondary malignant neoplasm of adrenal gland*
198.82	*Secondary malignant neoplasm of genital organs*

Coding for Off-Label PROVENGE® Services

The use of PROVENGE® off-label for the treatment of prostate cancer is left to the discretion of the Medicare Administrative Contractors. Claims with dates of service on and after July 1, 2011, for PROVENGE® paid off-label for the treatment of prostate cancer must be billed using either ICD-9 code 233.4 (carcinoma in situ of prostate), or ICD-9 code 185 (malignant neoplasm of prostate) in addition to HCPCS Q2043.

WPS does not cover Provenge for any off label indications.

280.3 - Types of Bill (TOB) and Revenue Codes

(Rev. 2339, Issued: 11-02-11, Effective: 06-30-11, Implementation: 08-08-11)

The applicable TOBs for PROVENGE® are 12X, 13X, 22X, 23X, 71X, 77X, and 85X.
On institutional claims, TOBs 12X, 13X, 22X, 23X, and 85X, use revenue code 0636 - drugs requiring detailed coding

280.4 – Payment Method

(Rev. 2339, Issued: 11-02-11, Effective: 06-30-11, Implementation: 08-08-11)

Payment for PROVENGE® is as follows:

- *TOBs 12X, 13X, 22X and 23X - based on the Average Sales Price (ASP) + 6%,*
- *TOB 85X – based on reasonable cost,*
- *TOBs 71X and 77X – based on all-inclusive rate.*

For Medicare Part B practitioner claims, payment for PROVENGE® is based on ASP + 6%.

Contractors shall not pay separately for routine costs associated with PROVENGE®, HCPCS Q2043, except for the cost of administration. (Q2043 is all-inclusive and represents all routine costs except for its cost of administration)

Coding Guidelines

1. ICD-9 codes must be listed to the most specific number. The fifth digit in the section on Neoplasms should be 0 - without mention of remission. The fifth digit 01 indicates the patient is in remission and therefore would not require chemotherapy. Accordingly, other sections of the ICD-9 classifications carry some sections out to the fifth place to indicate specific information. Carry out all ICD-9 codes out to the fifth space where indicated.
2. Use the appropriate J code to report the drug being used.
3. True codes reflect the dosage of the drug; the number of units should indicate the total number of units given in item 24G of the CMS 1500 form. If filing electronically, the total units should be

placed in the NSF Format, Record FAO-18.0, ANSI 837 format Segment SV1-05 (3032) or Segment SV2-04 (3052).

4. NOC drug billing:

Office/Clinic:

When using a drug NOC code (J9999, J3490, or J3590) list the name of the drug, the amount of the drug that is administered and wasted if applicable; method of administration in the electronic narrative that is equivalent to line 19 of the CMS 1500 form. List the units of service as **one** in 2400/SV1-04 data element of the ANSI X12 4010A1 or in item 24G of the CMS 1500 form.

Occasionally, the strength of the drug will also be needed on NOC claims. If the NOC ASP pricing file lists the name of the drug with its strength it must also be included on line 19. Example: Sodium Bicarbonate 8.4%.

ASC and Hospital Outpatient Departments:

HCPCS code C9399, Unclassified drug or biological, should be used for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned. If a product is compounded and a specific HCPCS code does not exist for the compounded product, the ASC should report an appropriate unlisted code such as J9999 or J3490.

5. 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:

1. indication is a Category 1 or 2A in NCCN, or Class I, Class IIa or Class IIb in DrugDex; or
2. narrative text in AHFS-DI or Clinical Pharmacology is supportive.

6. Self-administered drugs are not covered and should not be submitted to Medicare unless requested to do so by the beneficiary.

7. 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

Electronic submitters should indicate they have additional documentation or an invoice, which Medicare may require, by indicating "DOCUMENTATION AVAILABLE UPON REQUEST" in the electronic equivalent of item 19. If the additional documentation or an invoice you have is needed for Medicare to make its payment determination, a development letter will be sent requesting the information. If you do not indicate the availability of the additional

documentation, or the information is not returned timely, the claim will be returned as unprocessable.

8. To be covered, drugs and biologicals must be an expense to the physician or legal entity billing for the services or supplies. If the drug was supplied free to the physician, donated, or the patient brings in the drug to the physicians office to be administered, **the drug would not be billable**. The administration of the drug would be covered **if the drug is given for a covered indication**.

    a. When submitting a claim for the administration of a drug that was given for a covered indication, that the beneficiary brings in or was donated to them, indicate on line 19 the name of the drug. Failure to include the name of the drug in line 19 may result in denial.

    b. Drug administration services are not covered when the drug is given for a non-covered indication.

9. Requests for off label coverage consideration should be submitted via the LCD reconsideration process described on our Website http://www.wpsmedicare.com/ **or** submit a request with a copy of the compendia documenting the medically accepted category or narrative and or peer reviewed literature that is published in a CMS accepted journal supporting its use via e-mail to Policy Comments@wpsic.com

Reason for Denial:
Non-covered

Published/Website:
12/01/2011; 08/01/2011; 03/01/2009

Revision History and Explanation:
12/01/2011- Provenge information updated based on CR 7431 transmittal 2339: Q2043 is all-inclusive and represents all routine costs **except for its cost of administration** & limit of one (1) treatment regimen in a patient's lifetime, consisting of three (3) doses with each dose administered approximately two (2) weeks apart for a total treatment period not to exceed 30 weeks from the first administration.
.

08/01/2011-Added Autologous Cellular Immunotherapy treatment of Metastatic Prostate Cancer information from Change Request (CR) 7431 Transmittals 133 and 2254.