

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



News Flash – A new booklet titled “Introduction to the Medicare Program” is now available from the Medicare Learning Network® at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Introduction_to_Medicare_ICN906285.pdf on the Centers for Medicare & Medicaid Services website. This publication is designed to provide education on the Medicare Program, other health insurance plans, and organizations of interest to providers and beneficiaries.

MLN Matters® Number: MM7431 **Revised**

Related Change Request (CR) #: CR 7431

Related CR Release Date: January 6, 2012

Effective Date: June 30, 2011

Related CR Transmittal #: R2380CP and R140NCD

Implementation Date: August 8, 2011

Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer

Note: This article was updated on August 21, 2012, to reflect current Web addresses. Previously, this article was revised on January 10, 2012, to reflect a revised CR7431 issued on January 6, 2012. The article has been revised to show that a separate payment for the cost of administration is allowed. In addition, the transmittal numbers, release date, and the Web address for accessing CR7431 have been revised. All other information is the same.

Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, Fiscal Intermediaries (FIs) and/or A/B Medicare Administrative Contractors (A/B MACs)) for metastatic prostate cancer treatment services provided to Medicare beneficiaries are affected.

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Provider Action Needed



STOP – Impact to You

This article is based on Change Request (CR) 7431 regarding the use of autologous cellular immunotherapy treatment for metastatic prostate cancer.



CAUTION – What You Need to Know

The Centers for Medicare & Medicaid Services (CMS) finds 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. It is therefore reasonable and necessary to use for this on-label indication under the Social Security Act (1862(a)(1)(A)) effective for services performed on or after June 30, 2011.



GO – What You Need to Do

Make sure billing staff is aware of this article.

Background

In 2010 the Food and Drug Administration (FDA) approved Sipuleucel-T (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.

Change Request (CR) 7431 instructs that, effective for services performed on or after June 30, 2011, CMS concludes that the evidence is adequate to support the use of autologous cellular immunotherapy treatment - Sipuleucel-T; PROVENGE® for

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Medicare beneficiaries with asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer.

Medicare contractors will continue to process claims for PROVENGE® with dates of service on June 30, 2011, as they do currently when providers submit Not Otherwise Classified Healthcare Common Procedure Coding System (HCPCS) code(s) J3590, J3490 or C9273. **HCPCS code C9273 will be deleted on June 30, 2011.**

The new HCPCS code Q2043 will:

- Replace C9273 (Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion);
- Be implemented in the July 2011 Update of Quarterly HCPCS Drug/Biological Code Changes (CR 7303 (Transmittal R2227CP); see <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2227CP.pdf> on the CMS website); and
- Have an effective date of **July 1, 2011.**

The Ambulatory Surgical Center (ASC) Payment System will be updated to reflect these coding changes, and these changes will be announced in the ASC Quarterly Update CR for July 2011.

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.

The language given in the long descriptor of Provenge® that states "all other preparatory procedures" refers to the transportation process of collecting immune cells from a patient during a non-therapeutic leukapheresis procedure, subsequently sending the immune cells to the manufacturing facility, and then transporting the immune cells back to the site of service to be administered to the patient, as well as the infusion of the immune cells to the patient. Q2043 is all-inclusive and represents all routine costs with the exception of its administration - the cost of Provenge® administration can be billed separately.

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Note: For a local coverage determination by an individual MAC to cover PROVENGE® “off-label” for the treatment of prostate cancer, the International Classification of Diseases, Ninth Revision (ICD-9) diagnosis code must be either 233.4 (carcinoma in situ of prostate) or 185 (malignant neoplasm of prostate). ICD-9 diagnosis code 233.4 may not be used for “on-label” coverage claims.

Coding and Billing Information

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.

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ICD-9 code	Description
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

At the discretion of the local 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 185 (malignant neoplasm of prostate) in addition to HCPCS Q2043. Effective with the implementation date for ICD-10 codes, off-label PROVENGE® services must be billed with either ICD-10 code D075 (carcinoma in situ of prostate) or C61 (malignant neoplasm of prostate) in addition to HCPCS Q2043.

ICD-10 Diagnosis Coding

The appropriate ICD-10 code(s) that are listed below are for future implementation.

ICD-10	Description
C61	Malignant neoplasm of prostate (for on-label or off-label indications)
D075	Carcinoma in situ of prostate (for off-label indications only)
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes

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ICD-10	Description
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.7	Secondary malignant neoplasm of liver
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.82	Secondary malignant neoplasm of genital organs

Types of Bill (TOB) and Revenue Codes

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.

Payment Methods

Payment for PROVENGE® is as follows:

- TOBs 12X, 13X, 22X and 23X - based on the Average Sales Price (ASP) + 6%,

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- TOB 85X – based on reasonable cost,
- TOBs 71X and 77X – based on all-inclusive rate (drugs/supplies are not reimbursed separately).
- For Medicare Part B practitioner claims, payment for PROVENGE® is based on ASP + 6%.

Note: Medicare Contractors will not pay separately for routine costs associated with PROVENGE®. HCPCS Q2043 is all-inclusive and represents all routine costs associated with its administration.

Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs), and Group Codes

Medicare will use the following messages when denying claims for the on-label indication for PROVENGE®, HCPCS Q2043, submitted without ICD-9-CM diagnosis code 185 and at least one diagnosis code from the ICD-9 table shown above:

- RARC 167 - This (these) diagnosis (es) are not covered. Note: Refer to the 835 Healthcare Policy Identification segment (loop 2110 Service Payment Information REF), if present.
- Group Code - Contractual Obligation (CO)

Medicare will use the following messages when denying line items on claims for the off-label indication for PROVENGE®, HCPCS Q2043, submitted without ICD-9-CM diagnosis code 233.4 or 185:

- RARC 167 - This (these) diagnosis (es) are not covered. Note: Refer to the 835 Healthcare Policy Identification segment (loop 2110 Service Payment Information REF), if present.
- Group Code – CO.

When denying claims for PROVENGE®, HCPCS Q2043® that exceed three (3) payments in a patient's lifetime, contractors shall use the following messages:

- RARC N362 - The number of Days or Units of Service exceeds our acceptable maximum.
- CARC 149 - Lifetime benefit maximum has been reached for this service/benefit category.
- Group Code - CO.

When denying claims for PROVENGE®, HCPCS Q2043® that are provided more than 30 weeks from the date of the 1st PROVENGE® administration, contractors shall use the following messages:

- CARC B5 – Coverage/program guidelines were not met or were exceeded.

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- Group Code – CO.

Additional Information

The official instruction, CR 7431, was issued to carriers, FIs, and A/B MACs via two transmittals. The first modifies the National Coverage Determinations manual and it is at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R140NCD.pdf> on the CMS website. The second updates the Medicare Claims Processing Manual and it is at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2380CP.pdf> on the CMS website.

If you have any questions, please contact your carriers, FIs or A/B MACs, at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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