CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2254	**Date: July 8, 2011**
	Change Request 7431

SUBJECT: Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer

I. SUMMARY OF CHANGES: 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 DATE: June 30, 2011
IMPLEMENTATION DATE: August 8, 2011 and January 3, 2012 (CWF frequency edit only)

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	32/280/ Autologous Cellular Immunotherapy treatment of Metastatic Prostate Cancer
N	32/280.1/Policy
N	32/280.2/Healthcare Common Procedure coding System (HCPCS) Codes
N	32/280.3/Types of Bills (TOB) and Revenue Codes
N	32/280.4/Payment Method
N	32/280.5/Medicare Summary Notices(MSNs), Remittance Advice Remark Codes (RARCs),Claims Adjustment Reason Codes (CARCs),and Group Codes

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is

not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 2254	Date: July 8, 2011	Change Request: 7431

SUBJECT: Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer

EFFECTIVE DATE: June 30, 2011

IMPLEMENTATION DATE: August 8, 2011 and January 3, 2012 (CWF frequency edit only)

I. GENERAL INFORMATION

A. Background: 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. Once the patient has castration-resistant, metastatic prostate cancer the median survival is less than two years.

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.

B. Policy: 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.

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.

Contractors shall continue to process claims for PROVENGE® with dates of service on June 30, 2011, as they do currently when providers submit Not Otherwise Classified code(s) J3590, J3490 or C9273. C9273 will be deleted on June 30, 2011.

The new Q2043 code that 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) will be implemented in the July 2011 Update of Quarterly HCPCS Drug/Biological Code Changes (CR 7303) with a July 1, 2011, effective date. Additionally, the Ambulatory Surgical Center (ASC) Payment System will be updated to reflect these coding changes. These changes will be announced in the ASC Quarterly Update CR for July 2011.

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 associated with its administration. Thus contractors will not pay separately for any claims of routine costs associated with PROVENGE®, such as Common Procedure Terminology (CPT) code 96365, intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour.

Note: The off-label use of POVENGE® for the treatment of prostate cancer is left to the discretion of the Medicare Administrative Contractors (MACs). For a local coverage determination by an individual MAC to cover PROVENGE® off-label for the treatment of prostate cancer, the primary ICD-9 diagnosis code must be either 233.4 (carcinoma in situ of prostate), or 185 (malignant neoplasm of prostate). Note that ICD-9 233.4 may not be used for on-label coverage claims.

II. BUSINESS REQUIREMENTS TABLE

<table>
<tr><th rowspan="3">Number</th><th rowspan="3">Requirement</th><th colspan="10">Responsibility (place an “X” in each applicable column)</th></tr>
<tr><th rowspan="2">A/B MAC</th><th rowspan="2">DME MAC</th><th rowspan="2">FI</th><th rowspan="2">CARRIER</th><th rowspan="2">RHHI</th><th colspan="4">Shared-System Maintainers</th><th rowspan="2">OTHER</th></tr>
<tr><th>FISS</th><th>MCS</th><th>VMS</th><th>CWF</th></tr>
<tr><td>7431-04.1</td><td>For claims for services performed on June 30, 2011, contractors shall continue to process claims for nationally covered PROVENGE® for asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer as they do currently, provided the claim contains HCPCS code C9273, J3490, or J3590.</td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>7431-04.2</td><td>Effective for claims with dates of service on and after July 1, 2011, contractors shall allow payment for nationally covered PROVENGE®, the on-label indication of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer according to NCD 110.22, provided the claim contains the following:
HCPCS code Q2043, AND,
ICD-9 code 185, malignant neoplasm of prostate, AND,
At least one of the following ICD-9 codes:
<table><tr><th>ICD-9 code</th><th>Description</th></tr><tr><td>196.1</td><td>Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes</td></tr><tr><td>196.2</td><td>Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes</td></tr><tr><td>196.5</td><td>Secondary and unspecified malignant neoplasm of lymph nodes of inguinal</td></tr></table></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

	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

7431-04.2.1	Effective for claims with dates of service on or after July 1, 2011, contractors shall line-item deny claims for PROVENGE®, on-label indication, billed without the following: • HCPCS code Q2043, **AND,** • ICD-9 code 185, **AND,** • At least one diagnosis code from the ICD-9 table in BR 7431.2	X		X	X						

7431-04.2.2	Contractors shall return the following Group Code, Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARC), and Medicare Summary Notice (MSN) when denying PROVENGE® claims, on-label indication, submitted without the following: • ICD-9 diagnosis code 185, **AND**, • At least one diagnosis code from the ICD-9 table in BR 7431.2. CARC 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) MSN 14.9 – “Medicare cannot pay for this service for the diagnosis shown on the claim.” Spanish Version: “Medicare no puede pagar por este servicio debido al diagnóstico indicado en la reclamación.”	X		X	X						
7431-04.3	Effective for services performed on and after July 1, 2011, contractors may, at their discretion, allow payment for PROVENGE® off-label for the treatment of prostate cancer according to NCD 110.22, provided the claim contains the following: • HCPCS code Q2043, **AND,** • ICD-9 code 233.4, carcinoma in situ of prostate, **OR** • ICD-9 code 185, malignant neoplasm of prostate.	X		X	X						
7431-04.3.1	Effective for claims with dates of service on or after July 1, 2011, contractors shall line-item deny claims for PROVENGE® off-label for the treatment of prostate cancer billed without the following: • HCPCS code Q2043, **AND,** • ICD-9 diagnosis code 233.4, **OR** • ICD-9 diagnosis code 185.	X		X	X						
7431-04.3.2	Contractors shall return the following Group Code, CARC, RARC, and MSN when denying PROVENGE® claims, off-label indication, submitted without ICD-9 diagnosis code 233.4 or ICD-9 diagnosis code 185. CARC 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)	X		X	X						

	MSN 14.9 – “Medicare cannot pay for this service for the diagnosis shown on the claim.” Spanish Version: “Medicare no puede pagar por este servicio debido al diagnóstico indicado en la reclamación.”										
7431-04.4	Effective for claims with dates of service on and after July 1, 2011, contractors shall allow payment for PROVENGE® provided that institutional claims (TOBs 12X, 13X, 22X, 23X, and 85X) contain revenue code 0636.	X		X							
7431-04.5	Effective for claims with dates of service on and after July 1, 2011, contractors shall pay claims for PROVENGE®, HCPCS Q2043, based on the average sales price + 6% to types of bills (TOBs): 12X (hospital IP B), 13X (hospital OP), 22X (SNF IP B), and 23X (SNF OP).	X		X							OPPS Pricer
7431-04.5.1	Effective for claims with dates of service on and after July 1, 2011, contractors shall pay claims for PROVENGE®, HCPCS Q2043, based on reasonable cost to TOB 85X (CAH).	X		X							
7431-04.5.2	Effective for claims with dates of service on and after July 1, 2011, contractors shall pay claims for PROVENGE®, HCPCS Q2043, based on all-inclusive rate to TOBs 71X and 77X (drugs/supplies are not reimbursed separately).	X		X							
7431-04.6	Effective for claims with dates of service on and after July 1, 2011, contractors shall pay claims for PROVENGE®, HCPCS Q2043, based on the average sales price + 6% to Medicare Part B practitioner claims.	X			X						
7431-04.7	Effective for claims with dates of service on and after July 1, 2011, contractors shall not pay separately for routine costs associated with PROVENGE®, HCPCS Q2043 (Q2043 is all-inclusive and represents all routine costs associated with its administration).	X		X	X						
7431-04.8	Effective for claims with dates of service on or after January 3, 2012, CWF shall reject and contractors shall deny more than three (3) payments of PROVENGE®, Q2043, in a patient’s lifetime.	X		X	X					X	
7431-04.8.1	Contractors shall use the following messages when denying claims for PROVENGE®, Q2043, that exceed three (3) payments in a patient’s lifetime: CARC 149: “Lifetime benefit maximum has been reached for this service/benefit category.” RARC N362“The number of Days or Units of Service exceeds our acceptable maximum.” MSN 20.5 – “These services cannot be paid because	X		X	X						

<table>
<tr><td></td><td>your benefits are exhausted at this time.”

Spanish Version: “Estos servicios no pueden ser pagados porque sus beneficios se han agotado.”

Group Code – CO</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>7431-04.9</td><td>Effective for claims with dates of service on or after January 3, 2012, CWF shall reject and contractors shall deny any additional claims for PROVENGE®, that are provided after 30 weeks from the date of the 1st PROVENGE® administration.</td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td>X</td><td></td></tr>
<tr><td>7431-04.9.1</td><td>Contractors shall use the following messages when denying claims for PROVENGE®, Q2043 that were provided more than 30 weeks from the date of the 1st PROVENGE® administration:

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

MSN 20.5 – “These services cannot be paid because your benefits are exhausted at this time.”

Group Code – CO</td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>7431-04.10</td><td>Contractors shall note the appropriate ICD-10 code(s) that are listed below. Contractors shall track the ICD-10 codes and ensure that the updated edit is turned on as part of the ICD-10 implementation no later than 10/1/2013. NOTE: You will not receive a separate change request instructing you to implement the updated edits.

<table>
<tr><th>ICD-10</th><th>Description</th></tr>
<tr><td>C61</td><td>Malignant neoplasm of prostate (for on-label or off-label indications)</td></tr>
<tr><td>D075</td><td>Carcinoma in situ of prostate (for off-label indications only)</td></tr>
<tr><td>C77.1</td><td>Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes</td></tr>
<tr><td>C77.2</td><td>Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes</td></tr>
<tr><td>C77.4</td><td>Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes</td></tr>
<tr><td>C77.5</td><td>Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes</td></tr>
<tr><td>C77.8</td><td>Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions</td></tr>
<tr><td>C77.9</td><td>Secondary and unspecified malignant neoplasm of lymph node, unspecified</td></tr>
<tr><td>C78.00</td><td>Secondary malignant neoplasm of</td></tr>
</table></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

	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

Number	Requirement	A/B MAC	DME MAC	FI	CARRIER	RHHI	FISS	MCS	VMS	CWF	OTHER
7431-04.11	Contractors shall not search for and adjust any claims for PROVENGE®, that are provided after 30 weeks from the date of the 1st PROVENGE® administration or for any claims where there have been more than three (3) payments of PROVENGE®, Q2043, in a patient's lifetime prior to the January 3, 2012, implementation date for the CWF edits. However, contractors may adjust claims brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7431-04.12	A provider education article related to this instruction will be available at http://www.cms.gov/MLNMattersArticles shortly after the CR is released. You will receive	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with local information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

Section A: for any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: NA

V. CONTACTS: Pre-Implementation Contact(s): Leslye Fitterman, coverage, 410-786-1806, leslye.fitterman3@cms.hhs.gov, Patricia Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov, William Ruiz, institutional claims processing, Cheryl Gilbreath, coverage, 410-786-5919, cheryl.gilbreath@cms.hhs.gov, 410-786-9283, William.ruiz@cms.hhs.gov, Thomas Dorsey, practitioner claims processing, 410-786-7434, Thomas.Dorsey@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING: Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers:* No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*: The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the

contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual
Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev. 2254, 07-08-11)

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

280.4 - Payment Method

280.5 - Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claims Adjustment Reason Codes (CARCs), and Group Codes

280 – Autologous Cellular Immunotherapy Treatment of Prostate Cancer

(Rev. 2254, Issued: 07-08-11, Effective: 06-30-11, Implementation: 08-08-11 and 01-03-12 (CWF frequency edit only)

280.1 – Policy

(Rev. 2254, Issued: 07-08-11, Effective: 06-30-11, Implementation: 08-08-11 and 01-03-12 (CWF frequency edit only)

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. 2254, Issued: 07-08-11, Effective: 06-30-11, Implementation: 08-08-11 and 01-03-12 (CWF frequency edit only)

HCPCS Codes

Effective for claims with dates of service on June 30, 2011, Medicare providers shall report one of the following HCPCS codes for PROVENGE®:

- *C9273 - Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion, or*
- *J3490 – Unclassified Drugs, or*
- *J3590 – Unclassified Biologics.*

***NOTE**: Contractors shall continue to process claims for HCPCS code C9273, J3490, and J3590, with dates of service June 30, 2011, as they do currently.*

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. 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

Contractors shall note the appropriate ICD-10 code(s) that are listed below for future implementation. Contractors shall track the ICD-10 codes and ensure that the updated edit is turned on as part of the ICD-10 implementation effective October 1, 2013.

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*
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*

280.3 - Types of Bill (TOB) and Revenue Codes

(Rev. 2254, Issued: 07-08-11, Effective: 06-30-11, Implementation: 08-08-11 and 01-03-12 (CWF frequency edit only)

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. 2254, Issued: 07-08-11, Effective: 06-30-11, Implementation: 08-08-11 and 01-03-12 (CWF frequency edit only)

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 is all-inclusive and represents all routine costs associated with its administration.

280.5 - Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs), and Group Codes

(Rev. 2254, Issued: 07-08-11, Effective: 06-30-11, Implementation: 08-08-11 and 01-03-12 (CWF frequency edit only)

Contractors shall 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 in Section 280.2 above:

MSN 14.9 - Medicare cannot pay for this service for the diagnosis shown on the claim.

Spanish Version - Medicare no puede pagar por este servicio debido al diagnóstico indicado en la reclamación.

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)

Contractors shall use the following messages when denying claims for the off-label indication for PROVENGE®, HCPCS Q2043, submitted without either ICD-9-CM diagnosis code 233.4 or ICD-9-CM diagnosis code 185:

MSN 14.9 - Medicare cannot pay for this service for the diagnosis shown on the claim.

Spanish Version - Medicare no puede pagar por este servicio debido al diagnóstico indicado en la reclamación.

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 exceeds three (3) payments in a patient's lifetime, contractors shall use the following messages:

MSN 20.5 - These services cannot be paid because your benefits are exhausted at this time.

Spanish Version - Estos servicios no pueden ser pagados porque sus beneficios se han agotado.

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:

MSN 20.5 - These services cannot be paid because your benefits are exhausted at this time.

Spanish Version - Estos servicios no pueden ser pagados porque sus beneficios se han agotado.

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

Group Code – CO