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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 2394 | Date: January 25, 2012 |
| | Change Request 7659 |

SUBJECT: CWF Editing for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (PROVENGE®)

I. SUMMARY OF CHANGES: This CR will provide for edits, implemented on July 2, 2012, for CWF to reject and contractors to deny claims for PROVENGE therapy where more than 3 claims had been paid in a patient's lifetime.

EFFECTIVE DATE: June 30, 2011 for- (claims with dates of service on or after July 1, 2011 processed on or after July 2, 2012).

IMPLEMENTATION DATE: July 2, 2012

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/revise 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 |
|--------------|--|
| R | 32/280/280.5/Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim 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: 2394 | Date: January 25, 2012 | Change Request: 7659 |
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SUBJECT: CWF Editing for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (PROVENGE®)

EFFECTIVE DATE: June 30, 2011 — (for claims with dates of service on or after July 1, 2011 processed on or after July 2, 2012).

IMPLEMENTATION DATE: July 2, 2012

I. GENERAL INFORMATION

A. Background: Change Request (CR) 7431, Transmittal 2254 (later re-issued as CR 7431, Transmittal 2339, November 2, 2011) provided billing instructions for Autologous Immunotherapy Treatment (PROVENGE®) of metastatic prostate cancer. Per CR 7431, 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. This CR provides Common Working File (CWF) editing for PROVENGE®, Q2043 services.

B. Policy: Effective for claims processed on or after July 1, 2012, CWF shall perform frequency editing for PROVENGE®, Q2043 services. CWF shall deny claims for PROVENGE®, Q2043 that exceed (3) services in a patient’s lifetime.

II. BUSINESS REQUIREMENTS TABLE

| Number | Requirement | Responsibility (place an “X” in each applicable column) | | | | | | | | | | |
|--------|--|---|-----------------------|-------------|----------------------------|------------------|---------------------------|--|--|--|-------|--|
| | | A / B M A C | D M M A C | F I | C A R I E R | R H H I | Shared-System Maintainers | | | | OTHER | |
| | | F I S S | M I C S | V M S | C M W F | | | | | | | |
| 7659.1 | Effective for claims with dates of service on or after July 1, 2011, processed on and after July 2, 2012, CWF shall only allow a frequency of three (3) services of nationally covered PROVENGE® for asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer, Q2043, in a patient’s lifetime. | | | | | | X | | | | X | |
| 7659.2 | Effective for claims with dates of service on or after July 1, 2011 processed on and after July 2, 2012, upon receipt of the CWF edit contractors shall deny services of PROVENGE®, Q2043, when billed in excess of three (3) times in a patient’s lifetime. | X | | X | X | | | | | | | |
| 7659.3 | Contractors shall use the following messages when denying claims for PROVENGE®, Q2043, that exceed three (3) services in a patient’s lifetime: | X | | X | X | | | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|--------|---|---|--------------------------------|---------------------------|-----------------------|--------------------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B M A C | D M E M A C | F I M A C | C A R E R | R H I I S S | Shared-System Maintainers | | | | OTHER |
| | | | | | | | F I S S | M C S | V M S | C W F | |
| | <p>Claim Adjustment Reason Code (CARC) 149 - "Lifetime benefit maximum has been reached for this service/benefit category."</p> <p>Remittance Advice Remark Code (RARC) N362 - "The number of Days or Units of Service exceeds our acceptable maximum."</p> <p>Medicare Summary Notice (MSN) 20.5 - "These services cannot be paid because your benefits are exhausted at this time."</p> <p>Spanish Version - "Estos servicios no pueden ser pagados porque sus beneficios se han agotado."</p> <p>Group Code - CO (Contractor Obligation)</p> | | | | | | | | | | |
| 7659.4 | Contractors shall not search for and adjust PROVENGE®, Q2043, claims paid prior to the implementation of this change request. 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 M A C | D M E M A C | F I M A C | C A R E R | R H I I S S | Shared-System Maintainers | | | | OTHER |
| | | | | | | | F I S S | M C S | V M S | C W F | |
| | None. | | | | | | | | | | |

IV. SUPPORTING INFORMATION

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

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|---|
| CR 7431 | Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer |

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): William Ruiz, institutional claims processing, 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

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

(Rev.2394, Issued: 01-25-12, Effective: 06-30-11 for-(claims with dates of service on or after 07-01- 11 processed on or after July 02-12, Implementation: 07-02-12)

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 – CO (Contractual Obligation)

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

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 (Contractual Obligation)

For claims with dates of service on or after July 1, 2012, processed on or after July 2, 2012, when denying claims for PROVENGE®, HCPCS Q2043® that exceed three (3) *services* 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 (Contractual Obligation)