

## LCD for Epoetin (L11463)

### Contractor Information

**Contractor Name**

[NHIC, Corp.](#)

**Contractor Number**

16003

**Contractor Type**

DME MAC

### LCD Information

**LCD ID Number**

L11463

**LCD Title**

Epoetin

**Contractor's Determination Number**

EPO

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**CMS National Coverage Policy**

CMS Pub. 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 50.5.2

**Primary Geographic Jurisdiction**

Connecticut  
District of Columbia  
Delaware  
Massachusetts  
Maryland  
Maine  
New Hampshire  
New Jersey  
New York - Entire State  
Pennsylvania  
Rhode Island  
Vermont

## LCD Information

### Oversight Region

Region I

### DME Region LCD Covers

Jurisdiction A

### Original Determination Effective Date

For services performed on or after 10/01/1993

### Original Determination Ending Date

### Revision Effective Date

For services performed on or after 09/01/2009

### Revision Ending Date

### Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.

Statutory coverage criteria for epoetin are specified in the related Policy Article.

### Coverage Topic

Prescription Drugs

## Coding Information

### CPT/HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

### HCPCS MODIFIERS:

EY – No physician or other licensed health care provider order for this item or service

## Coding Information

GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit

KX - Requirements specified in the medical policy have been met

### HCPCS CODES:

J0881 INJECTION, DARBEPOETIN ALFA, 1 MICROGRAM (NON-ESRD USE)

J0882 INJECTION, DARBEPOETIN ALFA, 1 MICROGRAM (FOR ESRD ON DIALYSIS)

J0885 INJECTION, EPOETIN ALFA, (FOR NON-ESRD USE), 1000 UNITS

J0886 INJECTION, EPOETIN ALFA, 1000 UNITS (FOR ESRD ON DIALYSIS)

### ICD-9 Codes that Support Medical Necessity

Not specified

### Diagnoses that Support Medical Necessity

Not specified

### ICD-9 Codes that DO NOT Support Medical Necessity

Not specified

### ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

### Diagnoses that DO NOT Support Medical Necessity

Not specified.

## General Information

### Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The order must indicate the dose and frequency of administration. A new order is needed if there is a change in the dose or frequency of administration.

The most recent hematocrit value prior to the From date on the claim should be reported in the narrative field of the electronic record.

If additional information is requested for patients with hematocrits in excess of 36%, and if the goal is to maintain the hematocrit at greater than 36%, the supplier must send in documentation (e.g., diagnosis, patient symptoms, etc.) supporting the medical necessity for the higher target hematocrit. If additional documentation is requested and if the goal is to maintain the hematocrit between 30-36%, the supplier must send a copy of the flow sheet/log for the past 3 months

## General Information

documenting hematocrit dates and dates of epoetin (EPO) order changes. (In this policy, the term EPO applies to both epoetin alfa and darbepoetin alfa.)

### GY AND KX MODIFIERS:

Suppliers must add a KX modifier to codes for EPO if all coverage criteria (#1-9) listed in the Non-Medical Necessity Coverage and Payment Rules section of the related Policy Article are met. If the hematocrit prior to initiation of EPO therapy is greater than or equal to 31%, or if other coverage criteria are not met, the KX modifier must not be used.

If all the criteria in the related Policy Article are not met, the GY modifier must be added to the EPO code.

Claim lines billed without a GY or KX modifier will be rejected as missing information.

Refer to the Supplier Manual for more information on documentation requirements.

## Appendices

### Utilization Guidelines

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

### Sources of Information and Basis for Decision

### Advisory Committee Meeting Notes

### Start Date of Comment Period

### End Date of Comment Period

### Start Date of Notice Period

01/01/1995

### Revision History Number

EPO006

### Revision History Explanation

Revision Effective Date: 09/01/2009

## General Information

### CMS NATIONAL COVERAGE POLICY:

Added: CMS Pub. 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 50.5.2.

### HCPCS CODES AND MODIFIERS:

Added: GY modifier.

Revised: KX modifier.

### DOCUMENTATION REQUIREMENTS:

Added: Instructions for use of GY modifier.

### **03/01/2008**

In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) LCD L11463 from DME PSC TriCenturion (77011) LCD L11463.

### **Revision Effective Date: 07/01/2007**

#### INDICATIONS AND LIMITATIONS OF COVERAGE:

Removed: DMERC references.

#### DOCUMENTATION REQUIREMENTS:

Removed: DMERC references.

### **06/01/2007**

In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

### **03/01/2006**

In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

### **Revision Effective Date: 01/01/2006**

#### HCPCS CODES AND MODIFIERS:

Added: J0881, J0882, J0885, J0886

Deleted: Q0136, Q0137, Q4054, Q4055

### **Revision Effective Date: 10/01/2005**

LMRP converted to LCD and Policy Article.

#### DOCUMENTATION REQUIREMENTS:

Added: The requirement to list the hematocrit on each claim.

### **Revision Effective Date: 04/01/2004**

#### HCPCS CODES AND MODIFIERS:

Added: Q0136, Q0137, Q4054, Q4055

Discontinued: J0880, Q9920-Q9940

#### INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised: Statements concerning when EPO is noncovered by the DMERCs.

#### CODING GUIDELINES:

Eliminated: Coding guidelines for codes Q9920-Q9940.

Added: Rounding instructions for billing darbepoetin.

### **Revision Effective Date: 04/01/2003**

#### HCPCS CODES AND MODIFIERS:

Added: J0880, EY modifier.

#### INDICATIONS AND LIMITATIONS OF COVERAGE:

Added: Standard language concerning coverage of items without an order.

Stated: The policy applies to darbepoetin alpha as well as epoetin alpha.

Clarified: If the coverage criteria are not met, the denial will be noncoverage denial.

Clarified: The claim filing jurisdiction for self-administered and non- self-administered EPO.

#### CODING GUIDELINES:

Added: Instruction for billing darbepoetin alpha.

#### DOCUMENTATION REQUIREMENTS:

## General Information

Added: Standard language concerning use of EY modifier for items without an order.  
Eliminated: Requirement to use a specific ICD-9 code.

**The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.**

07/01/2002 - Updated the target hematocrit range to 33–36% (this is already in effect). Added a requirement to use ICD-9 code V45.1 if the patient is on Method II home hemodialysis. Replaced the ZX modifier with KX. Even though the effective date of the policy revision is October 1, 2002, the KX modifier should be used in place of the ZX modifier (as described in the current policy) beginning with DOS on or after July 1, 2002. Effective for dates of service on or after October 1, 2002, required that KX modifier be used on every claim for EPO if policy criteria are met.

Eliminated use of the EJ modifier with subsequent EPO claims.

04/01/1995 – Revised statement in Documentation section as follows: Changed “The specified coverage criteria in the medical policy have been met and documentation is available in the supplier’s records.” to Specified requirements found in the documentation section of the medical policy have been met and evidence is available in the supplier’s records.”

### Reason for Change

### Last Reviewed On Date

### Related Documents

#### Article(s)

[A35345 - Epoetin – Policy Article – Effective September 2009](#)

### LCD Attachments

There are no attachments for this LCD

**Article for Epoetin – Policy Article – Effective September 2009 (A35345)**

**Contractor Information**

**Contractor Name**

[NHIC, Corp.](#)

**Contractor Number**

16003

**Contractor Type**

DME MAC

**Article Information**

**Article ID Number**

A35345

**Article Type**

Article

**Key Article**

Yes

**Article Title**

Epoetin – Policy Article – Effective September 2009

**Primary Geographic Jurisdiction**

Connecticut  
District of Columbia  
Delaware  
Massachusetts  
Maryland  
Maine  
New Hampshire  
New Jersey  
New York - Entire State  
Pennsylvania  
Rhode Island  
Vermont

**DME Region Article Covers**

Jurisdiction A

**Original Article Effective Date**

10/01/2005

## Article Information

### Article Revision Effective Date

09/01/2009

### Article Text

#### NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

Epoetin (EPO) (J0882, J0886) and items related to its administration are covered when all of the following criteria are met. (In this policy, the term EPO applies to both epoetin alfa and darbepoetin alfa.)

1. The patient is on dialysis which is being administered as Method II home dialysis.
2. The EPO is self administered in the home by the patient (or patient caregiver) who is determined by the physician or back-up dialysis facility to be competent to use the drug and to be capable of understanding and implementing a plan of care.
3. Prior to initiation of home EPO therapy, the back-up dialysis facility or the physician responsible for all dialysis-related services furnished to the patient has made a comprehensive assessment that includes the following:
  - a. Measurement of the patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure,
  - b. Assurance that the patient or a caregiver who assists the patient is:
    - i. Trained by the facility to inject EPO and is capable of carrying out the procedure,
    - ii. Capable of reading and understanding the drug labeling, and
    - iii. Trained in, and capable of observing, aseptic techniques,
  - c. Assurance that the EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child having access to the drug and syringes.
4. The patient has anemia and the most recent hematocrit prior to initiating EPO treatment was 30% or less (or hemoglobin level was less than 10.1 gm% [gm/dl] or less) unless there is medical documentation showing the need for EPO treatment despite a hematocrit of 31% or higher (or hemoglobin is 10.2 gm% or higher. For example, patients with severe angina, severe pulmonary distress, or severe hypotension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.
5. For patients who are being treated with EPO, the hematocrit is between 30 and 36% (or comparable hemoglobin level).
6. The patient is under the care of a back-up dialysis facility which has a written care plan for monitoring home use of EPO which includes the following:
  - a. Review of diet and fluid intake for aberrations as indicated by hyperkalemia and

## Article Information

elevated blood pressure secondary to volume overload;

b. Review of medications to ensure adequate provision of supplemental iron;

c. Ongoing evaluations of hematocrit and iron stores;

d. Re-evaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume;

e. A method for the physician and back-up dialysis facility to follow-up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results;

f. Training of the patient to identify the signs and symptoms of hypotension and hypertension; and

g. The decrease or discontinuance of EPO if hypertension is uncontrollable.

7. The patient is under the care of a physician who is responsible for all dialysis-related services and who orders the EPO and follows the drug labeling instructions when monitoring the EPO home therapy.

8. The patient's physician or back-up dialysis facility develops a protocol that follows the drug label instructions, makes the protocol available to the patient to ensure safe and effective home use of EPO.

9. The back-up dialysis facility maintains adequate records to allow quality assurance for review by the network and State survey agencies.

If all of the above criteria are not met, the EPO will be denied as noncovered.

The patient's dialysis physician or facility must maintain a flow sheet or log recording the dates and results of hematocrit tests, iron studies, and the EPO prescription with dates of change. This information must be available upon request.

Supplies (e.g., syringe, needle, alcohol) used for the administration of EPO are included in the allowance for the EPO. These supplies must not be billed separately.

The EPO must be supplied by the Method II supplier of home dialysis equipment and supplies. The amount of EPO that the patient has on hand must be limited to a two-month supply.

EPO that is self-administered by a patient (or caregiver) is billed to the DME MAC. The only claims that are eligible for coverage are those for patients who are on Method II home dialysis and that are submitted by the dialysis supplier. Therefore, claims for codes J0882 and J0886 that are submitted for home administration of EPO by patients who are on facility-based dialysis or Method I home dialysis will be denied as noncovered. Claims for codes J0885 and J0881 that are submitted for home administration of EPO by patients who are not on dialysis will be denied as noncovered. Claims for EPO for Method II home dialysis patients that are not submitted by the home dialysis supplier will be denied as noncovered. EPO that is not self-administered by a patient (or caregiver) is billed either to the Medicare intermediary or the local carrier. If a Method II home dialysis patient is in a Part A covered stay in a SNF and the Method II supplier provides EPO, it is separately payable from the SNF consolidated billing reimbursement. The Method II supplier should submit the claim to the DME MAC.

## Article Information

### CODING GUIDELINES

Codes J0882 and J0886 may only be used on claims for EPO administered to patients who are on dialysis. EPO administered to patients who are not on dialysis must be billed with codes J0885 and J0881.

Code Q4081 (Injection, epoetin alfa, 100 units, for ESRD on dialysis) is invalid for claim submission.

One unit of service of epoetin alfa is reported for each 1000 units dispensed. For example if 20,000 units are dispensed, bill 20 units. If the dose dispensed is not an even multiple of 1,000, rounded down for 1-499 units (e.g. 20,400 units dispensed = 20 units billed), round up for 500-999 units (e.g. 20,500 units dispensed = 21 units billed). One unit of service for darbepoetin alfa is 1 mcg. Similar rounding rules apply.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

### Coverage Topic

Prescription Drugs

## Coding Information

**No Coding Information has been entered in this section of the article.**

## Other Information

### Other Comments

### Revision History Explanation

#### Revision Effective Date: 09/01/2009

CODING GUIDELINES:  
Changed: SADMERC to PDAC.

#### 03/01/2008

In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A35345 from DME PSC TriCenturion (77011) Article A35345.

#### 06/01/2007

In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

#### Revision Effective Date: 01/01/2007

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  
Removed references to the DMERC.  
Replaced: DMERC references with DME MAC.  
CODING GUIDELINES:  
Identified: New code Q4081 as invalid for claim submission.

#### 03/01/2006

In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

## Other Information

### **Revision Effective Date: 01/01/2006**

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Updated: Section with HCPCS code changes.

CODING GUIDELINES:

Updated: Section with HCPCS code changes.

### **Revision Effective date: 10/01/2005**

LMRP converted to LCD and Policy Article.

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Changed: The hematocrit target for ongoing treatment to 30-36%.

Added: Statement concerning coverage and billing when the patient is in a Part A covered SNF stay.

### **Related Documents**

#### **LCD(s)**

[L11463 - Epoetin](#)