

# Levocarnitine for use in the Treatment of Carnitine Deficiency in ESRD Patients (NCD 230.19)

<b>Policy Number</b>	230.19	<b>Approved By</b>	UnitedHealthcare Medicare Reimbursement Policy Committee	<b>Current Approval Date</b>	12/18/2013
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### IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®\*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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## Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. CPT codes and descriptions are copyright 2010 American Medical Association (or such other date of publication of CPT). All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Current Dental Terminology (CDT), including procedure codes, nomenclature, descriptors, and other data contained therein, is copyright by the American Dental Association, 2002, 2004. All rights reserved. CDT is a registered trademark of the American Dental Association. Applicable FARS/DFARS apply.

## Summary

### Overview

Carnitine is a naturally occurring substance that functions in the transport of long-chain fatty acids for energy production by the body. Deficiency can occur due to a congenital defect in synthesis or utilization, or from dialysis. The causes of carnitine deficiency in hemodialysis patients include dialytic loss, reduced renal synthesis and reduced dietary intake.

### Reimbursement Guidelines

Intravenous levocarnitine, for one of the following indications, will only be covered for those ESRD patients who have been on dialysis for a minimum of three months. Patients must have documented carnitine deficiency, defined as a plasma free carnitine level <40 micromol/L (determined by a professionally accepted method as recognized in current literature), along with signs and symptoms of:

- Erythropoietin-resistant anemia (persistent hematocrit <30% with treatment) that has not responded to standard erythropoietin dosage (that which is considered clinically appropriate to treat the particular patient) with iron replacement, and for which other causes have been investigated and adequately treated, or
- Hypotension on hemodialysis that interferes with delivery of the intended dialysis despite application of usual measures deemed appropriate (e.g., fluid management). Such episodes of hypotension must have occurred during at least 2 dialysis treatments in a 30-day period.

Continued use of levocarnitine will not be covered if improvement has not been demonstrated within 6 months of initiation of treatment. All other indications for levocarnitine are non-covered in the ESRD population.

For a patient currently receiving intravenous levocarnitine, Medicare will cover continued treatment if:

- Levocarnitine has been administered to treat erythropoietin-resistant anemia (persistent hematocrit <30 percent with treatment) that has not responded to standard erythropoietin dosage (that which is considered clinically appropriate to treat the particular patient) with iron replacement, and for which other causes have been investigated and adequately treated, or hypotension on hemodialysis that interferes with delivery of the intended dialysis despite application of usual measures deemed appropriate (e.g., fluid management) and such episodes of hypotension occur during at least 2 dialysis treatments in a 30-day period; and
- The patient's medical record documents a pre-dialysis plasma free carnitine level <40 micromol/L prior to the initiation of treatment; or
- The treating physician certifies (documents in the medical record) that in his/her judgment, if treatment with levocarnitine is discontinued, the patient's pre-dialysis carnitine level would fall below 40 micromol/L

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and the patient would have recurrent erythropoietin-resistant-anemia or intradialytic hypotension.

### CPT/HCPCS Codes

Code	Description
J1955	Injection, levocarnitine, per 1 g

### References Included (but not limited to):

#### **CMS NCD**

NCD 230.19 Levocarnitine for use in the Treatment of Carnitine Deficiency in ESRD Patients

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

Numerous LCDs

#### **CMS Article(s)**

Numerous Articles

#### **CMS Benefit Policy Manual**

Chapter 11; 20.3 Drugs and Biologicals

#### **CMS Transmittals**

Transmittal, 2134 Change Request 7064, Dated 01/14/2011 End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services

#### **UnitedHealthcare Medicare Advantage Coverage Summaries**

Dialysis Services

#### **UnitedHealthcare Reimbursement Policies**

Erythropoietin Stimulating Agent (ESA)

Medically Unlikely Edits (MUE)

#### **UnitedHealthcare Medical Policies**

Drug Coverage Guidelines

#### **MLN Matters**

Article MM7064, End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services

Article MM2554, Levocarnitine for Use in the Treatment of Carnitine Deficiency in ESRD Patients

#### **Others**

Decision Memo for Levocarnitine for End Stage Renal Disease, CMS Website

### History

Date	Revisions
12/18/2013	Annual re-review completed with no changes/updates
06/13/2012	Administrative updates
04/11/2012	Annual review
01/27/2010	Administrative updates