LEVOCARNITINE FOR USE IN THE TREATMENT OF CARNITINE DEFICIENCY IN ESRD PATIENTS (NCD 230.19)

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INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY 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.

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

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<th>HCPCS Code</th>
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<tr>
<td>J1955</td>
<td>Injection, levocarnitine, per 1 g</td>
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**REFERENCES**

**CMS National Coverage Determinations (NCDs)**

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

**CMS Local Coverage Determinations (LCDs)**

<table>
<thead>
<tr>
<th>LCD</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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<tr>
<td>L33971 (Levocarnitine (Carnitor®, L-carnitine®)) First Coast Retired 04/14/2016</td>
<td>FL, PR, VI</td>
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<tr>
<td>L28899 (Levocarnitine (Carnitor®, L-carnitine®)) First Coast Retired 09/30/2015</td>
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<td>L28921 (Levocarnitine (Carnitor®, L-carnitine®)) First Coast Retired 09/30/2015</td>
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**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)

**MLN Matters**

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

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

**UnitedHealthcare Commercial Policies**

Drug Coverage Guidelines

**Others**

Decision Memo for Levocarnitine for End Stage Renal Disease, CMS Website
## GUIDELINE HISTORY/REVISION INFORMATION

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<th>Date</th>
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