Medlearn Matters
Information for Medicare Providers

Related Change Request (CR) #: 2554
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Implementation Date: January 1, 2004

Medlearn Matters Number: MM2554

Levocarnitine for Use in the Treatment of Carnitine Deficiency in ESRD Patients

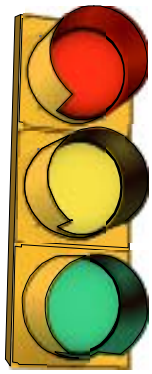
Note: This article was revised to include Web addresses that conform to the new CMS Website.

Provider Types Affected

Providers who bill for intravenous levocarnitine received by End Stage Renal Disease (ESRD) patients on or after January 1, 2003.

Provider Action Needed

Affected providers should be aware of these payment instructions for intravenous levocarnitine provided to End Stage Renal Disease (ESRD) patients on or after January 1, 2003. Although these changes were effective on January 1, 2003, they will be implemented in Medicare's claims processing systems on January 1, 2004.



STOP

Levocarnitine will be covered by Medicare only if certain coverage rules are met. All other indications for levocarnitine are non-covered in the ESRD population.

CAUTION

This article explains the coverage requirements for Medicare payment for levocarnitine.

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Be sure to follow these guidelines when billing for levocarnitine to assure accurate and prompt payments from Medicare for this drug.

Background

Initial Use

The use of intravenous levocarnitine will only be covered for End Stage Renal Disease (ESRD) patients who have been on dialysis for a minimum of 3 months ***and*** must have documented carnitine deficiency (defined as a plasma free carnitine level<40 micromol/L) ***and*** signs and symptoms of:

1. 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
2. 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 treatment. All other indications for levocarnitine are non-covered in the ESRD population.

Continued Use

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

1. Levocarnitine has been administered to treat a)erythropoietin-resistant anemia or b) hypotension on hemodialysis, as described above, ***and***
2. The patient's medical record documents a pre-dialysis plasma free carnitine level <40 micromol/L prior to the initiation of treatment; ***or***
3. The treating physician certifies 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.

Implementation

The implementation date is January 1, 2004, and the effective date of the change is January 1, 2003.

Related Instructions

Billing Requirements

For Claims Submitted to Intermediaries: The applicable bill type is 72x.

Note: A Free-standing ESRD Facility is reimbursed at 95% of AWP; Hospital-based ESRD Facility is reimbursed at cost (Deductible and coinsurance apply)).

When using the UB-92 flat file, use record type 40 for bill type. When using the hard copy UB-92 report, the applicable bill type is Form Locator (FL) 4 "Type of Bill."

This drug should be billed on Form CMS-1450 (or electronic equivalent) under the revenue code 0636 along with HCPC J1955. When using the UB-92 flat file use record type 61 for the Revenue Code (Field No.5); for the HCPC, use Field No. 6. When using the hard copy UB-92, report revenue code in FL 42 "Revenue Code" and report the HCPC code in FL 44 "CPT/Rates."

For Claims Submitted to Carriers: Follow the general instruction for preparing claims in §2010 Medicare Carriers Manual (MCM) Part 4, Chapter 2, Purpose of Health Insurance Claim Form CMS-1500. Submit claims for Levocarnitine on health insurance claim Form CMS-1500 or electronic equivalent. Claims should be processed in accordance with §4020, MCM, Review of Health Insurance Claim Form CMS-1500, Part 3.

Coinsurance and deductible apply.

If providers submit claims that do not meet one or more of the requirements described above, they will receive the following message on their remittance advice:

> *"6.5- Medicare cannot pay for this injection because one or more requirements for coverage were not met."*

To view the actual Medicare transmittal for this issue, please visit http://www.cms.hhs.gov/Transmittals/downloads/AB03130.pdf on the CMS web site.