Program Memorandum Intermediaries/Carriers

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal AB-03-130 **Date: AUGUST 22, 2003**

CHANGE REQUEST 2554

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

This Program Memorandum corrects Program Memorandum AB-02-0165, Change Request 2438 dated November 8, 2002. All information is the same except for the deletion of bill types 13x and 85x; and the addition of payment methodology for hospital-based ESRD facilities.

General Information

This Program Memorandum (PM) contains payment instructions for intravenous levocarnitine for End Stage Renal Disease (ESRD) patients received on or after January 1, 2003.

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.

Intravenous levocarnitine will only be covered for those ESRD patients who have been on dialysis for a minimum of 3 months for one of the following indications.

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:

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 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:

1. Levocarnitine has been administered to treat erythropoietin-resistent 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

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 (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.

Billing Requirements

Intermediaries

The applicable bill type: 72x - Free-standing ESRD Facility - Reimbursed at 95% of AWP
Hospital-based ESRD Facility - 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 in Form locator (FL) 4 "Type of Bill." For those using X12N 837 formats, the following is provided to assist in your implementation efforts: The Medicare A 837 Health Care Claim version 3051 implementations 3A.01 and 1A.C1 (Appendix C of both documents have UB-92 mapping), along with the UB-92 version 6.0 are at http://cms.hhs.gov/providers/edi/edi3.asp. These formats are effective through October 16, 2003. The X12N 837 to UB-92 version 6.0 mapping is at http://cms.hhs.gov/providers/edi/hipaadoc.asp. The HIPAA 837 can be downloaded at www.wpc-edi.com.

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), and 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."

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. Claims for Levocarnitine are to be submitted 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.

Medicare Summary Notices (MSN) and Remittance Advice

Use the following MSN when appropriate:

6.5 – Medicare cannot pay for this injection because one or more requirements for coverage were not met.

Spanish version – 6.5 – Medicare no puede pagar por esta inyeccion porque uno o mas requisitos para la cubierta no fueron cumplidos.

The *effective date* for this Program Memorandum PM is January 1, 2003.
The *implementation date* for this PM is January 1, 2004.

These instructions should be implemented within your current operating budget.

This PM may be discarded after January 1, 2005.