

Contractor's Policy Number

97-15

Contractor Name

CareFirst of Maryland Inc., Medicare Part A

Contractor Number

00190

Contractor Type

Fiscal Intermediary

LMRP Title

Levocarnitine (Carnitor™, L-Carnitine™)

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CMS National Coverage Policy

- Establishment of national policy supercedes all previous contractor policy statements, including Local Medical Policy coverage guidelines.
- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Primary Geographic Jurisdiction

Maryland

Washington, DC

Secondary Geographic Jurisdiction

Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

CMS Region

Region III

CMS Consortium

Northeast

Original Policy Effective Date

April 28, 1997

Original Policy Ending Date

01/01/2003

Revision Effective Date

Revision Ending Date

LMRP Description

Levocarnitine is an essential co-factor of fatty acid metabolism.

Indication and Limitations of Coverage and/or Medical Necessity

Levocarnitine is indicated for patients who meet all of the following criteria:

- Are on hemodialysis longer than one year;
- Have exercise intolerance, and/or failure to thrive that is having a significant negative effect on their quality of life;
- Have skeletal muscle weakness, cramping, and malaise, that has not responded to diet or pharmacological intervention despite correction of anemia with EPO;
- Have cardiac dysfunction or cardiomyopathy induced by hemodialysis (a specific sign may be a large volume of hypertonic saline or dextran use to support blood pressure during dialysis);
- Exhibit high catabolic rate with anorexia and evidence of protein wasting, despite adequate caloric intake;
- Have hyperlipidemia Type IV; and,
- Have anemia not responding to standard EPO dosage, despite adequate iron stores or dialysis.

Levocarnitine is available for oral and parenteral administration. Parenteral administration is indicated for these specific ESRD patients on dialysis for a period of three months. After three months, therapeutic levels of levocarnitine can be maintained with oral administration of the drug in most patients. The medical record must indicate the medical necessity of extending parenteral administration of levocarnitine beyond three months.

CPT/HCPCS Section & Benefit Category

Type of Bill Code

Revenue Codes

CPT/HCPCS Codes

J1955 Injection, levocarnitine, 1 gm

Not Otherwise Classified (NOC)

ICD-9 Codes that Support Medical Necessity

Covered for:

7913 Myoglobinuria (deficiency of carnitine palmitoyl transferase)

585 Chronic renal failure

One of the following codes must be submitted with diagnosis code 585:

4258 Cardiomyopathy in other diseases classified elsewhere

4259 Secondary cardiomyopathy, unspecified

7282 Muscular wasting and disuse atrophy, not elsewhere classified

7830 Anorexia

Diagnosis that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

Diagnosis that DO NOT Support Medical Necessity

Reasons for Denial

- All other indications not listed in the “Indications and Limitations of Coverage,” section of this policy;
- The service is not medically necessary;

- The medical record does not verify that the service described by the HCPCS code was provided; and,
- The service does not follow the guidelines of this policy.

Medicare national policy excludes coverage of drugs, which can be self-administered. Medicare will not cover parenteral levocarnitine after the initial three-month treatment period unless the medical record supports the medical necessity for extending the parenteral administration

Non-covered ICD-9 Code(s)

Any diagnosis code not listed in the “ICD-9 Codes that Support Medical Necessity” section of this policy.

Non-covered Diagnosis

Coding Guidelines:

- To report these services, use the appropriate HCPCS code J1955;
- All of the coverage criteria must be met before this service can be reimbursed by Medicare;
- Diagnosis (es) must be present on any claim submitted, and must be coded to the highest level of specificity; and,
- The diagnosis code (s) must be representative of the patient’s condition.

Documentation Requirements:

Documentation supporting the medical necessity of levocarnitine should be legible, maintained in the patient’s medical record, and must be made available to Medicare upon request

Utilization Guidelines

Other Comments

Sources of Information and Basis for Decision:

Labonia, Walter Dario, M.D., 1995. "L-Carnitine Effects on Anemia in Hemodialyzed Patients Treated with Erythropoietin." American Journal of Kidney Diseases. Vol. 26 (November): 757-764.

Ahmad, Suhail, et al. 1990. "Multicenter Trial of L-Carnitine in Maintenance Hemodialysis Patients. II Clinical and Biochemical Effects." Kidney International . Vol. 38: 912-916.

Advisory Committee Notes:

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

Advisory Committee meeting date:

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

Revision History

<u>Number</u>	<u>Date</u>	<u>Changes</u>
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N/A
01/01/2003.

01/01/2003

NCD implemented/effective

Policy archived.

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ISSUED AFTER OCTOBER 1,1999 ARE AVAILBABLE AT NO-COST FROM OUR WEBSITE AT www.marylandmedicare.com

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