

MARYLAND MEDICARE PART A

Policy No: 96-06

Topic: Neupogen

Beginning Effective Date

October 12, 1996

Ending Effective Date

Not applicable at this time.

Description:

- Neupogen or Amgen (Filgrastim) is a human granulocyte colony stimulating factor (G-CSF) produced by recombinant DNA technology. G-CSF regulates the production of neutrophils within the bone marrow. It has been shown to be safe and effective in accelerating the recovery of neutrophil counts following a variety of chemotherapy regimens.
- During a chemotherapy cycle, Neupogen should not be administered within 24 hours of chemotherapy. Neupogen should be administered daily for up to 2 weeks. The duration of therapy needed may depend on the particular myelosuppressive chemotherapy regimen used and the patient's neutrophil response.

Policy Type

Local Medical Review Policy

Indications and Limitations of Coverage and/or Medical Necessity

- Neupogen is approved for use after cancer chemotherapy in patients with non-myeloid malignancies to decrease the incidence of infection. It is shown to be effective in reducing the severity and duration of neutropenia in cancer patients receiving chemotherapy, and reducing the incidence of hospitalizations associated with infection, often resulting in a significant decreased need for antibiotic treatment or hospitalization.
- Dosage must not exceed that recommended by the drug manufacturer, and may be given subcutaneously (SQ) or intravenously, not by pump infusion. **Self-**

administration will not be reimbursed.

- For subcutaneous or intravenous injection, the recommended starting dose is 5 mcg/kg/day, administered as a single daily injection. Doses may be increased in increments of 5 mcg/kg for each chemotherapy cycle.
- A complete blood count (CBC) and platelet count should be obtained twice per week during Neupogen therapy to avoid leukocytosis and to monitor the neutrophil count.

HCPCS Section/Benefit Category

HCPCS Level II Code

Type of Bill

Not included in the development of this policy.

Revenue Code

Not included in the development of this policy.

HCPCS Code(s):

J1995 Injection, levocarnitine, 1 gm

ICD-9-CM Codes That Support Medical Necessity:**Covered for:**

791.3	Myoglobinuria (deficiency of carnitine palityl transferase)
585	Chronic renal failure
One of the following codes must be submitted with diagnosis code 585:	
425.8	Cardiomyopathy in other diseases classified elsewhere
425.9	Secondary cardiomyopathy, unspecified
728.2	Muscular wasting and disuse atrophy, not elsewhere classified
783.0	Anorexia

Non-covered ICD-9-CM Code(s)

All diagnosis codes not listed I the “ICD-9-CM Codes that Support Medical Necessity” section in this policy.

HCFA National 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.

Reasons for Denial

- All other indications not listed in the “Indications and Limitations of Coverage” section 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.
- 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.

Sources of Information

- 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 I maintenance Hemodialysis Patients. 11. Clinical and Biochemical Effects.” Kidney International. Vol. 38:912-918

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 for this procedure should be legible, maintained in the patient's medical record, and available to Medicare upon request. All supporting documentation should be supplied when medical records are requested.

Start Date of Comment Period

Start Date of Notice Period

March 28, 1997

Revision Date

Revision Number

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