

## **L-Carnitine Use in U.S. Dialysis Patients before 2003 National Coverage Decision.**

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Prior to 2003, no consistent Medicare (CMS) policy for carnitine reimbursement existed. We described characteristics of dialysis patients using carnitine before the new CMS policy. We studied a national cohort of adult, Medicare dialysis patients (N=86,904) prevalent on 1/1/2000, erythropoietin (EPO) treated, and with Medicare as a primary payer. The first intravenous (IV) carnitine dose from 1/1/2000 to 7/31/2001 defined the start of a 6-mo. carnitine treatment period. Patients with carnitine in 5 or 6 out of 6 mos., and with at least 10 g per mo. were classified as consistently dosed; otherwise, inconsistently dosed. Patients without carnitine were also included as a comparison group (start of treatment period was randomly assigned). Patients were characterized during a 6-mo. entry period preceding the treatment period. A logistic regression model provided odds ratios of starting carnitine treatment, adjusting for age, gender, race, ethnicity, primary diagnosis, duration of dialysis, and these entry-period values: weekly EPO dose, infectious and non-infectious hospital days, vascular access procedures, blood transfusions, urea reduction ratio, IV iron use, iron tests, anemia, and comorbidities. 82,149 patients did not receive carnitine; 2,973 and 1,782 received consistent and inconsistent carnitine therapy, respectively. Groups with significantly higher ( $P < 0.05$ ) odds of receiving carnitine were as follows: age  $\geq 75$  yrs (vs.  $< 45$ ), white race (vs. black), Hispanic ethnicity (vs. non-Hispanic), dialysis duration  $< 2$  yrs or  $\geq 5$  yrs (vs. 2- $< 5$ ), 1-4 vascular access procedures (vs. 0),  $\geq 1$  blood transfusion (vs. 0), Hb  $< 11$  g/dL (vs.  $\geq 11$ ), with (vs. without) iron tests, weekly EPO dose  $\geq 19,800$  U (vs. 12,150- $< 19,800$ ), without (vs. with) peripheral vascular or liver disease, with (vs. without) congestive heart failure (CHF)/cardiomyopathy or cancer. Prior to the new CMS policy, only 3.4% of dialysis patients received consistent carnitine therapy. Patients who were white, had CHF/cardiomyopathy, lower Hb levels or higher weekly EPO doses were more likely to receive carnitine.