

January 25, 2012

Pilar Williams, Chief
Pharmacy Benefits Division, MS 4604
Department of Health Care Services
P.O. Box 997413
Sacramento, CA 95899

RE: Additional clarification regarding Medi-Cal coverage of enteral nutritional supplements for dialysis patients

Dear Ms. Williams:

On behalf of the more than 50,000 dialysis patients in California, Dialysis Patient Citizens (DPC) would like to thank you for your response to our previous letters regarding Medi-Cal coverage of enteral nutritional supplements for dialysis patients. However, it has come to our attention that some dialysis patients continue to be denied coverage of these supplements that are essential for their health and well-being. DPC works to improve the quality of life of all kidney patients and access to medically necessary oral nutritional supplements is a vital part of maintaining this quality of life. We ask that additional clarification regarding Medi-Cal coverage of oral nutritional supplements for dialysis patients be given to providers and to those who review Treatment Authorization Requests (TAR) and Service Authorization Requests (SAR) submitted to the Department of Health Care Services (DHCS) to ensure all California dialysis patients receive the care they need to live full and productive lives.

As mentioned in our previous letters, we believe that patients with end stage renal disease (ESRD) qualify for Medi-Cal coverage of oral nutritional supplements due to the language in the law exempting those patients with malabsorption issues from coverage denials. In your response letter to me dated October 5, 2011, you state that “[p]atients diagnosed with kidney disease who also have the co-morbidity malabsorption diagnosis and require specialized elemental or semi-elemental enteral nutrition products” are protected under the exemption language. It is clear from this letter that the Department recognizes the need for kidney patients to have access to these life sustaining supplements, however, we are seeking additional clarification on your language concerning a “co-morbidity malabsorption diagnosis.” We strongly believe that a diagnosis of ESRD should qualify patients to receive nutritional supplements through Medi-Cal regardless of co-morbidities. Due to the nature of ESRD and the process of dialysis treatments, this beneficiary population has unique dietary needs that in many cases require supplements to ensure patients receive the necessary nutrients.

Patients on dialysis still have toxins in their bodies and suffer from depleted protein levels after the cleansing of their blood during dialysis treatments. Data from the United States Renal Data Systems shows that 78 percent of dialysis patients do not eat sufficient amounts of proteins and that 86 percent do not meet their recommended daily energy intake levels.¹ Additionally, dialysis patients have a restricted diet that limits their intake of fluids, sodium, phosphorus

¹ U.S. Renal Data System, USRDS 2008 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2008.

and other essential nutrients. For these reasons, it is our belief that by virtue of a diagnosis of ESRD, a dialysis patient should be eligible for coverage of oral nutritional supplements based on the exemption for those with malabsorption issues.

To address these concerns, the Department may want to consider making a distinction between chronic kidney disease (CKD) patients and ESRD patients on dialysis when determining coverage guidelines for these supplements. As a consequence of going through dialysis treatments several times a week, ESRD patients have a different set of nutritional considerations than those patients in the earlier stages of kidney disease. We encourage you to consider creating a specific coverage code for ESRD patients that does not require the same "co-morbidity malabsorption diagnosis" as is outlined for other kidney disease patients. These distinct coverage categories would help to ensure that those patients who truly require these nutritional supplements to maintain a high quality of life would have the access they need, while not adding additional burden to the State's budget.

Regardless of the Department's decision on distinct disease categories, additional clarification is needed to ensure patients are not being unfairly denied coverage. We are aware that some TARs and SARs submitted by patients to DHCS continue to be denied. Additional clarification should be given to providers in the Medi-Cal Provider Bulletin and Pharmacy and Allied Health Provider Manuals so that these TARs and SARs are completed correctly and submitted properly. It should be explicitly stated to providers that dialysis patients qualify for the malabsorption exemption under the law. Furthermore, clarification must be given to those at DHCS who review the TARs and SARs so that the exemption is fairly applied to all dialysis patients. It must be clearly stated to reviewers that dialysis patients are exempt from denials based on the law's exemption for those Medi-Cal patients with malabsorption issues to ensure these patients are receiving these necessary supplements.

With the right combination of dialysis treatments, prescription medications, doctor's visits and a proper nutritional regimen, dialysis patients can live full and productive lives and for this, it is crucial that patients have access to and coverage for oral nutritional supplements. Thank you again for your commitment to the health and well-being of dialysis patients covered by Medi-Cal. If you have any additional questions please feel free to contact us.

Sincerely,



Hrant Jamgochian
Executive Director

CC:

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