
SCHOOL OF MEDICINE

Department of Internal Medicine
Division of Pulmonary and Critical Care Medicine

February 17, 2011

Louis B. Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C1-09-06
Baltimore, Maryland 21244

Attn: Ms. Roya Lotfi, Lead Analyst

**Re: Formal Request for Reconsideration of National Coverage Determination (110.4):
Extracorporeal Photopheresis (ECP) for Lung Allograft Patients with Progressive
Bronchiolitis Obliterans Syndrome (BOS) Refractory to Immunosuppressive Drug
Treatment**

Dear Dr. Jacques,

Extracorporeal photopheresis (ECP) is currently covered by Medicare for three specific clinical conditions: skin manifestations of cutaneous T-cell lymphoma (CTCL) that have not responded to other therapy, acute cardiac allograft rejection refractory to standard immunosuppressive drug treatment, and chronic graft versus host disease refractory to standard immunosuppressive drug treatment.

Based on the information that follows, we formally request a reconsideration of the NCD for ECP (110.4) to include coverage for lung allograft patients with progressive bronchiolitis obliterans syndrome (BOS) that is refractory to immunosuppressive drug treatment.

Since an initial report in 1995 describing stabilization of pulmonary function in three lung transplant patients with treatment-refractory BOS, use of ECP therapy has increased in step with an expanding body of published evidence documenting its ability to stabilize or reverse deterioration of pulmonary function in the majority of patients with this very serious and difficult-to-manage condition.

While the population of post-lung transplant patients with progressive drug-refractory BOS is very small, approximately one-half of qualifying patients are Medicare beneficiaries. Currently there is widespread commercial insurance coverage of ECP for life-threatening refractory BOS, but the lack of Medicare coverage presents a serious patient access issue.

Louis B. Jacques, MD

Request for Reconsideration of NCD: Extracorporeal Photopheresis (110.4)

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We appreciate the helpful input of senior CMS staff in an informal discussion on May 21, and pursuant to their suggestions have included an extensive review of the literature to address the relationships between important health outcomes, including death, and the standard measure of pulmonary function (FEV₁) used to assess clinical utility of ECP and other treatment modalities for BOS.

If you have any questions, please direct them to Dr. Ramsey Hachem, or to any of us if he is not immediately available.

Thank you for your attention to this request for reconsideration.

Sincerely,



Ramsey R. Hachem, MD

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