Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

CONFIRMATION OF ELIGIBILITY - Case Report Form (CRF)

Important and Time-Sensitive: Please PRINT this subject's Confirmation of Eligibility (COE) Form, have an authorized physician investigator sign and date the COE form, and scan and upload the signed COE form along with the other Source Documents listed at the top of the COE Form. Per Protocol Section 3.7, submission of this signed COE Form with DCC Verification is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed. NOTE: ECP Treatment or study-related invasive procedures are not permitted for Observational Arm participants.

Please include the following types of source documents:

1. A Signed Confirmation of Eligibility Form must be uploaded
2. History and Physical Or Consultation Note
3. Operative Report of Transplant Procedure
4. Pulmonary Function Test Reports (for each FEV-1 submitted)

Source Document Type	Document Name	Submission Date

Select Source Document Type: A Signed Confirmation of Eligibility Form must be uploaded

Attach Source Document: Choose File No file chosen Upload

Save Submit

1. INCLUSION CRITERIA - all answers must be "YES" for subject to be eligible for study inclusion:

YES	NO	Age 18 years or greater
YES	NO	Medicare-eligible
YES	NO	Lung transplant recipient
YES	NO	Progressive BOS defined as ongoing decline in FEV1 despite immunosuppressive therapy
YES	NO	Has had at least 5 recorded FEV1 values post-transplant all within the last 6 months, separated by at least one week, of which one FEV1 value was recorded on or within one week prior to the day of enrollment

2. EXCLUSION CRITERIA - all answers must be "NO" for subject to be eligible for study inclusion:

YES	NO	Participant in another clinical treatment trial with an investigational agent
YES	NO	Any condition that may interfere with subject's ability to perform pulmonary function testing
YES	NO	Known allergy or hypersensitivity to pharmacologic agents used during ECP
YES	NO	Has acute condition that contraindicates ECP, including but not limited to new or evolving myocardial infarction or central nervous system disorder, hemodynamic instability or hypovolemia, acute bleeding, or respiratory distress; or other condition that poses unacceptable risk for study-related complications as judged by the referring clinician
YES	NO	Any condition that would significantly interfere with ability to adhere to the protocol or affect interpretability of the study results
YES	NO	Aphakia or absence of ocular lenses
YES	NO	Pregnancy (confirmed by a positive pregancy test)
YES	NO	Inability to provide informed consent or to comply with study treatments or assessments (e.g. due to cognitive impairment or geographic distance)
YES	NO	Recent (within the last 2 weeks) leukopenia (white blood cell count less than 4,000 cells/mm3)

3. PULMONARY EVALUATIONS - Up to 15 pulmonary evaluations were entered to determine study arm eligibility:

A. Date		**FEV1**	liters	**FVC**	liters
B. Date		**FEV1**	liters	**FVC**	liters
C. Date		**FEV1**	liters	**FVC**	liters
D. Date		**FEV1**	liters	**FVC**	liters
E. Date		**FEV1**	liters	**FVC**	liters

If additional FEV1 values have been obtained during the last 6 months, please provide:

F. Date		**FEV1**	liters	**FVC**	liters
G. Date		**FEV1**	liters	**FVC**	liters
H. Date		**FEV1**	liters	**FVC**	liters
I. Date		**FEV1**	liters	**FVC**	liters
J. Date		**FEV1**	liters	**FVC**	liters
K. Date		**FEV1**	liters	**FVC**	liters
L. Date		**FEV1**	liters	**FVC**	liters
M. Date		**FEV1**	liters	**FVC**	liters
N. Date		**FEV1**	liters	**FVC**	liters
O. Date		**FEV1**	liters	**FVC**	liters

4. CONFIRMATION OF ELIGIBILITY

A. Date eligibility status confirmed

B. Date the approved Informed Consent Form was signed by the subject

C. Informed Consent Form Version Date

D. Has the signed Confirmation of Eligibility CRF been uploaded? ○ **YES** ○ **NO**

5. INVESTIGATOR ATTESTATION

I have reviewed and confirmed that the information recorded on these CRF Pages is accurate. I attest that this patient meets all study eligibility criteria and is appropriate to enroll in the ECP Registry

Comments:

Investigator Name (please print) _____

Investigator Signature _____ **Date:** _____

Save Submit

CRF Version 5.0 (10/08/2015)