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 de-identified 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)
5. Complete Blood Count (CBC) Report
6. Source or FEV1 noting date new BOS diagnosed

Source Document Type	Document Name	Submission Date

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

Attach Source Document: Browse... No file selected. Upload

SECTION A. TRANSPLANT AND BASELINE

1. Date of lung transplantation:

2. ISHLT BASELINE MEASUREMENTS - The system will calculate the baseline pulmonary function testing results using the ISHLT definition = the average of the two highest FEV1 measurements obtained at least three weeks apart after transplantation. Please provide the results of the two component PFT assessments to be used for this calculation:

a. First component assessment:

i. Date:

ii. FEV1 (pre-bronchodilator): liters

iii. FVC (pre-bronchodilator): liters

b. Second component assessment:

i. Date:

ii. FEV1 (pre-bronchodilator): liters

iii. FVC (pre-bronchodilator): liters

c. Baseline FEV1 (pre-bronchodilator)(mean FEV1 values below): liters

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

○ YES ○ NO	Age 18 years or older
○ YES ○ NO	Medicare-eligible (i.e. patients with both Part A and B) status
○ YES ○ NO	Lung transplant recipient (combined organ transplant recipients, e.g. heart-lung or liver-lung recipients, are eligible)
○ YES ○ NO	Patients with a diagnosis of BOS using at least two laboratory based FEV1 values obtained at least three weeks apart that are both at least 20% lower than baseline FEV1 using the ISHLT definition (the average of the two highest FEV1 measurements obtained at least three weeks apart after transplantation)
○ YES ○ NO	At minimum five recorded FEV1 measurements obtained at intervals at least two weeks apart over the six months preceding study enrollment, of which one FEV1 must be within two weeks of enrollment
○ YES ○ NO	History of frequent spirometry monitoring, defined as having had regular FEV1 measurements during the preceding four months to enrollment with no time interval between FEV1 measurements that exceeds eight weeks
○ YES ○ NO	A documented clinical assessment including a physical assessment and CBC with WBC within two weeks prior to enrollment

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

○ YES ○ NO	Current participation 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 a) acute contraindication to receiving ECP due to any acute condition such as new or evolving myocardial infarction or central nervous system disorder, hemodynamic instability or hypovolemia, acute bleeding, respiratory distress; b) lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, albinism, or other dermatologic or ocular condition that contraindicates the use of methoxsalen or markedly enhances photosensitivity in the investigator's judgment; or c) 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 (a urine or blood pregnancy test must be obtained within two weeks prior to enrollment in women of childbearing potential)
○ 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 (i.e., within two weeks prior to enrollment) leukopenia (white blood cell count less than 3,000 cells/mm3)
○ YES ○ NO	Decline in lung function (FEV1) is related to either Restrictive CLAD or other causes that do not represent BOS such as pneumonia, heart failure, etc

SECTION D. BOS DIAGNOSIS INFORMATION

1. Date of diagnosis of post-transplantation BOS:

2. Laboratory-based FEV1 values used to confirm the initial diagnosis of BOS:

a. First component assessment:

i. Date:

ii. FEV1 (pre-bronchodilator): liters

iii. FVC (pre-bronchodilator): liters

b. Second component assessment:

i. Date:

ii. FEV1 (pre-bronchodilator): liters

iii. FVC (pre-bronchodilator): liters

c. Third component assessment (if needed):

i. Date:

ii. FEV1 (pre-bronchodilator): liters

iii. FVC (pre-bronchodilator): liters

SECTION E. PULMONARY EVALUATIONS

1. Please enter the FEV1 values from the oldest date at the top to the newest date at the bottom.

2. Three or more FEV1 values must have been obtained within the six months prior to the diagnosis of new BOS diagnosis and must not be greater than eight weeks apart.

3. At least 5 recorded FEV1 measurements obtained at intervals of at least two weeks apart, over the six months preceding study enrollment.

4. A minimum of two FEV1 must be obtained within six weeks of enrollment and are at least three weeks apart that are used for initial diagnosis of BOS. Therefore, the most recent FEV1 of these two must have been obtained within three weeks prior to enrollment

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
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
P. Date		**FEV1**	liters	**FVC**	liters
Q. Date		**FEV1**	liters	**FVC**	liters
R. Date		**FEV1**	liters	**FVC**	liters
S. Date		**FEV1**	liters	**FVC**	liters
T. Date		**FEV1**	liters	**FVC**	liters
U. Date		**FEV1**	liters	**FVC**	liters
V. Date		**FEV1**	liters	**FVC**	liters
W. Date		**FEV1**	liters	**FVC**	liters
X. Date		**FEV1**	liters	**FVC**	liters
Y. Date		**FEV1**	liters	**FVC**	liters
Z. Date		**FEV1**	liters	**FVC**	liters

SECTION F. CLINICAL ASSESSMENTS

1. **Date of most recent physical exam**
2. **Complete Blood Count**

Date of CBC:

WBCs: **(K/cumm)**

RBCs: **(M/cumm)**

Hemoglobin: **(g/dl)**

Platelets: **(K/cumm)**

SECTION G. 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**

SECTION H. 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:** _____