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

DEMOGRAPHICS/MEDICAL HISTORY - Case Report Form (CRF)

Please include the following types of source documents:

1. History and Physical Or Consultation Note
2. Operative Report of Transplant Procedure
3. Pulmonary Function Test Reports (for each FEV-1 submitted)

Source Document Type	Document Name	Submission Date

Select Source Document Type: History and Physical or Consultation Note

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

Save Submit

Date of Participant Enrollment in Study:

SECTION A. Demographic Information

1. Age:
2. Gender: Male Female
3. Race:
   - White
   - Black or African-American
   - Asian
   - American Indian
   - Alaska Native
   - Native Hawaiian or Other Pacific Islander
   - Other
   - No Response
4. Are you of Hispanic or Latino origin: YES NO

SECTION B. Previous Medical History and Pulmonary Function Testing Results

5. Please provide a description of the underlying disease necessitating lung transplantation:

- ☐ Chronic Obstructive Pulmonary Disease (COPD) including Emphysema
- ☐ Interstitial Lung Disease
- ☐ Cystic Fibrosis
- ☐ Pulmonary Hypertension
- ☐ Alpha 1-Antitrypsin Deficiency Emphysema
- ☐ Replacing previously transplanted lung that failed
- ☐ Other

If other, please describe:

6. Date of lung transplantation: [ ]

7. Operation performed:

- ○ Single
- ○ Bilateral
- ○ Heart-lung
- ○ Other

If other, please describe:

8. Weight at time of transplant: [ ] kilograms ☐ Not Available

9. Height: [ ] centimeters ☐ Not Available

10. Medical History - Co-Morbid Conditions at any time prior to enrollment:

○ YES	○ NO	Hypertension	
○ YES	○ NO	Diabetes	
○ YES	○ NO	GERD - if yes, treatment:	○ medical therapy ○ fundoplication
○ YES	○ NO	High Cholesterol	
○ YES	○ NO	Current Smoker	
○ YES	○ NO	Previous Smoker	
○ YES	○ NO	Coronary Artery Disease - if yes:	○ angina ○ myocardial infarction
○ YES	○ NO	Congestive Heart Failure	
○ YES	○ NO	Chronic Kidney Disease	
○ YES	○ NO	Stroke	
○ YES	○ NO	Neurologic Disorder	
○ YES	○ NO	Other Active Conditions	

If other active conditions, please describe:

11. Has the patient received any anti-platelet drug(s) within the last six months:

- YES NO **Anti-Thrombotic**
- YES NO **Anti-Platelet Agent**

12. Check all drugs that were <u>previously used as maintenance immunosuppression and/or BOS prevention</u> in this participant:

- YES NO **Tacrolimus**
- YES NO **Prednisone**
- YES NO **Alemtuzumab**
- YES NO **Sirolimus (Rapamycin)**
- YES NO **Everolimus**
- YES NO **Azathioprine**
- YES NO **Cyclosporine A**
- YES NO **Methotrexate**
- YES NO **Macrolide Antibiotic, Azithromycin**
- YES NO **Mycophenolate Mofetil (Cellcept or Myfortic)**
- YES NO **Anti-Thymocyte Globulin - ATG (Thymoglobulin or Atgam)**
- YES NO **Total Lymphoid Irradiation**
- YES NO **Other Drug(s)**

If YES for Other Drug(s), please provide the drug name(s)

13. Check all drugs that were <u>previously used as active treatment of BOS</u> in this participant:

- YES NO **Tacrolimus**
- YES NO **Prednisone**
- YES NO **Alemtuzumab**
- YES NO **Sirolimus (Rapamycin)**
- YES NO **Everolimus**
- YES NO **Azathioprine**
- YES NO **Cyclosporine A**
- YES NO **Methotrexate**
- YES NO **Macrolide Antibiotic, Azithromycin**
- YES NO **Mycophenolate Mofetil (Cellcept or Myfortic)**
- YES NO **Anti-Thymocyte Globulin - ATG (Thymoglobulin or Atgam)**
- YES NO **Total Lymphoid Irradiation**
- YES NO **Other Drug(s)**

If YES for Other Drug(s), please provide the drug name(s)

14. Has the participant received prednisone therapy within the last 6 months? ○ YES ○ NO

If yes, daily starting dose: _____ mg

15. During the last 6 months, has the patient required a prednisone dose escalation for any period of greater than 5 days? ○ YES ○ NO

If yes, to what daily dose: _____ mg

Estimate average daily dose over 6 months: _____ mg

16. Date of diagnosis of post-transplantation BOS: _____

17. Post-transplant BOS stage at diagnosis: ○ 0 ○ 0-p ○ 1 ○ 2 ○ 3

Stage	Definition
BOS Stage 0	FEV1 > 90% and FEF 25%-75% > 75% of baseline
BOS Stage 0-p	FEV1 = 81% to 90% of baseline and or FEF 25%-75% 75% of baseline
BOS Stage 1	FEV1 = 66% to 80% of baseline
BOS Stage 2	FEV1 = 51% to 65% of baseline
BOS Stage 3	FEV1 less than or equal to 50% of baseline

18. Please provide the baseline pulmonary function testing results using the ISHLT definition = the average of the two highest FEV1 measurements obtained 3 weeks apart after transplantation. Also please provide the results of the two component PFT assessments used for this calculation:

a. Baseline FEV1 (pre-bronchodilator)(mean FEV1 values below): _____ **liters**

b. First component assessment:

i. Date: _____

ii. FEV1 (pre-bronchodilator): _____ **liters**

iii. FVC (pre-bronchodilator): _____ **liters**

c. Second component assessment:

i. Date: _____

ii. FEV1 (pre-bronchodilator): _____ **liters**

iii. FVC (pre-bronchodilator): _____ **liters**

SECTION C. Clinical Status at or Within Two Weeks of Enrollment

19. Donor specific antibody at time of study enrollment? ○ YES ○ NO

20. Is the participant on any anticoagulant or anti-platelet drugs? ○ YES ○ NO

If yes, list drugs:

Name drug 1: _____

Name drug 2: _____

Name drug 3: _____

21. Date when the following baseline vital signs were obtained (values should be obtained within two weeks prior to enrollment): 11/01/2017

22. Weight: 94.0 **kilograms**

23. Blood pressure: **systolic** 120 **mmHg** **diastolic** 80 **mmHg**

24. Heart rate: 75 **beats per minute**

25. Respiratory rate: 17 **breaths per minute**

26. Resting oxygen saturation: 95 **%**

27. Is the participant receiving supplemental oxygen? ○ **YES** ◉ **NO**

If yes, how much? **Select delivery method:**

28. Comments: