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... 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
- Intersitial 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

9. Height: Centimeters

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 previously used as maintenance immunosuppression and/or BOS prevention in this participant:

- YES NO **Tacrolimus**
- YES NO **Prednisone**
- YES NO **Alemtuzumab**
- YES NO **Sirolimus (Rapamycin)**
- YES NO **Everolimus**
- YES NO **Cyclosporine A**
- YES NO **Methotrexate**
- YES NO **Macrolide Antibiotic, Azithromycin**
- YES NO **Mycophenolate Mofetil (Cellcept or Myfortic)**
- YES NO **Anti-Therymocyte Globulin - ATG (Thymoglobulin or Atgam)**

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

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

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 One Week 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 one week prior to enrollment):

22. Weight: **kilograms**

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

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

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

26. Resting oxygen saturation: **%**

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

If yes, how much? liters/minute

28. Comments:

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