

# Post-Airway Inflammatory Syndrome (PAIR) in COVERT II STUDY

For the CONVERTII Trial, this document will explain the potential adverse effect known as Post-Airway Inflammatory Syndrome (PAIR) in patients who have undergone the AeriSeal® procedure. Your vigilance and prompt management are crucial for the safety and well-being of these study participants.

## **Background: The CONVERT II Trial and AeriSeal Procedure**

As you know, our institution is a participating site for the CONVERT II Trial. This trial is evaluating the AeriSeal System, a foam-based lung sealant, to block collateral ventilation in patients with severe emphysema. The goal is to convert these patients to become eligible for subsequent treatment with Zephyr Endobronchial Valves, offering them a potential new avenue for improving lung function and quality of life. Patients undergoing the AeriSeal procedure are admitted for close monitoring post-procedure.

## **Post-Airway Inflammatory Syndrome (PAIR)**

PAIR is an acute inflammatory response that can occur following the instillation of the AeriSeal foam into the airways. It is a known potential adverse event associated with this therapy.

## **Key Signs and Symptoms of PAIR:**

It's important to be aware of the common manifestations of PAIR, which often present within the first 24-48 hours post-procedure. These include:

- **Fever:** Often an early sign.
- **Leukocytosis:** Elevated white blood cell count.
- **Elevated C-Reactive Protein (CRP):** Indicating an inflammatory response.
- **General Malaise/Flu-like Symptoms:** Patients may report feeling generally unwell, fatigued, or experiencing body aches, headache, or nausea.
- **Respiratory Symptoms:**
  - Increased shortness of breath (dyspnea)
  - Chest discomfort or pleuritic pain
  - Cough (may be new or worsening)
- **Lobar Pneumonitis:** In some cases, a localized lung inflammation in the treated lobe may be observed.

## **Monitoring and Management of PAIR:**

Patients are admitted post-AeriSeal procedure for a minimum of two nights specifically to monitor for PAIR and other potential complications.

The management of PAIR is typically supportive and follows standard medical care. Based on available literature and clinical experience with lung sealants, the following approaches are often employed:

1. **Close Observation and Symptomatic Treatment:**

- Regular monitoring of vital signs, oxygen saturation, respiratory status, and laboratory markers (CBC, CRP).
  - Administer antipyretics for fever and analgesics for pain as needed.
1. **Corticosteroids:**
    - Systemic corticosteroids (e.g., oral prednisolone, typically around 30mg daily) are used prophylactically to manage the inflammatory response.
  3. **Broad-Spectrum Antibiotics:**
    - While PAIR is primarily an inflammatory rather than an infectious process, broad-spectrum antibiotics are often administered prophylactically or **if an infection cannot be definitively ruled out**, especially in the presence of fever and leukocytosis. This is a supportive measure, as cultures may not yield a specific pathogen.
  3. **Respiratory Support:**
    - Supplemental oxygen if required to maintain adequate oxygen saturation.
    - Ensure continuation of usual COPD/emphysema medications unless contraindicated.

**Expected Course:**

With appropriate supportive management, the symptoms of PAIR typically resolve within 24-48 hours, although in some instances, they may persist for several days. Continued monitoring is essential until clinical and laboratory parameters normalize.

**Communication:**

Please ensure any suspected cases of PAIR or other significant adverse events are promptly communicated to the CONVERT II Trial Assigned IP Staff Call or Principal Investigator (Avi Cohen). This allows for appropriate reporting and ensures consistent management.

Your expertise in managing these complex respiratory patients is highly valued. This refresher is intended to support your critical role in the CONVERT II Trial. Please do not hesitate to reach out if you have any questions or require further clarification.