

DALIRESP® (roflumilast)

**GPI CODING:**

44450065000320

**DESCRIPTION:**

Roflumilast is a phosphodiesterase-4 (PDE-4) inhibitor. The mechanism by which roflumilast and its active metabolite (roflumilast N-oxide) reduce inflammation in lung tissue is by selectively inhibiting PDE-4, leading to accumulation of intracellular cyclic AMP (cAMP). Intracellular cyclic-3',5'-adenosine monophosphate (cyclic AMP) in turn activates protein kinase A (PKA) phosphorylating key cellular proteins leading to a broad suppression of inflammatory cell activity (Trophy et al, 2001). Anti-inflammatory effects include suppression of cytokine release and inhibition of lung infiltration by neutrophils and other leukocytes.

**APPROVAL DURATION:**

Approval duration: lifetime

Quantity limit: 30 tablets per 30 days.

**CRITERIA FOR DARILESP:**

- I. Patient is  $\geq 18$  years of age **AND**
- II. Patient has a diagnosis of severe COPD (defined as  $FEV_1 \leq 50\%$  of predicted and  $FEV_1/FVC < 0.7$ ) associated with chronic bronchitis **AND**
- III. Patient has a history of COPD exacerbations which required the use of systemic corticosteroids **AND**
- IV. Roflumilast is being used as adjunctive therapy to bronchodilator treatment (i.e. anticholinergics in combination with long-acting beta<sub>2</sub> agonists or inhaled corticosteroids; or inhaled corticosteroid long-acting beta<sub>2</sub> agonist combinations) to reduce the risk of COPD exacerbations **AND**
- V. Patient does NOT have moderate to severe liver impairment (Child-Pugh B or C)

Roflumilast is not approved for use in any of the following:

- I. Asthma
- II. Pulmonary fibrosis
- III. Non-insulin dependent diabetes
- IV. Relief of acute bronchospams