

## Roflumilast (Daliresp®) Criteria for Use

**VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives**

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.***

*The Product Information should be consulted for detailed prescribing information.*

### **Exclusion Criteria (If the answer to ANY item below is met, then the patient should NOT receive roflumilast)**

- Asthma without COPD
- Moderate-severe hepatic impairment (Child Pugh B or C)
- Women who are nursing
- Patient **with** a mental health disorder such as, but not limited to, psychotic disorder, bipolar disorder, major depressive disorder, or PTSD (or prior suicide attempt more than 12 months prior to prescribing) or positive PHQ-2 screening for depression [http://www.cqaimh.org/pdf/tool\\_phq2.pdf](http://www.cqaimh.org/pdf/tool_phq2.pdf) or positive PTSD screen <http://www.ptsd.va.gov/professional/provider-type/doctors/screening-and-referral.asp>

*‡Suicidal ideation and behavior, including completed suicide were reported in clinical trials. Three completed suicides (1 while on drug and 2 > 20 days after discontinuation) and 2 suicide attempts occurred in patients receiving roflumilast compared to 1 patient experiencing suicidal ideation in the placebo group. Among the 5 patients, 4 either had depression, were taking medications to treat depression or receiving medications associated with causing depression. Cases of suicidal ideation and behavior, including completed suicide, have been observed in the post-marketing setting in patients with or without a history of depression.*

### **Inclusion Criteria ( ALL of the following must be met in order to meet criteria)**

- Provider is a pulmonologist (or designated expert)
- COPD associated with chronic bronchitis (daily cough with production of sputum for 3 months, two years in a row)
- FEV1 ≤ 50% predicted
- ≥ 1 recorded COPD exacerbation requiring systemic steroids, unscheduled healthcare contact, or hospitalization in the previous year
- Maintenance bronchodilator therapy optimized (inhaled anticholinergics, long-acting beta-agonists)
- Inhaled corticosteroid therapy optimized\*\*

*\*\*Those unable to use inhaled corticosteroids (e.g., allergy to inhaled steroids, unable to use metered-dose and dry powder inhalers, etc.) or use of inhaled corticosteroids is inappropriate may receive roflumilast provided the other inclusion criteria are met*

### **Dosage and Administration**

One 500mcg tablet per day with or without food

### **Issues for Consideration**

- Roflumilast should not be used to treat acute bronchospasm
- Patients, families, and caregivers must be made aware of the possibility of emergence or worsening of insomnia, anxiety, depression, suicidal thoughts or other mood changes AND to contact their healthcare provider should such changes occur. Continued treatment with roflumilast should be carefully evaluated if such events occur.
- Patients should have their weight monitored regularly. Weight loss should be evaluated if unexplained or clinically significant weight loss occurs, and discontinuation of roflumilast should be considered.
- Roflumilast should not be used during labor and delivery (is a tocolytic in mice at exposures similar to humans)
- Consider risk versus benefit of using roflumilast in patients with mild hepatic impairment (Child-Pugh A)
- Roflumilast is metabolized by CYP3A4 and CYP1A2. Co-administration of drugs that inhibit these isoenzymes could lead to increased roflumilast exposure. Providers should weigh the benefits against the risks of such combinations.
- Co-administration of strong inducers of CYP3A4 and CYP1A2 with roflumilast decreases systemic concentration of roflumilast and may reduce its efficacy; therefore, concurrent use is not recommended.
- Do not co-administer with theophylline