

Roflumilast (Daliresp)

Criteria for Use

January 2022

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 USE 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

- Asthma without Chronic Obstructive Pulmonary Disease (COPD)
- Moderate-severe hepatic impairment (Child-Pugh B or C)
- Coadministration of strong CYP450 inducers¹
- Treatment of acute bronchospasm
- History of depression, anxiety, suicidal thoughts or behavior, unless determined, in consultation with a mental health specialist, that roflumilast can be used^{2,3}
- Pregnant or nursing

¹In addition, consider risk versus benefit of co-administration of CYP3A4 or dual CYP3A4/CYP1A2 **inhibitors** or oral contraceptives containing gestodene and ethinyl estradiol

²Insomnia and anxiety are commonly reported psychiatric adverse reactions. Use cautiously, if at all, in patients with anxiety, insomnia, depression, or suicidal ideation or behavior. Inform patients, families, or caregivers to be alert for emergence or worsening of insomnia, anxiety, depression, suicidal thoughts, or other mood changes, and to contact their healthcare provider if such changes occur.

³Although not part of the product labeling, use with caution in patients with other mental health disorders (e.g., psychotic disorder, bipolar disorder, PTSD, etc.), especially if not fully controlled. Discussion with mental health provider may be appropriate.

Inclusion Criteria

The answers to all of the following must be fulfilled in order to meet criteria.

- Care is provided by a VA/VA Community Care pulmonologist (or designated expert)
- COPD associated with chronic bronchitis (daily cough with production of sputum for 3 months, two years in a row)
- FEV1 less than or equal to 50% predicted
- At least 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 unless use determined to be medically inappropriate

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