# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME***
**(generic)**

**DALIRESP**
**(roflumilast)**

***Status: CVS Caremark Criteria***
***Type: Initial Prior Authorization*** ***Ref # 646-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

## FDA-APPROVED INDICATIONS

Daliresp is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

Limitations of Use

Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

## COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in a patient with severe COPD associated with chronic bronchitis and a history of exacerbations

## RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Daliresp is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

## REFERENCES


1. Daliresp [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, January 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed March 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed March 2020.


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| Written by: | UM Development (RP) |
| Date Written: | 04/2011 |
| Revised: | (RP) 06/2011 (revised question #2, added question #3), 02/2012, 10/2012 (extended duration); (RP) 02/2013, (TM) 11/2013; (RP) 11/2014, 11/2015 (no clinical changes), 11/2016, 11/2017 (no clinical changes); (KC) 11/2018 (no clinical changes), 04/2019 (changed DOA to 12 months); (RP) 03/2020 (no clinical changes) |
| Reviewed: | Medical Affairs (KP) 04/2011, 06/2011, 02/2012, 10/2012; (LS) 02/2013, (DC) 11/2013; (LMS) 11/2014; (ME) 11/2016; (GAD) 04/2019; (CHART) 03/26/2020<br>External Review: 06/2011, 06/2012, 06/2013, 04/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019, 06/2019, 06/2020 |

**CRITERIA FOR APPROVAL**

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|---|---|---|---|
| 1 | Is the requested drug being prescribed to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in a patient with severe COPD associated with chronic bronchitis and a history of exacerbations? | Yes | No |

| Mapping Instructions | | | |
|---|---|---|---|
| | **Yes** | **No** | **DENIAL REASONS – DO NOT USE FOR MEDICARE PART D** |
| 1. | Approve, 12 months | Deny | You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions:<br>- You have severe chronic obstructive pulmonary disease (COPD)<br>- Your condition is associated with chronic bronchitis and a history of exacerbations<br>Your request has been denied based on the information we have.<br>[Short Description: No approvable diagnosis] |