PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

DALIRESP
(roflumilast)

Status: CVS Caremark Criteria ***MDC-1***
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*

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.

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

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

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; August 2017.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 2017.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed November 2017.

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)
Reviewed:	Medical Affairs (KP) 04/2011, 06/2011, 02/2012, 10/2012; (LS) 02/2013, (DC) 11/2013; (LMS) 11/2014; (ME) 11/2016 External Review: 06/2011, 06/2012, 06/2013, 04/2014, 02/2015, 02/2016, 02/2017, 02/2018

CRITERIA FOR APPROVAL

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

Guidelines for Approval	
Duration of Approval	**36 Months**
Set 1	
Yes to question(s)	**No to question(s)**
1	None

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 36 months	Deny	Your plan covers this drug when you meet all of these conditions: - You have severe chronic obstructive pulmonary disease (COPD) - Your condition is associated with chronic bronchitis and a history of exacerbations Your use of this drug does not meet the requirements. This is based on the information we have.