Daliresp (roflumilast)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Daliresp (roflumilast)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Daliresp (roflumilast) may be approved when the following criteria are met:

- I.   Individual has been diagnosed with severe to very severe (GOLD 2021) chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis; **AND**
- II.   Individual has a history of exacerbations; **AND**
- III. Individual is currently or will be concomitantly using with a long-acting bronchodilator. (GOLD 2021).

Daliresp (roflumilast) may not be approved for the following:

- I.   Individual has a diagnosis of moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment; **OR**
- II.   Individual will be concomitantly using with a strong cytochrome P450 enzyme inducer (such as but not limited to phenobarbital, carbamazepine, phenytoin); **OR**
- III. Individual is requesting to treat acute bronchospasm.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 1, 2021.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2021. Available from: Available from: http://goldcopd.org. Accessed on: January 2, 2021.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.