

Alaska Medicaid

**DALIRESP®(roflumilast)**  
Available 500mcg tablets

**INDICATIONS and USAGE:**

“ 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.”<sup>1</sup>

- Daliresp is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C)
- Daliresp should not be used during pregnancy, labor or delivery, or by nursing mothers because excretion of roflumilast and/or its metabolites into human milk is probable.

**Criteria for Approval:**

1. Diagnosis of approved indication; **AND**
2. Spirometry results supporting diagnosis of severe COPD<sup>2</sup>; **AND**
  - a.  $FEV_1/FVC < 0.70$  **OR**
  - b.  $FEV_1 < 50\%$  predicted on post-bronchodilator  $FEV_1$
3. Current therapy with Long-acting bronchodilator therapy; **AND**
4. History of COPD exacerbations of two or more in the last 12 months

**Length of Authorization:**

1. Coverage may be approved for up to 12 months

**Dispensing Limit:**

1. The dispensing limit is a 30 day supply of medication with a **Quantity Limit of 1 per day.**

**References:**

<sup>1</sup> Daliresp® package insert is available at: <[http://www.frx.com/pi/Daliresp\\_pi.pdf](http://www.frx.com/pi/Daliresp_pi.pdf) >  
Accessed 8/31/12

<sup>2</sup> GOLD Spirometry Guide is available at:< <http://www.goldcopd.org/other-resources-gold-spirometry-guide.html> >  
Accessed 9/4/12