#### 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:**

Accessed 9/4/12

Daliresp criteria Version 1 Last updated 8/2/2012 Approved 11/16/2012

<sup>&</sup>lt;sup>1</sup> Daliresp® package insert is available at: < <a href="http://www.frx.com/pi/Daliresp\_pi.pdf">http://www.frx.com/pi/Daliresp\_pi.pdf</a> > Accessed 8/31/12

<sup>&</sup>lt;sup>2</sup> GOLD Spirometry Guide is available at:< <a href="http://www.goldcopd.org/other-resources-gold-spirometry-guide.html">http://www.goldcopd.org/other-resources-gold-spirometry-guide.html</a> >