PAC Instructions

roflumilast (Daliresp)

Policy Type: PA

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit
generic roflumilast	To reduce the risk of Chronic Obstructive Pulmonary Disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations	250 mcg tablet	Initial PA #1: 30 tablets/30 days* for one month at GPI-14
			<i>Initial PA #2</i> : none for this strength, see 500mcg tablet
			Renewal: no renewal
		500 mcg tablet	<i>Initial PA #2</i> : 30 tablets/30 days for months 2-12 at GPI-14
			<i>Renewal</i> : 30 tablets/30 days at GPI-14
roflumilast (Daliresp)		250 mcg tablet	Initial PA #1: 30 tablets/30 days* for one month at GPI-14
			<i>Initial PA #2</i> : none for this strength, see 500mcg tablet
			<i>Renewal</i> : no renewal
		500 mcg tablet	<i>Initial PA #2</i> : 30 tablets/30 days for months 2-12 at GPI-14
			<i>Renewal</i> : 30 tablets/30 days at GPI-14

*Coverage of 250 mcg daily dose limited to one month for medication titration; quantity exceptions not allowed.

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Additional Notes:

• The 250mcg tablet is to be used for initial dose titration for one month; thereafter, 500 mcg daily is used for maintenance. A 250mcg daily maintenance or quantity exceptions to utilize two x 250 mcg tablets daily are <u>not covered</u>. The 500mcg tablet is administered once daily and has an extended half-life, eliminating the need for twice daily dosing. Additionally, the 500mcg tablet is more cost efficient.