



BlueCross BlueShield
of Kansas City

An Independent Licensee of the
Blue Cross and Blue Shield Association

Daliresp (roflumilast)

Policy Number: 5.01.548
Origination: 06/2013

Last Review: 04/2014
Next Review: 04/2015

Policy

BCBSKC will provide coverage for Daliresp (roflumilast) when it is determined to be medically necessary because the following criteria are met.

When Policy Topic is covered:

The use of Daliresp may be considered **medically necessary** for the following:

COPD. Approve in patients who meet ALL of the following conditions (a, b, c, d, e, and f):

- a) Patient has severe COPD (defined as an FEV₁ < 50% predicted) or very severe COPD (defined as FEV₁ < 30% predicted), AND
- b) Patient has chronic bronchitis, AND
- c) Patient has a history of exacerbations, AND
- d) Patient has tried a long-acting beta₂-agonist (LABA) [e.g., salmeterol, formoterol], AND
- e) Patient has tried a long-acting anticholinergic (e.g., tiotropium), AND,
- f) Patient has tried an inhaled corticosteroid (ICS) [e.g., fluticasone].

When Policy Topic is not covered:

The use of Daliresp is considered **investigational** for all other indications including:

1. **Asthma.** The efficacy of roflumilast (formulation not specified) in patients with asthma⁵⁻⁶, allergic asthma⁷, and exercise-induced asthma⁸ has been evaluated. More data are needed to define the place in therapy of Daliresp in the treatment of asthma.
2. **Allergic rhinitis.** A small study (n = 25) concluded that roflumilast (formulation not specified) effectively controls symptoms of allergic rhinitis.⁹ More data are needed to define the place in therapy of Daliresp in the treatment of allergic rhinitis.

Considerations

Daliresp requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Daliresp, an oral selective phosphodiesterase-4 (PDE-4) inhibitor, is indicated as a treatment 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.¹ Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

Rationale

Daliresp has been studied in patients currently receiving treatment with short-acting bronchodilators and/or long-acting beta₂-agonists (LABAs), as well as add-on therapy to salmeterol or tiotropium.²⁻³ In the two primary pivotal studies, eligible patients had a clinical diagnosis of COPD (confirmed with a post-bronchodilator [albuterol 400 mcg] forced expiratory volume in 1 second [FEV₁]/forced vital capacity [FVC] ratio ≤ 70%), chronic cough and sputum production, and a post-bronchodilator FEV₁ of ≤ 50% of the predicted value.² All patients had at least one recorded COPD exacerbation requiring systemic glucocorticosteroids and/or treatment in the hospital in the previous year. Patients could continue using short-acting beta₂-agonists (SABAs) as needed, and LABAs or short-acting anticholinergics at stable doses. In two add-on studies, eligible patients had a post-bronchodilator FEV₁ of 40% to 70% of predicted, postbronchodilator FEV₁/FVC ratio ≤ 70%, and fixed airway obstruction (defined as an increase in baseline FEV₁ of ≤ 12% or ≤ 200 mL after receiving albuterol 400 mcg).³ Daliresp was studied as add-on therapy to salmeterol or tiotropium.

Guidelines

The 2011 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines state that the PDE-4 inhibitor Daliresp may be used to reduce exacerbations for patients with chronic bronchitis, severe and very severe COPD, and frequent exacerbations that are not adequately controlled by long-acting bronchodilators.⁴ For patients that have few symptoms but a high risk of exacerbations, the first choice treatments are an inhaled corticosteroid (ICS) plus LABA or a long-acting anticholinergic. Second choice treatment is a long-acting anticholinergic and LABA. Alternative treatments (to be used alone or in combination with other first or second choice options) include a PDE-4 inhibitor or theophylline. For patients that have many symptoms and a high risk of exacerbations, the first choice treatments are an ICS plus LABA or a long-acting anticholinergic. Second choice treatments include: a) ICS and long-acting anticholinergic; b) ICS plus LABA and long-acting anticholinergic; c) ICS plus LABA and PDE-4 inhibitor; d) long-acting anticholinergic and LABA; or e) long-acting anticholinergic and PDE-4 inhibitor.

References:

1. Daliresp[®] tablets [package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc.; September 2011.
2. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. National Institutes of Health, National Heart, Lung, and Blood Institute; 2011. Available at: <http://www.goldcopd.com>. Accessed on June 14, 2012.
3. Bateman ED, Izquierdo JL, Harnest U, et al. Efficacy and safety of roflumilast in the treatment of asthma. *Ann Allergy Asthma Immunol*. 2006;96:679-686.
4. Bousquet J, Aubier M, Sastre J, et al. Comparison of roflumilast, an oral anti-inflammatory, with beclomethasone dipropionate in the treatment of persistent asthma. *Allergy*. 2006;61:72-78.
5. Van Schalkwyk E, Strydom K, Williams Z, et al. Roflumilast, an oral, once-daily phosphodiesterase 4 inhibitor, attenuates allergen-induced asthmatic reactions. *J Allergy Clin Immunol*. 2005;116:292-298.
6. Timmer W, Leclerc V, Birraux G, et al. The new phosphodiesterase 4 inhibitor roflumilast is efficacious in exercise-induced asthma and leads to suppression of LPS-stimulated TNF-alpha ex vivo. *J Clin Pharmacol*. 2002;42:297-303.
7. Schmidt BMW, Kusma M, Feuring M, et al. The phosphodiesterase 4 inhibitor roflumilast is effective in the treatment of allergic rhinitis. *J Allergy Clin Immunol*. 2001;108:530-536.
8. Calverley PM, Rabe KF, Goehring UM, et al. Roflumilast in symptomatic chronic obstructive pulmonary disease: two randomized clinical trials. *Lancet*. 2009;374:685-694.
9. Fabbri LM, Calverley PMA, Izquierdo-Alonso JL, et al. Roflumilast in moderate-to-severe chronic obstructive pulmonary disease treated with longacting bronchodilators: two randomized clinical trials. *Lancet*. 2009;374:695-703.

Billing Coding/Physician Documentation Information

N/A Daliresp is considered a pharmacy benefit.

Additional Policy Key Words

Policy Number:

Related Topics

N/A

Policy Implementation/Update Information

06/2013 New Policy titled Daliresp
04/2014 Reviewed – no changes made

This Medical Policy is designed for informational purposes only and is not an authorization, an explanation of benefits, or a contract. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there is any exclusion or other benefit limitations applicable to this service or supply. Medical technology is constantly changing and Blue Cross and Blue Shield of Kansas City reserves the right to review and revise medical policy. This information is proprietary and confidential and cannot be shared without the written permission of Blue Cross and Blue Shield of Kansas City.