Clinical Policy: roflumilast (Daliresp®)
Reference Number: ERX.NSMN.20
Effective Date: 12/15
Last Review Date: 09/16

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This policy is current at the time of approval, may be updated and therefore is subject to change. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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Description
The intent of the criteria is to ensure that patients follow selection elements established by Envolve Pharmacy Solutions for the use of roflumilast (Daliresp®).

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that roflumilast (Daliresp®) is medically necessary for members meeting the following criteria:

Initial Approval Criteria (must meet all):
A. Diagnosis of chronic obstructive pulmonary disease (COPD);
B. Age ≥ 18 years;
C. FEV₁ < 50% within the last 30 days;
D. Failure of ≥ 12 weeks of adherent use of one of the following:
   a. PDL combination inhaled corticosteroid (ICS)/long-acting beta₂ adrenergic agonist (LABA) agent;
   b. PDL combination inhaled long-acting anticholinergic/LABA;
   c. PDL inhaled long-acting anticholinergic;
   d. PDL LABA;
E. Use of a combination ICS/LABA agent, combination inhaled long-acting anticholinergic/LABA agent, inhaled long-acting anticholinergic, or LABA for ≥ 30 days in the last 60 days;
F. Daliresp will be used concurrently with an agent containing a LABA or long-acting anticholinergic;
G. Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: 12 months
Continued Approval (must meet all):
   A. Previously received medication via health plan benefit or member has previously met all initial approval criteria;
   B. Daliresp is used concurrently with an agent containing a LABA or long-acting anticholinergic as evidenced by pharmacy claims history or documentation from prescriber;
   C. If request is for a dose increase, request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: 12 months

Workflow Document

Background
Description/Mechanism of Action
Roflumilast is a first in class phosphodiesterase-4 (PDE4) inhibitor. The PDE4 enzyme is preferentially expressed in pro-inflammatory cells; inhibition results in intracellular accumulation of cyclic-AMP, a process which appears to down-regulate inflammation.

FDA Approved Indications
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. Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

References

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<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>Policy created.</td>
<td>09/15</td>
<td>12/15</td>
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<tr>
<td>Updated to new template (converted algorithm to bulleted criteria, added background and references). Modified trial/failure criteria to include LABA and combination inhaled long-acting anticholinergic/LABA agents and added requirement for concurrent use.</td>
<td>07/16</td>
<td>09/16</td>
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<td>use of Daliresp with a long-acting bronchodilator (LABA or long-acting anticholinergic) per GOLD guidelines.</td>
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