Long-acting Beta-agonist/Corticosteroid Combination (LABA/ICS)

Goals:
- Promote use that is consistent with Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines. See also: [http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html](http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html)
- Step-therapy required prior to coverage:
  - Asthma: short-acting beta-agonist and inhaled corticosteroid or moderate to severe persistent asthma.
  - COPD: short-acting bronchodilator and previous trial of a long-acting bronchodilator (inhaled anticholinergic or beta-agonist) or GOLD C/D COPD. Preferred LABA/ICS products do NOT require prior authorization.

Length of Authorization:
- Up to 12 months

Requires PA:
- Non-preferred LABA/ICS products

Covered Alternatives:
- Preferred alternatives listed at [http://www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

### Approval Criteria

<table>
<thead>
<tr>
<th>1. What diagnosis is being treated?</th>
<th>Record ICD10 Code</th>
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<tbody>
<tr>
<td>2. Will the provider consider a change to a preferred product?</td>
<td>Yes: Inform provider of covered alternatives in class</td>
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<td>Message:</td>
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<tr>
<td>- Preferred products do not require PA or a copay.</td>
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<td>- Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&amp;T) Committee.</td>
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<tr>
<td>3. Does the patient have a diagnosis of asthma or reactive airway disease (<a href="https://icd.who.int//codes-J440-J4522,J45901-45998">ICD10</a>)?</td>
<td>Yes: Go to #7</td>
</tr>
</tbody>
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| Approval Criteria                                                                 | Yes: Go to #5                                                                 | No: Pass to RPh. Deny; medical appropriateness.  
|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| 4. Does the patient have a diagnosis of COPD (ICD10 J449), chronic bronchitis (ICD10 J410-418, J42, J440-449) and/or emphysema (ICD10 J439)? | Yes: Go to #5                                                                 | No: Pass to RPh. Deny; medical appropriateness.  
| 5. Does the patient have an active prescription for an on-demand short-acting bronchodilator (anticholinergic or beta-agonist)? | Yes: Go to #6                                                                 | No: Pass to RPh. Deny; medical appropriateness.  
| 6. Is there a documented trial of an inhaled long-acting bronchodilator (anticholinergic or beta-agonist), or alternatively has the patient been assessed with GOLD C/D COPD? | Yes: Approve for up to 12 months. Stop coverage of all other LABA and ICS inhalers. | No: Pass to RPh. Deny; medical appropriateness.  
| 7. Does the patient have an active prescription for an on-demand short-acting beta-agonist (SABA) or an alternative rescue medication for acute asthma exacerbations? | Yes: Go to #8                                                                 | No: Pass to RPh; Deny, medical appropriateness.  
| 8. Is there a documented trial of an inhaled corticosteroid (ICS) or does the patient have moderate to severe persistent asthma (Step 3 or higher per NIH EPR 3)? | Yes: Approve for up to 12 months. Stop coverage of all other ICS and LABA inhalers. | No: Pass to RPh; Deny, medical appropriateness.  

_P&T/DUR Review:_ 11/15 (KS); 9/15; 11/14; 11/13; 5/12; 9/09; 2/06  
_Implementation:_ TBD; 1/15; 1/14; 9/12; 1/10
**Goals:**
- Promote COPD therapy that is consistent with Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines. See also: [http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html](http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html)
- Step-therapy required prior to coverage:
  - COPD: short-acting bronchodilator and previous trial of a long-acting bronchodilator (inhaled anticholinergic or beta-agonist) or GOLD C/D COPD. Preferred LAMA and LABA products do NOT require prior authorization.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All LAMA/LABA products

**Covered Alternatives:**
- Preferred alternatives listed at [http://www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

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### Approval Criteria

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<td>1. What diagnosis is being treated?</td>
<td>Record ICD10 Code</td>
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</table>
| 2. Will the prescriber consider a change to a preferred product? | Yes: Inform prescriber of preferred LAMA and LABA products in each class  
No: Go to #3 |

**Message:**
- Preferred products do not require PA or a copay.
- Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee.
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<td><strong>3.</strong> Does the patient have a diagnosis of asthma or reactive airway disease (ICD10 J440-J4522, J45901-45998)?</td>
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</table>
| Yes: Pass to RPh. Deny; medical appropriateness.  
Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. |
| No: Go to #4 |
| **4.** Does the patient have a diagnosis of COPD (ICD10 J449), chronic bronchitis (ICD10 J410-418, J42, J440-449) and/or emphysema (ICD10 J439)? |
| Yes: Go to #5  
No: Pass to RPh. Deny; medical appropriateness.  
Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. |
| **5.** Does the patient have an active prescription for an on-demand short-acting bronchodilator (anticholinergic or beta-agonist)? |
| Yes: Go to #6  
No: Pass to RPh. Deny; medical appropriateness. |
| **6.** Has the patient been assessed with GOLD C/D COPD? |
| Yes: Approve for up to 12 months. Stop coverage of all other LAMA and LABA inhalers.  
No: Go to #7 |
| **7.** Is there a documented trial of a LAMA or LABA, or alternatively a trial of a fixed dose combination short-acting anticholinergic with beta-agonist (SAMA/SABA) (ie, ipratropium/albuterol)? |
| Yes: Approve for up to 12 months. Stop coverage of all other LAMA and LABA inhalers or scheduled SAMA/SABA inhalers (PRN SABA or SAMA permitted).  
No: Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 11/15 (KS); 9/15; 11/14; 11/13; 5/12; 9/09; 2/06  
Implementation: TBD; 1/15; 1/14; 9/12; 1/10*