289 LaClair Coos Bay OR 97420
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Non-Preferred Inhaler Drug Use Criteria

Created: May 19, 2021
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Includes:

Brand©	Generic	FDA-Approved Indication
Advair Diskus© 500/50	*fluticasone/salmeterol*	*asthma and COPD*
Advair HFA©	*fluticasone/salmeterol*	*asthma*
Asmanex HFA©	*mometasone*	*asthma*
Asmanex Twisthaler©	*mometasone*	*asthma*
Atectura Breezhaler©	*mometasone/indacaterol*	*asthma*
Breo Ellipta©	*fluticasone furoate/vilanterol*	*asthma and COPD*
Dulera ©	*mometasone/formoterol*	*asthma*
Flovent Diskus© 250mcg	*fluticasone*	*asthma*
Pulmicort Flexhaler©	*budesonide*	*asthma*
Spiriva Respimat©	*tiotropium*	*asthma and COPD*
Wixela Inhub©	*fluticasone propionate/salmeterol*	*asthma and COPD*

*****Preferred short-acting beta agonist (SABA):**

- Albuterol HFA approved for rescue in asthma or COPD

*****Preferred inhaled corticosteroids (ICS):**

- Alvesco© (ciclesonide) FDA approved for asthma in patients aged 12 and up.
- Flovent Diskus© (fluticasone) 50mcg and 100mcg. Both are FDA approved for asthma in patients aged 4 and up.
- Fluticasone HFA FDA approved for asthma in patients aged 4 and up.
- Qvar FDA approved for asthma in patients aged 4 and up.

*****Preferred inhaled corticosteroid/long-acting beta agonist (ICS/LABA):**

- Fluticasone/salmeterol (AirDuo RespiClick©) FDA approved for asthma in patients 12 and up.
- Fluticasone/salmeterol (Advair Diskus©) 100mcg/50mcg and 250mcg/50mcg. Both strengths are FDA approved for asthma and COPD in patients aged 4 and up.
- Budesonide/formoterol FDA approved for asthma in patients aged 4 and up. Also approved for COPD in adults 18 years and older.

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*****Preferred long acting antimuscarinic (LAMA):**

- Incruse Ellipta© FDA approved for COPD in adults 18 years and older.
- Tiotropium handihaler FDA approved for COPD in adults 18 years and older.

*****Preferred long acting antimuscarinic/long-acting beta agonist (LAMA/LABA):**

- Anoro Ellipta© (umeclidinium/vilanterol) FDA approved for COPD in adults 18 years and older.
- Stiolto Respimat© (tiotropium/olodaterol) FDA approved for COPD in adults 18 years and older.

GUIDELINE FOR USE:

Initial Request:

1. Is the medication prescribed for a funded condition?
    a. If yes, go to 3
    b. If no, go to 2

2. Is there a comorbid condition that would allow coverage of the medication?
    a. If yes, go to 3
    b. If no, deny as not meeting criteria. The Oregon Health Plan does not pay for treatment of this condition.

3. Is the medication prescribed for an FDA-approved indication?
    a. If yes, go to 4
    b. If no, deny as criteria not met. Off-label use of medication is not a covered benefit under the Oregon Health Plan.

4. Has the member had an adequate trial and failure of a preferred inhaler? ~~or is medical necessity for requested inhaler included in submitted documentation? (generic AirDuo Respiclick©, generic Advair Diskus©, Flovent Diskus©, Alvesco©, fluticasone HFA, or budesonide/formoterol)? (Adequate trial is defined as adherent to therapy for at least 90 consecutive days and documentation of persistent symptoms).~~
    a. If yes, ~~and the request is for a low or medium dose ICS or ICS/LABA~~, approve for up to ~~6 months~~ 12 months.
    b. ~~If yes, and the request is for a high dose ICS alone. If no recent history of exacerbation, recommend change to medium dose ICS/LABA combination. If agreeable to change, approve for up to 6 months. If current or recent history of exacerbation (documentation of hospitalization or oral steroids), approve for up to 3 months.~~ If no, deny as criteria not met. Recommend trial of formulary alternative based on the below table:

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Medication Class	Criteria	Recommendation
Short-Acting Beta-Agonists (SABA)*	**Asthma:** rescue **COPD:** rescue; **Group A****	Preferred: albuterol (step therapy required for levalbuterol)
anti-inflammatory reliever (AIR) ^	**Asthma:** rescue	budesonide/formoterol
Inhaled Corticosteroids (ICS)	**Asthma:** Persistent asthma	See "Preferred ICS" products section
ICS/LABA Combination Inhalers	**Asthma:** not adequately controlled on ICS alone. **COPD:** asthma overlap. ICS/LABA is not encouraged in COPD.^^ ~~Moderate to severe disease with 1 or more exacerbation in the past year or asthma-COPD overlap~~	See "Preferred ICS/LABA" products section
Long-Acting Muscarinic Antagonists (LAMA)	**COPD:** Moderate to severe airflow limitation	See "Preferred LAMA" products section
LABA/LAMA Combination Inhalers	**COPD: Group B or E**;** not adequately controlled on monotherapy	See "Preferred LABA/LAMA" products section
Triple Therapy (ICS + LABA + LAMA)	**Asthma:** add-on therapy for patients 6 or older with severe asthma, not controlled on ICS/LABA . Requires specialist documentation and adequate trial with first line therapy. **COPD: Group E****; continued symptoms or exacerbations despite trial with good compliance on dual therapy (LABA/LAMA) and/ or eosinophil count ≥ 300 cells/microL	PA required

*SABA-only treatment is not recommended by GINA for adults, adolescents or children 6-11 years with asthma.

^anti-inflammatory reliever (AIR): ~~preferred controller option.~~ Low dose ICS-formoterol or low-dose ICS with as needed SABA relieves symptoms and reduces inflammation in patients with asthma. AIR with ICS-formoterol or low dose ICS with as needed SABA significantly reduces the risk of severe exacerbations across treatment steps, compared with SABA (albuterol) alone in asthma.

**GOLD assessment tool is based on symptoms (mMRC or CAT), severity of airflow (GOLD grades 1-4) and frequency of exacerbations.

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^^ICS/LABA is not encouraged in COPD per GOLD guidelines. If there is an indication for an ICS then LAMA/LABA/ICS has been shown to be superior to ICS/LABA and therefore is the preferred choice.

Renewal Request:

1. Has pulmonary condition improved and is there support for continued therapy?
    a. Yes, approve for up to 6 months for treatment of asthma.
    b. Yes, approve for 12 months for treatment of COPD.
    c. No, deny as criteria not. Chart notes submitted do not support that the condition has improved or that there is a need for continued therapy. Recommend formulary alternative or forward to MD for review.

Rationale:

To ensure medical appropriateness for use of inhalers and optimization of less costly formulary alternatives.

FDA Approved Indications:

Please see individual FDA-approved package inserts for prescribing information.

Mechanism of Action:

Please see individual FDA-approved package inserts for prescribing information.

Dosing:

Please see individual FDA-approved package inserts for prescribing information.

Contraindications:

Please see individual FDA-approved package inserts for prescribing information.

References:

1. Global Initiative for Asthma (GINA). *Global Strategy for Asthma Management and Prevention*. 2024Update. Available at: https://ginasthma.org.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease*. 2025 Report. Available at: https://goldcopd.org.
3. U.S. Food and Drug Administration (FDA). *Drugs@FDA: FDA-Approved Drug Products*. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/.
4. National Heart, Lung, and Blood Institute. *Guidelines for the Diagnosis and Management of Asthma (EPR-3)*. NIH Publication No. 07-4051, 2007. Available at: https://www.nhlbi.nih.gov.
5. American Thoracic Society/European Respiratory Society. *ATS/ERS Recommendations for COPD Pharmacologic Treatment*. *American Journal of Respiratory and Critical Care Medicine*. 2020;201(9):e56-e69.

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