

Non-Preferred Inhaler Drug Use Criteria

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Includes:

<u>Brand©</u>	<u>Generic</u>	<u>FDA-Approved Indication</u>
Advair Diskus© 500/50	fluticasone/salmeterol	asthma and COPD
Advair HFA©	fluticasone/salmeterol	asthma
Asmanex HFA©	mometasone	asthma
Asmanex Twisthaler©	mometasone	asthma
Aectura 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.

Approved by Western Oregon Advanced Health Pharmacy & Therapeutics Committee on August 2017
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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?
 - a. If yes, approve for up to 12 months.
 - b. If no, deny as criteria not met. Recommend trial of formulary alternative based on the below table:

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*. 2024 Update. 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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