

Non-Preferred Inhaler Drug Use Criteria

Created: May 19, 2021
Revised: January 9, 2024

Includes:

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

***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.

***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:

Approved by Western Oregon Advanced Health Pharmacy & Therapeutics Committee on August 28, 2017

Approved by Advanced Health Pharmacy and Therapeutics Committee May 13, 2019, 2/14/2024

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 BTL. 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. Is the request for a non-preferred inhaler for the treatment of asthma and has spirometry confirmed diagnosis/assessed severity? (Spirometry must include reversibility test).
 - a. If request is for COPD, go to #6.
 - b. If yes, go to #5.
 - c. If no, deny as criteria not met. Please resubmit PA request with spirometry. Or change to formulary alternative.
5. Has the member had an adequate trial and failure of a preferred inhaler (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.
 - 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.
 - c. If no, deny as criteria not met. Recommend trial of formulary alternative.
6. Is the request for a non-preferred inhaler for the treatment of COPD and has spirometry confirmed diagnosis/assessed severity? (Spirometry must include reversibility test).
 - a. If yes, go to #7.
 - b. If no, deny as criteria not met. Please resubmit PA request with spirometry. Or change to formulary alternative.
7. Is the request for non-preferred ICS/LABA inhaler for treatment of COPD and has documentation included appropriate clinical rationale for use? (Per GOLD guideline, factors to consider when initiating ICS treatment in combination with one or two long-acting bronchodilators: history of hospitalization(s) for exacerbations of COPD OR 2 or more moderate exacerbations of COPD per year despite appropriate long-acting bronchodilator maintenance therapy, blood eosinophils over 300cells/microL, history of, or concomitant asthma. ICS/LABA inhaler could also be considered in members with history of 1 moderate exacerbation of COPD per year despite appropriate long-acting bronchodilator maintenance therapy or blood eosinophils 100-300cells/microL. GOLD guidelines recommend against use of ICS/LABA inhaler if member has had repeated pneumonia events, blood eosinophils less than 100cells/microL or history of mycobacterial infection.)
 - a. If yes, approve for up to 12 months.
 - b. If no, deny as criteria not met. Recommend formulary alternative, Incruse, Anoro Ellipta®, or Stiolto Respimat® or submit to MD for review.

Renewal Request:

1. Has pulmonary condition improved and is there support for continued therapy?

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- 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:

- Global Initiative for Asthma (GINA). https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf
- Global Initiative for Chronic Obstructive Lung Disease (GOLD). <https://goldcopd.org/2024-gold-report/>

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