

Non-Preferred Inhaler Drug Use Criteria

Created: May 19, 2021

Reviewed:

Includes:

Non-preferred medication	Generic name	FDA-approved indication
Advair Diskus® 500/50	<i>fluticasone/salmeterol</i>	asthma and COPD
Advair HFA®	<i>fluticasone/salmeterol</i>	asthma
Asmanex HFA®	<i>mometasone</i>	asthma
Asmanex Twisthaler®	<i>mometasone</i>	asthma
Atecura Breezhaler®	<i>mometasone/indacaterol</i>	asthma
Breo Ellipta®	<i>fluticasone furoate/vilanterol</i>	asthma and COPD
Dulera®	<i>mometasone/formoterol</i>	asthma
Flovent Diskus® 250mcg	<i>fluticasone</i>	asthma
Flovent HFA®	<i>fluticasone</i>	asthma
Pulmicort Flexhaler®	<i>budesonide</i>	asthma
Spiriva®	<i>tiotropium</i>	asthma and COPD
Symbicort®	<i>budesonide/formoterol</i>	asthma and COPD
Wixela Inhub®	<i>fluticasone propionate/salmeterol</i>	asthma and 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.
- 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.

***Preferred long acting antimuscarinic (LAMA)

- Incruse Ellipta® 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. Yes, go to #2.
 - b. No, deny as BTL.

2. Is the medication prescribed for an FDA-approved indication?
 - a. Yes, go to #3.
 - b. No, deny as criteria not met. Off-label use of an inhaler is not a covered benefit.

Approved by Advanced Health Pharmacy and Therapeutics Committee 10/13/2021

3. Is request for a non-preferred inhaler for treatment of asthma and has spirometry confirmed diagnosis/assessed severity? (Spirometry must include reversibility test).
 - a. Yes, go to #4.
 - b. No, deny as criteria not met. Please resubmit PA request with spirometry.
 - c. No, go to #5 if diagnosis is COPD.

4. Has the member had an adequate trial and failure of a preferred inhaler (generic AirDuo Respiclick®, generic Advair Diskus®, Flovent Diskus®, or Alvesco®)? (Adequate trial is defined as adherent to therapy for at least 90 consecutive days and documentation of persistent symptoms).
 - a. Yes, and the request is for a low or medium dose ICS or ICS/LABA, approve for up to 6 months.
 - b. 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 up to 3 months.
 - c. No, deny as criteria not met. Recommend trial of formulary alternative.

5. Is request for a non-preferred inhaler for treatment of COPD and has spirometry confirmed diagnosis/assessed severity? (Spirometry must include reversibility test).
 - a. Yes, go to #6.
 - b. No, deny as criteria not met. Please resubmit PA request with spirometry.

6. Is 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. Yes, approve for 12 months.
 - b. No, deny as criteria not met. Recommend formulary alternative, Incruse or request change to Anoro Ellipta® or submit to MD for review.

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. 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.

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

References:

1. Global Initiative for Asthma (GINA). https://ginasthma.org/wp-content/uploads/2020/06/GINA-2020-report_20_06_04-1-wms.pdf
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). https://goldcopd.org/wp-content/uploads/2020/11/GOLD-REPORT-2021-v1.1-25Nov20_WMV.pdf
3. Alvesco Prescribing Information. Revised 11/2017. <https://www.alvesco.us/resources/100296-Alvesco-PI-Nov%202017.pdf>
4. Flovent Diskus Prescribing Information. Revised 2/2020. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Flovent_Diskus/pdf/FLOVENT-DISKUS-PI-PIL-IFU.PDF
5. Fluticasone/Salmeterol (AirDuo RespiClick) Prescribing Information. Revised 3/2018. <https://www.myairduo.com/globalassets/myairduo/pdf/genericpi.pdf>
6. Fluticasone/Salmeterol (Advair Diskus) Prescribing Information. Revised 8/2020. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Advair_Diskus/pdf/ADVAIR-DISKUS-PI-PIL-IFU.PDF
7. UpToDate: Drug information: Advair HFA, Wixela Inhub. https://www.uptodate.com/contents/fluticasone-and-salmeterol-drug-information?search=advair&source=panel_search_result&selectedTitle=1~26&usage_type=panel&kp_t ab=drug_general&display_rank=1.
8. Drug information: Ateectura Breezhaler. https://www.uptodate.com/contents/search?search=ateectura&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchOffset=1&autoComplete=false&language=en&max=10&index=&autoCompleteTerm=
9. Drug information: Breo Ellipta. https://www.uptodate.com/contents/search?search=breo%20ellipta&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchOffset=1&autoComplete=true&language=en&max=10&index=0~6&autoCompleteTerm=breo%20
10. Drug information: Dulera. https://www.uptodate.com/contents/mometasone-and-formoterol-drug-information?search=dulera&source=panel_search_result&selectedTitle=1~11&usage_type=panel&kp_t ab=drug_general&display_rank=1.
11. Drug information: Symbicort. https://www.uptodate.com/contents/search?search=symbicort&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchOffset=1&autoComplete=false&language=en&max=10&index=&autoCompleteTerm=