Clinical Policy: Inhaled Agents for Asthma and COPD

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Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are inhaled agents for asthma and/or chronic obstructive pulmonary disease (COPD) requiring prior authorization:

Drug Name	Asthma	COPD
ICS		
Alvesco	X (Age ≥ 12 years)	
ArmonAir Digihaler	X (Age ≥ 4 years)	
Asmanex Twisthaler	X (Age ≥ 4 years)	
Flovent Diskus, Flovent HFA	X (Age ≥ 4 years)	
Pulmicort Flexhaler	X (Age ≥ 6 years)	
Pulmicort Respules	X (Age 1-8 years)	
LABA		
Arcapta Neohaler		X
Brovana		X
Perforomist		X
Striverdi Respimat		X
LAMA		
Lonhala Magnair		X
Seebri Neohaler		X
Spiriva Respimat	X (Age ≥ 6 years)	X
Yupelri		X
ICS/LABA		
Advair Diskus	X (Age ≥ 4 years)	X
Advair HFA	X (Age ≥ 12 years)	
AirDuo Digihaler	X (Age ≥ 12 years)	
AirDuo RespiClick	X (Age ≥ 12 years)	
Breo Ellipta	X (Age ≥ 5 years)	X
Dulera	X (Age ≥ 5 years)	
Symbicort	X (Age ≥ 6 years)	X
Symbicort Aerosphere		X
LABA/LAMA		
Anoro Ellipta		X
Bevespi Aerosphere		X
Duaklir Pressair		X
Stiolto Respimat		X

Drug Name	Asthma	COPD
Utibron Neohaler		X
ICS/LABA/LAMA		
Breztri Aerosphere		X
Trelegy Ellipta	X (Age ≥ 18 years)	X
PDE3/PDE4 Inhibitor		
Ohtuvayre		X

- Short acting beta-2 agonist (SABA): albuterol or levalbuterol (ProAir Respiclick® Ventolin HFA®, Xopenex®, Xopenex HFA®)
- Inhaled corticosteroid (ICS): budesonide (Pulmicort Respules®*, Pulmicort Flexhaler™), ciclesonide (Alvesco®), mometasone (Asmanex HFA®), beclomethasone (QVAR®)
- Long acting beta-2 agonist (LABA): arformoterol (Brovana®), formoterol (Perforormist), indacaterol (Arcapta® Neohaler®), olodaterol (Striverdi® Respimat®)
- Long acting muscarinic antagonist (LAMA): glycopyrrolate (Seebri™ Neohaler®, Lonhala® Magnair®), revefenacin (Yupelri®)
- Combination ICS/LABA: fluticasone/vilanterol (Breo Ellipta®)
- Combination LABA/LAMA: aclidnium/formoterol (Duaklir® Pressair®), glycopyrrolate/formoterol (Bevespi Aerosphere™), indacaterol/glycopyrrolate (Utibron™ Neohaler®), tiotropium/olodaterol (Stiolto® Respimat®)
- Combination ICS/LAMA/LABA: fluticasone/umeclidinium/vilanterol (Trelegy™ Ellipta®), budesonide/glycopyrrolate/formoterol (Breztri Aerosphere™)

**Generic agents do not require prior authorization.*

FDA Approved Indication(s)

ProAir Digihaler is indicated for the:

- Treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease
- Prevention of exercise-induced bronchospasm (EIB) in patients 4 years of age and older

The other inhaled agents are indicated as follows:

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that inhaled agents for asthma and COPD are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Inhaled Agents for Asthma or Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Diagnosis of asthma or COPD as FDA-approved for the requested agent (*see FDA Approved Indications section*);
2. Age is one of the following (a or b):
   a. Asthma (i or ii):
      i. For Flovent HFA: ≤ 12 years;
      ii. Appropriate age limit per the prescribing information for the requested agent (*see FDA Approved Indications section*);
   b. COPD: ≥ 18 years;
3. Failure of the following formulary agent(s) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:

Requested Agent	Required Step Through Agent(s)
ProAir Digihaler, Xopenex®, Xopenex HFA®, levalbuterol, levalbuterol HFA,ProAir Respiclick®, Ventolin, Ventolin HFA ®	Two generic albuterol sulfate HFA products, each from a different manufacturer
Brand Pulmicort Respules	Medical justification supports inability to use generic Pulmicort Respules (e.g., contraindications to excipients) *AND* either age is between 1 to 8 years or documentation supports inability to use inhaler devices
All other ICS: Alvesco, ArmonAir Digihaler, Arnuity® Ellipta®, Asmanex HFA , Pulmicort Flexhaler, Qvar® RediHaler™,	Asmanex® Twisthaler For ages 1-8 years: budesonide or documentation supports inability to use inhaler devices
LABA: Arcapta Neohaler, Brovana, Perforomist, Striverdi Respimat	Serevent® Diskus®, unless request is for a nebulized LABA and documentation supports inability to use inhaler devices * Asthma: only to be used in combination with an ICS COPD: 18 years and older
LAMA: Lonhala Magnair, Seebri Neohaler, Yupelri	Spiriva-COPD: 18 years and older Spiriva Respimat- COPD: 18 years and older, Ashtma: 6 years and older Incruse Ellipta®- COPD: 18 years and older *Unless request is for a nebulized LAMA and documentation supports inability to use inhaler devices
Generic fluticasone/salmeterol products (eg. Wixela™ Inhub)	Medical justification supports inability to use Brand products Advair Diskus, ™ or Advair HFA (e.g., contraindications to excipients)
Generic Symbicort, Symbicort Aerosphere	Medical justification supports inability to use Brand Symbicort (e.g., contraindications to excipients)

Requested Agent	Required Step Through Agent(s)
Breo Ellipta	• For age ≥ 6 years Asthma and >18 years COPD: fluticasone/salmeterol Advair Diskus) *AND* budesonide/formoterol (Symbicort) • For Asthma age < 6 years: fluticasone/salmeterol (Advair Diskus) •
All other ICS/LABA	• AirDuo, RespiClick, Dulera • Symbicort, Advair HFA, Advair Diskus,
LABA/LAMA: Bevespi Aerosphere, Duaklir Pressair, Stiolto Respimat, Utibron Neohaler	• For COPD only: one LABA (e.g., Serevent Diskus) in combination with one LAMA (e.g., Anoro Ellipta, Incruse Ellipta) • For asthma only: fluticasone/salmeterol (brand Advair Diskus) *AND* budesonide/formoterol (brand Symbicort)
ICS/LABA/LAMA: Breztri Aerosphere, Trelegy Ellipta	• For COPD only: one LABA (e.g., Serevent Diskus) in combination with one LAMA (e.g., Anoro Ellipta, Incruse Ellipta) • For asthma only: fluticasone/salmeterol (brand Advair Diskus or Advair HFA) *OR* budesonide/formoterol (Symbicort)
Ohtuvayre	• One LABA (e.g., Serevent Diskus) in combination with one LAMA (e.g., Incruse Ellipta) *AND* • For members with blood eosinophil count ≥ 100 cells/mcL: Breztri Aerosphere *OR* Trelegy Ellipta • *Note: Prior failure of triple therapy (ICS/LABA/LAMA) satisfies the requirement for failure of dual therapy (LABA/LAMA).*

4. For requests for an agent with a digital component (e.g., Digihaler products): Medical justification supports necessity of the digital component (i.e., rationale why inhaler usage cannot be tracked manually);
5. Request does not exceed one of the following (a,b or c):
   a. The health plan quantity limit;
   b. Symbicort only: quantity does not exceed 3 inhalers per month. Exceptions will be made for school, foster placement, daycare, home use in multiple caregiver residencies.
   c. The FDA-approved maximum dose for the relevant indication (see *Section V*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Inhaled Agents for Asthma or Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, request does not exceed one of the following (a,b or c):
   a. The health plan quantity limit;
   b. Symbicort only: quantity does not exceed 3 inhalers per month. Exceptions will be made for school, foster placement, daycare, home use in multiple caregiver residencies.
   c. The FDA-approved maximum dose for the relevant indication (see *Section V*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease
EIB: exercise-induced bronchospasm
FDA: Food and Drug Administration
ICS: inhaled corticosteroid
GINA: Global Initiative for Asthma
GOLD: Global Initiative for Chronic Obstructive Lung Disease
LABA: long acting beta-2 agonist
LAMA: long acting muscarinic antagonist
SABA: short acting beta-2 agonist

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
albuterol (Proventil HFA®, Ventolin HFA®)	*Metered-dose inhaler (MDI)*: 2 puffs every 4 to 6 hours as needed *Nebulization solution:* 2.5 mg via oral inhalation every 6 to 8 hours as needed	*MDI*: 12 puffs/day *Nebulization solution*: 4 doses/day or 10 mg/day Higher maximum dosages for inhalation products have been recommended in National Asthma Education and Prevention Program guidelines for acute exacerbations of asthma.
Arnuity Ellipta (fluticasone furoate)	Asthma: ≥ 12 years: 100-200 mcg inhaled QD 5-11 years: 50 mcg inhaled QD	Asthma: ≥ 12 years: 200 mcg/day 5-11 years: 50 mcg/day
budesonide/formoterol (Symbicort)	Asthma: 2 inhalations BID COPD: 2 inhalations (160/4.5 mcg) BID	Asthma/COPD: 160/4.5 mcg BID
fluticasone/salmeterol (Advair Diskus, Wixela Inhub)	Asthma: 1 inhalation BID (starting dosage is based on asthma severity	Asthma: 500/50 mcg BID

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	COPD: 1 inhalation of 250/50 mcg BID	COPD: 250/50 mcg BID
Incruse Ellipta (umeclidinium)	COPD: 1 inhalation (62.5 mcg) QD	COPD: 62.5 mcg/day
Serevent (salmeterol)	Asthma/COPD: 1 inhalation (50 mcg) BID	Asthma/COPD: 100 mcg/day
Tudorza Pressair (aclidinium)	COPD: 1 inhalation (400 mcg) BID	COPD: 800 mcg/day
Asmanex HFA	Asthma: 2 inhalations BID (starting dosage is based on age and asthma severity)	800 mcg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - All agents: hypersensitivity to any component of the requested agent or the following as additionally specified:
    - Advair Diskus, AirDuo Digihaler/RespiClick, Anoro Ellipta, ArmonAir Digihaler, Asmanex Twisthaler, Breo Ellipta, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler, Trelegy Ellipta: milk proteins
    - Brovana: racemic formoterol
  - Advair HFA/Diskus, AirDuo Digihaler/RespiClick, Alvesco, ArmonAir Digihaler, Asmanex Twisthaler, Breo Ellipta, Dulera, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler/Respules, Trelegy Ellipta: primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures
  - Anoro Ellipta, Arcapta Neohaler, Bevespi Aerosphere, Brovana, Duaklir Pressair, Stiolto Respimat, Striverdi Respimat, Perforomist, Utibron Neohaler: use of a LABA without an ICS in patients with asthma
- Boxed warning(s): none reported

Appendix D: General Information

- Although inhaler devices with a digital component may offer increased convenience with tracking of inhaler usage, there is currently no evidence that this leads to improved clinical outcomes, including safety and effectiveness.
- Per the Global Initiative for Chronic Obstructive Lung Disease (GOLD) COPD guidelines, combination therapy (LAMA + LABA or ICS + LAMA + LABA) is recommended for Group B and E patients (i.e., those who are very symptomatic or are at high risk of exacerbation). Selection of which combination to use depends on the individual patient:
  - For those with more severe symptoms, LAMA + LABA may be used.
  - For those who are inadequately controlled by dual therapy or with blood eosinophil counts at least 300 cells/uL, triple therapy with ICS + LAMA + LABA may be used.

  - As of the 2023 guideline update, use of LABA + ICS in COPD is no longer encouraged. If there is an indication for an ICS, then LABA + LAMA + ICS has been shown to be superior to LABA + ICS and is therefore the preferred choice.
- Historical management of asthma has involved an as-needed short-acting beta agonist for reliever therapy, with stepwise approach to add on controller maintenance therapies such as inhaled corticosteroids and long-acting beta agonists. In 2019, the Global Initiative for Asthma (GINA) guidelines for asthma management and prevention began recommending that inhaled corticosteroids be initiated as soon as possible after diagnosis of asthma, including use as reliever therapy (to be administered as-needed alongside a short-acting beta agonist). The National Asthma Education and Prevention Program from the National Heart, Lung, and Blood Institute followed suit with their recommendations in 2020.
- Alvesco: Use in pediatric patients < 12 years of age: Two identically designed randomized, double-blind, parallel, placebo-controlled clinical trials of 12-weeks treatment duration were conducted in 1,018 patients aged 4 to 11 years with asthma but efficacy was not established. In addition, one randomized, double-blind, parallel, placebo-controlled clinical trial did not establish efficacy in 992 patients aged 2 to 6 years with asthma.
- Trelegy Ellipta: In its pivotal trial for asthma, all patients enrolled were inadequately controlled on their current treatments of combination therapy (ICS + LABA). In addition, per the GINA guidelines, the addition of a LAMA to combination medium/high dose ICS + LABA can be considered as an alternative controller option at steps 4/5, following use of /medium/high dose ICS + LABA.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Advair Diskus	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	500/50 mcg BID
	COPD	1 inhalation of 250/50 mcg BID	250/50 mcg BID
Advair HFA	Asthma	2 inhalations BID (starting dosage is based on asthma severity)	2 inhalations of 230/21 mcg BID
AirDuo Digihaler	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	232/14 mcg BID
AirDuo RespiClick	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	232/14 mcg BID
Alvesco	Asthma	Starting dose for patients who received bronchodilators alone: 80 mcg inhaled BID Starting dose for patients who received inhaled corticosteroids: 80 mcg inhaled BID Starting dose for patients who received oral corticosteroids: 320 mcg inhaled BID	320 mcg/day 640 mcg/day 640 mcg/day
Anoro Ellipta	COPD	One inhalation by mouth QD	1 inhalation/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
Arcapta Neohaler	COPD	75 mcg inhaled orally QD	75 mcg/day
ArmonAir Digihaler	Asthma	1 inhalation BID (starting dosage is based on asthma severity and age)	232 mcg BID
Asmanex Twisthaler	Asthma	Dose varies based on previous therapy and age: 1 inhalation QD-BID	880 mcg/day
Bevespi Aerosphere	COPD	2 inhalations BID	4 inhalations/day
Breo Ellipta	Asthma	Age ≥ 18 years: 1 inhalation of 100/25 or 200/25 mcg QD Age 12-17 years: 1 inhalation of 100/25 mcg QD Age 5-11 years: 1 inhalation of 50/25 mcg QD	200/25 mcg/day
	COPD	1 inhalation of 100/25 mcg QD	100/25 mcg/day
Breztri Aerosphere	COPD	2 inhalations by mouth BID	4 inhalations/day
Brovana	COPD	One 15 mcg/2 mL vial inhaled via nebulizer every 12 hours	30 mcg/day
Duaklir Pressair	COPD	One inhalation by mouth BID	2 inhalations/day
Dulera	Asthma	Age 5 to 11 years: 2 inhalations of 50/5 mcg BID Age ≥ 12 years: 2 inhalations of 100/5 mcg or 200/5 mcg BID (starting dosage is based on asthma severity)	200/5 mcg/day 800/20 mcg/day
Flovent Diskus	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	2,000 mcg/day
Flovent HFA	Asthma	Patients aged 12 years and older: 88 mcg twice daily up to a maximum dosage of 880 mcg twice daily. Pediatric patients aged 4 to 11 years: 88 mcg twice daily	880 mcg BID
Lonhala Magnair	COPD	One 25 mcg vial inhaled via nebulizer BID	50 mcg/day
Perforomist	COPD	One 20 mcg/2 mL vial inhaled via nebulizer every 12 hours	40 mcg/day
ProAir Digihaler	Treatment or prevention of bronchospasm	2 inhalations every 4 to 6 hours	12 inhalations/day
	Prevention of EIB	2 inhalations 15 to 30 minutes before exercise	2 inhalations before exercise

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pulmicort Flexhaler	Asthma	Starting dose of 180-360 mcg inhaled BID	720 mcg BID
Pulmicort Respules	Asthma	Starting dose for patients who received bronchodilators alone or inhaled corticosteroids: 0.5 mg inhaled per day (0.5 mg QD or 0.25 mg BID; for inhaled corticosteroids, may go up to 0.5 mg BID) Starting dose for patients who received oral corticosteroids: 1 mg inhaled per day (1 mg QD or 0.5 mg BID)	Bronchodilator alone: 0.5 mg/day Inhaled or oral corticosteroid: 1 mg/day
Seebri Neohaler	COPD	One inhalation (15.6 mcg) BID	2 inhalations/day
Spiriva Handihaler	COPD	Two inhalations (18 mcg) QD	18 mcg/day
Spiriva Respimat	Asthma	Two inhalations (1.25 mcg) QD	2.5 mcg/day
	COPD	Two inhalations (2.5 mcg) QD	5 mcg/day
Stiolto Respimat	COPD	Two inhalations by mouth QD at the same time of day	2 inhalations/day
Striverdi Respimat	COPD	Two inhalations QD	5 mcg/day
Symbicort	Asthma	2 inhalations BID (starting dosage is based on asthma severity)	320/9 mcg BID
	COPD	2 inhalations (160/4.5 mcg) BID	320/9 mcg BID
Symbicort Aerosphere	COPD	2 inhalations (160/4.8 mcg) BID	320/9.6 mcg BID
Trelegy Ellipta	COPD	1 inhalation (100/62.5/26 mcg) by mouth QD	1 inhalation/day
	Asthma	1 inhalation (100/62.5/26 mcg or 200/62.5/26 mcg) by mouth QD	1 inhalation/day
Utibron Neohaler	COPD	Inhalation of the contents of one capsule BID	2 capsules/day
Yupelri	COPD	One 175 mcg mcg vial inhaled via nebulizer QD	175 mcg/day

VI. Product Availability

Drug Name	Availability
Advair Diskus	Inhalation powder containing fluticasone/salmeterol: 100/50 mcg, 250/50 mcg, 500/50 mcg
Advair HFA	Inhalation aerosol containing fluticasone/salmeterol: 45/21 mcg, 115/21 mcg, 230/21 mcg

Drug Name	Availability
AirDuo Digihaler	Inhalation powder: In each actuation: 55/14 mcg contains 55 mcg of fluticasone propionate and 14 mcg of salmeterol; 113/14 mcg contains 113 mcg of fluticasone propionate and 14 mcg of salmeterol; 232/14 mcg contains 232 mcg of fluticasone propionate and 14 mcg of salmeterol. AirDuo Digihaler contains a built-in electronic module
AirDuo RespiClick	Inhalation powder: In each actuation: 55 mcg/14 mcg contains 55 mcg of fluticasone propionate and 14 mcg of salmeterol; 113 mcg/14 mcg contains 113 mcg of fluticasone propionate and 14 mcg of salmeterol; 232 mcg/14 mcg contains 232 mcg of fluticasone propionate and 14 mcg of salmeterol
Alvesco	Inhalation aerosol: 80 mcg/actuation, 160 mcg/actuation
Anoro Ellipta	Inhalation powder: 62.5 mcg umeclidinium and 25 mcg vilanterol (62.5/25 mcg) per actuation
Arcapta Neohaler	Inhalation powder hard capsules: 75 mcg
ArmonAir Digihaler	Inhalation powder containing 30 mcg, 55 mcg, 113 mcg, or 232 mcg of fluticasone propionate per actuation. ArmonAir Digihaler contains a built-in electronic module
Asmanex Twisthaler	Inhalation device: 110 mcg (delivers 100 mcg/actuation), 220 mcg (delivers 200 mcg/actuation)
Besvespi Aerosphere	Inhalation aerosol: pressurized metered dose inhaler containing a combination of glycopyrrolate (9 mcg) and formoterol fumarate (4.8 mcg) per inhalation; two inhalations equal one dose
Breo Ellipta	Foil blister strips with inhalation powder containing fluticasone/vilanterol: 50/25 mcg, 100/25 mcg, 200/25 mcg
Breztri Aerosphere	Inhalation aerosol: pressurized metered dose inhaler containing a combination of budesonide (160 mcg), glycopyrrolate (9 mcg), and formoterol fumarate (4.8 mcg) per inhalation
Brovana	Inhalation solution (unit-dose vial for nebulization): 15 mcg/2 mL
Duaklir Pressair	Inhalation powder: 30 and 60 metered dose dry powder inhaler metering 400 mcg aclidinium bromide and 12 mcg formoterol fumarate per actuation
Dulera	Inhalation aerosol containing mometasone/formoterol: 50/5 mcg, 100/5 mcg, 200/5 mcg per actuation
Flovent Diskus	Inhalation powder: Inhaler containing fluticasone propionate (50, 100, or 250 mcg) as a powder formulation for oral inhalation
Flovent HFA	Inhalation aerosol: 44 mcg, 110 mcg, 220 mcg per actuation
Lonhala Magnair	Sterile solution for inhalation in a unit-dose vial: 25 mcg/mL
Perforomist	Inhalation solution (unit dose vial for nebulization): 20 mcg/2 mL solution
ProAir Digihaler	Inhalation powder: dry powder inhaler 108 mcg of albuterol sulfate (equivalent to 90 mcg of albuterol base) from the mouthpiece per actuation. The inhaler is supplied for 200 inhalation doses. ProAir Digihaler includes a built-in electronic module

Drug Name	Availability
Pulmicort Flexhaler	Inhalation device with powder: 90 mcg, 180 mcg
Pulmicort Respules	Inhalation suspension: 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
Seebri Neohaler	Inhalation powder in capsules: 15.6 mcg of glycopyrrolate inhalation powder for use with the Neohaler device
Spiriva Handihaler	Inhalation powder in capsules: 18 mcg tiotropium powder for use with Handihaler device
Spiriva Respimat	Inhalation spray: 1.25 mcg or 2.5 mcg tiotropium per actuation; two actuations equal one dose (2.5 mcg or 5 mcg)
Stiolto Respimat	Inhalation spray: 2.5 mcg tiotropium (equivalent to 3.124 mcg tiotropium bromide monohydrate), and 2.5 mcg olodaterol (equivalent to 2.736 mcg olodaterol hydrochloride) per actuation; two actuations equal one dose
Striverdi Respimat	Inhalation spray: Each actuation from the mouthpiece contains 2.7 mcg olodaterol hydrochloride, equivalent to 2.5 mcg olodaterol. Two actuations equal one dose
Symbicort	Metered-dose inhaler: budesonide (80 or 160 mcg) and formoterol (4.5 mcg) as an inhalation aerosol
Symbicort Aerosphere	Metered-dose inhaler: budesonide (160 mcg) and formoterol (4.8 mcg) as an inhalation aerosol
Trelegy Ellipta	Inhalation powder: disposable inhaler containing 2 foil strips of 30 blisters each: one strip with fluticasone furoate (100 mcg or 200 mcg per blister), and the other strip with a blend of umeclidinium and vilanterol (62.5 mcg and 25 mcg per blister, respectively)
Utibron Neohaler	Inhalation powder in capsule, for use with the Neohaler device: 27.5 mcg of indacaterol and 15.6 mcg glycopyrrolate
Yupelri	Inhalation solution (unit-dose vial for nebulization): 175 mcg/3 mL

VII. References

SABA

1. ProAir Digihaler Prescribing Information. Parsippany, NJ: Teva Pharmaceuticals USA, Inc; September 2020. Available at: https://www.digihaler.com/globalassets/proair_digihaler/proair_digihaler_pi.pdf. Accessed October 31, 2022.
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ICS

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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7601	Ensifentrine, inhalation suspension, fda approved final product, non-compounded, administered through dme, unit dose form, 3 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved individual drug policies - CP.PMN.07 Xopenex HFA/Inhalation Solution, CP.PMN.31 Advair Diskus/HFA, CP.PMN.146 Trelegy Ellipta, CP.PMN.147 Utibron Neohaler, CP.PMN.148 Anoro Ellipta, CP.PMN.200 Duaklir Pressair, CP.PMN.201 Brovana, CP.PMN.203 Arcapta Neohaler, CP.PMN.204 Striverdi Respimat, CP.PMN.229 Breo Ellipta, and CP.PMN.230 Dulera (all to be retired) and CP.PMN.259 for migration to HFS PDL	7.26.23	
Typo corrected, levalbuterol and QVAR added to the criteria	3.11.24	
Added language for increased quantity limit for Symbicort; updated table in initial criteria.	9.18.24	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q2025 Annual Review: updated FDA approved indications table; updated language in initial criteria section; added ohtuvayre; added coding; added diagnosis clarification per PA team request; references reviewed.	1.17.25	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.