Clinical Policy: Inhaled Agents for Asthma and COPD

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Line of Business: HIM

Coding Implications
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:

- Short acting beta-2 agonist (SABA): albuterol (ProAir® Digihaler®)
- Inhaled corticosteroid (ICS): budesonide (Pulmicort Respules®)*, ciclesonide (Alvesco®), fluticasone (ArmonAir® Digihaler™), mometasone (Asmanex® HFA, Asmanex® Twisthaler®, Flovent® HFA, Flovent® Diskus®)
- Long acting beta-2 agonist (LABA): arformoterol (Brovana®), formoterol (Perforormist)
- Long acting muscarinic antagonist (LAMA): aclidinium bromide (Tudorza® Pressair®), glycopyrrolate (Seebri™ Neohaler®, Lonhala® Magnair®), revefenacin (Yupelri®), tiotropium bromide monohydrate (Spiriva® Handihaler®)*
- Combination ICS/LABA: budesonide/formoterol (Symbicort®*, Symbicort Aerosphere®), fluticasone/salmeterol (Advair Diskus®*, Advair HFA®*, AirDuo® Digihaler™, AirDuo® RespiClick®), mometasone/formoterol (Dulera®)
- Combination LABA/LAMA: aclidnium/formoterol (Duaklir® Pressair®), glycopyrrolate/formoterol (Bevespi Aerosphere™), indacaterol/glycopyrrolate (Utibron™ Neohaler®)
- Phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor: ensifentrine (Ohtuvayre™)

**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:

Drug Name	Asthma	COPD
ICS		
Alvesco	X (Age ≥ 12 years)	
ArmonAir Digihaler	X (Age ≥ 4 years)	
Asmanex HFA	X (Age ≥ 5 years)	
Asmanex Twisthaler	X (Age ≥ 4 years)	
Pulmicort Respules	X (Age 1-8 years)	
Flovent Diskus, Flovent HFA	X (Age ≥ 4 years)	

Drug Name	Asthma	COPD
LABA		
Brovana		X
Perforomist		X
LAMA		
Lonhala Magnair		X
Seebri Neohaler		X
Spiriva Handihaler		X
Tudorza Pressair		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)	
Dulera	X (Age ≥ 5 years)	
Symbicort	X (Age ≥ 6 years)	X
Symbicort Aerosphere		X
LABA/LAMA		
Bevespi Aerosphere		X
Duaklir Pressair		X
Utibron Neohaler		X
PDE3/PDE4 Inhibitor		
Ohtuvayre		X

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: Appropriate 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	Two generic albuterol sulfate HFA products, each from a different manufacturer
Pulmicort Respules	Age is between 1 to 8 years or documentation supports inability to use inhaler devices *AND* if request is for brand Pulmicort Respules, medical justification supports inability to use generic Pulmicort Respules (e.g., contraindications to excipients)
Flovent Diskus	Fluticasone propionate diskus (Flovent Diskus authorized generic)
Flovent HFA	Fluticasone propionate HFA (Flovent HFA authorized generic)
All other ICS: Alvesco, ArmonAir Digihaler, Asmanex HFA, Asmanex Twisthaler	Qvar® RediHaler™ *AND* Pulmicort Flexhaler™ *AND* Arnuity® Ellipta® *AND* fluticasone proprionate HFA (Flovent HFA authorized generic) *AND* fluticasone proprionate diskus (Flovent Diskus authorized generic)
LABA: Brovana, Perforomist	Generic (i.e., formoterol for Perforomist requests, arformoterol for Brovana requests) *AND* Serevent® Diskus® *AND* Striverdi® Respimat®, unless request is for a nebulized LABA and documentation supports inability to use inhaler devices
Brand Spiriva Handihaler	Medical justification supports inability to use generic tiotropium bromide monohydrate (generic Spiriva Handihaler) (e.g., contraindications to excipients)
All other LAMA: Lonhala Magnair, Seebri Neohaler, Tudorza Pressair, Yupelri	Incruse® Ellipta® *AND* tiotropium bromide monohydrate (generic Spiriva Handihaler)/Spiriva® Respimat®, unless request is for a nebulized LAMA and documentation supports inability to use inhaler devices
Brand Advair Diskus	Medical justification supports inability to use generic fluticasone/salmeterol products (generic Advair Diskus, Wixela™ Inhub™) (e.g., contraindications to excipients)
Brand Advair HFA	Medical justification supports inability to use fluticasone-salmeterol HFA (Advair HFA authorized generic) (e.g., contraindications to excipients)
Brand Symbicort, Symbicort Aerosphere	Medical justification supports inability to use generic Symbicort (e.g., contraindications to excipients)
All other ICS/LABA: AirDuo Digihaler, AirDuo RespiClick	fluticasone-salmeterol HFA (Advair HFA authorized generic) *AND* budesonide/formoterol (Symbicort authorized generic) *AND* fluticasone/salmeterol (generic Advair Diskus or Wixela Inhub) *AND* Breo Ellipta® (brand Breo Ellipta or [fluticasone furoate-vilanterol] Breo Ellipta authorized generic) *AND* Dulera

Requested Agent	Required Step Through Agent(s)
LABA/LAMA: Bevespi Aerosphere, Duaklir Pressair, Utibron Neohaler	Anoro® Ellipta® *AND* Stiolto® Respimat®
Ohtuvayre	• Anoro Ellipta *OR* Stiolto Respimat *OR* 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. For requests for Ohtuvayre, both of the following (a and b):
   a. Member has moderate-to-severe COPD as evidenced by one of the following (i or ii):
      i. Pre- and post-albuterol forced expiratory volume (FEV_1)/forced vital capacity (FVC) ratio of < 0.70;
      ii. Post-albuterol FEV_1 ≥ 30 % and ≤ 70% of predicted normal;
   b. Ohtuvayre is not prescribed in combination with Daliresp®;
6. Request meets one of the following (a, b, or c):
   a. Requested quantity does not exceed the health plan quantity limit;
   b. Requested dose does not exceed the FDA-approved maximum dose for the relevant indication (see *Section V*);
   c. Request is for a Georgia member with asthma or other life-threatening bronchial ailments for inhalants prescribed by the treating physician.

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: HIM.PA.33 for health insurance marketplace; 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: HIM.PA.103 for health insurance marketplace; 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: HIM.PA.154 for health insurance marketplace.

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 meets one of the following (a, b, or c):
   a. Requested quantity does not exceed the health plan quantity limit;
   b. Requested dose does not exceed the FDA-approved maximum dose for the relevant indication (see *Section V*);
   c. Request is for a Georgia member with asthma or other life-threatening bronchial ailments for inhalants prescribed by the treating physician.

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: HIM.PA.33 for health insurance marketplace; 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: HIM.PA.103 for health insurance marketplace; 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: HIM.PA.154 for health insurance marketplace.

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 – HIM.PA.154 for health insurance marketplace 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
FEV_1: forced expiratory volume
FVC: forced vital capacity

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
PDE: phosphodiesterase
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
fluticasone-salmeterol HFA (Advair HFA authorized generic)	Asthma: 2 inhalations BID (starting dosage is based on asthma severity)	Asthma: 2 inhalations of 230/21 mcg BID
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.
Anoro Ellipta (umeclidinium/ vilanterol)	COPD: 1 inhalation by mouth QD	COPD: 1 inhalation/day
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
Breo Ellipta (fluticasone/ vilanterol)	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	Asthma: 200/25 mcg/day COPD: 100/25 mcg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	COPD: 1 inhalation of 100/25 mcg QD	
Breztri Aerosphere	COPD: 2 inhalations by mouth BID	4 inhalations/day
budesonide/formoterol (Symbicort)	Asthma: 2 inhalations BID COPD: 2 inhalations (160/4.5 mcg) BID	Asthma/COPD: 160/4.5 mcg BID
Flovent Diskus (fluticasone)	Asthma: 1 inhalation BID (starting dosage is based on asthma severity)	Asthma: 2,000 mcg/day
Flovent HFA (fluticasone)	Asthma: 1 inhalation BID	Asthma: 1,760 mcg/day
fluticasone/salmeterol (Advair Diskus, Wixela Inhub)	Asthma: 1 inhalation BID (starting dosage is based on asthma severity COPD: 1 inhalation of 250/50 mcg BID	Asthma: 500/50 mcg BID COPD: 250/50 mcg BID
Incruse Ellipta (umeclidinium)	COPD: 1 inhalation (62.5 mcg) QD	COPD: 62.5 mcg/day
Pulmicort Flexhaler (budesonide)	Asthma: Starting dose of 180-360 mcg inhaled BID	Asthma: 720 mcg BID
Qvar RediHaler (beclomethasone)	Asthma: ≥ 12 years: 40 mcg, 80 mcg, 160 mcg, or 320 mcg inhaled BID 4-11 years: 40 mcg or 80 mcg inhaled BID	Asthma: ≥ 12 years: 640 mcg/day 4-11 years: 160 mcg/day
Serevent (salmeterol)	Asthma/COPD: 1 inhalation (50 mcg) BID	Asthma/COPD: 100 mcg/day
tiotropium bromide monohydrate (Spiriva Handihaler)	COPD: 2 inhalations (18 mcg) QD	COPD: 18 mcg/day
Spiriva Respimat (tiotropium bromide monohydrate)	Asthma: 2 inhalations (1.25 mcg) QD COPD: 2 inhalations (2.5 mcg) QD	Asthma: 2.5 mcg/day COPD: 5 mcg/day
Stiolto Respimat (tiotropium/olodaterol)	Two inhalations by mouth QD at the same time of day	2 inhalations/day
Striverdi Respimat (olodaterol)	COPD: 2 inhalations QD	COPD: 5 mcg/day
Trelegy Ellipta (fluticasone/ umeclidinium/ vilanterol)	Asthma: 1 inhalation (100/62.5/26 mcg or 200/62.5/26 mcg) by mouth QD COPD: 1 inhalation (100/62.5/26 mcg) by mouth QD	Asthma: 200/62.5/26 mcg/day COPD: 100/62.5/26 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, ArmonAir Digihaler, Asmanex Twisthaler, Tudorza Pressair, Trelegy Ellipta, Flovent Diskus: milk proteins
    - Brovana: racemic formoterol
    - Spiriva Handihaler: ipratropium
  - Advair Diskus, AirDuo Digihaler/RespiClick, Alvesco, ArmonAir Digihaler, Asmanex HFA/Twisthaler, Dulera, Pulmicort Respules, Flovent Diskus, Flovent HFA: primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures
  - Bevespi Aerosphere, Brovana, Duaklir Pressair, 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.
  - Ohtuvayre may be considered in patients experiencing dyspnea despite LABA + LAMA therapy. For patients experiencing exacerbations despite LABA + LAMA therapy, triple therapy with ICS + LAMA + LABA is instead recommended. This is because while Ohtuvayre improves lung function, its effect on exacerbations has not been evaluated in patients at increased exacerbation risk; conversely, ICS + LAMA + LABA has been shown to reduce exacerbations and may also confer mortality benefit.
- 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.

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
ArmonAir Digihaler	Asthma	1 inhalation BID (starting dosage is based on asthma severity and age)	232 mcg BID
Asmanex HFA	Asthma	2 inhalations BID (starting dosage is based on age and asthma severity)	800 mcg/day
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
Brovana	COPD	One 15 mcg/2 mL vial inhaled via nebulizer every 12 hours	30 mcg/day
Duaklir Pressair	COPD	1 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	200/5 mcg/day 800/20 mcg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		(starting dosage is based on asthma severity)	
Flovent Diskus	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	1,000 mcg BID
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
Ohtuvayre	COPD	3 mg (one ampule) inhaled via nebulizer BID	6 mg/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
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	1 inhalation (15.6 mcg) BID	2 inhalations/day
Spiriva Handihaler	COPD	2 inhalations (of one 18 mcg capsule) QD	2 inhalations/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
Tudorza Pressair	COPD	1 inhalation (400 mcg) BID	800 mcg/day
Utibron Neohaler	COPD	Inhalation of the contents of one capsule BID	2 capsules/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
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
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
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 HFA	Inhalation aerosol containing 50 mcg, 100 mcg, or 200 mcg of mometasone furoate per actuation
Asmanex Twisthaler	Inhalation device: 110 mcg (delivers 100 mcg/actuation), 220 mcg (delivers 200 mcg/actuation)
Bevespi 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
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
Ohtuvayre	Inhalation suspension in unit-dose ampule: 3 mg/2.5 mL
Perforomist	Inhalation solution (unit dose vial for nebulization): 20 mcg/2 mL solution

Drug Name	Availability
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
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 of tiotropium powder (equivalent to 22.5 mcg tioptropium bromide monohydrate) for use with Handihaler device
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
Tudorza Pressair	Inhalation powder in a multi-dose dry powder inhaler: 400 mcg/actuation
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 28, 2024.
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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.PCH.35 Alvesco, CP.PCH.36 Asmanex, HIM.PA.48 Pulmicort Respules, HIM.PA.102 Utibron Neohaler, HIM.PA.150 Breztri Aerosphere, and HIM.PA.151 Duaklir Pressair (all to be retired); added additional agents and revised criteria to reflect SDC CY2021 strategy/prior clinical guidance; added requirement for medical justification for requests for agents with digital component.	10.29.20	02.21
Added option for request to not exceed the health plan quantity limit.	04.23.21	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Per October SDC, removed Breztri Aerosphere from criteria.	10.27.21	
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.21.21	02.22
Per March SDC for brand Perforomist and Brovana added redirection to generic formoterol/arformoterol.	03.22.22	05.22
RT4: updated ArmonAir Digihaler per prescribing information for pediatric extension down to 4 years of age and older, added new 30 mcg strength; references reviewed and updated.	05.16.22	
Per August SDC, revised AirDuo Digihaler, AirDuo RespiClick, Dulera redirection to include only Symbicort authorized generic rather than both brand and generic. Template changes applied to other diagnoses/indications and continued therapy section.	08.23.22	11.22
1Q 2023 annual review: no significant changes; updated Appendix D with updated 2023 GOLD guideline recommendations; references reviewed and updated.	01.11.23	02.23
Per April SDC, removed Xopenex from policy.	04.20.23	
RT4: added newly approved dosage form Symbicort Aerosphere to policy with redirection to generic Symbicort per SDC and prior clinical guidance; updated dosing for Breo Ellipta in Appendix B per prescribing information for pediatric extension down to 5 years of age and older. Corrected maximum dose for Bevespi Aerosphere from 2 inhalations/day to 4 inhalations/day per dosing regimen (2 inhalations BID); added redirection to generic Symbicort for brand Symbicort per SDC and prior clinical guidance.	05.26.23	
Per April SDC and prior clinical guidance, revised redirection from brand Flovent HFA/Flovent Diskus to instead redirect to fluticasone proprionate HFA (Flovent HFA authorized generic); added Flovent HFA and Advair HFA to policy requiring redirection to authorized generic; revised redirection to brand Advair HFA to instead redirect to authorized generic; for LABA/LAMA revised redirection to Bevespi Aerosphere to instead redirect to Stiolto Respimat; added Bevespi Aerosphere to policy with redirection to Anoro Ellipta and Stiolto Respimat; for AirDuo Digihaler, AirDuo RespiClick, Dulera, updated redirection to include both Breo Ellipta authorized generic and brand Breo Ellipta. Added dose/quantity limit bypass for Georgia members with asthma or other life-threatening bronchial ailments for inhalants prescribed by the treating physician.	09.21.23	12.23
1Q 2024 annual review: no significant changes; references reviewed and updated.	10.09.23	02.24
Per March SDC, for "All other ICS" requests added additional redirection to fluticasone propionate diskus (Flovent Diskus authorized generic); revised Flovent Diskus redirection requirements	03.12.24	05.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
to fluticasone propionate diskus (Flovent Diskus authorized generic) in a new row; for "All other ICS/LABA" requests added additional redirection to Dulera.		
RT4: added newly approved agent Ohtuvayre with redirections per SDC.	07.03.24	11.24
HCPCS code added [J7601].	11.07.24	
1Q 2025 annual review: no significant changes; updated Appendix D with latest GOLD guideline recommendations on Ohtuvayre; references reviewed and updated. Per Ambetter core formulary status and SDC, added brand Spiriva Handihaler to the policy requiring step through of the generic and revised "All other LAMA" redirection from "Spiriva Handihaler" to "tiotropium bromide monohydrate (generic Spiriva Handihaler)".	01.15.25	02.25
Removed redirection to Arcapta Neohaler as it is no longer commercially available.	08.04.25	

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.