

### **Clinical Policy: Inhaled Agents for Asthma and COPD**

Reference Number: CP.CPA.350

Effective Date: 03.01.21 Last Review Date: 02.25 Line of Business: Commercial

Coding Implications
Revision Log

See <u>Important Reminder</u> 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): 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<sup>®</sup> Pressair<sup>®</sup>), glycopyrrolate (Seebri<sup>™</sup> Neohaler<sup>®</sup>, Lonhala<sup>®</sup> Magnair<sup>®</sup>), revefenacin (Yupelri<sup>®</sup>)
- Combination ICS/LABA: budesonide/formoterol (Symbicort<sup>®</sup>\*, Symbicort Aerosphere<sup>®</sup>), fluticasone/salmeterol (Advair Diskus<sup>®</sup>\*, Advair HFA<sup>®</sup>\*, AirDuo<sup>®</sup> Digihaler<sup>™</sup>, AirDuo<sup>®</sup> RespiClick<sup>®</sup>), mometasone/formoterol (Dulera<sup>®</sup>)
- Combination LABA/LAMA: aclidnium/formoterol (Duaklir<sup>®</sup> Pressair<sup>®</sup>), glycopyrrolate/formoterol (Bevespi Aerosphere<sup>™</sup>), indacaterol/glycopyrrolate (Utibron<sup>™</sup> Neohaler<sup>®</sup>)
- Phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor: ensifentrine (Ohtuvayre<sup>TM</sup>)

### 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	$X \text{ (Age } \ge 12 \text{ years)}$	
Armonair Digihaler	$X \text{ (Age } \ge 12 \text{ years)}$	
Asmanex HFA	$X (Age \ge 5 \text{ years})$	
Asmanex Twisthaler	$X (Age \ge 4 \text{ years})$	
Flovent Diskus, Flovent HFA	$X (Age \ge 4 \text{ years})$	
LABA		
Brovana		X
Perforomist		X

<sup>\*</sup>Generic agents do not require prior authorization.



Drug Name	Asthma	COPD
LAMA		
Lonhala Magnair		X
Seebri Neohaler		X
Tudorza Pressair		X
Yupelri		X
ICS/LABA		
Advair Diskus	$X (Age \ge 4 \text{ years})$	X
Advair HFA	$X (Age \ge 12 \text{ years})$	
AirDuo Digihaler	$X (Age \ge 12 \text{ years})$	
AirDuo RespiClick	$X (Age \ge 12 \text{ years})$	
Dulera	$X \text{ (Age } \geq 5 \text{ years)}$	
Symbicort	$X (Age \ge 6 \text{ years})$	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<sup>®</sup> that inhaled agents for asthma and COPD are **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

- A. All Requests (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:  $\geq$  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
Flovent HFA	Fluticasone propionate HFA (Flovent HFA authorized
	generic)



Requested Agent	Required Step Through Agent(s)
All other ICS: Alvesco,	Qvar <sup>®</sup> RediHaler <sup>™</sup> AND Pulmicort Flexhaler AND
Armonair Digihaler,	Arnuity® Ellipta® AND fluticasone proprionate HFA
Asmanex HFA, Asmanex	(Flovent HFA authorized generic)
Twisthaler, Flovent	,
Diskus	
LABA: Brand Brovana	Medical justification supports inability to use generic
	arformoterol (generic Brovana), Serevent® Diskus®
	AND Striverdi® Respimat®, unless documentation
TABA B. 1	supports inability to use inhaler devices
LABA: Brand	Medical justification supports inability to use generic
Perforomist	formoterol (generic Perforomist), Serevent® Diskus®
	AND Striverdi® Respirat®, unless documentation
I AMA I autata	supports inability to use inhaler devices
LAMA: Lonhala Magnair, Seebri	Incruse <sup>®</sup> Ellipta <sup>®</sup> AND Spiriva <sup>®</sup> Handihaler <sup>®</sup> / Respimat <sup>®</sup> , unless request is for a nebulized LAMA
Neohaler, Tudorza	-
Pressair, Yupelri	and documentation supports inability to use inhaler devices
Brand Advair Diskus	Medical justification supports inability to use generic
Brand Advan Diskus	fluticasone/salmeterol products (generic Advair
	Diskus, Wixela <sup>™</sup> Inhub <sup>™</sup> ) (e.g., contraindications to
	excipients)
Brand Advair HFA	Medical justification supports inability to use
Brana riavan ili ri	fluticasone-salmeterol HFA (Advair HFA authorized
	generic) (e.g., contraindications to excipients)
Brand Symbicort,	Medical justification supports inability to use generic
Symbicort Aerosphere	Symbicort (e.g., contraindications to excipients)
All other ICS/LABA –	fluticasone-salmeterol HFA (Advair HFA authorized
for California Exchange	generic) AND Breo Ellipta®/fluticasone furoate-
<i>Plans ONLY</i> : AirDuo	vilanterol (Breo Ellipta authorized generic) AND
Digihaler, AirDuo	budesonide/formoterol (generic Symbicort) AND
RespiClick	fluticasone/salmeterol (generic Advair Diskus or
	Wixela Inhub) AND Dulera
All other ICS/LABA –	fluticasone-salmeterol HFA (Advair HFA authorized
for all other Commercial	generic) AND Breo Ellipta®/fluticasone furoate-
formularies: AirDuo	vilanterol (Breo Ellipta authorized generic) AND
Digihaler, AirDuo	budesonide/formoterol (generic Symbicort) AND
RespiClick, Dulera	fluticasone/salmeterol (generic Advair Diskus or Wixela Inhub)
LABA/LAMA: Bevespi	Stiolto® Respimat® AND Anoro® Ellipta®
Aerosphere, Duaklir	Shorto Respinate 1112 Inforto Empta
Pressair, Utibron	
Neohaler	
Ohtuvayre	Anoro Ellipta <i>OR</i> Stiolto Respimat <i>OR</i> one LABA
J	(e.g., Serevent Diskus) in combination with one
	LAMA (e.g., Incruse Ellipta)



Requested Agent	Required Step Through Agent(s)
	<ul> <li>AND</li> <li>For members with blood eosinophil count ≥ 100 cells/mcL: Breztri Aerosphere OR Trelegy Ellipta®</li> </ul>
	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<sub>1</sub>)/forced vital capacity (FVC) ratio of < 0.70;
    - ii. Post-albuterol FEV<sub>1</sub>  $\geq$  30 % and  $\leq$  70% of predicted normal;
  - b. Ohtuvayre is not prescribed in combination with Daliresp®;
- 6. Request does not exceed one of the following (a or b):
  - a. The health plan quantity limit;
  - b. 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.CPA.190 for commercial; 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.CPA.190 for commercial; 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.CPA.09 for commercial.

### **II. Continued Therapy**

### A. All Requests in Section I (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 or b):
  - a. The health plan quantity limit;
  - b. 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.CPA.190 for commercial; 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.CPA.190 for commercial; 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.CPA.09 for commercial.

### 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.CPA.09 for commercial 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<sub>1</sub>: 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	Asthma: 2 inhalations BID (starting dosage is based on asthma severity)	Asthma: 2 inhalations of 230/21 mcg BID
authorized generic)		



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	MDI: 12 puffs/day  Nebulization solution:
, <i>,</i>	Nebulization solution: 2.5 mg via oral inhalation every 6 to 8 hours as needed	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	Asthma: 200/25 mcg/day
Vitaliterory	Age 12-17 years: 1 inhalation of 100/25 mcg QD Age 5-11 years: 1 inhalation of 50/25 mcg QD	COPD: 100/25 mcg/day
	COPD: 1 inhalation of 100/25 mcg QD	
Breztri Aerosphere	COPD: 2 inhalations by mouth BID	4 inhalations/day
budesonide/formoterol	Asthma: 2 inhalations BID	Asthma/COPD:
(Symbicort)	COPD: 2 inhalations (160/4.5 mcg) BID	160/4.5 mcg BID
Flovent Diskus	Asthma: 1 inhalation BID (starting	Asthma: 2,000
(fluticasone)	dosage is based on asthma severity)	mcg/day
Flovent HFA (fluticasone)	Asthma: 1 inhalation BID	Asthma: 1,760 mcg/day



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fluticasone/salmeterol (Advair Diskus, Wixela Inhub)	Asthma: 1 inhalation BID (starting dosage is based on asthma severity	Asthma: 500/50 mcg BID
,	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
Pulmicort Flexhaler (budesonide)	Asthma: Starting dose of 180-360 mcg inhaled BID	Asthma: 720 mcg BID
Qvar RediHaler	Asthma:	Asthma:
(beclomethasone)	$\geq$ 12 years: 40 mcg, 80 mcg, 160 mcg,	$\geq$ 12 years: 640
	or 320 mcg inhaled BID	mcg/day
	4-11 years: 40 mcg or 80 mcg inhaled	4-11 years: 160
	BID	mcg/day
Serevent (salmeterol)	Asthma/COPD: 1 inhalation (50 mcg)	Asthma/COPD: 100
	BID	mcg/day
Spiriva Handihaler	COPD: 2 inhalations (18 mcg) QD	COPD: 18 mcg/day
(tiotropium bromide		
monohydrate)		
Spiriva Respimat (tiotropium bromide	Asthma: 2 inhalations (1.25 mcg) QD	Asthma: 2.5 mcg/day
monohydrate)	COPD: 2 inhalations (2.5 mcg) QD	COPD: 5 mcg/day
Stiolto Respimat	COPD: 2 inhalations QD at the same	COPD: 2
(tiotropium/olodaterol)	time of day	inhalations/day
Striverdi Respimat	COPD: 2 inhalations QD	COPD: 5 mcg/day
(olodaterol)		
Trelegy Ellipta	Asthma: 1 inhalation (100/62.5/26 mcg	Asthma: 200/62.5/26
(fluticasone/	or 200/62.5/26 mcg) by mouth QD	mcg/day
umeclidinium/		-
vilanterol)	COPD: 1 inhalation (100/62.5/26 mcg)	COPD: 100/62.5/26
	by mouth QD	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, Flovent Diskus: milk proteins
    - Brovana: racemic formoterol
  - o Advair HFA/Diskus, AirDuo Digihaler/RespiClick, Alvesco, ArmonAir Digihaler, Asmanex HFA/Twisthaler, Dulera, Flovent Diskus, Flovent HFA: primary treatment



- of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures
- o 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:
  - o 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	<b>Maximum Dose</b>
Advair Diskus	Asthma	1 inhalation BID (starting dosage is	500/50 mcg BID
		based on asthma severity)	
	COPD	1 inhalation of 250/50 mcg BID	250/50 mcg BID
Advair HFA	Asthma	2 inhalations BID (starting dosage is	2 inhalations of
		based on asthma severity)	230/21 mcg BID
AirDuo	Asthma	1 inhalation BID (starting dosage is	232/14 mcg BID
Digihaler		based on asthma severity)	
AirDuo	Asthma	1 inhalation BID (starting dosage is	232/14 mcg BID
RespiClick		based on asthma severity)	
Alvesco	Asthma	Starting dose for patients who received bronchodilators alone: 80 mcg inhaled BID	320 mcg/day
		Starting dose for patients who received inhaled corticosteroids: 80 mcg inhaled BID	640 mcg/day
		Starting dose for patients who received oral corticosteroids: 320 mcg inhaled BID	640 mcg/day
ArmonAir Digihaler	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	232 mcg BID
Asmanex	Asthma	2 inhalations BID (starting dosage is	800 mcg/day
HFA		based on age and asthma severity)	
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	COPD	One inhalation by mouth BID	2 inhalations/day
Pressair		,	
Dulera	Asthma	Age 5 to 11 years: 2 inhalations of 50/5 mcg BID Age ≥ 12 years: 2 inhalations of	200/5 mcg/day 800/20 mcg/day
		100/5 mcg or 200/5 mcg BID (starting dosage is based on asthma severity)	800/20 meg/day
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.	880 mcg BID



<b>Drug Name</b>	Indication	Dosing Regimen	<b>Maximum Dose</b>
		Pediatric patients aged 4 to 11 years: 88 mcg twice daily	
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
Seebri Neohaler	COPD	One inhalation (15.6 mcg) BID	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
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



Drug Name	Availability
ArmonAir	Inhalation powder containing 55 mcg, 113 mcg, or 232 mcg of fluticasone
Digihaler	propionate per actuation. ArmonAir Digihaler contains a built-in
	electronic module
Asmanex	Inhalation aerosol containing 50 mcg, 100 mcg, or 200 mcg of
HFA	mometasone furoate per actuation
Asmanex	Inhalation device: 110 mcg (delivers 100 mcg/actuation), 220 mcg
Twisthaler	(delivers 200 mcg/actuation)
Bevespi	Inhalation aerosol: pressurized metered dose inhaler containing a
Aerosphere	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	Inhalation powder: 30 and 60 metered dose dry powder inhaler metering
Pressair	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	Inhalation powder: Inhaler containing fluticasone propionate (50, 100, or
Diskus	250 mcg) as a powder formulation for oral inhalation
Flovent HFA	Inhalation aerosol: 44 mcg, 110 mcg, 220 mcg per actuation
Lonhala	Sterile solution for inhalation in a unit-dose vial: 25 mcg/mL
Magnair	
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
ProAir	Inhalation powder: dry powder inhaler 108 mcg of albuterol sulfate
Digihaler	(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
Seebri	Inhalation powder in capsules: 15.6 mcg of glycopyrrolate inhalation
Neohaler	powder for use with the Neohaler device
Symbicort	Metered-dose inhaler: budesonide (80 or 160 mcg) and formoterol (4.5
	mcg) as an inhalation aerosol
Symbicort	Metered-dose inhaler: budesonide (160 mcg) and formoterol (4.8 mcg) as
Aerosphere	an inhalation aerosol
Tudorza	Inhalation powder in a multi-dose dry powder inhaler: 400 mcg/actuation
Pressair	
Utibron	Inhalation powder in capsule, for use with the Neohaler device: 27.5 mcg
Neohaler	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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### **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, and CP.CPA.348 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	
Per October SDC, removed Breztri Aerosphere from criteria.	10.27.21	



Reviews, Revisions, and Approvals	Date	P&T
		Approval Date
1Q 2022 annual review: no significant changes; references reviewed		02.22
and updated.		
Per May SDC and prior clinical guidance, for Brovana and		
Perforomist added requirement for use of their respective generics, in		
addition to previously required Serevent Diskus and Striverdi		
Respimat.		
Template changes applied to other diagnoses/indications and	09.28.22	
continued therapy section.		
1Q 2023 annual review: no significant changes; updated Appendix D	01.11.23	02.23
with updated 2023 GOLD guideline recommendations; references		
reviewed and updated.		
RT4: added newly approved dosage form Symbicort Aerosphere to	05.26.23	
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).		
Per September SDC and prior clinical guidance, revised redirection	09.21.23	12.23
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 from brand Advair HFA to		
instead redirect to fluticasone-salmeterol HFA (Advair HFA		
authorized generic), revised redirection to Breo Ellipta to allow either		
brand or authorized generic.		
1Q 2024 annual review: no significant changes; references reviewed	10.09.23	02.24
and updated.		
Per March SDC, for "All other ICS/LABA" created separate row for	03.12.24	05.24
California Exchange Plans requiring an additional redirection to		
Dulera.		
RT4: added newly approved agent Ohtuvayre with redirections per	07.03.24	11.24
SDC.	11.06.24	
HCPCS code added [J7601].		
1Q 2025 annual review: no significant changes; updated Appendix D		02.25
with latest GOLD guideline recommendations on Ohtuvayre;		
references reviewed and updated.	08.04.25	
Removed Arcapta Neohaler from criteria as it is no longer		
commercially available.		



### **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.

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