Clinical Policy: Inhaled Agents for Asthma and COPD

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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): beclomethasone (Qvar RediHaler®), budesonide (Pulmicort Flexhaler™, Pulmicort Respules®*), ciclesonide (Alvesco®), fluticasone (ArmonAir® Digihaler™, Arnuity Ellipta®*), mometasone (Asmanex Twisthaler®),
•Long acting beta-2 agonist (LABA): arformoterol (Brovana®), formoterol (Perforormist), salmeterol (Serevent Diskus®)
•Long acting muscarinic antagonist (LAMA): aclidinium bromide (Tudorza Pressair®), revefenacin (Yupelri®), umeclidinium (Incruse Ellipta®), tiotropium (Spiriva® Handihaler*)
•Combination ICS/LABA: budesonide/formoterol (Symbicort®, Symbicort Aerosphere®)*, fluticasone/vilanterol (Breo Ellipta®), fluticasone/salmeterol (Advair Diskus®*, Advair HFA®*, AirDuo® Digihaler™, AirDuo® RespiClick®)
•Combination LABA/LAMA: aclidnium/formoterol (Duaklir® Pressair®), glycopyrrolate/formoterol (Bevespi Aerosphere™),umeclidinium/vilanterol (Anoro Ellipta®*)
•Combination ICS/LAMA/LABA: budesonide/glycopyrrolate/formoterol (Breztri Aerosphere™)
•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)	
Arnuity Ellipta	X (Age ≥ 4 years)	
Asmanex Twisthaler	X (Age ≥ 4 years)	
Pulmicort Flexhaler	X (Age ≥ 6 years)	
Pulmicort Respules	X (Age 1-8 years)	
Qvar Redihaler	X (Age ≥ 5 years)	

LABA		
Brovana		X
Perforomist		X
Serevent Diskus		X
LAMA		
Incruse Ellipta		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)	
Breo Ellipta	X (Age ≥ 5 years)	X
Symbicort	X (Age ≥ 6 years)	X
Symbicort Aerosphere	X (Age ≥ 12 years)	X
LABA/LAMA		
Bevespi Aerosphere		X
Duaklir Pressair		X
ICS/LABA/LAMA		
Breztri Aerosphere	X (Age ≥ 12 years)	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 PA Health & Wellness® 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. For all other agents: 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	Two generic albuterol sulfate HFA products, each from a different manufacturer
Brand Arnuity Ellipta®	Medical justification supports inability to use authorized generic Arnuity® Ellipta® (e.g., contraindications to excipients)
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, Asmanex Twisthaler, Qvar® RediHaler™	At least two of the following: fluticasone propionate diskus (Flovent Diskus authorized generic), fluticasone propionate HFA (Flovent HFA authorized generic), Pulmicort Flexhaler™, fluticasone furoate (Arnuity® Ellipta® authorized generic), *or* Asmanex® HFA
LABA: Brovana, Perforomist, Serevent® Diskus®	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 Spiriva® Handihaler (e.g., contraindications to excipients)
LAMA: Incruse Ellipta, Tudorza Pressair, Yupelri	Spiriva® Respimat® *AND* generic Spiriva® Handihaler, unless request is for a nebulized LAMA and documentation supports inability to use inhaler devices
Brand Advair Diskus, Advair HFA	Medical justification supports inability to use generic fluticasone/salmeterol products (generic Advair Diskus, Wixela™ Inhub™) (e.g., contraindications to excipients)
Requested Agent	**Required Step Through Agent(s)**
Brand Symbicort, Symbicort Aerosphere	Medical justification supports inability to use generic Symbicort (e.g., contraindications to excipients)
Breo Ellipta	• For age ≥ 6 years: fluticasone/salmeterol (generic Advair Diskus or Wixela Inhub) *AND* budesonide/formoterol (generic Symbicort) • For age < 6 years: fluticasone/salmeterol (generic Advair Diskus or Wixela Inhub)

All other ICS/LABA: AirDuo Digihaler, AirDuo RespiClick	Fluticasone/salmeterol (generic Advair Diskus or Wixela Inhub) *AND* budesonide/formoterol (generic Symbicort)
LABA/LAMA: Bevespi Aerosphere, Duaklir Pressair	• For COPD only: Either umeclidinium/vilanterol (Anoro Ellipta authorized generic) OR Stiolto Respimat OR one LABA (e.g., Striverdi Respimat) in combination with one LAMA (e.g., Spiriva Respimat, generic Spiriva Handihaler) • For asthma only: fluticasone/salmeterol (generic Advair Diskus or Wixela Inhub) *AND* budesonide/formoterol (generic Symbicort)
Brand Anoro Ellipta	Medical justification supports inability to use authorized generic Anoro Ellipta (e.g., contraindications to excipients)
ICS/LABA/LAMA: Breztri Aerosphere	• For COPD only: one LABA (e.g., Striverdi Respimat) in combination with one LAMA (e.g., Spiriva Respimat, generic Spiriva Handihaler) • For asthma only: fluticasone/salmeterol (generic Advair Diskus or Wixela Inhub) *OR* budesonide/formoterol (generic Symbicort)
Ohtuvayre	Either umeclidinium/vilanterol (Anoro Ellipta authorized generic) OR Stiolto Respimat OR one LABA (e.g., Striverdi Respimat) in combination with one LAMA (e.g., Spiriva Respimat, generic Spiriva Handihaler))*AND* • For members with blood eosinophil count ≥ 100 cells/mcL: 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 $FEV_1 \geq 30$ % and ≤ 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

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
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: up to a total duration of 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53

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

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
WHO: World Health Organization

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 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	Asthma: ≥ 12 years: 200 mcg/day
budesonide/formoterol (Symbicort)	Asthma: Maintenance therapy only: 2 inhalations BID Maintenance +Reliever therapy (MART): 1-2 inhalations every 4 hours COPD: 2 inhalations (160/4.5 mcg) BID	Asthma/COPD: 160/4.5 mcg BID MART: 12 inhalations/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
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
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
tiotropium bromide monohydrate (Spiriva Handihaler)	COPD: Two inhalations (18 mcg) QD	18 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, Breztri Aerosphere, Pulmicort Flexhaler, Trelegy Ellipta: milk proteins
    - Brovana: racemic formoterol
  - Advair HFA/Diskus, AirDuo Digihaler/RespiClick, Alvesco, ArmonAir Digihaler, Asmanex Twisthaler, Breo Ellipta, Dulera, Pulmicort Flexhaler/Respules, Symbicort Aerosphere,Trelegy Ellipta: primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures
  - Anoro Ellipta, Bevespi Aerosphere, Brovana, Duaklir Pressair, Stiolto Respimat, Striverdi Respimat, Perforomist: 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.
- 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
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	Asthma	2 inhalations of 160/18/4.8 mcg by mouth BID	4 inhalations/day
	COPD	2 inhalations of 160/9/4.8 mcg 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	200/5 mcg/day 800/20 mcg/day

		(starting dosage is based on asthma severity)	
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 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
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	Asthma	2 inhalations (80 mcg/4.8 mcg or 160/4.8 mcg; starting dosage is based on asthma severity) BID	320/9.6 mcg BID
	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
Tudorza Pressair	COPD	1 inhalation (400 mcg) by mouth BID	800 mcg/day

Yupelri	COPD	One 175 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
Anoro Ellipta	Inhalation powder: 62.5 mcg umeclidinium and 25 mcg vilanterol (62.5/25 mcg) per 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 Twisthaler	Inhalation device: 110 mcg (delivers 100 mcg/actuation), 220 mcg (delivers 200 mcg/actuation)
Drug Name	**Availability**
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 or 18 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
Incruse Ellipta	Inhalation powder: 62.5 mcg umeclidinium per actuation
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 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 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
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 (80 or 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)
Tudorza Pressair	Multi-dose dry powder inhaler: 400 mcg of aclidinium bromide per actuation
Yupelri	Inhalation solution (unit-dose vial for nebulization): 175 mcg/3 mL

V. References

SABA

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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
Policy created	09/2025
2Q 2026 annual reviewRemoved Arcapta Neohaler, Flovent Diskus, Flovent HFA, Lonhala Magnair, Seebri Neohaler, Utibron Neohaler from criteria as they are no longer commercially available. Added newly launched authorized generic products for Arnoro Ellipta and Arnuity Ellipta; references reviewed and updated. RT4: per updated prescribing information – for Breztri Aerosphere, added new indication for asthma in patients 12 years of age and older	05/2026

Reviews, Revisions, and Approvals	Date
and new strength of 18 mcg glycopyrrolate; for Symbicort Aerosphere, added new indication for asthma in patients 12 years of age and older and new strength of 80 mcg budesonide.	