

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

<b>POLICY:</b>	Asthma/COPD	<b>P&amp;T DATE</b>	2/9/2021
<b>CLASS:</b>	Respiratory Disorders	<b>REVIEW HISTORY</b>	2/20, 2/19, 12/17,12/16,
<b>LOB:</b>	Medi-Cal	(MONTH/YEAR)	5/15, 9/14, 2/13, 5/12

*This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee*

## OVERVIEW

Asthma is a reversible, chronic, inflammatory disorder that involves narrowing of the respiratory airways leading to wheezing, chest tightness, and shortness of breath. Inhaled corticosteroids are the mainstay of therapy and the goal of treatment is to reverse airway obstruction and maintain respiratory control. Chronic obstructive pulmonary disease (COPD) is another chronic airway disorder. Unlike asthma, COPD is not reversible. The goal of COPD management is to slow disease progression. COPD is managed with a combination of inhaled corticosteroids and anticholinergics. Some patients exhibit both features of asthma and COPD; this is called Asthma-COPD Overlap Syndrome (ACOS). The below criteria, limits, and requirements for asthma & COPD agents are in place to ensure appropriate use and to help members achieve control of their Asthma or COPD.

**Table 1: Available Asthma/COPD Medications (Current as of 1/2020)**

Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Avg Cost per 30 days	Notes/Restriction Language
<b>Single Agents</b>				
<b>Short Acting Beta Agonist (SABA)</b>				
Albuterol	90 mcg/act	QL	\$53.28	Limit 2 inhalers per 30 days; Limit 7 inhalers per 180 days. Overuse of Short Acting Bronchodilators may indicate poor Asthma/COPD control.
Albuterol (ProAir HFA, Proventil HFA, ProAir Digihaler (108 mcg/act), ProAir Respiclick, Ventolin HFA)	90 mcg/act	NF	ProAir: \$97.40 Proventil: \$157.33 Respiclick \$61.91	Non-Formulary: Alternative is Ventolin
Albuterol Syrup	2 mg/5 mL Syrup	NF	--	Non-Formulary: Alternatives are Ventolin, Albuterol nebulizer solution
Albuterol Sulfate IR, ER Tablets (Vospire ER)	2 mg, 4 mg IR Tablet 4 mg, 8 mg ER Tablet	NF	--	Non-Formulary: Alternatives are Ventolin, Albuterol nebulizer solution
Ephedrine/ Guaifenesin Tablets (Primatene Asthma)	12.5/200 mg Tablets	NF	--	
Levalbuterol (Xopenex HFA)	45 mcg/act	QL	\$56.57	.Limit 2 inhalers per 30 days; Limit 7 inhalers per 180 days. Overuse of Short Acting Bronchodilators may indicate poor Asthma/COPD control.
	Xopenex HFA	NF	\$69.75	
Metaproterenol	10 mg/5 mL Syrup, 10 mg, 20 mg Tablet	NF	--	

Short Acting Anticholinergic (SAMA)				
Ipratropium (Atrovent HFA)	17 mcg/act	QL	\$11.01	Limit 2 packages per 30 days. Overuse of Short Acting Bronchodilators may indicate poor Asthma/COPD control.
	Atrovent HFA	NF	\$397.05	
Long Acting Beta Agonist (LABA)				
Salmeterol Xinafoate (Serevent Diskus)	50 mcg/act	NF	\$395.03	Non-Formulary: Alternative is Striverdi Respimat
Formoterol Fumarate (Foradil)	12 mcg Inhalation Capsule	PA; ST; QL	--	<b>For Asthma:</b> Concurrent use of ICS is required. <b>For COPD:</b> Restricted to COPD Grade II or worse, group B or worse Limit 1 package per 30 days.
Indacaterol Maleate (Arcapta Neohaler)	75 mcg/act	NF	--	Non-Formulary: Alternative is Striverdi Respimat
Olodaterol Hydrochloride (Striverdi Respimat)	2.5 mcg/act	PA; ST; QL	\$216.07	<b>For Asthma:</b> Concurrent use of ICS is required. <b>For COPD:</b> Restricted to COPD Grade II or worse, group B or worse Limit 1 package per 30 days.
Long Acting Anticholinergic (LAMA)				
Tiotropium Bromide (Spiriva)	Handihaler: 18 mcg Inhalation Capsule Respimat: 2.5 mcg/act	PA; QL (Respimat)	Handihaler \$437.05 Respimat: \$437.41	Documentation of diagnosis of COPD GOLD Group B is required for approval. Respimat: Limit 1 package per 30 days.
Tiotropium Bromide (Spiriva Respimat)	1.25mcg/act	ST	\$437.49	Step therapy to Montelukast AND one of the following: Symbicort (160 mcg/4.5 mcg), AirDuo(232 mcg/14 mcg), OR Dulera (200 mcg/5 mcg) within the last 30 days.
Acidinium Bromide (Tudorza Pressair)	400 mcg/act	PA; QL	\$406.01	Documentation of diagnosis of COPD GOLD Group B is required for approval. Limit 1 package per 30 days.
Seebri Neohaler (glycopyrrolate)	15.6mcg	NF	--	--
Umeclidinium Bromide (Incruse Ellipta)	62.5 mcg/act	NF	\$340.46	Non-Formulary: Alternatives are Spiriva Handihaler, Spiriva Respimat 2.5 mcg, Tudorza

Inhaled Corticosteroid (ICS)				
Beclomethasone dipropionate (Qvar Redihaler)	40 mcg/act 80 mcg/act	QL	\$244.54	Limit 1 package per 30 days
Budesonide (Pulmicort Flexhaler)	90 mcg/act	NF	\$329.86	Non-Formulary: Alternatives are Flovent HFA 44 mcg, Flovent Diskus 50 mcg, Asmanex Twisthaler 110 mcg, Qvar 40 mcg
Budesonide (Pulmicort Flexhaler)	180 mcg/act	QL	\$466.58	Limit 1 package per 30 days
Ciclesonide (Alvesco)	80 mcg/act 160 mcg/act	NF	--	Non-Formulary: Alternatives are Pulmicort Flexhaler, Asmanex Twisthaler, Qvar, Flovent HFA/Diskus, Arnuity Ellipta

Flunisolide (Aerospan)	80 mcg/act	NF	--	Non-Formulary: Alternatives are Pulmicort Flexhaler, Asmanex Twisthaler, Qvar, Flovent HFA/Diskus
Fluticasone furoate (Arnuity Ellipta)	100 mcg/act 200 mcg/act	AL; QL	\$403.77	Restricted to patients 12 years and older. Limit 1 device per 30 days.
Fluticasone propionate (Flovent HFA/Diskus)	Diskus: 50 mcg/act 100 mcg/act 250 mcg/act HFA: 44 mcg/act 110 mcg/act 220 mcg/act	QL	Diskus: \$406.71 HFA: \$546.61	Limit 1 package per 30 days
Fluticasone propionate (ArmonAir Respiclick)	55 mcg 113 mcg 232 mcg	NF	--	Limit 1 package per 30 days
Mometasone furoate (Asmanex Twisthaler)	110 mcg/act (30 doses) 220 mcg/act (30, 60, or 120 doses)	AL (110 mcg); QL	\$467.07	Limit 1 package per 30 days. 110 mcg: Restricted to patients under the age of 12.
Mometasone furoate (Asmanex HFA)	100 mcg/act 200 mcg/act	NF	--	Non-Formulary: Alternatives are Pulmicort Flexhaler, Asmanex Twisthaler, Qvar, Flovent HFA/Diskus
<b>Combination Agents</b>				
<b>Short Acting Combination</b>				
Ipratropium/Albuterol (Combivent Respimat)	20 mcg/100 mcg	QL	\$377.48	Limit 1 package per 30 days. Should not be used with Tiotropium.
<b>Long Acting Combination</b>				
Budesonide/ Formoterol (Symbicort)	80 mcg/4.5mcg 160 mcg/4.5 mcg	QL	\$311.00	Limit 1 package per 30 days
Fluticasone/ Salmeterol (AirDuo Respiclick, Advair Diskus or HFA)	Respiclick: 55/14 mcg 113/14 mcg 232/14 mcg	QL	\$83.66	Limit 1 package per 30 days
	Diskus: 100 mcg/50 mcg 250 mcg/50 mcg 500 mcg/50 mcg  HFA: 45 mcg/21mcg 115 mcg/21mcg 230 mcg/21 mcg		Diskus: \$711.87 HFA: \$401.38	
Fluticasone/Vilanterol (Breo Ellipta)	100 mcg-25 mcg 200 mcg-25 mcg	QL	\$671.20	Limit 1 package per 30 days.
Aclidinium/Formoterol (Duklir)		NF		
Fluticasone, Umeclidinium, and Vilanterol (Trelegy Ellipta)	100 mcg/ 62.5 mcg/25 mcg	PA	--	[1] Reserved for patients with COPD GOLD grade 3 or 4 Group D with compliant use of ICS+LABA or LABA+LAMA [2] Limit: 1 Inhaler per 30 days

Mometasone/ Formoterol (Dulera)	100 mcg-5mcg 200 mcg-5mcg	QL	\$313.46	Limit 1 package per 30 days
Tiotropium/ Otodaterol (Stiolto Respimat)	2.5 mcg-2.5 mcg	PA, QL	\$373.41	Reserved for patients with at least B COPD confirmed by PFTs. Limit 1 inhaler per 30 days.
Umeclidinium/ Vilanterol (Anoro Ellipta)	62.5 mcg-25 mcg	PA, QL	--	
Glycopyrrolate/ Indacaterol (Utibron Neohaler)	27.5 mcg-15.6 mcg	NF	--	Non-Formulary: Alternatives include AirDuo, Symbicort, Dulera, Combivent, Stiolto Respimat
Glycopyrrolate/ Formoterol (Bevespi Aerosphere)	9 mcg-4.8 mcg	NF	--	Non-Formulary: Alternatives include AirDuo, Symbicort, Dulera, Combivent, Stiolto Respimat
<b>Leukotriene Receptor Antagonist</b>				
Montelukast Sodium (Singulair)	4 mg, 5 mg Chewable Tablet 10 mg Tablet	QL	Tablets \$5.55	Limit 30 tablets per 30 days
	4 mg Oral Granules	NF	\$112.63	
Zafirlukast (Accolate)	10 mg, 20 mg Tablet	NF	\$101.14	Non-Formulary: Alternative is montelukast
<b>5-Lipoxygenase Inhibitor</b>				
Zileuton (Zyflo, Zyflo CR)	600 mg Tablet 600 mg ER Tablet	NF	\$2,611.59	Indicated for Asthma only
<b>Xanthine/Phosphodiesterase Enzyme Inhibitor, Nonselective</b>				
Theophylline (Theo-24, Elixophyllin, Theochron)	80mg/15mL Oral Elixir/Solution 100 mg, 200 mg, 300 mg, ER Cap (Theo-24) 100 mg, 200 mg, 300 mg ER Tab (Theochron, 12-hr) 400 mg, 600 mg ER Tab (24-hr) 450 mg ER Tab (Theochron, 12-hr)	--	Theo-24: \$109.40  Theophylli ER : \$43.29	Narrow therapeutic window. Should be reserved as last line therapy.
Theophylline (Theo-24)	400 mg ER Cap	NF	--	Non-Formulary: Alternative is theophylline 400 mg ER tablet
Theophylline	400 mg, 800 mg IV Solution	NF	--	
Aminophylline	25 mg/ml, 50 mg/ml injection	NF	--	
<b>PDE-4 Inhibitor</b>				
Roflumilast (Daliresp)	250 mcg, 500 mcg Tablet	PA; ST	\$1,228.79	[1] Reserved for patients with GOLD Grade 4, Group D [2] Limit: Daliresp 250 mcg #30 in 365 days. Daliresp 500 mcg #30 per 30 days. [3] Treatment failure or intolerant to high dose ICS plus LABA plus LAMA in the past 12 weeks.

<b>Monoclonal Antibody, Anti-Asthmatic</b>				
Dupilumab (Dupixent)	200 mg/1.14 ml, 300 mg/2 ml syringe	PA, ST, SP	\$2,918.36	<p><b>For Eosinophilic asthma:</b> Reserved as an add on therapy for patients 12 years and older with moderate to severe asthma.</p> <p><b>For Oral corticosteroid dependent asthma:</b> Reserved as an add on therapy for patients 12 years and older who are dependent on oral steroid</p> <p><b>See below for detailed information</b></p>
Omalizumab (Xolair)	75 mg/ 0.5 ml, 150 mg/ ml syringes	PA	\$2,312.14	Reserved for inadequate asthma control or uncontrolled chronic idiopathic urticaria
Mepolizumab (Nucala)	100 mg Vial	PA, SP	\$2,921.43	Reserved for patients ages 6 and older with poorly controlled, severe eosinophilic asthma
	Autoinjector 100 mg/ml		--	
	Prefilled syringes 100 mg/ml		--	
Benralizumab (Fasenra)	30mg Injection	NF	--	Reserved for patients with poorly controlled, severe eosinophilic asthma
Reslizumab (Cinqair)	100 mg/10 mL IV Solution	NF	--	Indicated for Asthma only. Dose is weight-dependent (3 mg/kg).
<b>Solution for Nebulization</b>				
<b>Short Acting Beta Agonist (SABA)</b>				
Albuterol Sulfate	0.63 mg/3 mL	QL	\$31.76	Limit 375 mL per 30 days
	1.25 mg/3 mL			
	2.5 mg/0.5 mL (0.083%)			
	2.5 mg/3 mL			
	5 mg/mL (0.5%)			
Levalbuterol Hydrochloride	0.31 mg/3 mL	QL	\$132.09	Limit 375 mL per 30 days
	0.63 mg/3 mL			
	1.25 mg/3 mL			
	1.25 mg/0.5 mL			
<b>Short Acting Anticholinergic</b>				
Ipratropium Bromide	0.02% Nebulization Solution	--	\$13.61	
<b>Long Acting Anticholinergic</b>				
Revefenacin (Yupelri)	175 mcg Nebulization solution	NF	--	
<b>Short Acting Combination</b>				
Ipratropium/ Albuterol (Duoneb)	0.5 mg/3 mg (2.5 mg Base)/3 mL	QL	\$23.73	Limit 375 mL per 30 days
<b>Inhaled Corticosteroid</b>				
Budesonide	0.25 mg/2 mL 0.5 mg/2 mL 1 mg/2 mL	AL; QL	\$818.65	Limit 120 mL per 30 days. Restricted to members ≤ 4 years old.
<b>Long Acting Antimuscarinic</b>				

Glycopyrrolate (Lonhala Magnair)	25 mcg vial	NF	--	Non-Formulary
<b>Long Acting Beta Agonist</b>				
Formoterol Fumarate Dihydrate (Perforomist)	20 mcg/2 mL	NF	\$975.66	Non-Formulary: Formulary alternative is Serevent Diskus
Arformoterol (Brovana)	15 mcg/2 ml	NF	\$986.55	Non-Formulary: Formulary alternative is Serevent Diskus
<b>General Inhalation Solutions</b>				
Sodium chloride Vials	0.9%	--	\$12.74	
	Nebusal 3%	NF	\$12.94	
	3%	NF	\$24.84	
	Hyper-Sal 3.5%	NF	\$45.05	
	Hyper-Sal 7% Vial	NF	\$45.05	
	7%	--	\$23.32	
<b>Mast Cell Stabilizer</b>				
<b>Cromolyn Sodium</b>	20 mg/2 mL	--	--	--
<b>Medical Equipment</b>				
<b>Peak Air Peak Flow Meter</b>				
Peak Flow Meter		QL	\$14.46	Limit 1 per lifetime
Bubbles the Fish II Pedi Mask	--	QL	--	Limit 1 per lifetime. Submit PA for lost/broken.
Optichamber Adult Mask	Large	QL	\$9.89	Limit 2 per year
Optichamber Diamond with mask	Large Medium Small	QL	\$27.90	Limit 2 per year
Vortex Holding Chamber with + without mask	Child Mask (Frog) Toddler Mask (Ladybug)	QL	\$23.73	Limit 2 per year
<b>Nebulizer</b>				
Nebulizer	--	QL	--	Limit 1 per lifetime. Max amount = \$100.

PA = Prior Authorization; QL = Quantity Limit; AL = Age Limit; NF = Non-formulary

## ⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

### **Short Acting Beta Agonists**

*Albuterol sulfate (Ventolin HFA, ProAir HFA, Proventil HFA, albuterol syrup, albuterol tablets), Levalbuterol tartrate (Xopenex HFA)*

#### **Albuterol Sulfate, Levalbuterol Tartrate**

- **Coverage Criteria:** None
- **Limits:** 2 inhalers per 30 days; 7 inhalers per 180 days
- **Required Information for Approval:** N/A
- **Other Notes:** Use of more than 7 inhalers per 180 day period may indicate uncontrolled asthma. Consider starting or titrating a controller agent.
- **Non-Formulary:** ProAir, Proventil, Albuterol syrup, Albuterol tablets

### **Short Acting Anticholinergics**

*Ipratropium bromide (Atrovent HFA)*

- **Coverage Criteria:** None
- **Limits:** 2 inhalers per 30 days
- **Required Information for Approval:** N/A
- **Other Notes:** Usage above the quantity limit may indicate uncontrolled disease. Consider adding or titrating a controller agent.

### **Inhaled Corticosteroid**

*Fluticasone Propionate (Flovent HFA/Diskus), Fluticasone Furoate (Arnuity Ellipta), Mometasone Furoate (Asmanex Twisthaler/HFA), Beclomethasone Dipropionate (Qvar), Budesonide (Pulmicort Flexhaler), Flunisolide (Aerospan), Ciclesonide (Alvesco)*

#### **Fluticasone Propionate (Flovent HFA/Diskus), Beclomethasone Dipropionate (Qvar)**

- **Coverage Criteria:** None
- **Limits:** 1 inhaler/device per 30 days
- **Required Information for Approval:** N/A
- **Other Notes:** None
- **Non-Formulary:** Flunisolide (Aerospan), (Ciclesonide (Alvesco)

#### **Fluticasone Furoate (Arnuity Ellipta)**

- **Coverage Criteria:** Fluticasone Furoate (Arnuity Ellipta) is reserved for patients 12 years and older.
- **Limits:** 1 inhaler per 30 days
- **Required Information for Approval:** N/A
- **Other Notes:** None

#### **Mometasone Furoate (Asmanex Twisthaler), Budesonide (Pulmicort Flexhaler 180 mcg)**

- **Coverage Criteria:** Mometasone Furoate (Asmanex Twisthaler) 110 mcg and Budesonide (Pulmicort Flexhaler) 180 mcg are reserved for patients under the age of 12.
- **Limits:** 1 inhaler/device per 30 days
- **Required Information for Approval:** N/A
- **Other Notes:** Asmanex Twisthaler 220 mcg has no age restriction.
- **Non-Formulary:** Asmanex HFA, Pulmicort Flexhaler 90 mcg

### Long Acting Beta Agonist

*Salmeterol Xinafoate (Serevent Diskus), Formoterol Fumarate (Foradil Aerolizer), Indacaterol Maleate (Arcapta Neohaler), Olodaterol Hydrochloride (Striverdi Respimat)*

#### **Olodaterol HCl (Striverdi Respimat) and Formoterol Fumarate (Foradil Aerolizer)**

- **Coverage Criteria:** Olodaterol HCl (Striverdi Respimat) and Formoterol Fumarate (Foradil Aerolizer) are step therapy to Inhaled Corticosteroid use for Asthma. For COPD, restricted to COPD Grade II or worse, group B or worse
- **Limits:** 1 inhaler/package per 30 days. For Asthma concurrent use of Inhaled Corticosteroid required.
- **Required Information for Approval:** Chart notes with clinical documentation of Confirmed diagnosis of COPD at least Grade II, Pulmonary function test, CAT/mMRC score indicating at least group B for monotherapy. For use with LAMA, Chart notes with clinical documentation of confirmed diagnosis of COPD, Pulmonary function test, CAT/mMRC score indicating GOLD grade 3 and 4, exacerbation history in the last 12 months, group D for current use with LAMA.
- **Other Notes:** Due to an increased risk of asthma related death, LABAs are not recommended for monotherapy in asthma. Foradil Aerolizer was discontinued by the manufacturer in October 2015. Marketing end date is scheduled for 1/31/17.
- **Non-Formulary:** Indacaterol Maleate (Arcapta Neohaler), Salmeterol Xinafoate (Serevent Diskus)

### Long Acting Anticholinergic

*Tiotropium Bromide (Spiriva, Spiriva Respimat), Aclidinium Bromide (Tudorza Pressair), Umeclidinium Bromide (Incruse Ellipta), Seebri Neohaler*

#### **For COPD**

##### **Tiotropium Bromide (Spiriva/Spiriva Respimat 2.5mcg), aclidinium bromide (Tudorza Pressair)**

- **Coverage Criteria:** Spiriva, Spiriva Respimat 2.5mcg, and Tudorza Pressair are reserved for patients with COPD confirmed by PFTs and are in GOLD Group B.
- **Limits:** Spiriva Respimat 2.5 mcg and Tudorza Pressair: 1 package per 30 days
- **Required Information for Approval:** Chart notes detailing diagnosis of COPD (post bronchodilator FEV1/FVC < 0.70. Please include patient's exacerbation history and the patient's mMRC and/or CAT score within the past year.
- **Other Notes:** Long-Acting Anticholinergics should not be used in combination with Combivent Respimat due to the increased risk of anticholinergic side effects.
- **Non-Formulary:** Umeclidinium Bromide (Incruse Ellipta), Seebri Neohaler,

#### **For Asthma**

##### **Tiotropium Bromide (Spiriva Respimat 1.25mcg)**

- **Coverage Criteria:** Spiriva Respimat 1.25mcg is step therapy to Montelukast AND one of the following: Symbicort (160 mcg/4.5 mcg), Air-Duo (232 mcg/14 mcg), or Dulera (200 mcg/5 mcg) within the last 30 days.
- **Limits:** None
- **Required Information for Approval:** Fills of Montelukast and one of the following: Symbicort (160 mcg/4.5 mcg), Air-Duo (232 mcg/14 mcg), or Dulera (200 mcg/5 mcg) within the last 30 days.
- **Other Notes:** Criteria applies only to Spiriva Respimat 1.25 mcg. Spiriva Respimat 2.5mcg and Spiriva Handihaler are restricted for COPD use only.

### Leukotriene Receptor Antagonist

*Montelukast Sodium (Singulair), Zafirlukast (Accolate)*

#### **Montelukast Sodium (Singulair)**

- **Coverage Criteria:** None
- **Limits:** 30 tablets per 30 days
- **Required Information for Approval:** N/A
- **Other Notes:** None
- **Non-Formulary:** Zafirlukast (Accolate)



### **Xanthine/Phosphodiesterase Enzyme Inhibitor, Nonselective**

*Theophylline (Theo-24, Elixophyllin, Theochron)*

**Theophylline 80mg/15mL Oral Elixir/Solution; 100 mg, 200 mg, 300 mg, ER capsules (Theo-24); 100 mg, 200 mg, 300 mg ER tablets (Theochron, 12-hour); 600 mg ER tablets (24-hour); 450 mg ER tablets (Theochron, 12-hour)**

- **Coverage Criteria:** None
- **Limits:** None
- **Required Information for Approval:** N/A
- **Other Notes:** Theophylline should be initiated and monitored by an experienced physician, due to the narrow therapeutic window.
- **Non-Formulary:** Theophylline IV Solution, Theo-24 400 mg ER capsules

### **PDE-4 Inhibitor**

*Roflumilast (Daliresp)*

- **Coverage Criteria:** Daliresp is reserved for patients in GOLD Grade 4, Group D who are compliant with, or intolerant to, use of high dose ICS plus LABA plus LAMA in the past 12 weeks.
- **Limits:** None
- **Required Information for Approval:**
  - (a) Chart notes with clinical documentation of COPD GOLD Grade 4, group D
  - (b) PFT and documentation of GOLD grade 4
  - (c) mMRC/CAT score.
  - (d) Exacerbation history in the last 12 months
  - e) Pharmacy fill history of compliant use of high dose ICS plus LAMA+LABA for the past 12 weeks.
- **Other Notes:** None

### **Monoclonal Antibody**

*Omalizumab (Xolair), Mepolizumab (Nucala), Reslizumab (Cinqair), benralizumab (Fasenra), Dupilumab (Dupixent)*

#### **Omalizumab (Xolair)**

- **Coverage Criteria:** For asthma, Xolair is reserved for poorly controlled moderate-severe allergic asthma patients with baseline serum IgE levels between 30-700 IU/ml, with FEV1 < 80% predicted, despite being compliant with dose-optimized [1] Inhaled Corticosteroids (ICS) + Long-Acting Beta-2 Agonist (LABA), [2] Spiriva Respimat, and [3] leukotriene modifier or theophylline.
- **Limits:** None
- **Required Information for Approval:** Patients must meet all of the following criteria:
  - Asthma classified as moderate to severe persistent asthma
  - Pretreatment level of IgE  $\geq 30$  IU/ml and  $< 700$  IU/ml
  - Positive skin test of in vitro reactivity to at least 1 perennial aeroallergen
  - Dose optimized inhaled corticosteroids without adequate asthma control (as evidenced by fill history and clinic documentation)
  - Dose optimized combination inhaled corticosteroid/long-acting beta2-agonist and leukotriene modifier or theophylline.
- **Other Notes:** Initial approval is 6 months. Continuing approval will require updated clinic notes with documented therapeutic response in the form of improved symptomology. Perennial aeroallergens include: cat or dog dander, house-dust mites, and pollens. Evidence is limited for molds and cockroaches.<sup>2</sup>

#### **Mepolizumab (Nucala)**

- ❑ **Coverage Criteria:** Nucala is reserved for patients ages 6 and older, with poorly controlled, severe eosinophilic asthma with baseline serum eosinophil counts of either  $\geq 150$  cells/ $\mu$ L at initiation of treatment or  $\geq 300$  cells/ $\mu$ L in the past 12 months AND 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] Inhaled Corticosteroids (ICS) + Long-Acting Beta-2 Agonist (LABA), [2] Spiriva Respimat, and [3] leukotriene modifier or theophylline. Must be prescribed by an allergist.
- ❑ **Limits:** None

- ❑ **Required Information for Approval:** Patients must meet all of the following criteria:
  - Diagnosis of asthma
  - Eosinophil level of either  $\geq 150$  cells/ $\mu$ L at initiation of treatment or  $\geq 300$  cells/ $\mu$ L in the past 12 months
  - 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] Inhaled Corticosteroids (ICS) + Long-Acting Beta-2 Agonist (LABA), [2] Spiriva Respimat, and [3] leukotriene modifier or theophylline.
- ❑ **Other Notes:** Initial approval is 6 months. Continuing Approval will require updated clinic notes with documented therapeutic response in the form of improved symptomology.
- **Non-Formulary:** Reslizumab (Cinqair), benralizumab (Fasenra)

### **Dupilumab (Dupixent)**

- ❑ **Coverage Criteria:**
  - For Eosinophilic asthma:**
    - [1] Reserved as an add on therapy for patients 12 years and older with moderate to severe asthma.
    - [2] Must meet **ALL** of the following:
      - (a) Pretreatment eosinophil  $\geq 150$  cells/ $\mu$ L
      - (b) Tried and failed or intolerance to compliant use of high dose ICS plus LAMA+LABA+LTRA for at least 3 months
      - (c)  $\geq 2$  exacerbation requiring systemic corticosteroids for  $\geq 3$  days or hospitalization or ER requiring systemic corticosteroids while on high dose ICS plus LAMA+LABA+LTRA.
  - For Oral corticosteroid dependent asthma:**
    - [1] Reserved as an add on therapy for patients 12 years and older who are dependent on oral steroid
    - [2] Must meet **ALL** of the following:
      - (a) Minimal dose of 5 mg Prednisone per day or equivalent dose for 6 months.
      - (b) Tried and failed or has intolerance to compliant use of high dose ICS plus 2 controller medications for at least 3 months
      - (c) Treatment plan is to reduce or completely eliminate oral corticosteroid use
- ❑ **Limits:** None
- ❑ **Required Information for Approval:** Patients must meet all of the following criteria:
  - **For Eosinophilic asthma:**
    - [1] Eosinophil level  $\geq 150$  cells/ $\mu$ L
    - [2] Clinical documentations and fill history of compliant use of high dose ICS plus LAMA+LABA+LTRA for at least 3 months
    - [3] Clinical documentation of  $\geq 1$  exacerbation requiring systemic corticosteroids for  $\geq 3$  days or hospitalization or ER requiring systemic corticosteroids while on high dose ICS plus LAMA+LABA+LTRA.
  - **For Oral corticosteroid dependent asthma:**
    - [1] Clinical documentations and fill history of minimal dose of 5 mg Prednisone per day or equivalent dose for 6 months
    - [2] Clinical documentations and fill history of compliant use (unless intolerant) of ICS plus 2 controller medications for at least 3 months
    - [3] Treatment plan is to reduce or completely eliminate oral corticosteroid use.
- ❑ **Other Notes:** Initial approval is 6 months. Continuing Approval will require updated clinic notes with documented therapeutic response in the form of improved symptomology.

<b>Short Acting Combination</b>
<i>Ipratropium/Albuterol (Combivent Respimat)</i>
<ul style="list-style-type: none"> <li>▪ <b>Coverage Criteria:</b> None</li> <li>▪ <b>Limits:</b> 1 Inhaler per 30 days</li> <li>▪ <b>Required Information for Approval:</b> None</li> <li>▪ <b>Other Notes:</b> Should not be used with Tiotropium (Spiriva).</li> </ul>

### **Long Acting Combination**

*Fluticasone/Salmeterol (Advair), Fluticasone/Salmeterol (AirDuo Resplick), Budesonide/Formoterol (Symbicort), Mometasone/Formoterol (Dulera), Fluticasone/Vilanterol (Breo Ellipta), Tiotropium/Otodaterol (Stiolto Respimat), Umeclidinium/ Vilanterol (Anoro Ellipta), Glycopyrrolate/ Indacaterol (Utibron Neohaler), Glycopyrrolate/ Formoterol (Bevespi Aerosphere)*

### **Budesonide/Formoterol (Symbicort), Fluticasone/Salmeterol (Advair Diskus and HFA), Mometasone/Formoterol (Dulera), Fluticasone/Vilanterol (Breo Ellipta), Fluticasone/Salmeterol (AirDuo Resplick)**

- **Coverage Criteria:** None
- **Limits:** 1 Inhaler per 30 days
- **Required Information for Approval:** None
- **Other Notes:** None

### **Umeclidinium/ Vilanterol (Anoro Ellipta), Tiotropium/Otodaterol (Stiolto Respimat)**

- **Coverage Criteria:** Reserved for patient with at least Group B COPD confirmed by pulmonary function testing (PFTs).
- **Limits:** 1 Inhaler per 30 days
- **Required Information for Approval:** PFTs showing post-bronchodilator FEV1/FVC is <0.7 and GOLD Group B. Send exacerbation history and the patient's mMRC and/or CAT score for the last year.
- **Other Notes:** None
- **Non-Formulary:** Glycopyrrolate/ Indacaterol (Utibron Neohaler), Glycopyrrolate/ Formoterol (Bevespi Aerosphere),

### **Trelegy (Fluticasone furoate, Umeclidinium and Vilanterol)**

- **Coverage Criteria:** Trelegy is reserved for patients with COPD GOLD grade 3 or 4 Group D with compliant use of ICS+LABA or LABA+LAMA
- **Limits:** 1 Inhaler per 30 days
- **Required Information for Approval:**
  - (a) Chart notes with clinical documentation of COPD Diagnosis and is GOLD Grade 3 or 4, group D (b) PFT and documentation of GOLD grade 3 or 4
  - (c) mMRC/CAT score.
  - (d) Exacerbation history in the last 12 months (e) Pharmacy fill history of compliant use of high dose ICS +LABA or ICS+LAMA for the past 12 weeks.

### **Solution for Nebulization**

*Albuterol Sulfate, Ipratropium-Albuterol (Duoneb), Ipratropium Bromide, Levalbuterol Hydrochloride, Budesonide, Cromolyn Sodium, Formoterol Fumarate Dihydrate (Perforomist), Arformoterol (Brovana), Revefenacin (Yupelri), Glycopyrrolate (Lonhala Magnair)*

### **Albuterol Sulfate, Levalbuterol Hydrochloride, Ipratropium-Albuterol (Duoneb)**

- **Coverage Criteria:** None
- **Limits:** 375mL per 30 days
- **Required Information for Approval:** N/A
- **Other Notes:** None
- **Non Formulary:** Formoterol Fumarate Dihydrate (Perforomist), Arformoterol (Brovana)

### **Ipratropium Bromide**

- **Coverage Criteria:** None
- **Limits:** None
- **Required Information for Approval:** N/A
- **Other Notes:** None
- **Non-Formulary:** Revefenacin (Yupelri), Glycopyrrolate (Lonhala Magnair)

### **Budesonide**

- **Coverage Criteria:** Restricted to members less than or equal to 4 years of age.
- **Limits:** 120 mL per 30 days
- **Required Information for Approval:** N/A
- **Other Notes:** Members older than 4 should use a mask and spacer to facilitate delivery of ICS products. Formulary agents include Qvar, Flovent HFA/Diskus, and Asmanex Twisthaler.

### **Cromolyn Sodium**

- **Coverage Criteria:** None
- **Limits:** None
- **Required Information for Approval:** N/A
- **Other Notes:** None

<b>Medical Equipment</b>
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<i>Peak Flow Meter, Mask/Spacer, Nebulizer</i>
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### **Peak Flow Meter, Nebulizer**

- **Coverage Criteria:** None
- **Limits:** 1 per lifetime
- **Required Information for Approval:** N/A
- **Other Notes:** Nebulizers will be paid at a maximum of \$100 per machine.

### **Optichamber Adult Mask (Large), Optichamber Diamond with Mask, Vortex Holding Chamber with/without mask, Bubbles the Fish II Pedi Mask**

- **Coverage Criteria:** None
- **Limits:** 2 per year
- **Required Information for Approval:** N/A
- **Other Notes:** None
- **Non-Formulary:** Aerochamber Plus Flow-VU/Plus Z-Stat/Z-stat Plus with mask, Inspira chamber with mask, Easivent Holding Chamber with mask

## **CLINICAL JUSTIFICATION**

Diagnosis and treatment recommendations are based on the National Asthma Education and Prevention Program (NAEPP) 2007, Global Initiative for Asthma (GINA) 2020, Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) 2017 [ACOS] & 2019 [COPD], and International European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines.<sup>1-5, 52</sup>

### **Asthma**

Asthma is a dynamic condition requiring constant assessment in order to provide optimal control of symptoms. The HPSJ formulary is designed to make controller agents accessible, as these are the mainstay of therapy according to NAEPP and GINA guidelines. Controller medications for asthma include inhaled corticosteroids, long-acting beta-2 agonists, leukotriene antagonists, theophylline, cromolyn, and zileuton. Concerns about the risks of using short-acting  $\beta_2$ -agonists (SABA) alone has led to the recent update in the Global Initiative for Asthma (GINA) recommendations. New 2019 GINA updated guideline recommends either a symptom driven or daily inhaled corticosteroid treatment in all adults and adolescents with asthma.<sup>49</sup> Short acting-inhalers should only be used on an as-needed basis, and no longer recommended as a monotherapy. HPSJ has a quantity limits on short-acting inhalers to encourage appropriate use. Frequent use of short-acting inhalers can be an indicator of poorly controlled asthma.

Short-acting beta-2 agonists (SABAs) are commercially available as oral syrups or tablets. However, these formulations are not on HPSJ's formulary due to NAEPP guideline recommendations, which state inhaled route is preferred because they cause fewer systemic side effects than oral agents. Additionally, oral extended-release tablets have not been adequately studied as adjunctive therapy with ICS.<sup>2</sup>

Dupixent recently received FDA approval for indication of eosinophilic asthma treatment. Currently there are 5 monoclonal antibodies Dupixent, Xolair, Nucala, Cinqair, and Fasenra, with FDA approved indication for asthma. Since NAEPP and GINA guidelines list these agents as add-on therapies for patients with severe, uncontrolled disease, they are reserved for patients who have failed ICS, LABA, LAMA, and leukotriene antagonists. Xolair, Nucala, Cinqair, Fasenara, and Dupixent are specifically indicated in patients with allergic asthma, and therefore requires additional lab testing to establish medical necessity.

## **Chronic Obstructive Pulmonary Disease (COPD)**

Spirometry remains vital for the diagnosis of COPD, therefore, HPSJ requires pulmonary function testing to ensure appropriate use. GOLD 2019 update recommends repeat of Spirometry on a separate occasion if post-bronchodilator FEV<sub>1</sub>/FVC ratio is between 0.6 and 0.8. <sup>41</sup> Based on updated GOLD COPD 2019 guidelines, blood eosinophil levels are required for certain COPD medications.

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## **REVIEW & EDIT HISTORY**

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Singulair Survey 7-06.doc	7/2006	Allen Shek PharmD BCPS
Update to Policy	ICS Review 9-06.doc	9/2006	Allen Shek PharmD BCPS
Update to Policy	Albuterol HFA 11-06.doc	11/2006	Allen Shek PharmD BCPS
Update to Policy	ICS-LABA combo status 9-07.doc	9/2007	Allen Shek PharmD BCPS
Update to Policy	Symbicort 9-11-07.doc	9/2007	Allen Shek PharmD BCPS
Update to Policy	Asthma_Xopenex 9-08.doc	9/2008	Allen Shek PharmD BCPS
Update to Policy	ICS Review 9-16-08.doc	9/2008	Allen Shek PharmD BCPS
Update to Policy	Spacer utilization.doc	3/2009	Allen Shek PharmD BCPS
Update to Policy	ICS post P&T Survey recap.doc	3/2009	Allen Shek PharmD BCPS
Update to Policy	Daliresp Monograph 11-20-12.doc	11/2012	Allen Shek PharmD BCPS
Update to Policy	Tudorza 5-21-2013.docx	5/2013	Allen Shek PharmD BCPS
Update to Policy	HPSJ Coverage Policy – Respiratory – Asthma & COPD 2015-05.docx	9/2015	Jonathan Szkotak, PharmD, BCACP
Update to Policy	HPSJ Coverage Policy – Respiratory – Asthma & COPD 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Respiratory – Asthma & COPD 2017-12.docx	12/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Respiratory – Asthma & COPD 2019-2.docx	2/2019	Matthew Garrett, PharmD

Update to Policy	HPSJ Coverage Policy – Respiratory – Asthma & COPD 2020-2.docx	2/2020	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Respiratory – Asthma & COPD 2021-2.docx	2/2021	Matthew Garrett, PharmD

*Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy*