MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	Asthma/COPD	**P&T DATE**	6/20/2023
CLASS:	Respiratory Disorders	**REVIEW HISTORY** (MONTH/YEAR)	5/22, 2/21, 2/20, 2/19, 12/17,12/16, 5/15, 9/14, 2/13, 5/12
LOB:	Medi-Cal		

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.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit. All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

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

CPT code	Generic Name (Brand Name)	Strength & Dosage form	Pharmacy Benefit	Medical Benefit (restrictions)
Single Agents				
Short Acting Beta Agonist (SABA)				
--	Albuterol	90 mcg/act	Yes	No
--	Albuterol (ProAir HFA, Proventil HFA, ProAir Digihaler (108 mcg/act), ProAir Respiclick, Ventolin HFA)	90 mcg/act	Yes	No
--	Albuterol Syrup	2 mg/5 mL Syrup	Yes	No
--	Albuterol Sulfate IR, ER Tablets (Vospire ER)	2 mg, 4 mg IR Tablet 4 mg, 8 mg ER Tablet	Yes	No
--	Ephedrine/ Guaifenesin Tablets (Primatene Asthma)	12.5/200 mg Tablets	Yes	No
--	Levalbuterol (Xopenex HFA)	45 mcg/act	Yes	No
		Xopenex HFA	Yes	No
--	Metaproterenol	10 mg/5 mL Syrup, 10 mg, 20 mg Tablet	Yes	No
Short Acting Anticholinergic (SAMA)				
--	Ipratropium (Atrovent HFA)	17 mcg/act	Yes	No
	Atrovent HFA	17 mcg/act	Yes	No

Long Acting Beta Agonist (LABA)				
--	Salmeterol Xinafoate (Serevent Diskus)	50 mcg/act	Yes	No
--	Formoterol Fumarate (Foradil)	12 mcg Inhalation Capsule	Yes	No
--	Indacaterol Maleate (Arcapta Neohaler)	75 mcg/act	Yes	No
--	Olodaterol Hydrochloride (Striverdi Respimat)	2.5 mcg/act	Yes	No
Long Acting Anticholinergic (LAMA)				
--	Tiotropium Bromide (Spiriva)	Handihaler: 18 mcg Inhalation Capsule Respimat: 2.5 mcg/act	Yes	No
--	Tiotropium Bromide (Spiriva Respimat)	1.25mcg/act	Yes	No
--	Aclidinium Bromide (Tudorza Pressair)	400 mcg/act	Yes	No
--	Glycopyrrolate (Seebri Neohaler)	15.6mcg	Yes	No
--	Umeclidinium Bromide (Incruse Ellipta)	62.5 mcg/act	Yes	No
	Inhaled Corticosteroid (ICS)			
--	Beclomethasone dipropionate (Qvar Redihaler)	40 mcg/act 80 mcg/act	Yes	No
--	Budesonide (Pulmicort Flexhaler)	90 mcg/act	Yes	No
--	Budesonide (Pulmicort Flexhaler)	180 mcg/act	Yes	No
--	Ciclesonide (Alvesco)	80 mcg/act 160 mcg/act	Yes	No
--	Flunisolide (Aerospan)	80 mcg/act	Yes	No
--	Fluticasone furoate (Arnuity Ellipta)	100 mcg/act 200 mcg/act	Yes	No
--	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	Yes	No
--	Fluticasone propionate (ArmonAir Respiclick)	55 mcg 113 mcg 232 mcg	Yes	No
--	Mometasone furoate (Asmanex Twisthaler)	110 mcg/act (30 doses) 220 mcg/act (30, 60, or 120 doses)	Yes	No
--	Mometasone furoate (Asmanex HFA)	100 mcg/act 200 mcg/act	Yes	No

Table 1: Available Asthma/COPD Medications (continued)

CPT code	Generic Name (Brand Name)	Strength & Dosage form	Pharmacy Benefit	Medical Benefit (restrictions)
--	**Combination Agents**			
--	**Short Acting Combination**			
--	Ipratropium/Albuterol (Combivent Respimat)	20 mcg/100 mcg	Yes	No
--	**Long Acting Combination**			
--	Budesonide/Formoterol (Symbicort)	80 mcg/4.5mcg 160 mcg/4.5 mcg	Yes	No
--	Fluticasone/Salmeterol (AirDuo Respiclick, Advair Diskus or HFA)	Respiclick: 55/14 mcg 113/14 mcg 232/14 mcg	Yes	No
--		Diskus: 100 mcg/50 mcg 250 mcg/50 mcg 500 mcg/50 mcg HFA: 45 mcg/21mcg 115 mcg/21mcg 230 mcg/21 mcg		No
--	Fluticasone/Vilanterol (Breo Ellipta)	100 mcg-25 mcg 200 mcg-25 mcg	Yes	No
--	Aclidinium/Formoterol (Duklir)	400 mcg - formoterol 12 mcg	Yes	No
--	Fluticasone, Umeclidinium, and Vilanterol (Trelegy Ellipta)	100 mcg/ 62.5 mcg/25 mcg	Yes	No
--	Mometasone/ Formoterol (Dulera)	100 mcg-5mcg 200 mcg-5mcg	Yes	No
--	Tiotropium/ Otodaterol (Stiolto Respimat)	2.5 mcg-2.5 mcg	Yes	No
--	Umeclidinium/ Vilanterol (Anoro Ellipta)	62.5 mcg-25 mcg	Yes	No
--	Glycopyrrolate/ Indacaterol (Utibron Neohaler)	27.5 mcg-15.6 mcg	Yes	No
--	Glycopyrrolate/ Formoterol (Bevespi Aerosphere)	9 mcg-4.8 mcg	Yes	No
Leukotriene Receptor Antagonist				
--	Montelukast Sodium (Singulair)	4 mg, 5 mg Chewable Tablet 10 mg Tablet	Yes	No
--		4 mg Oral Granules	Yes	No
--	Zafirlukast (Accolate)	10 mg, 20 mg Tablet	Yes	No
5-Lipoxygenase Inhibitor				
--	Zileuton (Zyflo, Zyflo CR)	600 mg Tablet 600 mg ER Tablet	Yes	No

Xanthine/Phosphodiesterase Enzyme Inhibitor, Nonselective				
--	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)	Yes	No
--	Theophylline (Theo-24)	400 mg ER Cap	Yes	No
PDE-4 Inhibitor				
--	Roflumilast (Daliresp)	250 mcg, 500 mcg Tablet	Yes	No
Monoclonal Antibody, Anti-Asthmatic				
--	Dupilumab (Dupixent)	200 mg/1.14 ml, 300 mg/2 ml syringe	Yes	No
J2357	Omalizumab (Xolair)	75 mg/ 0.5 ml, 150 mg/ ml syringes	Yes	Yes
J2182	Mepolizumab (Nucala)	100 mg Vial	Yes	Yes. PA, QL. See criteria below.
		Autoinjector 100 mg/ml		Yes. PA, QL. See criteria below.
		Prefilled syringes 100 mg/ml		Yes. PA, QL. See criteria below.
J0517	Benralizumab (Fasenra)	30mg Injection	Yes	Yes. PA, QL. See criteria below.
J2786	Reslizumab (Cinqair)	100 mg/10 mL IV Solution	Yes	Yes. PA, QL. See criteria below.
J2356	Tezepelumab (Tezspire)	210MG/1.91ML Prefilled Syringe	Yes	Yes. PA, QL. See criteria below.
	Solution for Nebulization			
	Short Acting Beta Agonist (SABA)			
--	Albuterol Sulfate	0.63 mg/3 mL 1.25 mg/3 mL 2.5 mg/0.5 mL (0.083%) 2.5 mg/3 mL 5 mg/mL (0.5%)	Yes	No
--	Levalbuterol Hydrochloride	0.31 mg/3 mL 0.63 mg/3 mL 1.25 mg/3 mL 1.25 mg/0.5 mL	Yes	No
Short Acting Anticholinergic				
--	Ipratropium Bromide	0.02% Nebulization Solution	Yes	No
Long Acting Anticholinergic				
--	Revefenacin (Yupelri)	175 mcg Nebulization solution	Yes	No
Short Acting Combination				
--	Ipratropium/Albuterol (Duoneb)	0.5 mg/3 mg (2.5 mg Base)/3 mL	Yes	No

Inhaled Corticosteroid				
--	Budesonide	0.25 mg/2 mL 0.5 mg/2 mL 1 mg/2 mL	Yes	No
Long Acting Antimuscarinic				
--	Glycopyrrolate (Lonhala Magnair)	25 mcg vial	Yes	No
Long-Acting Beta Agonist				
--	Formoterol Fumarate Dihydrate (Perforomist)	20 mcg/2 mL	Yes	No
--	Arformoterol (Brovana)	15 mcg/2 ml	Yes	No
General Inhalation Solutions				
--	Sodium chloride Vials	0.9%	Yes	No
--		Nebusal 3%	Yes	No
--		3%	Yes	No
--		Hyper-Sal 3.5%	Yes	No
--		Hyper-Sal 7% Vial	Yes	No
--		7%	Yes	No
Mast Cell Stabilizer				
--	Cromolyn Sodium	20 mg/2 mL	Yes	No
Medical Equipment				
Peak Air Peak Flow Meter, Spacer				
--	Peak Flow Meter	--	Yes	No
--	Inhaler, Assist Devices (Spacer, bag or reservoir, with or without mask, for use with metered dose inhaler)	Large Medium Small	Yes	No
Nebulizer				
E0570	Nebulizer machine	--	No	Yes, Restricted to HPSJ-preferred vendor.
Varies	Nebulizer accessories	--	No	Yes, Restricted to HPSJ-preferred vendor.

PA = Prior Authorization, QL = Quantity Limit

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

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 medium to high-dose Inhaled Corticosteroids (ICS) + Long-Acting Beta-2 Agonist (LABA). Xolair must not be used as monotherapy.
- **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 ≥30IU/ml and <700IU/ml

- Positive skin test of in vitro reactivity to at least 1 perennial aeroallergen
- Dose optimized inhaled corticosteroids and long-acting beta2-agonist without adequate asthma control (as evidenced by fill history and clinic documentation)

- **Other Notes:** 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.[2]

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 ≥ 150 cells/µL at initiation of treatment or ≥ 300 cells/µL in the past 12 months AND 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] High-dose Inhaled Corticosteroids (ICS) + [2] A second controller (e.g. Long-Acting Beta-2 Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), leukotriene modifier, systemic corticosteroids). Must be prescribed by an allergist. Nucala must not be used as monotherapy.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Patients must meet all of the following criteria:
  - Diagnosis of asthma
  - Eosinophil level of either ≥ 150 cells/µL at initiation of treatment or ≥ 300 cells/µL in the past 12 months
  - 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] Inhaled Corticosteroids (ICS) + [2] A second controller (Long-Acting Beta-2 Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), leukotriene modifier, systemic corticosteroids)

Benralizumab (Fasenra)

- ❒ **Coverage Criteria:** Fasenra is reserved for patients ages 12 and older, with poorly controlled, severe eosinophilic asthma with baseline serum eosinophil counts of either ≥ 150 cells/µL at initiation of treatment or ≥ 300 cells/µL in the past 12 months AND 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] High-dose Inhaled Corticosteroids (ICS) + [2] A second controller (e.g. Long-Acting Beta-2 Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), leukotriene modifier, systemic corticosteroids). Must be prescribed by an allergist. Fasenra must not be used as monotherapy.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Patients must meet all of the following criteria:
  - Diagnosis of asthma
  - Eosinophil level of either ≥ 150 cells/µL at initiation of treatment or ≥ 300 cells/µL in the past 12 months
  - 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] Inhaled Corticosteroids (ICS) + [2] A second controller (Long-Acting Beta-2 Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), leukotriene modifier, systemic corticosteroids)
- ❒ **Other Notes:** Initial approval is 6 months. Continuing Approval will require updated clinic notes with documented therapeutic response in the form of improved symptomology.

Reslizumab (Cinqair)

- ❒ **Coverage Criteria:** Cinqair is reserved for patients ages 18 and older, with poorly controlled, severe eosinophilic asthma with baseline serum eosinophil counts of either ≥ 150 cells/µL at initiation of treatment or ≥ 300 cells/µL in the past 12 months AND 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] High-dose Inhaled Corticosteroids (ICS) + [2] A second controller (e.g. Long-Acting Beta-2 Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), leukotriene modifier, systemic corticosteroids). Must be prescribed by an allergist. Cinqair must not be used as monotherapy.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Patients must meet all of the following criteria:

- Diagnosis of asthma
- Eosinophil level of either ≥ 150 cells/μL at initiation of treatment or ≥ 300 cells/μL in the past 12 months
- 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] Inhaled Corticosteroids (ICS) + [2] A second controller (Long-Acting Beta-2 Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), leukotriene modifier, systemic corticosteroids)

Tezepelumab (Tezspire)

- ❒ **Coverage Criteria:** Tezspire is reserved for patients ages 12 and older, with **severe asthma** AND 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] High-dose Inhaled Corticosteroids (ICS) + [2] A second controller (e.g. Long-Acting Beta-2 Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), leukotriene modifier, systemic corticosteroids). Must be prescribed by an allergist. Tezspire must not be used as monotherapy. Must not be used with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Patients must meet all of the following criteria:
  - Diagnosis of asthma
  - 2 or more exacerbations in the past 12 months, despite being compliant with dose-optimized [1] Inhaled Corticosteroids (ICS) + [2] A second controller (Long-Acting Beta-2 Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), leukotriene modifier, systemic corticosteroids)

Medical Equipment
Nebulizer

Nebulizer

- **Coverage Criteria:** None
- **Limits:** 1 per lifetime
- **Required Information for Approval:** N/A

CLINICAL JUSTIFICATION

Diagnosis and treatment recommendations are based on the National Asthma Education and Prevention Program (NAEPP) 2007, Global Initiative for Asthma (GINA) 2022, Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) 2017 [ACOS] & 2022 [COPD], and International European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines.[1-5, 52]

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 β2-agonists (SABA) alone has led to the recent update in the Global Initiative for Asthma (GINA) recommendations. 2019 GINA updated guideline recommends either a symptom driven or daily inhaled corticosteroid treatment in all adults and adolescents with asthma.[49] Short acting-inhalers should only be used on an as-needed basis, and no longer recommended as a monotherapy. Frequent use of short-acting inhalers can be an indicator of poorly controlled asthma.

Currently there are 6 monoclonal antibodies Tezspire, 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_1 /FVC ratio is between 0.6 and 0.8. [41] 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
Update to Policy	Asthma & COPD	05/2022	Matthew Garrett, PharmD
Review of Policy	Asthma & COPD	06/2023	Matthew Garrett, PharmD

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