Drug Utilization Review: Asthma Guideline Update

New York State Medicaid Drug Utilization Review Board
November 6, 2026

NEW YORK STATE | Department of Health | Office of Health Insurance Programs
SUNY The State University of New York

Purpose

- This review examines inhaled and systemic therapies for the treatment of asthma and their utilization across the entire New York State Medicaid population, including the NYRx program
- Recommendations will be provided to the Drug Utilization Review Board based on a review of the available literature and the results from utilization data analyses

Pathophysiology

- Asthma is a chronic inflammatory lower airway disease characterized by symptoms of wheeze, cough, and shortness of breath, which vary over time and in intensity and include acute attacks (i.e., exacerbations)
- Physiologic elements leading to symptoms include airway narrowing from bronchial smooth muscle contraction, airway edema, mucus secretion, and airway remodeling caused by inflammation

Melén, et al. *Am J Respir Crit Care Med*. 2024. doi:10.1164/rccm.202312-2249SO
Rhoads, et al. *Pharmacol Rev*. 2025. doi:10.1016/j.pharmr.2025.100062

Pathophysiology

- Asthma is a heterogeneous disease state and has come to be considered an “umbrella diagnosis” covering various clinical characteristics (phenotypes) driven by distinct pathophysiologic mechanisms (endotypes)
- CD4+ T-helper cell response promotes the inflammation cascade and defines the 2 main endotypes
  - Type-2 inflammation is the dominant process in 80% of asthma patients
    - Eosinophilic inflammation driven by T-helper 2 cells
  - Non-Type-2 inflammation is driven by other immune cells
    - E.g., neutrophilic inflammation possibly linked to T-helper 1 and T-helper 17 cells

Grunwell, et al. *Respir Care*. 2025. doi:10.1089/respcare.12352
Kuruvilla, et al. *Clin Rev Allergy Immunol*. 2019. doi:10.1007/s12016-018-8712-1
Melén, et al. *Am J Respir Crit Care Med*. 2024. doi:10.1164/rccm.202312-2249SO
Rhoads, et al. *Pharmacol Rev*. 2025. doi:10.1016/j.pharmr.2025.100062

Endotypes and Phenotypes

Type 2 (T2 High) Eosinophilic asthma	Non-Type 2 (T2 Low) Non-eosinophilic asthma
Early-onset atopic (allergic) asthma • Most common phenotype, 40 – 50% of adults and children • Allergic sensitization; steroid-sensitive Late-onset eosinophilic asthma • Severe from onset, more frequent exacerbations Aspirin-exacerbated respiratory disease • Severe from onset, more frequent exacerbations	Non-atopic • Adult onset, variable course Smokers • Older adults, more frequent exacerbations Obesity-related • More frequent in females, severe symptoms Elderly • >50 years to >65 years, steroid-resistant

Kuruvilla, et al. *Clin Rev Allergy Immunol*. 2019. doi:10.1007/s12016-018-8712-1
American Academy of Allergy, Asthma, and Immunology. https://www.aaaai.org/tools-for-the-public/conditions-library/asthma/asthma-is-a-disease-of-different-phenotypes April 8, 2026.

Risk Factors and Prevalence

- Asthma often starts in childhood and runs in families due to shared genetic and environmental risk factors
- Environmental and potentially modifiable risk factors include:
  - Exposure to secondhand smoke, outdoor air pollution, smoking and vaping, occupational exposures, physical inactivity, obesity
- Asthma is highly prevalent and carries a significant socioeconomic burden:
  - 300 million people worldwide
  - 25 million people in the United States, including 20 million (8.0%) adults and 5 million (6.5%) children
  - 9.8% of adults in New York State
  - Total projected direct + indirect costs of uncontrolled asthma in United States adults and adolescents during 2019 – 2038 have been estimated at $983 billion

Koppelman, et al. *Lancet Respir Med*. 2025. doi:10.1016/S2213-2600(25)00256-5
Jayasooriya, et al. *Lancet Respir Med*. 2025. doi:10.1016/S2213-2600(24)00383-7
US Centers for Disease Control and Prevention. https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm May 2023.
US Centers for Disease Control and Prevention. https://www.cdc.gov/asthma/most_recent_data_states.htm May 2023.
Yaghoubi, et al. *Am J Respir Crit Care Med*. 2019. doi:10.1164/rccm.201901-0016OC

Pharmacologic Treatment

- The cornerstone of pharmacologic management in both children and adults focuses on controlling symptoms of airway constriction and underlying inflammation with bronchodilators and corticosteroids
  - Short-acting beta agonists (SABA): FDA-approved for as-needed rescue/reliever therapy
    - Induce rapid relaxation of bronchial smooth muscle
  - Inhaled corticosteroids (ICS): FDA-approved as daily maintenance/controller therapy
    - Provide anti-inflammatory efficacy with lower risk of serious adverse effects associated with chronic use of oral corticosteroids
  - Long-acting beta agonists (LABA): FDA-approved for daily use in combination with ICS
    - Provide bronchodilation for up to 12 or 24 hours
    - ICS/formoterol is compendia supported for both maintenance and reliever therapy due to fast onset of formoterol

FDA=Food and Drug Administration

Rhoads, et al. *Pharmacol Rev*. 2025. doi:10.1016/j.pharmr.2025.100062
DRUGDEX. Merative Micromedex. www.micromedexsolutions.com July 2026.

Pharmacologic Treatment

- Additional inhaled or oral agents FDA-approved for management of asthma symptoms in children and adults
  - Often used as add-on therapy:
    - Leukotriene receptor antagonists (LTRA)
      - Provide anti-inflammatory and mild bronchodilatory effects
    - Long-acting muscarinic antagonists (LAMA)
      - Provide anti-cholinergic effects, inhibiting bronchoconstriction and mucous production
  - Not widely used:
    - Mast cell stabilizers (e.g., cromolyn) – much less effective than inhaled corticosteroids (ICS)
    - Methylxanthines (e.g., theophylline) – weak bronchodilator, narrow therapeutic index

Rhoads, et al. *Pharmacol Rev*. 2025. doi:10.1016/j.pharmr.2025.100062

Pharmacologic Treatment

- Systemic immunomodulators (i.e., asthma biologics)
  - Injectable monoclonal antibodies targeting multiple mechanisms in the Type 2 inflammation cascade
  - FDA-approved as add-on maintenance therapy for severe or moderate-to-severe asthma in patients with the appropriate asthma phenotype
  - Biomarkers for Type 2 phenotypes include: Blood or sputum eosinophil count, skin prick testing or serum specific allergen immunoglobulin E (IgE), high fractional exhaled nitric oxide (F_{ENO}), high total IgE

Gaberino, et al. *J Allergy Clin Immunol*. 2026. doi:10.1016/j.jaci.2026.01.002
Rhoads, et al. *Pharmacol Rev*. 2025. doi:10.1016/j.pharmr.2025.100062

Selected Drugs FDA-approved or Compendia-Supported for Treatment of Asthma

Generic (Brand) Drug Names	FDA Indication(s)			Formulation(s) for Asthma	Ages (Years) for Asthma	Dosage Range for Asthma
	Asthma Maintenance	Asthma Reliever	Other			
Inhaled Corticosteroids (ICS)						
Beclomethasone dipropionate (QVAR Redihaler®)	✓	--	--	40 mcg or 80 mcg pMDI	4+	1-4 inhalations twice daily
Budesonide (Pulmicort Flexhaler™)	✓	--	--	90 mcg or 180 mcg DPI	6+	1-2 inhalations twice daily
Budesonide (Pulmicort Respules®)	✓	--	--	0.25 mg, 0.5 mg, or 1 mg per 2 mL suspension	1 – 8	Inhalation via nebulization once or twice daily
Ciclesonide (Alvesco®)	✓	--	--	80 mcg or 160 mcg pMDI	12+	1-2 inhalations twice daily
Fluticasone furoate (Arnuity Ellipta®)	✓	--	--	50 mcg, 100 mcg, or 200 mcg DPI	5+	1 inhalation once daily
Fluticasone propionate diskus	✓	--	--	50 mcg, 100 mcg, or 250 mcg DPI	4+	1-4 inhalations twice daily
Fluticasone propionate HFA	✓	--	--	44 mcg, 110 mcg, or 220 mcg pMDI	4+	2-4 inhalations twice daily
Mometasone furoate (Asmanex® HFA)	✓	--	--	50 mcg, 100 mcg, or 200 mcg pMDI	5+	2 inhalations twice daily
Mometasone furoate (Asmanex® Twisthaler®)	✓	--	--	110 mcg or 220 mcg DPI	4+	1-2 inhalations once to twice daily

DPI=dry powder inhaler; FDA=Food and Drug Administration
pMDI=pressurized metered-dose inhaler
FDA labels available at: https://dailymed.nlm.nih.gov

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Generic (Brand) Drug Names	FDA Indication(s)			Formulation(s) for Asthma	Ages (Years) for Asthma	Dosage Range for Asthma
	Asthma Maintenance	Asthma Reliever	Other			
Inhaled Long-Acting Beta Agonist (LABA)						
Salmeterol xinafoate (Serevent Diskus®)	✓	--	COPD, EIB	50 mcg DPI	4+	1 inhalation twice daily with ICS
Inhaled Long-Acting Muscarinic Antagonist (LAMA)						
Tiotropium bromide (Spiriva® Respimat®)	✓	--	COPD*	1.25 mcg soft mist inhaler	6+	2 inhalations once daily
Inhaled Short-Acting Beta Agonist (SABA)						
Albuterol sulfate HFA (ProAir® Digihaler®, Ventolin® HFA)	--	✓	EIB	90 mcg pMDI	4+	1-2 inhalations every 4-6 hours
Albuterol sulfate (ProAir® Respiclick®)	--	✓	EIB	90 mcg DPI	4+	1-2 inhalations every 4-6 hours
Albuterol sulfate nebulizer solution	--	✓	--	Multiple strengths per 3 mL solution or 0.5 mL concentrate solution	2 – 12	Inhalation via nebulization 3-4 x daily as needed
Levalbuterol HCL nebulizer solution	--	✓	--	Multiple strengths per 3 mL solution or 0.5 mL concentrate solution	6+	Inhalation via nebulization 3 x daily (every 6-8 hours)
Levalbuterol tartrate (Xopenex® HFA)	--	✓	--	45 mcg pMDI	4+	1-2 inhalations every 4-6 hours

COPD=chronic obstructive pulmonary disease; DPI=dry powder inhaler; EIB=exercise-induced bronchospasm; FDA=Food and Drug Administration; pMDI=pressurized metered-dose inhaler
* Only the 2.5 mcg formulation of tiotropium bromide is FDA approved for COPD
FDA labels available at: https://dailymed.nlm.nih.gov

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Generic (Brand) Drug Names	FDA Indication(s)			Formulation(s) for Asthma	Ages (Years) for Asthma	Dosage Range for Asthma
	Asthma Maintenance	Asthma Reliever	Other			
Combination Inhaled Corticosteroid/Long-Acting Beta Agonist (ICS/LABA)						
Budesonide/formoterol (Symbicort®)	✓	✓†	COPD	80/4.5 mcg or 160/4.5 mcg pMDI	6+ 4-5†	6–11 years: 2 inhalations 80/4.5 mcg twice daily 12+ years: 2 inhalations either strength twice daily
Fluticasone/salmeterol (Advair® Diskus®)	✓	--	COPD	100/50 mcg, 250/50 mcg, or 500/50 mcg DPI	4+	4–11 years: 100/50 mcg twice daily 12+ years: 250/50 mcg or 500/50 mcg twice daily
Fluticasone/salmeterol (Advair® HFA)	✓	--	COPD	45/21 mcg, 115/21 mcg, 230/21 mcg pMDI	12+	2 inhalations twice daily
Fluticasone/salmeterol (AirDuo® Respiclick®)	✓	--	COPD	55/14 mcg, 113/14 mcg, 232/14 mcg pMDI	12+	1 inhalation twice daily
Fluticasone/vilanterol (Breo® Ellipta)	✓	--	COPD	50/25 mcg, 100/25 mcg, 200/25 mcg pMDI	5+	1 inhalation once daily
Mometasone/formoterol (Dulera®)	✓	✓†	--	50/5 mcg, 100/5 mcg, 200/5 mcg pMDI	5+ 4†	5–11 years: 2 inhalations 50/5 mcg twice daily 12+ years: 2 inhalations 100/50 mcg or 200/50 mcg twice daily

COPD=chronic obstructive pulmonary disease; DPI=dry powder inhaler; FDA=Food and Drug Administration; pMDI=pressurized metered-dose inhaler

† Denotes off-label, compendia-supported use; available at DRUGDEX. Merative Micromedex. www.micromedexsolutions.com

FDA labels available at: https://dailymed.nlm.nih.gov

Selected Drugs FDA-approved or Compendia-Supported for Treatment of Asthma

Generic (Brand) Drug Names	FDA Indication(s)			Formulation(s) for Asthma	Ages (Years) for Asthma	Dosage Range for Asthma
	Asthma Maintenance	Asthma Reliever	Other			
Combination Inhaled Corticosteroid/Long-Acting Muscarinic Antagonist/Long-Acting Beta Agonists (ICS/LAMA/LABA)						
Budesonide/glycopyrrolate /formoterol (Breztri® Aerosphere)	✓	--	COPD*	160/18/4.8 mcg pMDI	12+	2 inhalations twice daily
Fluticasone/umeclidinium /vilanterol (Trelegy® Ellipta)	✓	--	COPD	100/62.5/25 mcg or 200/62.5/25 mcg DPI	18+	1 inhalation once daily
Combination Short-Acting Beta Agonist/Inhaled Corticosteroid (SABA/ICS)						
Albuterol/budesonide (Airsupra®)	--	✓	--	90/80 mcg pMDI	18+	2 inhalations as needed for asthma symptoms
Combination Short-Acting Beta Agonist/Short-Acting Muscarinic Antagonists (SABA/SAMA)						
Albuterol/ipratropium (Combivent Respimat®)	--	✓†	COPD	100/20 mcg inhalation spray	Adults	1 inhalation 4 x daily
Albuterol/ipratropium nebulizer solution	--	✓†	COPD	3/0.5 mg per 3 mL inhalation solution	Adult and pediatric patients	Dosed by age via nebulizer Severe exacerbation: Every 20 minutes x 3 doses, then as needed up to 3 hours; Moderate to severe exacerbation in ages 12+ years: Every 4 – 6 hours

COPD=chronic obstructive pulmonary disease; DPI=dry powder inhaler; FDA=Food and Drug Administration; pMDI=pressurized metered-dose inhaler
* Only the 160/9/4.8 mcg formulation of budesonide/glycopyrrolate/formoterol is FDA-approved for COPD
† Denotes off-label, compendia-supported use; available at DRUGDEX. Merative Micromedex. www.micromedexsolutions.com
FDA labels available at: https://dailymed.nlm.nih.gov

Selected Drugs FDA-approved or Compendia-Supported for Treatment of Asthma

Generic (Brand) Drug Names	FDA Indication(s)			Formulation(s) for Asthma	Ages (Years) for Asthma	Dosage Range for Asthma
	Asthma Maintenance	Asthma Reliever	Other			
Inhaled Mast Cell Stabilizer						
Cromolyn sodium nebulizer solution	✓	--	--	20 mg/2 mL solution in single-dose vials	2+	Inhalation via nebulization 1 vial 4 x daily
Oral Short-Acting Beta Agonists (SABA)						
Albuterol sulfate syrup	--	✓	EIB	2 mg/5 mL syrup	2+	Age- and/or weight-based oral doses 3-4 x daily
Albuterol sulfate tablets	--	✓	EIB	2 mg, 4 mg tablets	6+	Age-based 2-4 mg doses 3-4 x daily
Terbutaline sulfate tablets	--	✓	Br, Em	2.5 mg, 5 mg tablets	12+	12–15 years: 2.5 mg 3 x daily 15+ years: 5 mg 3 x daily
Oral Leukotriene Receptor Antagonists (LTRA)						
Montelukast sodium (Singulair®)	✓	--	EIB, AR	10 mg tablet; 4 mg, 5 mg chewable tablets; 4 mg granules	1+	1–5 years: 4 mg once daily 6–14 years: 5 mg once daily 15+ years: 10 mg once daily
Zafirlukast (Accolate®)	✓	--	--	10 mg, 20 mg tablets	5+	5–11 years: 10 mg twice daily 12+ years: 20 mg twice daily
Zileuton (Zyflo® IR or generic ER)	✓	--	--	600 mg IR or ER tablets	12+	1 IR tablet 4 x daily or 2 ER tablets twice daily

AR=allergic rhinitis; Br=bronchitis; EIB=exercise-induced bronchospasm; Em=emphysema; ER=extended release; FDA=Food and Drug Administration; IR=immediate release
FDA labels available at: https://dailymed.nlm.nih.gov/dailymed/

Selected Drugs FDA-approved or Compendia-Supported for Treatment of Asthma

Generic (Brand) Drug Names	FDA Indication(s)			Formulation(s) for Asthma	Ages (Years) for Asthma	Dosage Range for Asthma
	Asthma Maintenance	Asthma Reliever	Other			
Methylxanthine						
Theophylline	✓	--	COPD	Oral solutions, tablets and IV solutions in multiple strengths	1+	Individualized dosing to achieve 10-20 mcg/mL peak serum concentration
Oral Corticosteroids (OCS)						
Dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone	Severe allergic conditions, including asthma, intractable to adequate trials of conventional treatment	--	Many other conditions, diseases, and disorders	Oral tablets, capsules, solutions, elixirs, syrups	Adult and pediatric patients	Multiple dosing regimens based on formulation

COPD=chronic obstructive pulmonary disease; FDA=Food and Drug Administration; IV=intravenous
FDA labels available at: https://dailymed.nlm.nih.gov/dailymed/

Selected Drugs FDA-approved or Compendia-Supported for Treatment of Asthma

Generic (Brand) Drug Names	FDA Indication(s)		Formulation(s) for Asthma	Ages (Years) for Asthma	Dosage Range for Asthma
	Asthma Maintenance	Other			
Systemic Immunomodulators (Biologics)					
Benralizumab (Fasenra®) • Anti-IL5Rα	Add-on for severe asthma with eosinophilic phenotype	EGPA, HES	10 mg/0.5 mL or 30 mg/mL single-dose prefilled syringe 30 mg/mL single-dose autoinjector pen All for subcutaneous injection	6+	6-11 years: weight-based dosing (10 mg or 30 mg) every 4 weeks for 3 doses then every 8 weeks 12+ years: 30 mg every 4 weeks for 3 doses, then every 8 weeks
Depemokimab-ulaa (Exdensur®) • Anti-IL5	Add-on for severe asthma with eosinophilic phenotype	--	100 mg/mL prefilled pen or syringe for subcutaneous injection	12+	100 mg every 6 months administered by healthcare provider
Dupilumab (Dupixent®) • Anti-IL4Rα/13	Add-on for moderate-to-severe asthma with eosinophilic phenotype or oral corticosteroid-dependent asthma	AD, AFRS, BP, COPD, CRSwNP, CSU, EoE, PN	200 mg/1.14 mL or 300 mg/2 mL single-dose prefilled syringe or pen for subcutaneous injection	6+	6-11 years: weight-based dosing, 300 mg every 4 weeks or 200 mg every 2 weeks 12+ years: 400 mg or 600 mg loading dose, then 200 mg or 300 mg every 2 weeks, respectively
Mepolizumab (Nucala®) • Anti-IL5/5Rα	Add-on for severe asthma with eosinophilic phenotype	COPD, CRSwNP, EGPA, HES	100 mg lyophilized powder for reconstitution; 100 mg/mL single-dose prefilled autoinjector or syringe 40 mg/0.4 mL single-dose prefilled syringe All for subcutaneous injection	6+	6-11 years: 40 mg every 4 weeks 12+ years: 100 mg every 4 weeks

AD=atopic dermatitis; AFRS=allergic fungal rhinosinusitis; BP=bullous pemphigoid; COPD=chronic obstructive pulmonary disease; CRSwNP=chronic rhinosinusitis with nasal polyps; CSU=chronic spontaneous urticaria; EGPA=eosinophilic granulomatosis with polyangiitis; EoE=eosinophilic esophagitis; FDA=Food and Drug Administration; HES=hypereosinophilic syndrome; PN=prurigo nodularis
FDA labels available at: https://dailymed.nlm.nih.gov/dailymed/

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Generic (Brand) Drug Names	FDA Indication(s)		Formulation(s) for Asthma	Ages (Years) for Asthma	Dosage Range for Asthma
	Asthma Maintenance	Other			
Systemic Immunomodulators (Biologics)					
Omalizumab (Xolair®) and omalizumab-igec (Omlyclo®) • Anti-IgE	Add-on for moderate-to-severe asthma with positive skin test or in vitro reactivity to a perennial aeroallergen and uncontrolled with ICS	CRSwNP, IgE-mediated food allergy, CSU	150 mg single-dose vial lyophilized powder for reconstitution; 75 mg/0.5 mL, 150 mg/mL, or 300 mg/2 mL single-dose prefilled syringe or autoinjector; all for subcutaneous injection	6+	75-375 mg every 2 or 4 weeks; dose and frequency determined by serum IgE level and body weight; must monitor for anaphylaxis
Reslizumab (Cinqair®) • Anti-IL5/5Rα	Add-on for severe asthma with eosinophilic phenotype	--	100 mg/10 mL single-use vial for IV infusion	18+	3 mg/kg every 4 weeks administered by a healthcare provider; must monitor for anaphylaxis
Tezepelumab-ekko (Tezspire®) • Anti-TSLP	Add-on for severe asthma	CRSwNP	210 mg/1.91 mL single-dose vial, syringe, or pen for subcutaneous injection	12+	210 mg administered every 4 weeks

CRSwNP=chronic rhinosinusitis with nasal polyps; CSU=chronic spontaneous urticaria; FDA=Food and Drug Administration; IgE=immunoglobulin E; IL=interleukin; TSLP=thymic stromal lymphopoietin
FDA labels available at: https://dailymed.nlm.nih.gov/dailymed/

Place in Therapy: Clinical Guidance

- Global Initiative for Asthma (GINA)
  - 2026 Global Strategy for Asthma Management and Prevention
- National Asthma Education and Prevention Program (NAEPP)
  - Sponsored by the United States National Heart Lung and Blood Institute of the National Institutes of Health
  - 2020 Focused Update to the Asthma Management Guidelines
- American College of Chest Physicians (CHEST)
  - 2026 Clinical Practice Guideline for Biologic Management in Severe Asthma for Adults

Global Initiative for Asthma. May 2026. www.ginasthma.org
National Asthma Education and Prevention Program. https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines
Oberle, et al. *Chest*. 2026. doi:10.1016/j.chest.2025.08.042

GINA 2026

- Goals of asthma management
  - Achieve the best possible long-term outcomes for the individual patient, including:
    - Long-term symptom control (e.g., few/no symptoms, no sleep disturbance, unimpaired physical activity)
    - Minimized long-term risk of asthma-related morbidity (e.g., exacerbations, airflow limitation, treatment side effects) and mortality
    - Additional patient goals
- Asthma control
  - Extent to which asthma symptoms and adverse outcomes are reduced or resolved by treatment

Global Initiative for Asthma. May 2026. www.ginasthma.org

GINA 2026

- Asthma exacerbation risk factors, in addition to uncontrolled symptoms and even in patients with few symptoms:
  - Overuse of short-acting beta agonists (SABA)
    - 3 or more 200-dose cannisters/year, and especially more than 1 cannister/month is associated with increased risk of exacerbation and mortality
    - Use of nebulized SABA is a red flag for high risk in adults and adolescents
  - Inadequate use of inhaled corticosteroids (ICS)
    - Not prescribed, poor adherence, or incorrect inhaler technique
  - Impaired lung function
    - Forced expiratory volume in 1 second (FEV_1) <60% predicted, high bronchodilator responsiveness
  - Presence of Type 2 inflammatory markers
    - Elevated blood eosinophils, high fractional exhaled nitric oxide (F_{ENO})
  - Exacerbation history
    - More than 1 exacerbation in previous year or any asthma-related intubation or intensive care unit hospitalization
  - Environmental exposures
  - Comorbid conditions or psychosocial issues

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www.ginasthma.org

GINA 2026

- Baseline and ongoing assessment and adjustment:
  - Assess: Confirm diagnosis if necessary; assess both symptom control and exacerbation risk, lung function, medication adherence, side effects, inhaler technique, comorbidities, patient/caregiver satisfaction
  - Adjust: Treatment of modifiable risk factors and comorbidities, non-pharmacologic strategies, education/skills training, medication adjustments
  - Review: Repeat assessment 2 – 4 weeks after treatment adjustments
    - Step down asthma medication if possible (if well-controlled at least 3 consecutive months)
    - Any step-up should be regarded as a therapeutic trial; if there is no response after 2 – 3 months, step down to previous level and consider alternatives
    - Consider Type 2 biomarkers if asthma remains uncontrolled

Global Initiative for Asthma. May 2026. www.ginasthma.org

GINA 2026

- Pharmacological step treatment approach:
  - Treatment recommendations differ by patient age group and the intensity of treatment necessary to control asthma symptoms, from step 1 (as-needed treatment only) up to step 4 (for ages 0 – 5 years) or step 5 (for ages 6 – 11 and ≥12 years) which include increasing doses of maintenance therapy along with referral for expert assessment and/or add-on therapies
  - For population-level decisions about asthma medications:
    - “Preferred” regimens in Steps 1 – 4 represent best evidence-based treatments for most patients, focusing on symptom burden and exacerbation risk
    - Step 5 also includes different recommendations based on inflammatory phenotype
  - For individual patients, shared decision-making should include:
    - Patient characteristics and environmental exposures that may predict risk of exacerbation, other adverse outcomes, and likely response to treatment; patient’s goals and concerns
  - Treatment goal = optimize inhaled therapy and non-pharmacologic strategies to reduce the need for oral corticosteroids

Global Initiative for Asthma. May 2026. www.ginasthma.org

GINA 2026

- Anti-inflammatory reliever (AIR) and maintenance-and-reliever therapy (MART):
  - Both AIR and MART are recommended for adults, adolescents, and children 6 – 11 years of age
  - AIR = use of a low dose of inhaled corticosteroid + a rapid-acting bronchodilator to relieve symptoms as needed (e.g., combination budesonide/formoterol, mometasone/formoterol, budesonide/albuterol or separate inhaled corticosteroid + albuterol)
  - MART = use of an inhaled corticosteroid + formoterol in a single device as both maintenance and reliever therapy
  - Dosing guidance is given for using budesonide/formoterol as either AIR or MART to allow for stepping dosing up or down as necessary for adequate symptom control

Global Initiative for Asthma. May 2026.
www.ginasthma.org

GINA 2026 Recommendations for Pharmacologic Treatment of Asthma

Step	Maintenance	Children ≤ 5 years	Children 6 – 11 years	Adults and Adolescents 12+ years
1	Preferred	Insufficient evidence for daily controller	AIR only (see reliever below)	AIR only: As needed low-dose ICS-formoterol
	Alternative	Consider short-course ICS at onset of viral illness	--	AIR only: Low-dose ICS + SABA
2	Preferred	Daily low-dose ICS	Daily low-dose ICS	AIR only: As needed low-dose ICS-formoterol
	Alternative	Daily LTRA or short-course ICS at onset of respiratory illness	AIR (see below) or daily LTRA	Low-dose maintenance ICS
3	Preferred	Double low-dose ICS	Medium-dose ICS or low-dose ICS-LABA or **low-dose ICS-formoterol MART**	**MART with low-dose maintenance ICS-formoterol**
	Alternative	Consider referral for expert assessment	Low-dose ICS + LTRA	Low-dose maintenance ICS-LABA
4	Preferred	Continue controller and refer for expert assessment	Medium-dose ICS-LABA or **double low-dose ICS-formoterol MART** or refer for expert advice	**MART with medium-dose maintenance ICS-formoterol**
	Alternative	--	Add tiotropium or LTRA to Step 3 preferred	Medium-dose maintenance ICS-LABA
5	Preferred	--	Refer for phenotype assessment; consider high-dose ICS-LABA or add-on LAMA or anti-IgE, anti-IL4Rα, anti-IL5	Refer for phenotype assessment; consider high-dose maintenance ICS-formoterol, add-on LAMA, or anti-IgE, anti-IL4Rα, anti-IL5/5R, anti-TSLP
	Alternative	--	Refer for expert advice	Same as above except consider high-dose ICS-LABA as alternative to ICS-formoterol
Reliever →		As-needed SABA	**AIR: As needed low-dose ICS-formoterol** or as-needed low-dose ICS-SABA (or as-needed SABA if AIR not available)	**Preferred AIR: As-needed low-dose ICS-formoterol** Alternative AIR: As-needed low-dose ICS-SABA (or as-needed SABA if AIR not available)

AIR=anti-inflammatory reliever; GINA=Global Initiative for Asthma; ICS=inhaled corticosteroid; Ig=immunoglobulin; IL=interleukin; LABA=long-acting beta2-adrenergic agonist; LAMA=long-acting muscarinic antagonist; LTRA=leukotriene receptor antagonist; MART=maintenance-and-reliever therapy with ICS-formoterol; SABA=short-acting beta2-adrenergic agonist; TSLP=thymic stromal lymphopoietin

Global Initiative for Asthma. May 2026.
www.ginasthma.org

Applying GINA 2026 Guidance for “AIR-only” and “MART” Dosing with Single Budesonide/Formoterol pMDI Device

- Children 6 – 11 years of age: budesonide/formoterol 80/4.5 mcg
  - Step 1-2 AIR-only: 1 inhalation as needed
  - Step 3 MART: 1 inhalation once daily + 1 inhalation as needed
  - Step 4 MART: 1 inhalation twice daily + 1 inhalation as needed
  - Step 5 MART: Not recommended
  - Seek medical attention if >8 inhalations are needed in any day
- Adults and adolescents ≥12 years of age: budesonide/formoterol 160/4.5 mcg
  - Step 1-2 AIR-only: 1 inhalation as needed
  - Step 3 MART: 1 inhalation once or twice daily + 1 inhalation as needed
  - Step 4-5 MART: 2 inhalations twice daily + 1 inhalation as needed
  - Seek medical attention if >12 inhalations are needed in any day

AIR=anti-inflammatory reliever; MART=maintenance-and-reliever therapy; pMDI=pressurized metered-dose inhaler

Global Initiative for Asthma. May 2026.
www.ginasthma.org

GINA 2026

- Asthma severity and severe vs. difficult-to-treat asthma
  - Severity is determined by retrospective assessment of level of treatment needed to control symptoms and exacerbations
    - Until modifiable factors are addressed, uncontrolled asthma is classified as difficult-to-treat
  - Severe asthma: Remains uncontrolled despite optimized treatment with high-dose ICS/LABA or requires high-dose ICS/LABA to prevent loss of control
  - Moderate asthma: Well-controlled with Step 3 or Step 4 treatment (e.g., low- or medium-dose ICS/LABA)
  - Mild asthma: Well-controlled with low intensity treatment (e.g., as-needed low-dose ICS/formoterol or low-dose ICS + as needed SABA)
  - Severity labels are clinically useful to identify patients with severe asthma refractory to high-intensity treatment with high-dose ICS/LABA who may benefit from add-on biologic therapy

ICS=inhaled corticosteroid; LABA=long-acting beta agonist; SABA=short-acting beta agonist

Global Initiative for Asthma. May 2026.
www.ginasthma.org

GINA 2026 Guidance on Difficult-to-Treat Asthma in Adults and Adolescents

Consider referral to specialist at any stage

1. Confirm asthma diagnosis
2. Look for factors contributing to symptoms (**including overuse of SABA**)
3. Optimize management (**including switch to MART**, considering non-biologic add-on, trial of high dose ICS/LABA if not currently using)
4. Review response after 3 – 6 months; if still uncontrolled, likely severe asthma diagnosis
5. Investigate differential diagnoses/comorbidities, etc. further to rule out other causes
6. After severe asthma diagnosis and while patient is taking high-dose ICS, determine if biomarkers suggest refractory or underlying Type 2 inflammatory phenotype
7. Consider other add-on non-biologic treatment based on phenotype; stop ineffective therapies
8. Consider add-on Type 2-targeted biologic therapy
9. Review response after 3 – 4 months, then every 3 – 6 months thereafter
   - If well-controlled, start by tapering/stopping oral corticosteroid
   - If still well-controlled, reduce/stop other add-ons
   - If still well-controlled, consider reducing dose of ICS/LABA but do not stop
   - Stopping biologic should not be considered unless well-controlled on medium-dose ICS/LABA at least 12 months
   - If no good response, stop biologic or consider switching to another biologic

ICS=inhaled corticosteroid; LABA=long-acting beta agonist; MART=maintenance and reliever therapy; SABA=short-acting beta agonist

Global Initiative for Asthma. May 2026.
www.ginasthma.org

GINA 2026

Summary on use of biologics:

- Use of biologic therapy is recommended only for patients with severe asthma and only after treatment has been optimized
- Add-on Type 2-targeted biologic therapy may be considered for patients with exacerbations or poor symptom control on high-dose ICS/LABA who have evidence of Type 2 inflammation
- “There is an urgent need for head-to-head comparisons of different biologics in patients eligible for more than one biologic.”

Global Initiative for Asthma. May 2026. www.ginasthma.org

GINA 2026 Guidance for Add-On Type 2-Targeted Biologic Therapy in Adults and Adolescents with Severe Asthma

Biologic	Typical eligibility criteria*	Potential predictors of good response
Anti-IgE for severe allergic asthma • Omalizumab • Omalizumab-igec	• Sensitization to inhaled allergens on skin prick testing or specific IgE • Total serum IgE and body weight within dosing range • More than a specified number of exacerbations within previous year	• Childhood onset of asthma • Clinical history of allergy-driven symptoms • Baseline IgE level is NOT a predictor of response
Anti-IL5 or anti-IL5Rα for severe eosinophilic asthma • Benralizumab • Depemokimab • Mepolizumab • Reslizumab	• More than a specified number of severe exacerbations within previous year • Blood eosinophils ≥150/μL or ≥300/μL	• Higher blood eosinophils • More exacerbations in previous year • Adult-onset asthma • Nasal polyps • Maintenance oral corticosteroid at baseline • FEV_1 <65% predicted
Anti-IL4Rα for severe eosinophilic asthma or if patient requires maintenance OCS • Dupilumab	• More than a specified number of severe exacerbations within previous year • Blood eosinophils ≥150/μL and ≤1500/μL or F_{ENO} ≥25 ppb or taking maintenance oral corticosteroid	• Higher blood eosinophils (including in children) • Higher F_{ENO} (including in children) • Nasal polyps
Anti-TSLP for severe asthma • Tezepelumab	• Severe exacerbations in the previous year	• With or without elevated Type 2 markers

* Add-on biologic eligibility criteria in addition to criteria for severe asthma

F_{ENO}=fractional exhaled nitric oxide; FEV_1=forced expiratory volume in 1 second; Ig=immunoglobulin; IL=interleukin; TSLP=thymic stromal lymphopoietin

- Co-indications for each biologic should also be considered, and a suggested initial trial of 4 months for all the biologics (except for depemokimab, which would be 6 months)

Global Initiative for Asthma. May 2026.
www.ginasthma.org

NEW YORK STATE Department of Health | Office of Health Insurance Programs

SUNY The State University of New York

National Asthma Education and Prevention Program (NAEPP)
2020 Focused Update to the Asthma Management Guidelines

- This focused update addressed key therapeutic topics, one of which related to use of inhaled corticosteroids (ICS) with long-acting beta agonists (LABA) for “single-maintenance-and-reliever therapy” (SMART), the same treatment referred to as MART in GINA 2026 guidelines
  - Based on results from a systematic review and meta-analysis which included a subgroup study of 4 – 11-year-old patients and demonstrated significantly reduced risk of asthma exacerbation with SMART in this age group as well as in ages ≥12 years, the NAEPP recommends SMART with ICS/formoterol in patients as young as 4 years of age with moderate to severe asthma
  - These guidelines are also cited in official compendia to support MART as an off-label use for both budesonide/formoterol and mometasone/formoterol
  - The recommended step treatment approach is similar to GINA guidelines, with slight variations in pediatric age groups

National Asthma Education and Prevention Program.
https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines.

NAEPP 2020 Recommendations for Pharmacologic Treatment of Asthma

Step Maintenance		Children 0 – 4 years	Children 5 – 11 years	Adults and Adolescents 12+ years
1	Preferred	Short-course daily ICS at onset of respiratory infection	Reliever only (see below)	Reliever only (see below)
	Alternative	--	--	--
2	Preferred	Low-dose ICS	Low-dose ICS	Low-dose ICS or reliever only with as-needed ICS + SABA
	Alternative	LTRA* or cromolyn*	LTRA* or cromolyn* or theophylline*	LTRA* or cromolyn* or theophylline*
3	Preferred	Medium-dose ICS; **For age 4 years only, see step 3 for ages 5-11 years →**	**MART with low-dose ICS-formoterol**	**MART with low-dose ICS-formoterol**
	Alternative	--	Medium-dose ICS or low-dose ICS-LABA or low-dose ICS + either LTRA* or theophylline*	Medium-dose ICS or low-dose ICS-LABA or low-dose ICS + either LAMA or LTRA*
4	Preferred	Medium-dose ICS-LABA; **For age 4 years only, see step 4 for ages 5-11 years →**	**MART with medium-dose ICS-formoterol**	**MART with medium-dose ICS-formoterol**
	Alternative	Medium-dose ICS + LTRA*	Medium-dose ICS-LABA or medium-dose ICS + either LTRA* or theophylline*	Medium-dose ICS-LABA or medium-dose ICS + either LAMA or LTRA* or theophylline*
5	Preferred	High-dose ICS-LABA	High-dose ICS-LABA Consider adding omalizumab	Medium-high dose ICS-LABA + LAMA Consider adding asthma biologics (e.g., anti-IgE, anti-IL5, anti-IL5R, anti-IL4/IL13)
	Alternative	High-dose ICS + LTRA*	High-dose ICS + either LTRA* or theophylline*	Medium-high dose ICS-LABA or high-dose ICS + LTRA*
6	Preferred	High-dose ICS-LABA + OCS	High-dose ICS-LABA + OCS Consider adding omalizumab	High-dose ICS-LABA + OCS Consider adding asthma biologics (e.g., anti-IgE, anti-IL5, anti-IL5R, anti-IL4/IL13)
	Alternative	High-dose ICS + LTRA* + OCS	High-dose ICS + LTRA* + OCS or high-dose ICS + theophylline* + OCS	--
Reliever →		As-needed SABA	As-needed SABA (except when MART is used at steps 3 & 4)	As-needed SABA (except when MART is used at steps 3 & 4)

ICS=inhaled corticosteroid; Ig=immunoglobulin; IL=interleukin; LABA=long-acting beta2-adrenergic agonist; LAMA=long-acting muscarinic antagonist; LTRA=leukotriene receptor antagonist; MART=maintenance-and-reliever therapy with ICS-formoterol; NAEPP=National Asthma Education and Prevention Program; OCS=oral corticosteroid; SABA=short-acting beta2-adrenergic agonist *Recommendations for these agents were not updated in 2020; they are less desirable due to limited availability and/or increased risk of adverse effects

National Asthma Education and Prevention Program. https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines.

American College of Chest Physicians

2026 Clinical Practice Guideline for Biologic Management in Severe Asthma for Adults

- Recommendations are based on a systematic review to address 7 questions using population, intervention, comparator, and outcome (PICO) format
  - The population included adult patients ≥18 years of age with severe asthma
  - Not an exhaustive list of choices when prescribing asthma biologics but represents common real-world clinical questions which may be encountered by non-asthma specialists
- Classify 3 asthma types:
  - Allergic asthma – Type 2 (T2) inflammation predominantly triggered by allergens
  - T2-High asthma (i.e., eosinophilic asthma) – clinically defined by:
    - Absolute eosinophil count (AEC) ≥300 cells/μL,
    - Fractional exhaled nitric oxide (F_{ENO}) ≥25 ppb, and/or
    - Sputum eosinophils ≥1% to 3%
  - T2-Low asthma – does not exhibit the features of allergic asthma or eosinophilic asthma
- Biologics should be considered for patients who continue to exacerbate after:
  - Escalations in standard treatments based on Global Initiative for Asthma guidelines, and
  - Confirmation of adherence and proper inhaler technique, and
  - Evaluation and treatment of comorbid conditions

Oberle, et al. *Chest*. 2026.
doi:10.1016/j.chest.2025.08.042

American College of Chest Physicians 2026 Guidelines for Use of Biologics in Adults with Severe Asthma

Biologic*	Mechanism of Action	Criteria for initiation based on FDA labeling		
		Asthma Type	Clinical History	Despite Current Therapy
Omalizumab	Anti-IgE	Allergic with sensitization to perennial aeroallergen	Uncontrolled symptoms	ICS
Dupilumab	Anti-IL4Rα/13	Eosinophilic (AEC ≥150)	Exacerbation or steroid dependency	Medium-high dose ICS-LABA
Benralizumab	Anti-IL5Rα	Eosinophilic (AEC ≥300)	≥2 exacerbations/year	Medium-high dose ICS-LABA
Mepolizumab	Anti-IL5	Eosinophilic (AEC ≥150)	≥2 exacerbations/year	ICS-LABA
Reslizumab	Anti-IL5	Eosinophilic (AEC ≥400)	Exacerbation	Medium or higher dose ICS
Tezepelumab	Anti-TSLP	T2-high or T2-low	Exacerbation and uncontrolled symptoms	Medium-high dose ICS-LABA

	Population	Intervention/Comparator	Outcome-Based Recommendation
Panel recommendations for drug selection based on PICO: All are conditional recommendations based on very low certainty of evidence			
1	Adults with moderate to severe allergic asthma + ≥1 exacerbation/year requiring OCS	Dupilumab vs. omalizumab	Either biologic is suggested
	a) If ≥2 exacerbations/year or any requiring hospitalization		Dupilumab suggested over omalizumab
	b) If <2 exacerbations/year and more severe QOL impairments		Omalizumab suggested over dupilumab
	c) If greater impairment of lung function (FEV_1 <70% predicted)		Dupilumab suggested over omalizumab
2	Adults with severe asthma and OCS dependent	Anti-IL5/5Rα vs. dupilumab	Either biologic is suggested
3	Adults with severe asthma and OCS dependent	Dupilumab vs. tezepelumab	Dupilumab suggested over tezepelumab
4	Adults with moderate to severe asthma + no response to omalizumab after 4 – 6 months	Anti-IL5/5Rα vs. dupilumab	Either biologic is suggested
5	Adults with severe asthma + no response to anti-IL5/5Rα therapy after 4 – 6 months	Dupilumab vs. tezepelumab	Either biologic is suggested
	a) If OCS dependent		Dupilumab suggested over tezepelumab
6	Adults with severe asthma + no response to dupilumab after 4 – 6 months	Anti-IL5/5Rα vs. tezepelumab	Either biologic is suggested
	a) If OCS dependent		Anti-IL5/5Rα suggested over tezepelumab
7	Adults with severe asthma + no response to anti-IL5/5Rα therapy after 4 – 6 months	Dupilumab based on F_{ENO}	Post-treatment F_{ENO} ≥25 ppb suggested to advise change to dupilumab

AEC=absolute eosinophil count in cells/μL; FDA=Food and Drug Administration; F_{ENO}=Fractional exhaled nitric oxide; FEV_1=Forced Expiratory Volume in 1 second; ICS=inhaled corticosteroid; Ig=immunoglobulin; IL=interleukin; LABA=long-acting beta agonist; OCS=oral corticosteroid; PICO=Population, intervention, comparator, outcome; TSLP=thymic stromal lymphopoietin

*Depemokimab, an anti-IL5 biologic, received FDA approval in December 2025 and was not mentioned in these 2026 guidelines

Oberle AJ, et al. *Chest.* 2026;169(2):336-348

Additional Literature

- Costs of single maintenance and reliever therapy (SMART) vs. traditional therapy for asthma (Pham et al., 2026)
  - Study funded by National Institutes of Health comparing the annual asthma management costs to US healthcare payers based on 2024 US dollars
  - Economic analysis using probabilistic decision-making tree with Monte Carlo simulations to determine annualized probability of 4 health outcomes
    - No severe exacerbation, treated outpatient, emergency department visit, or hospitalized inpatient
  - Included data from 6 RCTs comparing SMART (budesonide/formoterol) to traditional therapy (ICS/LABA maintenance + SABA reliever) in ~12,000 patients with moderate to severe asthma
  - SMART resulted in cost savings in 57% of simulations; inhaler cost was 80% of direct cost in both groups; per person annual asthma-related morbidity costs were lower with SMART, though not statistically significant
  - Authors concluded SMART was associated with modest cost savings and improved health outcomes compared to traditional therapy
  - Data on inhaler usage showed that some individuals may need up to 7 or 8 inhalers every 6 months to cover use for SMART

ICS=inhaled corticosteroid; LABA=long-acting beta agonist; RCT=randomized controlled trial; SABA=short-acting beta agonist; US=United States

Pham et al. *JAMA Netw Open*. 2026;9(2):e2556757

Comparator State Medicaid Programs

- Preferred Drug List criteria were reviewed in 9 comparator state Medicaid programs:
  - California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, and Washington
- In addition to standard prior authorization (PA) for nonpreferred agents, the following selected criteria were identified:
  - Inhaled combination agents:
    - 3 states have frequency/quantity/duration (F/Q/D) limits on all products
    - In 1 state, ICS/LABA/LAMA is preferred with PA, requiring documented failure of 6-week trial of LABA + LAMA or blood eosinophil count ≥300 µL and failed 6-week trial of a LABA or LAMA
  - Systemic immunomodulators (asthma biologics):
    - All 9 states restrict asthma biologics to FDA-indicated use and F/Q/D limits
    - 8 states require PA for all preferred and non-preferred asthma biologics with clinical criteria consistent with FDA labeling (e.g., age, weight, asthma severity diagnosis, use as add-on therapy)
    - 6 states specifically require documentation of phenotype with relevant biomarkers as well as documentation of poor control or exacerbation on current optimized controller therapy with ICS/LABA and/or other guideline-recommended add-on therapies
    - At least 4 states require documented improvement and continued optimized/guideline-recommended controller therapy for renewal of PA

FDA=Food and Drug Administration; ICS=inhaled corticosteroid; LABA=long-acting beta agonist; LAMA=long-acting muscarinic antagonist

NYRx Preferred Drug List Criteria

There are preferred and non-preferred agents among all the asthma drug groups
The following tables include the asthma drugs with clinical criteria on the Preferred Drug List

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
Respiratory Agents		
Beta2 Adrenergic Agents – Inhaled Long-Acting CC, F/Q/D		

Serevent Diskus®		**CLINICAL CRITERIA (CC)**
		• PA is required for all new long-acting beta agonist prescriptions for patients under FDA- or compendia-supported age as indicated
		  • Serevent Diskus® ≥4 years
		
		Frequency/Quantity/Duration (F/Q/D)
		  • Serevent Diskus® One diskus (30 blisters) per 30 days

Source: NYRx, the New York Medicaid Pharmacy Program Preferred Drug List. https://newyork.fhsc.com/downloads/providers/nyrx_pdp_pdl.pdf. Revised: 9/14/26. Accessed: 9/17/26.

NYRx Preferred Drug List Criteria

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
Respiratory Agents		
Corticosteroid/Beta2 Adrenergic Agent (Long-Acting) Combinations – Inhaled CC, F/Q/D		
Advair Diskus® BLTG Advair HFA® BLTG Dulera® Symbicort® BLTG	Breo Ellipta® budesonide/formoterol (gen Symbicort®) fluticasone/salmeterol (gen AirDuo™ RespiClick®) fluticasone/salmeterol (gen Advair Diskus®) fluticasone/salmeterol (gen Advair® HFA) fluticasone/vilanterol (gen Breo Ellipta®)	**CLINICAL CRITERIA (CC)** • PA is required for all new long-acting beta agonist prescriptions for patients under FDA- or compendia-supported age as indicated:

FDA / Compendia-Supported Age	
Advair Diskus® 100/50 mcg	≥4 years
Advair Diskus® 250/50 mcg, 500/50 mcg	≥12 years
Advair HFA®	≥12 years
Dulera® 50 mcg	≥4 years
Dulera® 100 mcg and 200 mcg	≥12 years
budesonide/formoterol (Symbicort®) 80/4.5 mcg	≥4 years
budesonide/formoterol (Symbicort®) 160/4.5 mcg	≥12 years
fluticasone/vilanterol (Breo Ellipta®) 50/25 mcg	≥5 years
fluticasone/vilanterol (Breo Ellipta®) 100/25 mcg	≥12 years
fluticasone/vilanterol (Breo Ellipta®) 200/25 mcg	≥18 years
Advair Diskus® 100/50 mcg	≥4 years

Frequency/Quantity/Duration (F/Q/D)

Advair Diskus®	One device every 30 days
Advair HFA®	
fluticasone/salmeterol	
fluticasone/vilanterol (Breo Ellipta®)	
budesonide/formoterol (Symbicort®)	Up to 8 inhalers every 180 days
Dulera®	

Source: NYRx, the New York Medicaid Pharmacy Program Preferred Drug List. https://newyork.fhsc.com/downloads/providers/nyrx_pdp_pdl.pdf. Revised: 9/14/26. Accessed: 9/17/26.

NEW YORK STATE | Department of Health | Office of Health Insurance Programs

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NYRx Preferred Drug List Criteria

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
Respiratory Agents		
COPD Agents		
Spiriva Respimat®	Breztri™ Aerosphere[CC] Trelegy Ellipta®	**CLINICAL CRITERIA (CC)** Breztri Aerosphere 160 mcg/18 mcg/4.8 mcg: • PA required for patients under FDA or compendia-supported age 12. • Trial of a preferred agent in the Corticosteroid/Beta2 Adrenergic Agent (Long-Acting) Combinations – Inhaled drug class required

Source: NYRx, the New York Medicaid Pharmacy Program Preferred Drug List. https://newyork.fhsc.com/downloads/providers/nyrx_pdp_pdl.pdf. Revised: 9/14/26. Accessed: 9/17/26.

NYRx Preferred Drug List Criteria

<table>
<tr><th>Preferred Drugs</th><th>Non-Preferred Drugs</th><th>Coverage Parameters</th></tr>
<tr><td colspan="3">Immunologic Agents</td></tr>
<tr><td colspan="3">Immunomodulators – Systemic CC, ST</td></tr>
<tr><td colspan="2">Interleukin Inhibitors</td><td rowspan="5">CLINICAL CRITERIA (CC)
• Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid-covered indication
STEP THERAPY (ST)
INDICATION-SPECIFIC REQUIREMENTS:
• Asthma
- History and concurrent use of a corticosteroid</td></tr>
<tr><td>Dupixent®
Fasenra®</td><td>Nucala®</td></tr>
<tr><td colspan="2">Miscellaneous</td></tr>
<tr><td>Xolair®</td><td></td></tr>
</table>

Source: NYRx, the New York Medicaid Pharmacy Program Preferred Drug List. https://newyork.fhsc.com/downloads/providers/nyrx_pdp_pdl.pdf. Revised: 9/14/26. Accessed: 9/17/26.

- Cinqair® (reslizumab) and Exdensur® (depemokimab-ulaa) are not on the Preferred Drug List but are listed on the New York Medicaid List of Practitioner Administered Drugs (PAD); prior authorization is not required with appropriate practitioner code

Utilization Analysis

- Objective:
  - To evaluate utilization of inhaled and systemic asthma therapies during State Fiscal Years 2025 and 2026 among New York State Medicaid members with an asthma diagnosis and recommend updated clinical criteria aligned with evidence-based guidelines

Methods

- A retrospective analysis of pharmacy and medical claims was conducted to evaluate the utilization of asthma drugs among New York State Medicaid members with a diagnosis of asthma
  - Diagnoses, including asthma severities, were identified using International Classification of Diseases-tenth revision (ICD-10) codes. The ICD-10 J45 category classifies asthma diagnoses. Members with more than 1 severity code were grouped by the highest severity indicated during the analysis period
  - Inclusion criteria:
    - Members with ≥2 distinct dates of service with any J45 diagnosis code during State Fiscal Years 2025 and/or 2026 AND with ≥1 pharmacy claim for an asthma drug during State Fiscal Year 2026
  - Exclusion criteria:
    - Members who also had an ICD-10 J44 diagnosis code during the analysis period; the J44 category classifies chronic obstructive pulmonary disease (COPD) and some of the asthma drugs also have indications for COPD
    - Medicaid/Medicare dual eligible members

Methods

- Data source: Medicaid Data Warehouse
- Analysis period: April 1, 2024 – March 31, 2026
  - State Fiscal Year 2025: April 1, 2024 – March 31, 2025
  - State Fiscal Year 2026: April 1, 2025 – March 31, 2026
- Of note, the Medicaid Confidential Data Cell Size Policy (OHIP-0001) requires that no cell containing a value of 1 to 30 be reported. The cell size value must be reported as ≤30 in all public-facing documents. Additionally, no cell can be reported that allows a value of 1 to 30 to be derived from other reported cells or information.
- Also, the following limitations should be considered:
  - While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete
  - Continuous enrollment between State Fiscal Years 2025 and 2026 was not considered

Results

Members with Asthma Diagnosis* in State Fiscal Years 2025 – 2026

Total Number of Members = 572,100	
Gender	% of Members
Female	57%
Male	43%

Data source: Medicaid Data Warehouse; date range: 4/1/2024 – 3/31/2026; extract date 6/1/2026

*Members with asthma diagnosis on ≥2 dates of service during the 2-year analysis period and no diagnosis of chronic obstructive pulmonary disease

Age distribution among members with asthma diagnosis during State Fiscal Years 2025 – 2026

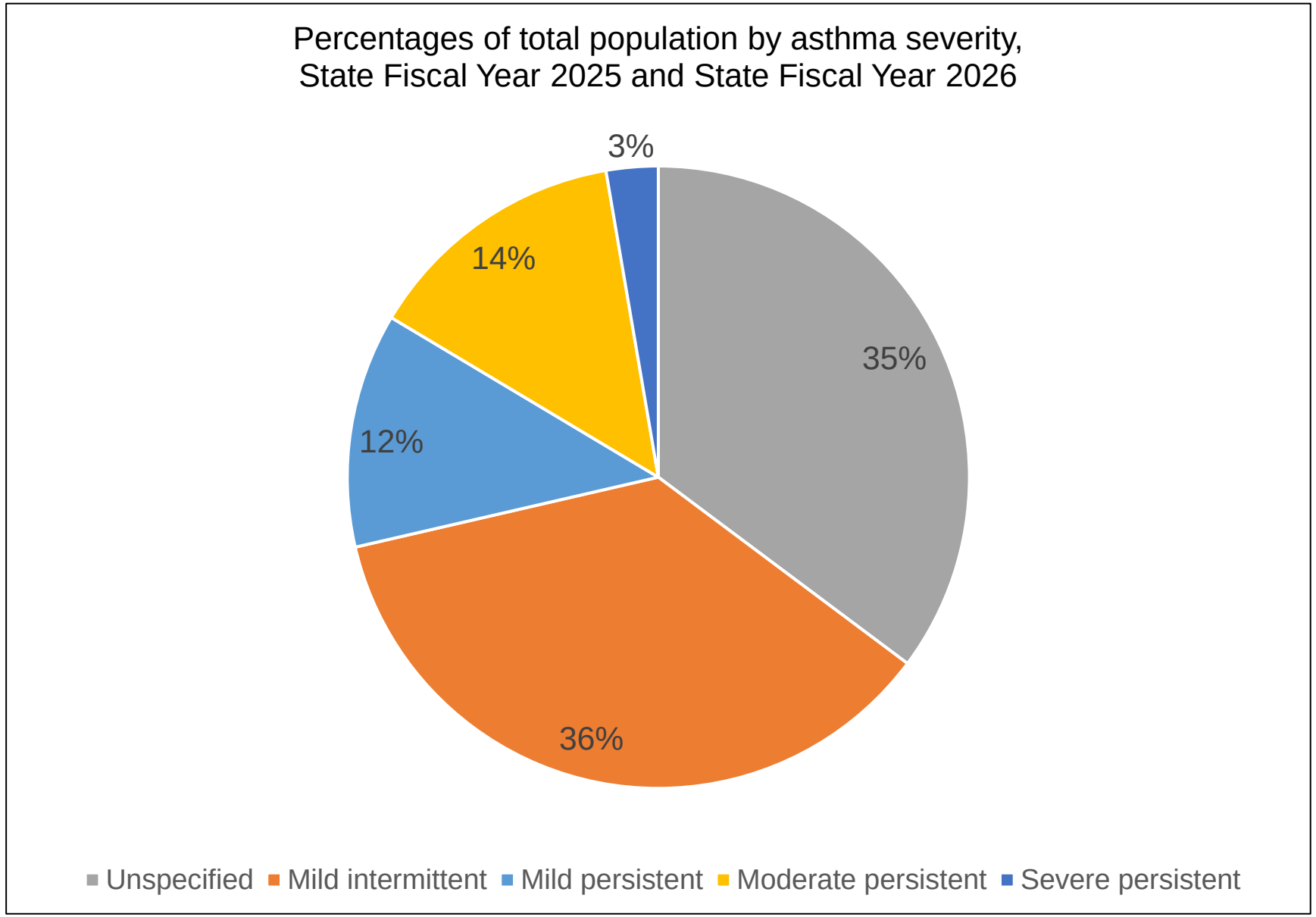
Members with Asthma Diagnosis* in State Fiscal Years 2025 – 2026: Total = 572,100			
Age Group (Years)	% of Members	GINA Age Category	% of Members
0 – 5	11%	0 – 5 years	11%
6 – 11	15%	6 – 11 years	15%
12 – 17	14%	12+ years	74%
18 – 24	12%		
25 – 44	29%		
45 – 64	18%		
65+	1%		
Total	100%	Total	100%

Data source: Medicaid Data Warehouse; date range: 4/1/2024 – 3/31/2026; extract date 6/1/2026

*Members with asthma diagnosis on ≥2 dates of service during the 2-year analysis period and no diagnosis of chronic obstructive pulmonary disease

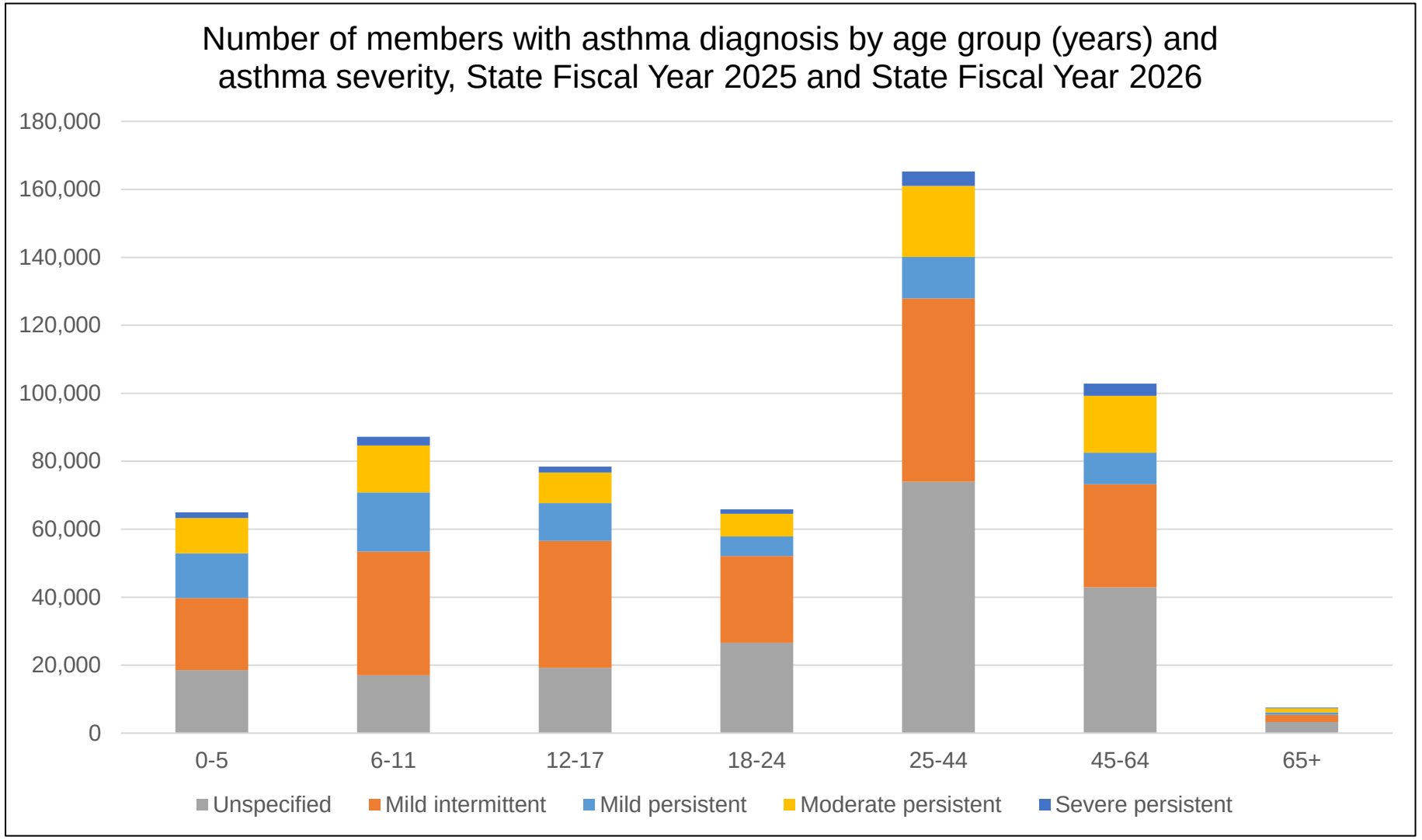
GINA=Global Initiative for Asthma

- Members 25 – 44 years of age made up the largest age segment (29%) of the population
- When grouped according to the 3 GINA guideline age categories for treatment recommendations, adults and adolescents ≥12 years of age were the largest segment (74%) of the population



- Nearly half (48%) of the total population with an asthma diagnosis (572,100 members) had either mild intermittent or mild persistent asthma; 17% had either moderate or severe asthma, and 35% had unspecified severity

Data source: Medicaid Data Warehouse; date range: 4/1/2024 – 3/31/2026; extract date 6/1/2026
Members had diagnosis of asthma on ≥2 dates of service during the 2-year analysis period and are grouped by highest severity indicated during the analysis period



- Mild intermittent asthma was the most common severity diagnosis observed among all age groups except the group of members 25 – 44 years of age, in which unspecified severity was most common

Data source: Medicaid Data Warehouse; date range: 4/1/2024 – 3/31/2026; extract date 6/1/2026
Members had diagnosis of asthma on ≥2 dates of service during the 2-year analysis period and are grouped by highest severity indicated during the analysis period

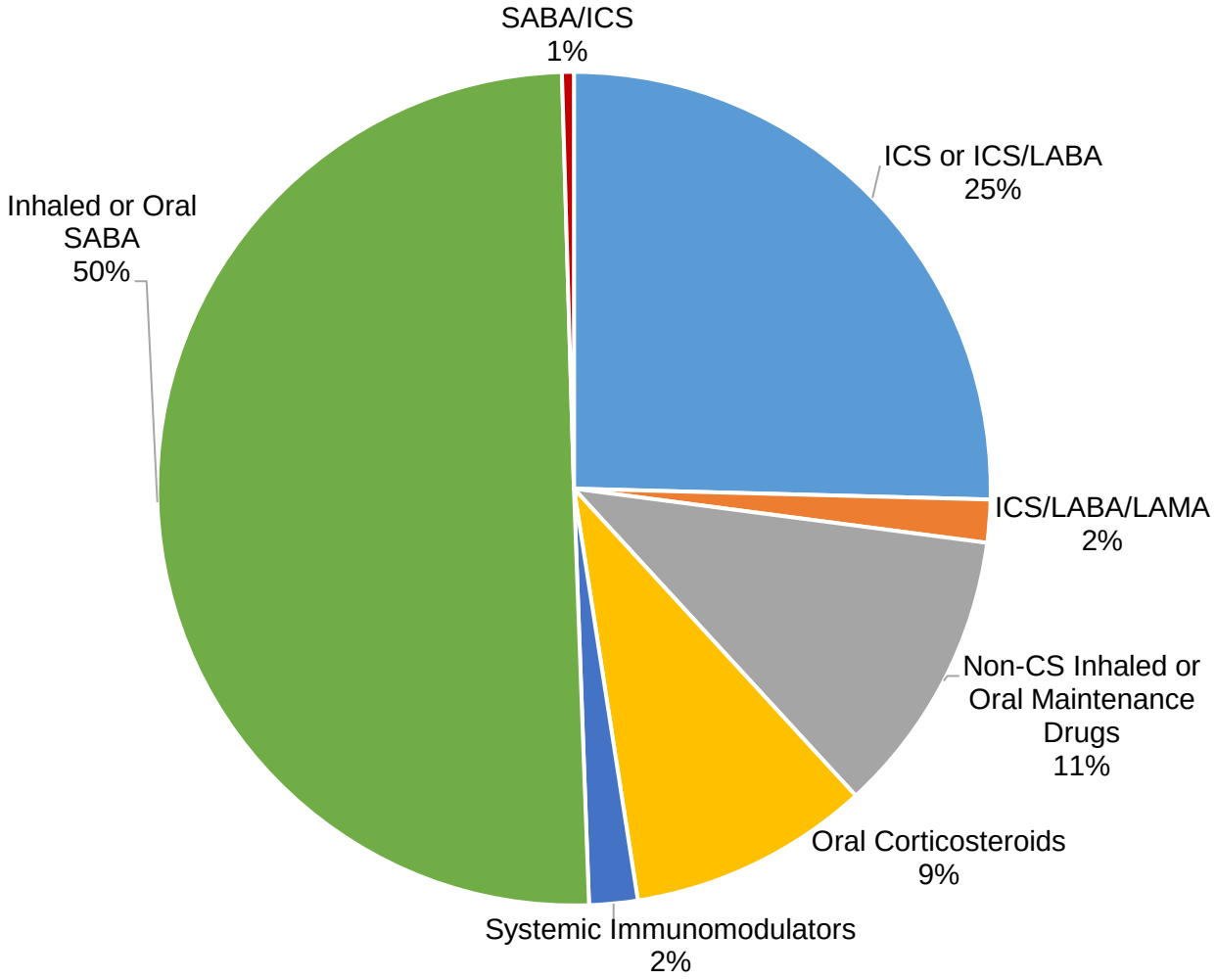
Overall utilization of asthma drugs among diagnosed members in State Fiscal Years 2025 and 2026

State Fiscal Year	Overall			Average per Member			Average per Claim	
	Members	Pharmacy Claims	Estimated Cost	Pharmacy Claims	Estimated Cost	Days' Supply	Estimated Cost	Days' Supply
2025	362,679	2,456,638	$380,070,213	6.8	$1,048	187	$155	28
2026	353,234	2,394,530	$437,579,496	6.8	$1,239	191	$183	28

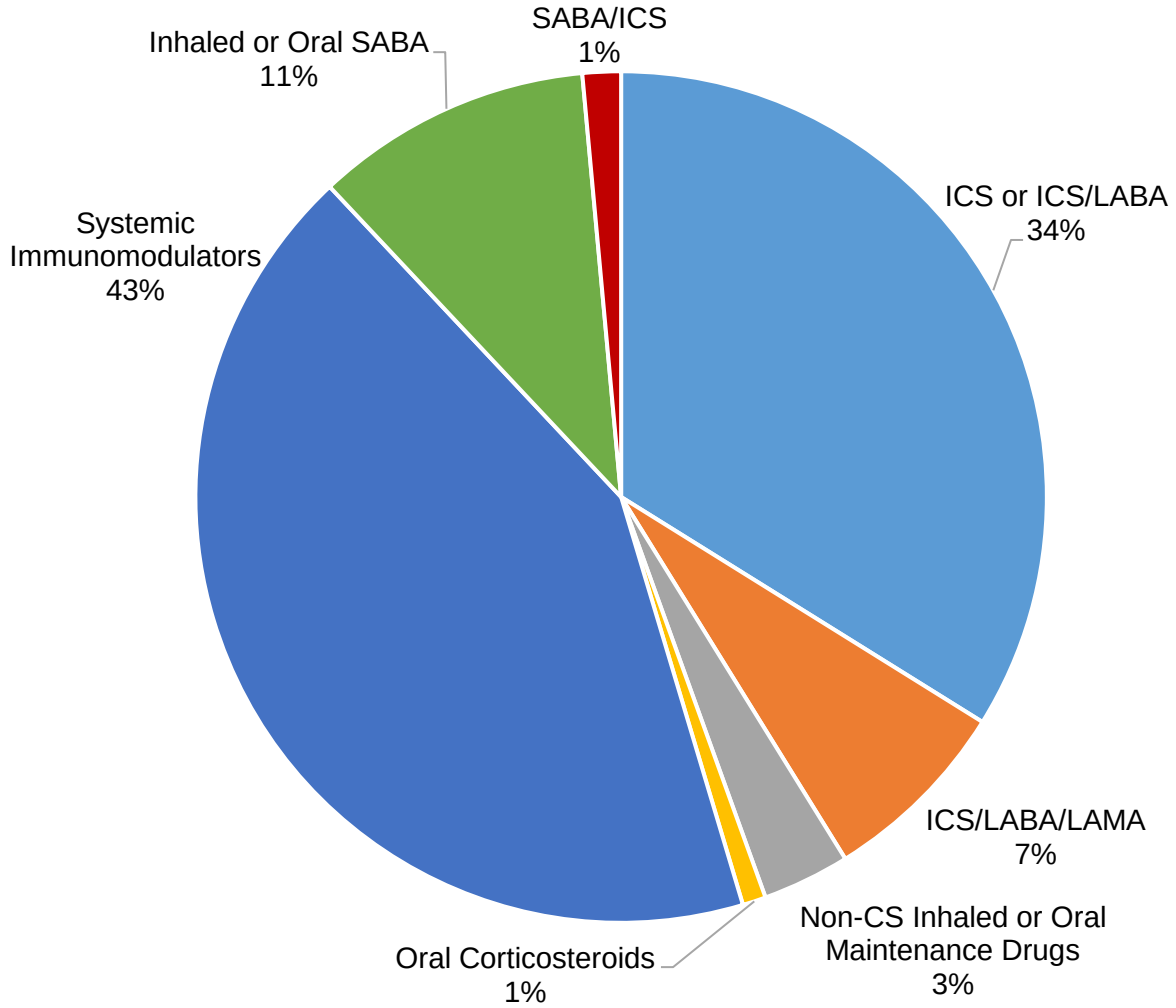
Data source: Medicaid Data Warehouse; date range: 4/1/2024 – 3/31/2026**;** extract date: 6/1/2026
Members had diagnosis of asthma on ≥2 dates of service during the analysis period.

- Overall, between State Fiscal Years 2025 and 2026:
  - Number of members who received asthma drugs decreased by 2.6% and number of claims decreased by 2.5%
  - Estimated cost increased by 15.1% (from $380,070,213 to $437,579,496)
- Per member, between State Fiscal Years 2025 and 2026:
  - Average number of claims and average days' supply per claim remained stable (6.8 claims and 28 days, respectively)
  - Average cost per claim increased by 18.1% (from $155 to $183)
- The main driver of the increase in estimated total cost of asthma drugs among members with an asthma diagnosis between State Fiscal Years 2025 and 2026 was the increase in average cost per claim

Percentages of PHARMACY CLAIMS by drug group, State Fiscal Year 2025 and State Fiscal Year 2026



Percentages of ESTIMATED TOTAL COST by drug group, State Fiscal Year 2025 and State Fiscal Year 2026



Data source: Medicaid Data Warehouse; date range: 4/1/2024 – 3/31/2026**;** extract date: 6/1/2026

ICS=inhaled corticosteroid; LABA=long-acting beta agonist; LAMA=long-acting muscarinic antagonist; Non-CS=non-corticosteroid; SABA=short-acting beta agonist

- Inhaled or oral SABA, SABA/ICS, and ICS or ICS/LABA accounted for 76% of the claim volume and 46% of the total estimated cost; conversely, systemic immunomodulators accounted for 2% of claims and 43% of the total estimated cost

Utilization of Maintenance and Reliever Therapies in State Fiscal Year 2026

Drug Claims Received	Number of Members *	% of Members *
Any asthma drug (or several)	353,234	--
Any reliever drug (includes MART drugs)	318,592	90%
Non-MART reliever drug	299,764	85%
Any maintenance drug (includes MART drugs)	189,648	54%
Non-MART maintenance drug	133,584	38%
Any MART Drug	88,506	25%
ONLY MART Drug(s)	12,601	4%
Any oral corticosteroid	124,532	35%
ONLY oral corticosteroid(s)	17,191	5%

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026**;** extract date: 6/1/2026; *Members and percents not additive
MART=maintenance-and-reliever-therapy drugs: budesonide/formoterol or mometasone/formoterol

- Utilization includes a breakdown of members who received budesonide/formoterol or mometasone/formoterol products, which are compendia-supported for both maintenance and reliever therapy (MART)
- The vast majority (90%) of members received claims for reliever drugs
- Significantly fewer (54%) members received claims for maintenance drugs
- More members received non-MART reliever drugs (85%) and/or non-MART maintenance drugs (38%) compared to those who received any MART drugs (25%) or only MART drugs (4%)
- 35% of members received oral corticosteroids, including 5% who received oral corticosteroids and no other asthma drugs during State Fiscal Year 2026

Utilization of Maintenance-And-Reliever-Therapy (MART) Drugs in State Fiscal Year 2026

- As described in the clinical review, MART with an inhaled corticosteroid (ICS)/formoterol drug is guideline-recommended as the preferred treatment option in adults, adolescents, and children as young as 4 years of age with moderate to severe asthma
- GINA 2026 guidelines also recommend budesonide/formoterol as a preferred anti-inflammatory reliever alone (AIR-only) in milder disease
- Of the 353,234 members who received any asthma drugs in State Fiscal Year 2026, a total of 78,795 (22%) had a diagnosis of moderate or severe asthma
- The 12,601 members who received only MART drugs in State Fiscal Year 2026 represent the best estimate of members who utilized either budesonide/formoterol or mometasone/formoterol for MART or may have used them as AIR-only

Asthma Severity Among Members with Claims for ONLY MART Drugs during State Fiscal Year 2026

Total = 12,601 Members	Asthma Severity				
	Unspecified	Mild Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent
Number (%) of Members	2,414 (19%)	4,773 (38%)	2,358 (19%)	2,771 (22%)	285 (2%)

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026**;** extract date: 6/1/2026
Members had diagnosis of asthma on ≥2 dates of service during the 2-year analysis period and are grouped by highest severity indicated during the analysis period; MART=maintenance-and-reliever-therapy drugs: budesonide/formoterol or mometasone/formoterol

- A total of 24% of members utilizing only MART drugs had a moderate (22%) or severe (2%) asthma diagnosis; use was more common among members with either a mild intermittent (38%) or mild persistent (19%) asthma diagnosis (total 57%)
- While the mild severity diagnoses may reflect clinical improvement with ongoing use of MART, it may also indicate higher utilization of ICS/formoterol drugs as AIR-only compared to MART

AIR=anti-inflammatory reliever
ICS=inhaled corticosteroid

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Inhaler Quantities for Members Utilizing Any MART Drugs during State Fiscal Year 2026

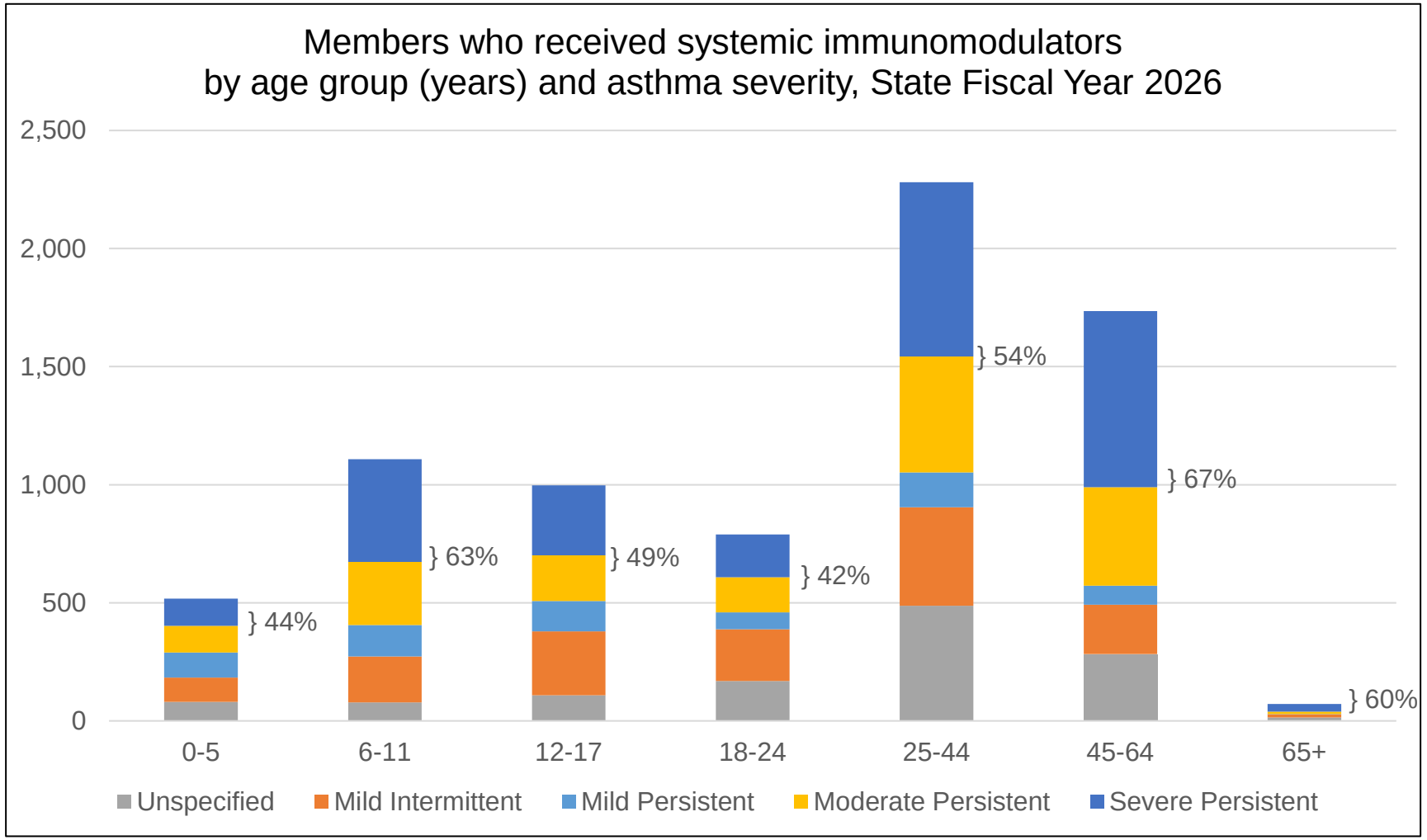
State Fiscal Year 2026	Budesonide/formoterol	Mometasone/formoterol
# Members with claims	85,497	3,572
Average # claims per member	3.8	4
Average # inhalers per claim	1.12	1.15
# (%) Members over FQD limit (>16 inhalers annually)	52 (<0.1%)	

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026; extract date: 6/1/2026
FQD=frequency/quantity/duration; MART=maintenance and reliever therapy

- Over 99.9% of members who received either MART drug received quantities at or below the limit on the NYRx Preferred Drug List
- Average claims per member and inhalers per claim amount to utilization of approximately 4 inhalers per year, which also may indicate use as anti-inflammatory reliever (AIR)-only rather than maintenance and reliever therapy (MART)

Utilization of Systemic Immunomodulators in State Fiscal Year 2026

- A total of 7,500 members with an asthma diagnosis received systemic immunomodulators (i.e., asthma biologics) during State Fiscal Year 2026
- Pharmacy claims were identified for 4 biologics in this population: benralizumab, dupilumab, mepolizumab, and omalizumab; dupilumab was the most commonly utilized agent
- Dupilumab and omalizumab are FDA-approved for add-on therapy in moderate to severe asthma; benralizumab and mepolizumab are FDA-approved for add-on therapy in severe asthma
- Global Initiative for Asthma guidelines recommend considering add-on biologics only when severe asthma is diagnosed after optimizing treatment



- Among all age groups, 56% (4,182 / 7,500) of members had a diagnosis of moderate or severe asthma; the remaining 44% had a diagnosis of mild asthma or unspecified severity
- Among all age groups, only 34% (2,544 / 7,500) of members had a diagnosis of severe asthma
- Less severe asthma diagnoses may reflect clinical improvement on therapy for some members; however, it cannot be ruled out that some members may have initiated biologics for treatment of milder disease

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026**;** extract date: 6/1/2026
Members had diagnosis of asthma on ≥2 dates of service during the 2-year analysis period and are grouped by highest severity indicated during the analysis period; percentages show members in each age category with a moderate or severe asthma diagnosis

Utilization of Systemic Immunomodulators in State Fiscal Year 2026

- In addition to exacerbation history, the Global Initiative for Asthma and the American College of Chest Physicians recommend phenotype testing for certain biomarkers (e.g., skin testing for aero-allergens, serum immunoglobulin E, blood eosinophil counts, fractional exhaled nitric oxide) as criteria for initiation of asthma biologics
  - Of the members who received asthma biologics in State Fiscal Year 2026, 86% (6,450 / 7,500) had claims during State Fiscal Years 2025 and 2026 for 1 or more laboratory procedures that would include such biomarker testing
  - It is unknown if the remaining 14% of members had biomarker testing before starting an asthma biologic prior to the analysis period
- Asthma biologics are FDA-approved as add-on therapy to optimized non-biologic therapy
  - 34% (2,581 / 7,500) did not have claims for other maintenance drugs, including maintenance and reliever therapy (MART) drugs
  - 15% (1,148 / 7,500) did not have claims for any other asthma drugs

Asthma Severity Among Members with Claims for Systemic Immunomodulators and No Other Asthma Drugs during State Fiscal Year 2026

Total = 1,148 Members	Asthma Severity				
	Unspecified	Mild Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent
Number (%) of Members	435 (38%)	398 (35%)	109 (9%)	125 (11%)	81 (7%)

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026; extract date 6/1/2026
Members had diagnosis of asthma on ≥2 dates of service during the 2-year analysis period and are grouped by highest severity indicated during the analysis period

- A total of 82% (942 / 1,148) of members with claims for systemic immunomodulators and no other asthma drugs had an unspecified or mild asthma diagnosis, which may reflect use of the biologic for a different indication
- Dupilumab has several FDA-approved indications in addition to asthma and was the most commonly used biologic among these members
- 86% (992 / 1,148) of these members did have another diagnosis for which the biologic they received was indicated; 14% (156 members) did not.

Utilization of Short-Acting Beta Agonist Relievers in State Fiscal Year 2026

- Short-acting beta agonist (SABA)-only inhalers (excludes nebulizer solutions)
  - A total of 269,622 members received SABA-only inhalers with or without maintenance therapy
  - 52% (139,838 / 269,622) also had claims for maintenance drugs (including MART drugs)
  - 48% (129,784 / 269,622) did not have claims for maintenance drugs

- Asthma severity among members who received SABA-only inhalers WITH maintenance drugs in State Fiscal Year 2026

Total = 139,838 Members	Asthma Severity				
	Unspecified	Mild Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent
Number (%) of Members	24,013 (17%)	30,386 (22%)	31,449 (23%)	43,529 (31%)	10,461 (7%)

  - 45% had a diagnosis of mild intermittent (22%) or mild persistent (23%) asthma; 38% had a diagnosis of moderate (31%) or severe (7%) asthma

- Asthma severity among members who received SABA-only inhalers WITHOUT maintenance drugs in State Fiscal Year 2026

Total = 129,784 Members	Asthma Severity				
	Unspecified	Mild Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent
Number (%) of Members	42,508 (33%)	66,994 (52%)	10,874 (8%)	8,576 (7%)	832 (<1%)

  - 60% had a diagnosis of mild intermittent (52%) or mild persistent (8%) asthma; <8% had a diagnosis of moderate (7%) or severe (<1%) asthma

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026; extract date 6/1/2026
Members had diagnosis of asthma on ≥2 dates of service during the 2-year analysis period and are grouped by highest severity indicated during the analysis period

Utilization of Short-Acting Beta Agonist Relievers in State Fiscal Year 2026

- Short-acting beta agonist / inhaled corticosteroid (SABA/ICS) inhalers
  - A total of 5,379 members received SABA/ICS (albuterol/budesonide) inhalers with or without maintenance therapy
  - 69% (3,719 / 5,379) also had claims for maintenance drugs (including MART drugs)
  - 31% (1,660 / 5,379) did not have claims for maintenance drugs
  - 259 members were 0 – 17 years of age, below the FDA-approved indication for ≥18 years of age

- Asthma severity among members who received inhaled SABA/ICS WITH maintenance drugs in State Fiscal Year 2026

Total = 3,719 Members	Asthma Severity				
	Unspecified	Mild Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent
Number (%) of Members	793 (21%)	626 (17%)	387 (10%)	1,268 (34%)	645 (17%)

  - 27% had a diagnosis of mild intermittent (17%) or mild persistent (10%) asthma; 51% had a diagnosis of moderate (34%) or severe (17%) asthma

- Asthma severity among members who received inhaled SABA/ICS WITHOUT maintenance drugs in State Fiscal Year 2026

Total = 1,660 Members	Asthma Severity				
	Unspecified	Mild Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent
Number (%) of Members	590 (36%)	586 (35%)	188 (11%)	267 (16%)	29 (2%)

  - 46% had a diagnosis of mild intermittent (35%) or mild persistent (11%) asthma; 18% had a diagnosis of moderate (16%) or severe (2%) asthma

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026; extract date 6/1/2026
Members had diagnosis of asthma on ≥2 dates of service during the 2-year analysis period and are grouped by highest severity indicated during the analysis period

Utilization of Short-Acting Beta Agonist (SABA) Relievers in State Fiscal Year 2026

- Global Initiative for Asthma guidelines note that SABA overuse is an independent risk factor for asthma exacerbation even in patients with few asthma symptoms
  - Use of 3 or more 200-dose cannisters/year, and especially more than 1 cannister/month, is associated with increased risk of exacerbation and mortality
- The table below summarizes the quantity distribution for the 269,622 members who received inhaled SABA-only (non-nebulizer) relievers with or without maintenance drugs in State Fiscal Year 2026

Number of SABA-Only* Inhalers	Number (%) of Members
1 – 2	138,064 (51%)
3 – 6	85,704 (32%)
7 – 9	22,863 (8.5%)
10 – 12	13,614 (5.0%)
>12	9,377 (3.5%)
	Total: 269,622

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026; extract date 6/1/2026; *Does not include nebulizers or SABA/ICS inhalers. SABA-only inhalers contain 200 actuations per cannister.

- Almost half (49%) of these members received ≥3 SABA-only inhalers and 3.5% received >12 inhalers in this 1-year period
- Additional analysis of **claims** identified the following:
  - 29% (77,117 / 269,622) of members received ≥3 claims for SABA-only inhalers and also had claims for maintenance drugs, including MART drugs
    - The largest subgroup was members with moderate asthma
  - 15% (39,938 / 269,622) of members received ≥3 claims for SABA-only inhalers WITHOUT claims for maintenance drugs
    - The largest subgroup was members with mild intermittent asthma

Utilization of Short-Acting Beta Agonist (SABA) Relievers in State Fiscal Year 2026

- A total of 105,181 members received claims for SABA nebulizer solution during State Fiscal Year 2026
  - 1% (1,260 / 105,181) of members received more than 12 claims (averaging >1 claim per month) for SABA nebulizer solution during the 1-year period
  - 23% (24,691 / 105,181) of members received ≥3 claims for SABA nebulizer solution and received claims for maintenance drugs, including MART drugs
    - 51% (12,588 / 24,691) of these members were ≥12 years of age
    - The largest subgroup was members 0 – 11 years of age with mild persistent or moderate asthma
  - 8% (8,402 / 105,181) of members received ≥3 claims for SABA nebulizer solution WITHOUT maintenance drugs
    - 47% (3,913 / 8,402) of these members were ≥12 years of age
    - The largest subgroup was members 0 – 11 years of age with mild intermittent asthma

Utilization of Short-Acting Beta Agonist (SABA) Relievers in State Fiscal Year 2026

- Global Initiative for Asthma guidelines classify SABA/ICS as an anti-inflammatory reliever (AIR) option
- The table below summarizes the quantity distribution for the 5,379 members who received the combination SABA/ICS inhaler albuterol/budesonide with or without maintenance drugs in State Fiscal Year 2026

Number of SABA/ICS Inhalers*	Number (%) of Members
1 – 2	2,995 (56%)
3 – 6	1,800 (33%)
7 – 9	356 (7%)
10 – 12	160 (3%)
>12	68 (1%)
	Total: 5,379

Data source: Medicaid Data Warehouse; date range: 4/1/2025 – 3/31/2026; extract date 6/1/2026
SABA/ICS=short-acting beta agonist/inhaled corticosteroid (albuterol/budesonide)
*Albuterol/budesonide inhalers contain 120 actuations per cannister

- A total of 44% of these members received ≥3 SABA/ICS inhalers and 1% received >12 inhalers in this 1-year period
- Additional analysis of **claims** identified the following:
  - 29% (1,565 / 5,379) of members received ≥3 claims for SABA/ICS inhalers and also had claims for maintenance drugs, including MART drugs
    - The largest subgroup was members with moderate asthma
  - 9% (495 / 5,379) of members received ≥3 claims for SABA/ICS inhalers WITHOUT claims for maintenance drugs
    - The largest subgroup was members with either unspecified or mild intermittent asthma

Conclusions

- Pharmacologic treatment of asthma in a stepwise approach is similarly outlined for both children and adults in Global Initiative for Asthma (GINA) guidelines and United States National Asthma Education Prevention Program (NAEPP) guidelines, and focuses on controlling asthma symptoms primarily with inhaled corticosteroids (ICS) and short- or long-acting beta agonist bronchodilators (SABA or LABA)
- Formoterol is a LABA with fast onset of action and ICS/formoterol in a single device is recommended (and compendia-supported) for both maintenance and reliever therapy (MART) for treatment of moderate to severe asthma in individuals as young as 4 years of age
- NYRx Preferred Drug List clinical criteria for budesonide/formoterol and mometasone/formoterol (i.e., MART drugs) allow for use in ages 4 years and older and quantities of up to 8 inhalers/180 days without prior authorization to allow for extra doses as reliever therapy beyond the maximum maintenance dose

Conclusions

- GINA guidelines also recommend the use of ICS/formoterol as the preferred anti-inflammatory reliever (AIR) option for all asthma severities to improve symptom control and reduce the risk of exacerbation associated with overuse of SABA
- In addition, GINA guidelines provide dosing guidance for using the same budesonide/formoterol inhaler device as either AIR-only or MART to facilitate stepping treatment up or down to achieve/maintain symptom control with the lowest dose needed
- The treatment goal is to optimize inhaled therapy and non-pharmacologic strategies to reduce the need for oral corticosteroids

Conclusions

- In cases of difficult-to-treat asthma GINA advises looking for factors contributing to symptoms, including overuse of SABA relievers, and optimizing management, including switching to MART and considering non-biologic add-on therapies
- Use of biologic therapies (i.e., systemic immunomodulators) is only recommended for patients with severe asthma and only after treatment has been optimized, at which point referral should be made for phenotype testing
- Add-on Type 2-targeted biologic therapy may be considered for patients with exacerbations or poor symptom control on a high-dose ICS/LABA who have evidence of Type 2 inflammation
- 8 of 9 comparator state Medicaid programs require prior authorization for all preferred and non-preferred asthma biologics, including clinical criteria consistent with FDA labeling (e.g., age, severity diagnosis, use as add-on to optimized maintenance therapy, drug-specific phenotype testing); some states require documentation of specific biomarkers

Conclusions

- Analysis of asthma drug utilization among the New York Medicaid population with a diagnosis of asthma (excluding members who also had a diagnosis of COPD) identified the following trends in State Fiscal Year 2026 which may possibly be addressed with updated clinical criteria:
  - Potential under-utilization of MART
    - A total of 22% of members who received asthma drugs had a diagnosis of moderate or severe asthma but only 4% of members who received asthma drugs received MART-only drugs
  - Potential overuse of SABA-only reliever therapies
    - Almost half (49%) of the members who received SABA-only inhalers received 3 or more inhalers and 3.5% received more than 12 inhalers (averaging >1 inhaler/month)
    - Approximately half of the members who received 3 or more claims for SABA nebulizer solutions were 12 years of age or older

Conclusions

- The members identified with potential overuse of SABA-only therapies may be at increased risk for asthma exacerbation and many of these members may be candidates for switching to budesonide/formoterol to use the same device as either AIR-only or MART to achieve better symptom control with the ability to step up or down as needed
- Potential off-label utilization of systemic immunomodulators
  - Only 56% of members with pharmacy claims for asthma biologics had a diagnosis of moderate or severe asthma; the remaining 44% had a diagnosis of mild asthma or unspecified severity
  - Only 66% of members received these systemic immunomodulators with other maintenance drugs; 15% of members received them without any other asthma drugs
  - 86% of members had 1 or more claims for laboratory procedures that would include phenotype biomarker testing; 14% did not

Xocova® (ensitrelvir) Review

Drug Utilization Review Board
November 6, 2026

NEW YORK STATE Department of Health Office of Health Insurance Programs
SUNY The State University of New York

Objectives

- Review the product, ensitrelvir (Xocova®), indicated for post-exposure prophylaxis of coronavirus disease 2019 (COVID-19).

- No utilization data are currently available.

Background

- COVID-19 is a respiratory illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that first appeared in 2019.
- The virus continues to evolve with new variants circulating, making it a public health concern.
- The following groups are at higher risk for serious illness: people ≥50 years of age, people with underlying health conditions (e.g., heart disease, lung disease, diabetes, obesity, or kidney disease), and immunocompromised individuals.
- To prevent or reduce severe illness, the following can be considered: receiving an annual COVID-19 vaccination, wearing a well-fitting mask or respirator, washing hands or using hand sanitizer containing ≥60% alcohol, avoiding crowded indoor spaces with poor ventilation, and avoiding people who are sick.

Centers for Disease Control and Prevention. COVID-19. CDC Yellow Book. Revised April 23, 2025. Available at COVID-19 | Yellow Book | CDC. Accessed July 2026.
Centers for Disease Control and Prevention. COVID. Revised June 13, 2024. Available at About COVID-19 | Covid | CDC. Accessed July 2026.

Drugs for the Treatment of COVID-19

- Paxlovid™ (nirmatrelvir tablets; ritonavir tablets), co-packaged for oral use, is the only product in the Anti-virals – COVID therapeutic category.
  - The product is preferred in the Anti-Virals – COVID therapeutic category with no clinical criteria.
  - Nirmatrelvir, a SARS-CoV-2 main protease (M^{pro}) inhibitor, and ritonavir, a human immunodeficiency virus type-1 protease inhibitor and cytochrome P450 3A (CYP3A) inhibitor, are indicated for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

- Remdesivir (Veklury®) is FDA-approved for the treatment of COVID-19.
  - Veklury® (remdesivir for infusion) is a practitioner-administered drug.

- Lagevrio® (molnupiravir capsules) is available under Emergency Use Authorization for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for severe illness and for whom other options are not accessible or appropriate.
  - The product is not available on the Medicaid List of Reimbursable Drugs.
  - The Emergency Use Authorization will be terminated June 29, 2027.

NYRx Preferred Drug Program. Available at NYPDP_PDL. Accessed August 2026.
Paxlovid™ [package insert]. New York, NY. Pfizer Labs. February 2026.
Lagevrio® [package insert].Rahway, NJ. Merck & Co., Inc.. June 2024.
HHS. Emgerency Use Authorization. Available at Emergency Use Authorization | FDA. Accessed September 2026.

Ensitrelvir (Xocova®)
Manufacturer: Shionogi Inc.

- Direct-acting antiviral approved by the FDA for ***post-exposure prophylaxis*** of COVID-19 in patients ≥ 12 years of age following contact with an individual who has COVID-19.
  - Ensitrelvir is the only Food and Drug Administration (FDA)-approved product for post-exposure prophylaxis of COVID-19.

- Inhibits the SARS-CoV-2 main protease (M^{pro} ; also referred to as 3 chymotrypsin-like protease [$3CL^{pro}$] or nonstructural protein 5 [nsp5] protease) inhibitor.

- Inhibiting M^{pro} disrupts viral replication.

- The wholesale acquisition cost for the complete 5-day regimen is $1400.

Xocova® [package insert]. Florham Park, NJ; Shionogi Inc., May 2026.

Ensitrelvir (Xocova®) Administration

- 5-day regimen:
  - 375 mg orally on Day 1 as three 125-mg tablets taken together, then
  - 125 mg orally once daily on Days 2–5, with or without food.

- Therapy should be started as soon as possible and within 72 hours of contact with an individual who is COVID-19 positive.

- Pregnancy status should be verified before starting therapy, as the drug may cause fetal harm.
  - For persons of childbearing potential, effective contraception during and for 2 weeks after the final dose should be used.

- Individuals should be advised not to breastfeed during use of ensitrelvir and for 2 weeks after the final dose.

- Drug interactions are a concern with ensitrelvir.
  - Ensitrelvir is contraindicated with drugs that are strong CYP3A inducers and with drugs primarily metabolized by CYP3A.

Xocova® [package insert]. Florham Park, NJ; Shionogi Inc., May 2026.

Drug Interactions: Co-Administration is Contraindicated

Drugs that Decrease Ensitrelvir Effectiveness

- Anticancer drugs: apalutamide, enzalutamide
- Anticonvulsants: carbamazepine, phenytoin
- Antimycobacterials: rifampin
- Cystic fibrosis drugs (cystic fibrosis transmembrane conductance regulator potentiators): lumacaftor/ivacaftor
- Herbal products: St. John's wort

Increases Toxicity of Coadministered Drug

- Antiarrhythmics: quinidine
- Antigout agents: colchicine
- Antipsychotics: lurasidone, pimozide
- Cardiovascular drugs: eplerenone, ivabradine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- Statins: simvastatin (discontinue use at least 12 hours prior to initiating Xocova®)
- Immunosuppressants: voclosporin
- Microsomal triglyceride transfer protein: lomitapide
- Mineralocorticoid receptor antagonists: finerenone
- Sedatives: triazolam

Xocova® [package insert]. Florham Park, NJ; Shionogi Inc., May 2026.

SCORPIO-PEP (NCT05897541)

- Phase 3, multicenter, double-blind, randomized, placebo-controlled trial conducted in participants who were SARS-CoV-2 - negative but had household contact with a person (index patient) with COVID-19.

- The primary endpoint was laboratory-confirmed COVID-19 within 10 days after administration of ensitrelvir or placebo.

- The results demonstrated a lower incidence of COVID-19 in the ensitrelvir group (2.9% [30/1030]) than in the placebo group (9.0% [91/1011]).
  - The risk ratio was 0.33 (95% confidence interval, 0.22 to 0.49; $p<0.001$), indicating a 67% relative risk reduction favoring ensitrelvir treatment.

- The most common adverse events (occurring in ≥1% of participants) were headache, diarrhea, nasopharyngitis, cough, fatigue, and influenza.

NEJM (2026); 394(19):1005-1915. doi:10.1056/NEJMoa2509306.

Conclusions

- FDA approved for post-exposure prophylaxis of COVID-19 in patients ≥ 12 years of age following contact with an individual who has tested positive for COVID-19.

- Must be started as soon as possible and within 72 hours of contact with an individual with COVID-19.

- Pregnancy status must be verified.
  - Effective contraception must be used during treatment and for 2 weeks after the final dose.
  - Should not be used while breastfeeding and for 2 weeks after the final dose.

- Drug interactions are of concern.
  - Ensitrelvir is contraindicated with drugs that are strong CYP3A inducers and with drugs primarily metabolized by CYP3A.

Xocova® [package insert]. Florham Park, NJ; Shionogi Inc., May 2026.

NEW YORK STATE | Department of Health | Office of Health Insurance Programs
SUNY The State University of New York

Evaluation of Zelsuvmi® (berdazimer 10.3% topical gel) and Ycanth® (cantharidin 0.7% topical solution) for the Treatment of Molluscum Contagiosum

Drug Utilization Review Board

November 6, 2026

NEW YORK STATE | Department of Health | Office of Health Insurance Programs
SUNY The State University of New York

Objectives

1. Review the use berdazimer 10.3% topical gel (Zelsuvmi®) and cantharidin 0.7% topical solution (Ycanth®) for the treatment of molluscum contagiosum.

2. Evaluate the utilization of berdazimer 10.3% topical gel (Zelsuvmi®) and cantharidin 0.7% topical solution (Ycanth®) in the NYRx Pharmacy Program.

Background

- Molluscum contagiosum is a contagious viral infection caused by a deoxyribonucleic acid poxvirus that primarily affects pediatric patients between 1 and 10 years of age, sexually active young adults, and immunocompromised people of all ages.

- The condition is self-limited and usually resolves spontaneously without treatment within 6 to 12 months in most immunocompetent patients.

- Accounts for about 1% of all skin diagnoses worldwide, and its prevalence in the general population in the United States is approximately 5%.

Current Infectious Disease Reports (2025). 27(8);1-17. doi10.1007/s11908-024-00853-9.
Journal of Clinical and Aesthetic Dermatology (2023). 16(8 Supplemental 1): S4-S11.
Centers for Disease Control and Prevention. About molluscum contagiosum. Revised November 20, 2025. Available at About Molluscum Contagiosum | Molluscum Contagiosum | CDC. Accessed June 2026.

Background

- Transmission occurs by direct contact with infected skin or contaminated items.
- The virus enters the body through a break in the skin, and the incubation period ranges from 2 to 6 weeks.
- Molluscum contagiosum lesions appear as small (<5 mm), pink or skin-colored, dome-shaped papules with a pit in the center on the face, torso, and/or extremities, and may occur as a single lesion or in clusters.
- To avoid spreading the infection on the patient's body or to others, the lesions should be covered with clothing or a bandage. Covering the lesions may also prevent bacterial infection.
- Children with molluscum contagiosum do not have to stay home from school or daycare. If the lesions are not open, the patient can continue to swim.

Current Infectious Disease Reports (2025). 27(8);1-17. doi10.1007/s11908-024-00853-9.
Journal of Clinical and Aesthetic Dermatology (2023). 16(8 Supplemental 1): S4-S11.
Centers for Disease Control and Prevention. About molluscum contagiosum. Revised November 20, 2025. Available at About Molluscum Contagiosum | Molluscum Contagiosum | CDC. Accessed June 2026.

Background

- Patients may seek treatment for cosmetic reasons and to reduce the risk of spreading the disease.

- Treatment may be considered for patients with:
  - A chronic skin condition (e.g., atopic dermatitis),
  - Immunocompromise,
  - Numerous lesions, or
  - The condition is bothersome (e.g., itchy).

- Treatment to remove lesions, if needed, includes:
  - Physical removal (e.g., curettage, cryosurgery, laser therapy, or electrocautery),
  - Berdazimer 10.3% topical gel (Zelsuvmi®)
  - Cantharidin 0.7% topical solution, or
  - Other agents not Food and Drug Administration approved (e.g., podophyllotoxin, tretinoin, tazarotene, and cimetidine).

Current Infectious Disease Reports (2025). 27(8);1-17. doi10.1007/s11908-024-00853-9.
Journal of Clinical and Aesthetic Dermatology (2023). 16(8 Supplemental 1): S4-S11.
Centers for Disease Control and Prevention. About molluscum contagiosum. Revised November 20, 2025. Available at About Molluscum Contagiosum | Molluscum Contagiosum | CDC. Accessed June 2026.

Berdazimer 10.3% Topical Gel (Zelsuvmi®)

- Food and Drug Administration approved in January 2024.
- Can be applied by the patient or a caregiver.
- Berdazimer is a nitric oxide-releasing agent.
  - Nitric oxide has activity against molluscum contagiosum.
- Before administration, the patient or caregiver must mix 0.5 mL from Tube A (containing berdazimer gel) and Tube B (containing hydrogel) using the dosing guide.
- The gel is administered once daily for up to 12 weeks.
- Wholesale acquisition cost is $61.88/ g ($1,918/ 31 g package).

Zelsuvmi®uvmi™ [package insert]. Durham, NC: LNHC, Inc.; January 2024.

Berdazimer 10.3% Gel (Zelsuvmi®) Clinical Trials

- Three identically designed phase 3 randomized, double-blind, vehicle-controlled, 12-week clinical trials were completed.

- Primary endpoint was percentage of participants who achieved complete clearance of all treatable molluscum contagiosum lesions at Week 12.

    - B-SIMPLE1 (n=352) and B-SIMPLE2 (n=355) did not achieve statistical significance for the primary endpoint of complete lesion clearance.

    - B-SIMPLE4 (n=891) did achieve statistical significance for the primary endpoint of complete lesion clearance.
        - 32.4% (n=144) of patients in the berdazimer gel group and 19.7% (n=88) of patients in the vehicle-controlled group achieved complete clearance of molluscum contagiosum lesions.
        - The absolute difference between the groups was 12.7% (95% confidence interval 7.1%, 18.6%) and the odds ratio was 2.0 (95% confidence interval 1.5-2.8; p<0.001).

JAMA Dermatology (2022). 158(8):871-873. doi:10.1001/jamadermatol.2022.2721.

Cantharidin 0.7% Topical Solution (Ycanth®)

- Food and Drug Administration approved in July 2023.
- Cantharidin 0.7% topical solution (Ycanth®) is a vesicant, which can cause blistering.
- The mechanism of action for the treatment of molluscum contagiosum is unknown.
- Applied by a practitioner trained to apply the product safely.
- The product is applied as a single application directly to each lesion every 3 weeks as needed, and no more than 2 applicators can be used during a treatment session.
  - Can be used for up to 12 weeks.
- The product is supplied as a drug-device combination consisting of a sealed glass ampule inside a single-use applicator with a tool to break the ampule.
- The product is highly toxic and is a flammable liquid, even after drying.
- Wholesale acquisition cost is $719/ unit (3.2 mg single-use applicator)

Ycanth® [package insert]. West Chester, PA: Verrica Pharmaceuticals; October 2024.

Cantharidin 0.7% Topical Solution (Ycanth®) Clinical Trials

- Evaluated in 2 identically designed phase 3, randomized, double-blind, vehicle-controlled clinical trials, CAMP-1 and CAMP-2, for the treatment of molluscum contagiosum.

- Participants were randomized 3:2 (n=528) to topical application of cantharidin (n= 310) or vehicle (n=218) to all treatable lesions every 21 days until complete lesion clearance or up to 4 treatments.

- The primary endpoint was the proportion of cantharidin–treated participants achieving complete clearance of all molluscum contagiosum lesions by day 84 (end of the study). The results of the studies were:
  - CAMP-1: 46.3% for cantharidin versus 17.9% for the vehicle-controlled group ($p<0.001$)
  - CAMP-2: 54.0% for cantharidin versus 13.4% for the vehicle-controlled group ($p< 0.001$)

NYRx Coverage

- Berdazimer 10.3% gel (Zelsuvmi®) is on the Medicaid Pharmacy List of Reimbursable Drugs.
  - The product is not subject to the Preferred Drug Program.
  - Based on the Food and Drug Administration-approved product information, the current NYRx quantity and duration limits are 31 gm/ 30 days with a total of 3 claims/ 365 days.

- Cantharidin 0.7% topical solution (Ycanth®) is a practitioner-administered drug and is not on the Medicaid Pharmacy List of Reimbursement Drugs.
  - The product is not subject to the Preferred Drug Program.

eMedNY. Medicaid Pharmacy List of Reimbursable Drugs. Available at Information - Formulary File. Accessed July 2026.
eMedNY. Practitioner administered drug (PAD) search tool. Available at Physician Administered Drug (PAD) List. Accessed July 2026.

Comparator State Medicaid Program Coverage

- Comparator state Medicaid programs: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, and Washington

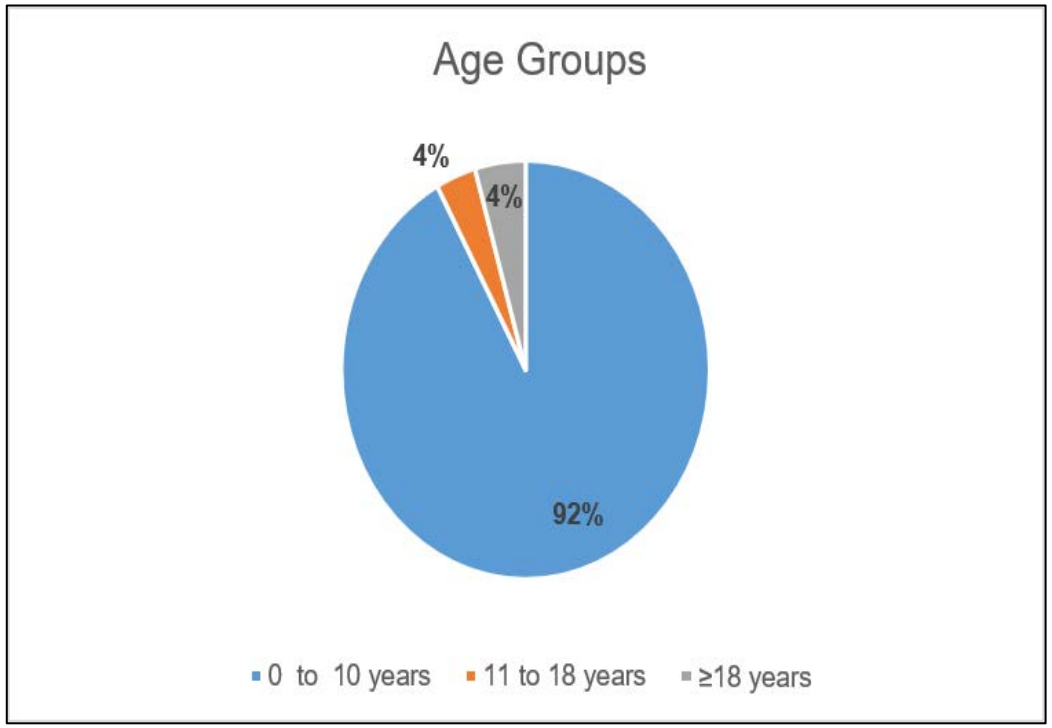
- 5/9 state Medicaid programs included Zelsuvmi® (berdazimer 10.3% topical gel) on their Preferred Drug List as non-preferred.

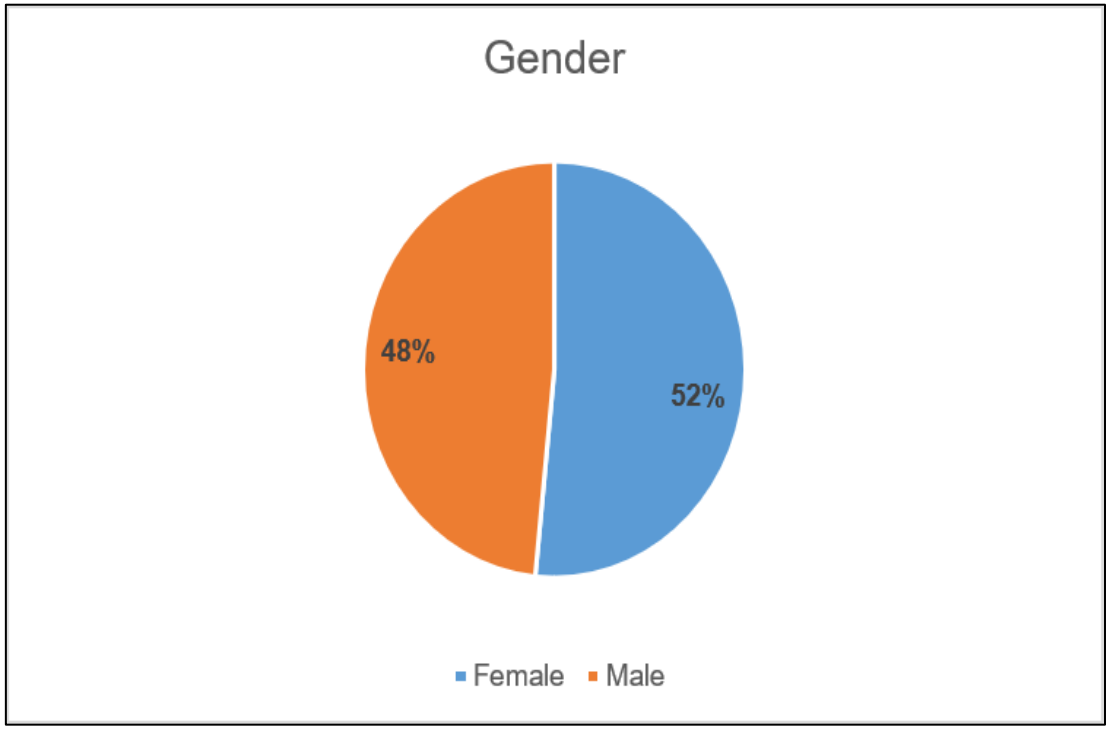
- 5/9 state Medicaid programs required prior authorization for Ycanth® (cantharidin 0.7% topical solution).

Methodology

- The Medicaid Confidential Data Cell Size Policy (OHIP-0001) requires that no cell containing a value of 1 to 30 be reported.
- A retrospective analysis of claims for both agents was conducted.
- The data source was the Medicaid Data Warehouse (MDW).
- Limitations:
  - While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete.
  - Due to the small sample size, reporting the raw numbers or the percentages of patients would violate the Medicaid Confidential Data Cell Size Policy.
  - An evaluation of physical removal (e.g., cryosurgery, curettage, and pulsed dye laser) of molluscum contagiosum lesions was not conducted.

Results:
Demographics of Members Utilizing Cantharidin 0.7% Topical Solution or Berdazimer 10.3% Gel (n=1192)





Timeframe: State Fiscal Year 2024 through State Fiscal Year 2026

Data source= Medicaid Data Warehouse Extract date= June 2026

Berdazimer 10.3% Topical Gel (Zelsuvmi®) Utilization

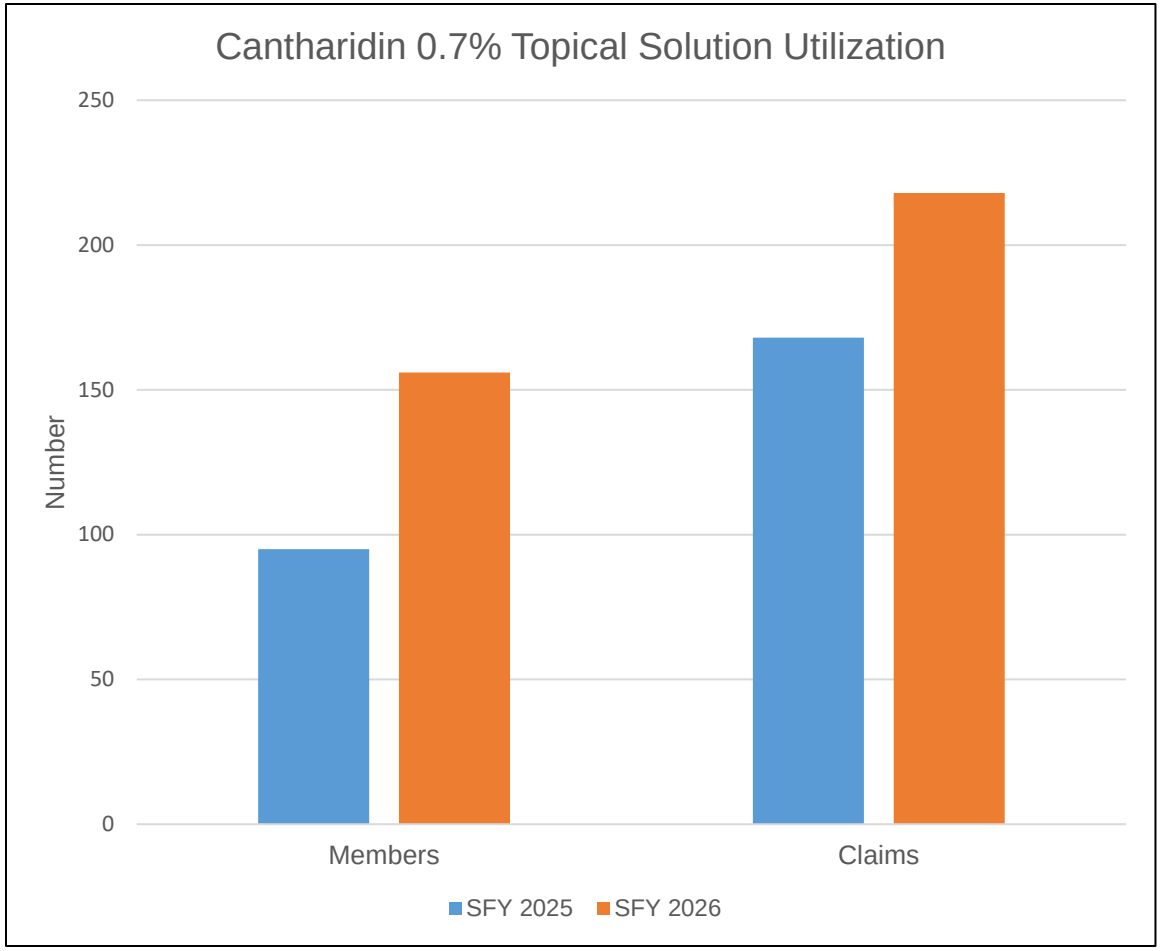
- Time Frame: State Fiscal Year 2026 (April 1, 2025 through March 31, 2026)
  - Food and Drug Administration approved in January 2024.

- 958 members utilized berdazimer 10.3% topical gel, resulting in 1,164 claims at an estimated cost of $2.2 million (not net/net of rebates).

Data source= Medicaid Data Warehouse Extract date= June 2026

Cantharidin 0.7% Topical Solution (Ycanth®) Utilization

- For State Fiscal Year 2024 through State Fiscal Year 2026:
  - A total of 246 members utilized cantharidin 0.7% topical solution,
  - Resulting in 392 claims at an estimated cost of $229,000 (not net/ net of rebates).
  - Note: ≤30 members received cantharidin 0.7% topical solution in State Fiscal Year 2024 and so cannot be reported.



Data source= Medicaid Data Warehouse Extract date= June 2026

Summary

- Molluscum contagiosum is a viral infection that is self-limited and usually disappears spontaneously within 6 to 12 months in most immunocompetent patients.

- Treatment to remove lesions, if needed, includes:
  - Physical removal (e.g., curettage, cryosurgery, laser therapy, or electrocautery),
  - Berdazimer 10.3% topical gel (Zelsuvmi®)
  - Cantharidin 0.7% topical solution (Ycanth®), or
  - Other agents not Food and Drug Administration-approved (e.g., podophyllotoxin, tretinoin, tazarotene, and cimetidine).

- Berdazimer 10.3% topical gel (Zelsuvmi®) can be applied by a caregiver or the patient.

- Cantharidin 0.7% topical solution (Ycanth®) is applied by a practitioner in an office setting.

NEW YORK STATE | Department of Health

Current NYRx Preferred Drug List for the Drug Classes on the Agenda

NYS MEDICAID DRUG UTILIZATION REVIEW BOARD

November 6, 2026

CLINICAL CRITERIA FOR NON-PREFERRED PRODUCTS

Non-Preferred Products remain available through the prior authorization process.

1. The preferred drug has been tried by the patient and has failed to produce the desired health outcome.

   Q: Has your patient experienced treatment failure with a preferred product?

2. The patient has tried the preferred drug and has experienced unacceptable adverse effects.

   Q: Has your patient experienced an adverse drug reaction with a preferred product?

3. The patient has been stabilized on a non-preferred drug and transition to the preferred drug would be medically contraindicated

   Q: Is there a documented history of successful therapeutic control with a non-preferred product and transition to a preferred product is medically contraindicated?

4. Other clinical indications for use of a non-preferred drug, which shall include consideration of the medical needs of special populations.

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IV. Central Nervous System		
Anticonvulsants – Other		
clobazam tablet ST, CC gabapentin capsule, solution, tablet F/Q/D, CC lacosamide tablet, solution lamotrigine tablet, chew levetiracetam levetiracetam ER Lyrica® capsule DO, F/Q/D, CC pregabalin capsule F/Q/D, CC tiagabine topiramate CC zonisamide	Banzel® brivaracetam (gen Briviact®) Briviact® clobazam suspension ST Diacomit® CC Elepsia® XR Epidiolex® CC Eprontia™ CC, F/Q/D felbamate Felbatol® Fintepla® Fycompa® DO gabapentin 100 mg, 400 mg tablet, 200 mg capsule F/Q/D, CC, MR Keppra® Keppra XR® Lamictal® tablet, chew, dosepak Lamictal® ODT tablet, dosepak Lamictal® XR tablet DO, dosepak lamotrigine dosepak lamotrigine ER lamotrigine ODT dosepak levetiracetam (gen Spritam®) Lyrica® solution F/Q/D, CC Lyrica® CR F/Q/D, CC Motpoly XR Neurontin® F/Q/D, CC Onfi® ST, CC perampanel (gen Fycompa®)	**DOSE OPTIMIZATION (DO)** • See Dose Optimization Chart for affected drugs and strengths **CLINICAL CRITERIA (CC)** • Clinical editing will allow patients currently stabilized on a non-preferred agent to continue to receive that agent without PA • Cannabidiol extract (Epidiolex®) – Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication, or; Institutional Review Board (IRB) approval with signed consent form • Lyrica®/Lyrica® CR (pregabalin/pregabalin ER) – PA required for the initiation of pregabalin at > 150 mg per day in patients currently on an opioid at > 50 MME per day • Neurontin® (gabapentin) – PA required for initiation of gabapentin at > 900 mg per day in patients currently on an opioid at > 50 MME per day • Stiripentol (Diacomit®) – Require diagnosis of FDA-approved or compendia-supported indication, or; Institutional Review Board (IRB) approval with signed consent form • Topiramate IR/ER (Eprontia™, Qudexy® XR, Topamax®, Trokendi XR™) – Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication • Onfi®/Sympazan® (clobazam): – Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication – PA required for initiation of clobazam therapy in patients currently on opioid or oral buprenorphine therapy – PA required for any clobazam prescription in patients currently on benzodiazepine therapy

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IV. Central Nervous System		
	pregabalin solution F/Q/D, CC pregabalin ER (gen Lyrica® CR) F/Q/D, CC Qudexy® XR CC, DO relgaabi MR rufinamide (gen Banzel®) Sabril® Spritam® Subvenite® suspension Sympazan® film ST, CC Topamax® CC topiramate 50mg Sprinkle CC topiramate ER (gen Qudexy® XR) CC, DO topiramate ER (gen Trokendi XR®) CC, DO topiramate solution (gen Eprontia™) CC, F/Q/D Trokendi XR® CC, DO vigabatrin Vigafyde™ CC Vimpat® Xcopri® Zonisade™ Ztalmy®	• Vigafyde™ (vigabatrin): – Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Eprontia™ (topiramate) – Maximum quantity: 473 mL per month • Lyrica®/Lyrica® CR (pregabalin/pregabalin ER) – Maximum daily dose of IR: 600 mg per day, and ER: 660 mg per day • Neurontin® (gabapentin) – Maximum daily dose of 3,600 mg per day **STEP THERAPY (ST)** • Onfi®/Sympazan® (clobazam) – Requires a trial with an SSRI or SNRI for treatment of anxiety

New York State Medicaid Drug Utilization Review Board Meeting – November 06, 2026
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IV. Central Nervous System		
Antipsychotics – Injectable		
Abilify Asimtufii® Abilify Maintena® Aristada® Aristada Initio® fluphenazine decanoate haloperidol decanoate Invega Hafyera™ Invega Sustenna® Invega Trinza® Perseris™ Risperdal Consta® BLTG Uzedy™ Zyprexa Relprevv®	Erzofri® risperidone injection (gen Risperdal Consta®) Rykindo®	

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IV. Central Nervous System		
Multiple Sclerosis Agents		
Avonex® Copaxone® 20 mg/mL BLTG dimethyl fumarate DR fingolimod (gen Gilenya®) Kesimpta® teriflunomide (gen Aubagio®)	Aubagio® Bafiertam™ Betaseron® cladribine (gen Mavenclad®) Copaxone® 40 mg/mL Gilenya® glatiramer Mavenclad® Mayzent® Plegridy® Ponvory™ F/Q/D Rebif® Rebif® Rebidose® Tascenso ODT™ Tecfidera® Vumerity® Zeposia® CC, ST	**CLINICAL CRITERIA (CC)** • Zeposia® (ozanimod): Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication **STEP THERAPY (ST)** • Zeposia® (ozanimod): For an indication of Ulcerative Colitis – Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a non-biologic disease-modifying anti-rheumatic drug (DMARD), and; – Trial of a preferred systemic immunomodulator **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Ponvory™ (ponesimod) starter pack; maximum quantity is 14, no refills • Ponvory™ (ponesimod**)**; maintenance limited to a 30-day supply

New York State Medicaid Drug Utilization Review Board Meeting – November 06, 2026
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
XII. Ophthalmics		
Antibiotics – Ophthalmic		
bacitracin/polymyxin B erythromycin gentamicin Natacyn® neomycin/gramicidin/polymyxin polymyxin/trimethoprim sulfacetamide solution tobramycin	Azasite® bacitracin neomycin/bacitracin/polymyxin sulfacetamide ointment Tobrex®	

Agents for the Treatment of Scabies

November 6, 2026
Drug Utilization Review Board Meeting

NEW YORK STATE | Department of Health | Office of Health Insurance Programs
SUNY The State University of New York

Purpose

- The aim of this review is to examine utilization of agents for the treatment of scabies in the New York State Medicaid population.

- Recommendations will be provided based on a review of the literature and results from utilization data analyses.

Scabies Infestation and Symptoms

- Classic scabies is a parasitic skin infection caused by the *Sarcoptes scabiei.*
- The mite burrows into the top layer of skin where the adult female will lay eggs. Eggs will hatch in 3-4 days, maturing into adult mites in 1-2 weeks.
- Mites are transferred between humans through direct skin-to-skin contact.
- Diagnosis is based on clinical symptoms and identifying burrows, mites, eggs, or the mites' feces from affected areas.
- Crusted (Norwegian) scabies is a more severe, aggressive infestation.
- At least 200 million people worldwide are estimated to be affected by scabies, with greater frequency observed in hot tropical countries or areas of high population density.

DiPiro's Pharmacotherapy: A Pathophysiologic Approach, 13th Edition. McGraw Hill; 2026.
JAMA. 2024;332(14):1189-1199. doi:10.1001/jama.2024.13896
Dtsch Arztebl Int. Oct 15 2021;118(41):695-704. doi:10.3238/arztebl.m2021.0296
MMWR Recomm Rep. Jul 23 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
StatPearls. StatPearls Publishing LLC.; 2026

Centers for Disease Control and Prevention Recommended Treatments

- First-line therapy:
  - Topical permethrin 5% cream or
  - Ivermectin oral tablets
    - Note: Oral ivermectin tablets are not a Food and Drug Administration (FDA)-approved treatment for classic scabies but are compendia supported for treatment of scabies.

- Second-line therapy:
  - Crotamiton 10% lotion or cream (Crotan, Pruradik, Eurax)
  - Spinosad 0.9% topical suspension (Natroba)
  - Sulfur 5% to 10% ointment
    - Sulfur ointment must be compounded
  - Malathion 0.5% lotion
    - Malathion is not FDA approved for the treatment of scabies but there is compendia support.

MMWR Recomm Rep. Jul 23 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1

Clinical Care of Scabies. Updated December 18, 2023. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-care/index.html

Crusted (Norwegian) Scabies

- More severe, aggressive infestation with a higher mite burden.
  - *Sarcoptes scabiei* causes this condition, which is the same causative ectoparasite as classic scabies.

- Occurs predominantly in immunocompromised, debilitated, or malnourished persons.

- Because of the high mite burden, transmission is more efficient, and treatment often involves multiple agents and multiple doses

MMWR Recomm Rep. Jul 23 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
Clinical Overview of Crusted Scabies. U.S. Centers for Disease Control and Prevention. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-overview/index.html
Clinical Care of Scabies. Updated December 18, 2023. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-care/index.html

First-line Therapy: Permethrin 5% Cream

- Can be used in members ≥2 months of age.
- Applied to all areas of the body from the neck down and washed off after 8-14 hours.
- A typical single application is approximately 30 g.
- A single application may be effective, but ≥2 applications a week apart may be needed to fully eliminate all mites.
- The product is available as a multi-source generic product, and the estimated maximum reimbursable amount is $0.22/ g ($26.40/ 120 g and $39.60/ 180 g).
- In eMedNY the quantity limit varies based on the national drug code from 120 g to 180 g with a maximum duration of 1 refill.

MMWR Recomm Rep. Jul 23 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
Clinical Care of Scabies. Updated December 18, 2023. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-care/index.html
Elmite. Permethrin Cream 5%: Aurobindo Pharma USA, INC.; 2024.
List of Medicaid Reimbursable Drugs, New York State Department of Health, Accessed October 1, 2026 https://www.emedny.org/info/formfile.aspx

First-Line Therapy: Ivermectin Oral Tablets

- Safety has not been established in pregnant persons or in children weighing <15 kg.

- Two doses of ivermectin 200 µg/kg 7 to 14 days apart are recommended to ensure eradication of the mites.

- The product is available as a multi-source generic product, and the estimated maximum reimbursable amount for the 3 mg tablet is $2.06 and for the 6 mg tablet is $9.70.
  - A single-source brand, Stromectol® 3 mg tablet, is available.

- Current NYRx Drug Utilization Review clinical criteria are confirmation of an FDA-approved diagnosis or a compendia-supported indication that is a Medicaid-covered indication.

MMWR Recomm Rep. Jul 23 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
Clinical Care of Scabies. Updated December 18, 2023. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-care/index.html
Stromectol. Ivermectin Tablets (Package Insert): Advagen Pharma Ltd; 2023.
List of Medicaid Reimbursable Drugs, New York State Department of Health, Accessed October 1, 2026 https://www.emedny.org/info/formfile.aspx

Second-Line Therapy: Crotamiton 10% Lotion and Cream

- FDA approved for use in adults.
- Applied over the whole body, including under the nail beds.
  - A second application is recommended 24 hours later.
  - Remove the product 48 hours after the last application.
- Multi-source products available are Crotan, Pruradik, and Eurax.
- Estimated maximum reimbursable amount is $3.24 g ($767/ 237 g).
- The current quantity limits are:
  - 237 g with a duration of 1 refill for the 237 g bottle and
  - 120 g with a duration of 1 refill for the 30 g bottle.

Clinical Care of Scabies. Updated December 18, 2023. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-care/index.html
Eurax. Crotamiton 10% cream (Package Insert): Journeu Medical Corporation; July 2021.
Crotan. Crotamiton 10% lotion (Package Insert): Marnel Pharmaceuticals; July 2021.
Pruradik. Crotamiton 10% lotion (Package Insert): Trifluent Pharma; June 2025.
List of Medicaid Reimbursable Drugs, New York State Department of Health, Accessed October 1, 2026 https://www.emedny.org/info/formfile.aspx

Second-Line Therapy: Spinosad 0.9% Topical Suspension

- FDA approved for treatment of scabies infestations in patients ≥4 years of age and for the treatment of head lice in patients ≥6 months of age.
- Applied over the whole body, allowed to dry for 10 minutes before dressing, and should remain on the skin for a minimum of 6 hours before bathing.
- Available as a multiple-source product and as Natroba, a single-source product.
- Estimated maximum reimbursable amount of $1.96/ mL ($235/ 120 mL).
- Current quantity limit is 120 mL with a maximum number of refills of 1.

Clinical Care of Scabies. Updated December 18, 2023. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-care/index.html
Natroba. Spinosad Suspension (Package Insert): Cipher Pharmaceuticals Inc.; 2011.
List of Medicaid Reimbursable Drugs, New York State Department of Health, Accessed October 1, 2026 https://www.emedny.org/info/formfile.aspx

Other Second-Line Therapies

- **Sulfur 5%-10% ointment** must be ***compounded***.
  - Sulfur in an ointment base (petrolatum) is safe for topical use in children, including infants under 2 months of age.

- **Malathion 0.5% lotion** is not FDA approved for the treatment of scabies but has compendia support.
  - The product is FDA approved for the treatment of *Pediculus humanus capitis* (head lice and their ova).
  - Malathion is no longer recommended in other countries due to toxicity.

Clinical Care of Scabies. Updated December 18, 2023. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-care/index.html
Ovide. Malathion (Package Insert): Merative; 2026.
Thadanipon K, Anothaisintawee T, Rattanasiri S, Thakkinstian A, Attia J. Efficacy and safety of antiscabietic agents: A systematic review and network meta-analysis of randomized controlled trials. Journal of the American Academy of Dermatology. 2019/05/01/ 2019;80(5):1435-1444

Comparator State Coverage

- Coverage of scabicidal agents in comparator state Medicaid programs was reviewed. Programs included were those of California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, and Washington (9 states in total).

- 8/9 Comparator State Medicaid Programs have the products on their Preferred Drug Program and/or have established clinical criteria.

Utilization Methodology

- Retrospective analysis of:
  - First-line therapies: permethrin 5% cream and ivermectin oral tablets
  - Second-line therapies: crotamiton 10% lotion and spinosad 0.9% topical suspension
  - Note: The utilization of malathion 0.5% lotion was not included as ≤30 members who utilized the product had a diagnosis of scabies.

- Data source was Medicaid Data Warehouse.

- Timeframes:
  - April 1, 2024 through March 31, 2025 (State Fiscal Year 2025)
  - April 1, 2025 through March 31, 2026 (State Fiscal Year 2026)

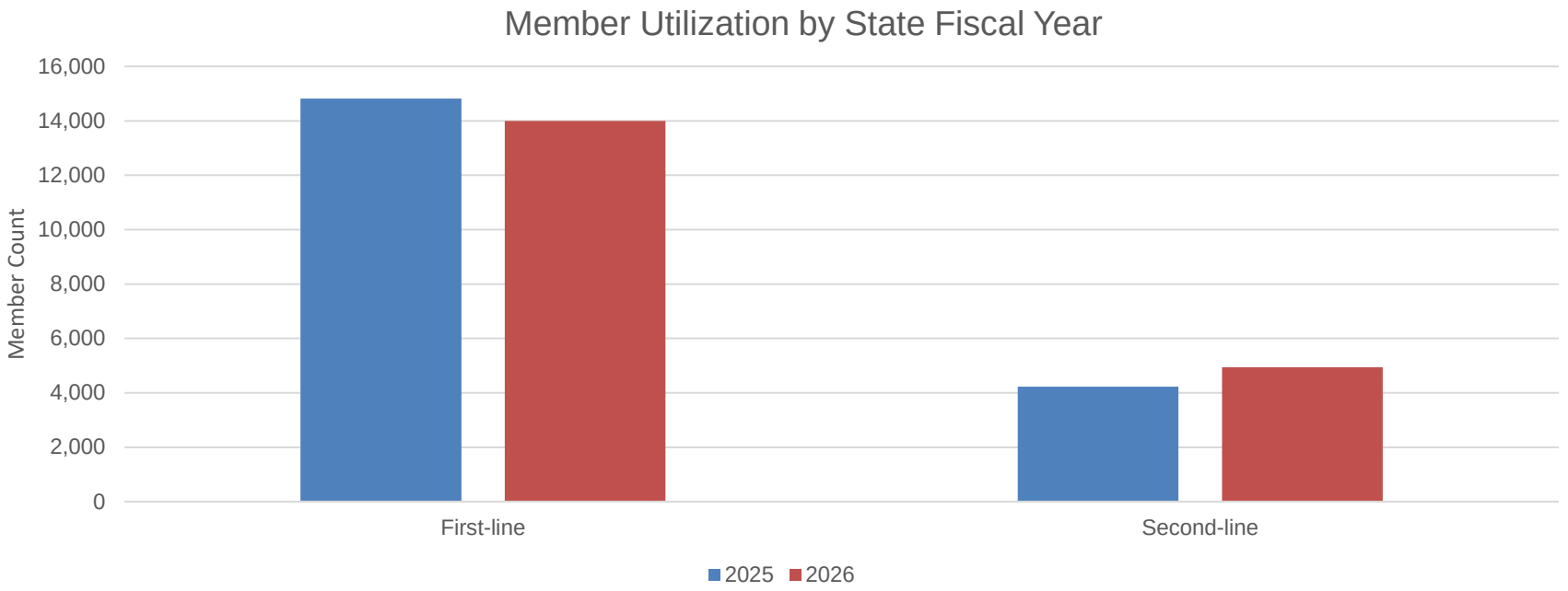
Utilization Methodology (*continued*)

- Medicaid Confidential Data Cell Size Policy (OHIP-0001) requires that no cell containing a value of 1 to 30 be reported.

- Dual-eligible members were excluded.

Members Receiving Treatment by State Fiscal Year

Members utilizing a first-line therapy declined by 5.6% while members utilizing a second-line therapy increased by 16.9% from State Fiscal Year 2025 to 2026.



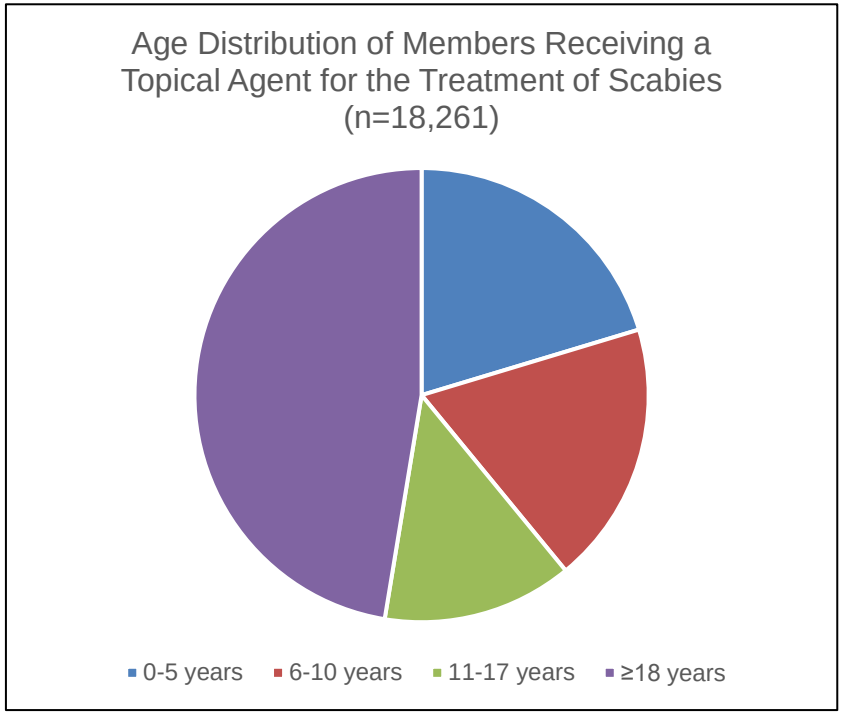
First-line agents: Oral ivermectin and topical permethrin
Second-line agents: Topical crotamiton and spinosad

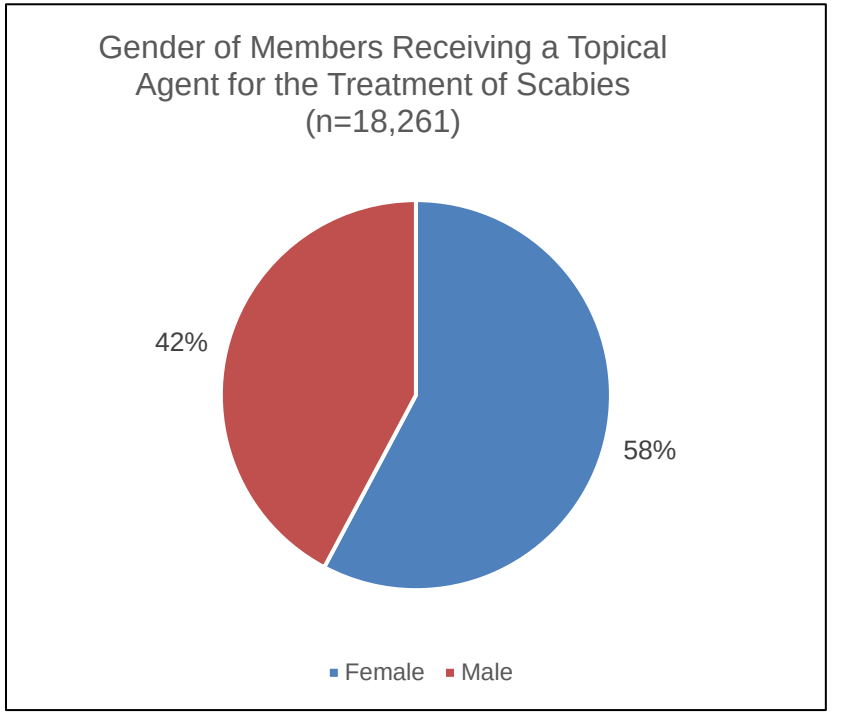
Data source: Medicaid Data Warehouse Extract date: June 2026

NEW YORK STATE Department of Health | Office of Health Insurance Programs

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Demographics of Members Utilizing a Topical Agent for State Fiscal Year 2026

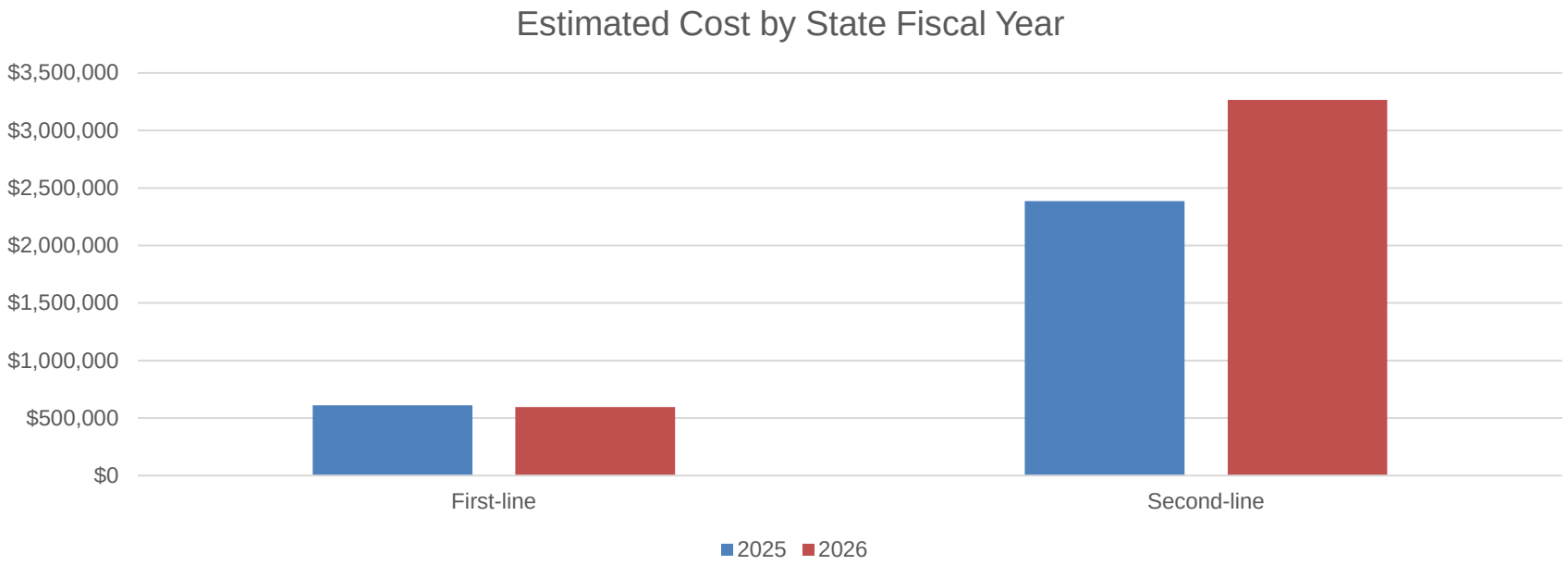




Data source: Medicaid Data Warehouse Extract date: June 2026

Estimated Cost by State Fiscal Year

- The estimated total cost increased 28.9% from State Fiscal Year 2025 to 2026. The estimated total cost increased by:
  - 2.6% for first-line therapies and
  - 36.8% for second-line therapies.



First-line agents: Oral ivermectin and topical permethrin
Second-line agents: Topical crotamiton and spinosad

Data source: Medicaid Data Warehouse
Extract date: June 2026

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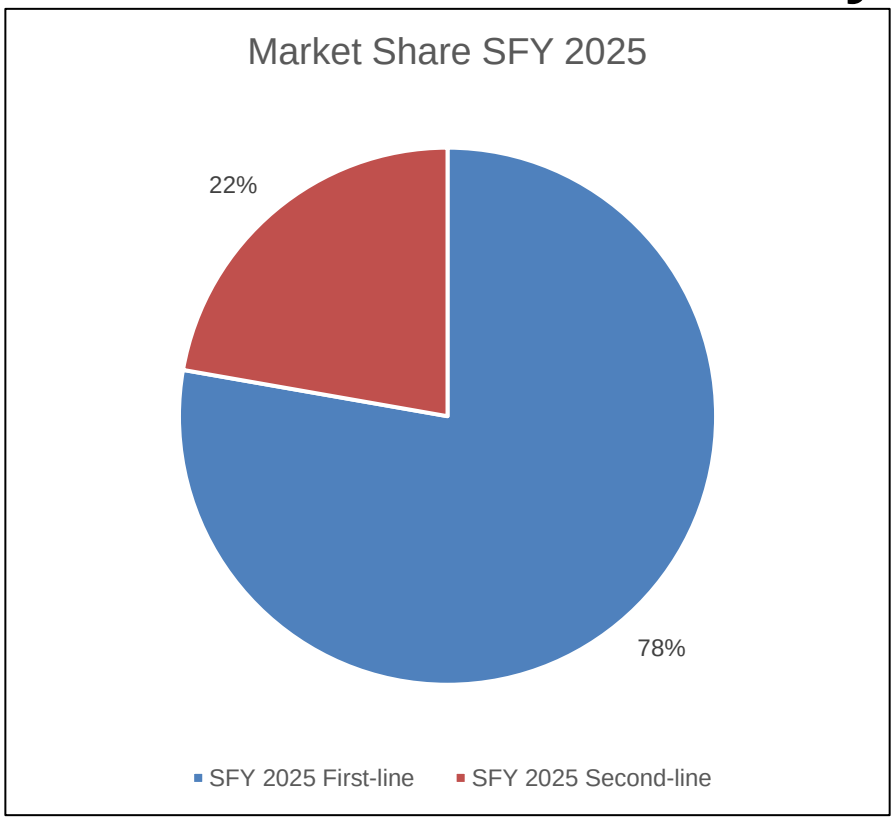
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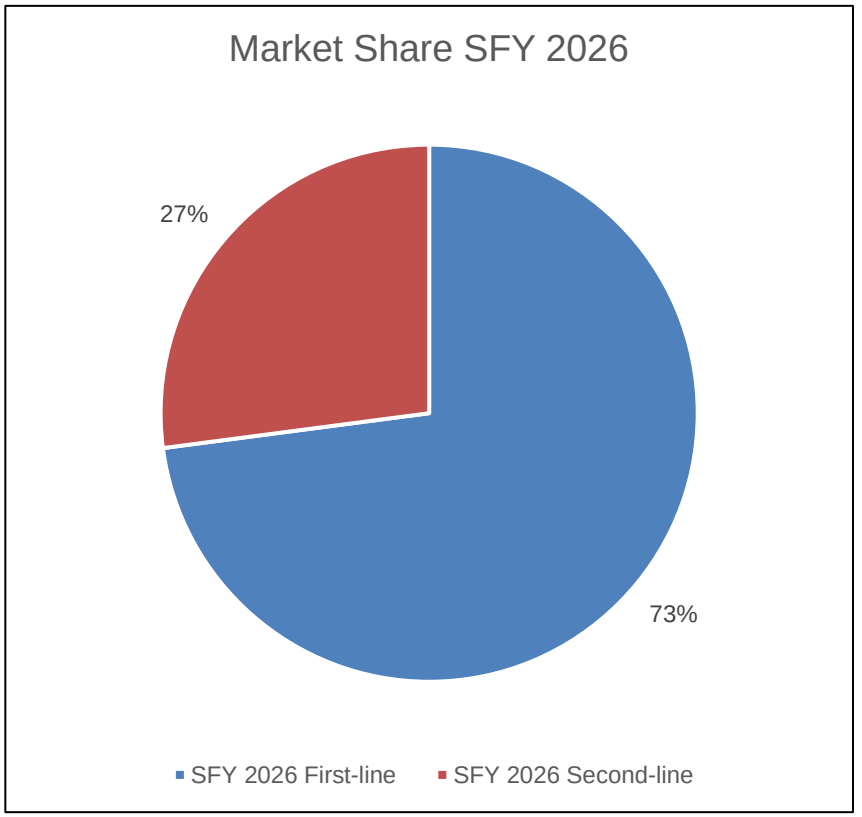
Total Quantity Used by Agent for State Fiscal Year 2026

Drug	Total Number of Members	Units and Availability	Total Quantity Dispensed for State Fiscal Year 2026	Percentage of Members
Crotamiton 10% Cream or Lotion	759	Units=Gram (g); eMedNY quantity limit is 237 g	≤237	27%
			238 to 454	13%
			455 to 908	33%
			909 to 1362	12%
			1363 to 4977	16%
Permethrin 5% Cream	13,805	Units=Gram (g); eMedNY quantity limit is 120 g to 180 g	≤120	84%
			121 to 454	15%
			455 to 3180	2%
Spinosad 0.9% Suspension	4,217	Units=Milliliter (mL); eMedNY quantity limit is 120 mL	≤120	73%
			121 to 240	20%
			241 to 360	5%
			361 to 1320	2%

Data source: Medicaid Data Warehouse
Extract date: June 2026

Market Share by State Fiscal Year





First-line agents: Oral ivermectin and topical permethrin
Second-line agents: Topical crotamiton and spinosad

The overall claims volume increased by approximately 2% from State Fiscal Year 2025 to 2026.

Data source: Medicaid Data Warehouse Extract date: June 2026

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Use of First-Line Therapies Prior to Second-Line Therapies in State Fiscal Year 2026 (n=4,941)

Variable	Percentage of Members (%)
New claim for topical crotamiton 10% lotion or spinosad 0.9% suspension*	96.5%
First-line agents, permethrin 5% cream and/or oral ivermectin tablets, used within 365-days prior to the initial claim of crotamiton 10% lotion or spinosad 0.9% suspension	9.7%
Crotamiton 10% lotion or spinosad 0.9% suspension used as first-line therapy€	86.8%

* A new claim is defined as having no prior utilization of either crotamiton or Spinosad within 90 days of the initial claim.
€First-line therapy is defined as having no claim history for permethrin 5% cream or oral ivermectin tablets in the 365 days prior.

Data source: Medicaid Data Warehouse Extract date: June 2026

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Conclusions

- Classic scabies is a parasitic skin infection caused by the *Sarcoptes scabiei.* Scabies is highly contagious and is transmitted via direct skin-to-skin contact. Symptoms of scabies infestation include intense pruritus and lesions caused by burrowing mites.

- The CDC guideline for treating scabies infestation recommends permethrin cream 5% and ivermectin oral tablets as first-line therapies. Second-line therapies include crotamiton 10% lotion and cream, malathion lotion 10%, and spinosad 0.9% topical suspension.

DiPiro's Pharmacotherapy: A Pathophysiologic Approach, 13th Edition. McGraw Hill; 2026.
JAMA. 2024;332(14):1189-1199. doi:10.1001/jama.2024.13896
MMWR Recomm Rep. Jul 23 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
Clinical Care of Scabies. Updated December 18, 2023. Accessed July 10, 2026. https://www.cdc.gov/scabies/hcp/clinical-care/index.html

Conclusions (cont.)

- A retrospective analysis was conducted to assess utilization of agents to treat scabies in the New York State Medicaid population. During the period of April 1, 2024 through March 31, 2026 (2 years: State Fiscal Year 2025 and 2026), there were 34,324 members with 59,044 claims for FDA-approved scabicidal agents, at an estimated total cost of $6,838,000.

- For the same period, there were 526 claims for oral ivermectin at a scabicidal treatment dose and quantity at an estimated total cost of $20,000. Estimated costs for second-line therapies were much greater than estimated costs for first-line therapy.

- In State Fiscal Year 2026, approximately 10% of members starting a crotamiton or spinosad product had prior utilization of a first-line therapy.

- Current eMedNY quantity limits for permethrin, spinosad, and crotamiton would be expected to be sufficient for a single course of treatment for classic scabies.

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14. Natroba. Spinosad Suspension (Package Insert): Cipher Pharmaceuticals Inc.; 2011.

15. Ovide. Malathion (Package Insert): Merative; 2026.

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Pancreatic Enzyme Replacement Therapy
November 6, 2026

Drug Utilization Review Board Meeting

NEW YORK STATE | Department of Health | Office of Health Insurance Programs
SUNY The State University of New York

Purpose

- The aim of this review is to examine pancreatic enzyme replacement therapy and their utilization in the New York State Medicaid population
- Recommendations will be provided based on a review of the literature and results from utilization data analyses

Background

- Exocrine pancreatic insufficiency: Reduced production and/or secretion of digestive enzymes leading to maldigestion and malabsorption of nutrients
  - Common causes: Pancreatectomy, pancreatic cancer, pancreatitis, cystic fibrosis, and gastrointestinal conditions (e.g., Crohn's disease, ulcerative colitis)
- Most common symptoms are abdominal pain, steatorrhea, bloating, and weight loss
- Treatment involves pancreatic enzyme replacement therapy taken during meals and snacks
  - Mixture of enzymes including lipases, proteases, and amylases
  - Dosage is based on the lipase content
  - Dosage is individualized based on symptoms, body weight, and fat content of diet
  - The total daily dosage in patients >12 months of age should reflect approximately 3 meals plus 2 – 3 snacks per day

See end of presentation for references

Pancreatic Enzyme Agents

Drug	Food and Drug Administration-Approved Indications	Initial Dosage	Maximum Dosage
Creon® (pancrelipase)	Exocrine pancreatic insufficiency in adult and pediatric patients	• Birth to 12 months: 3,000 lipase units (1 capsule) per 120 mL of formula or per breastfeeding • >12 months – <4 years: 1,000 lipase units/kg/meal • ≥4 years: 500 lipase units/kg/meal • Chronic pancreatitis or pancreatectomy: 500-1,000 lipase units/kg/meal	• Maximum dose for >12 months: 2,500 lipase units/kg/meal, 10,000 lipase units/kg/day, or 4,000 lipase units/grams of fat ingested/day
Pertzye® (pancrelipase)		• Birth to 12 months: 4,000 lipase units (1 capsule) per 120 mL of formula or per breastfeeding • >12 months – <4 years: 1,000 lipase units/kg/meal • ≥4 years including adults: 500 lipase units/kg/meal	
Zenpep® (pancrelipase)		• Birth to 12 months: 3,000 lipase units (1 capsule) per 120 mL of formula or per breastfeeding • >12 months – <4 years: 1,000 lipase units/kg/meal • ≥4 years: 500 lipase units/kg/meal	
Viokace® (pancrelipase)	Exocrine pancreatic insufficiency in adult patients caused by chronic pancreatitis or pancreatectomy; must be used in combination with a proton pump inhibitor	• Adults: 500 lipase units/kg/meal	

- The maximum recommended dose should not be exceeded in patients >12 months of age without further investigation
- Higher dosages may be be administered if documented effective by fecal fat measures or improvement of malabsorption

See end of presentation for product labeling references

How Supplied and Storage Recommendations

Drug	How Supplied
Creon®	• 3,000 USP units of lipase: 70 capsules/bottle • 6,000, 12,000 USP units of lipase: 100 or 250 capsules/bottle • 24,000, 36,000 USP units of lipase: 100, 240, or 250 capsules/bottle
Pertzye®	• 4,000 USP units of lipase: 100 capsules/bottle • 24,000 USP units of lipase: 80, 200, or 240 capsules/bottle • All other doses: 100 or 250 capsules/bottle
Zenpep®	• 3,000, 5,000, 10,000, 15,000, 20,000, 25,000, 40,000, 60,000 USP units of lipase: 100 capsules/bottle
Viokace®	• 10,440, 20,880 USP units of lipase: 100 tablets/bottle

- The manufacturers recommend that these products be dispensed in the original bottles due to extreme sensitivity to moisture and humidity; the bottles are made with moisture-resistant materials and contain specialized desiccants

See end of presentation for product labeling references

Adverse Events and Warnings

- Most common side effects: Vomiting, dizziness, diarrhea, abdominal pain, and indigestion
- No contraindications
- Warnings include the risk for development of fibrosing colonopathy, oral mucosal irritation, hyperuricemia, increased viral transmission, and risk of hypersensitivity reactions (due the presence of proteins of porcine origin)
- Viokace® also has a warning regarding hypersensitivity to lactose

See end of presentation for product labeling references

Guidelines – Exocrine Pancreatic Insufficiency

Guidelines	Recommendations
European guidelines (2025)*	• Recommend pancreatic enzyme replacement treatment in addition to dietary advice and support for exocrine pancreatic insufficiency • Diagnosis involves assessment of symptoms, nutritional status, and pancreatic function; confirmation of pancreatic exocrine insufficiency may not always require pancreatic function tests especially in patients with a high likelihood • The fecal elastase test is commonly used in place of more invasive tests for diagnosis • If a diagnosis of pancreatic insufficiency cannot be established, assessment of the response to empiric pancreatic enzyme replacement may be useful • Initial doses depend on the patient's age, severity of the condition, and fat content of the meal • Successful treatment includes resolution of nutritional deficiencies and symptomatic relief • Dosage increases should be made on an individualized basis
European guidelines (2025)**	• Recommend that exocrine pancreatic insufficiency should always be treated • Diagnosis of pancreatic exocrine insufficiency should be based on symptoms, nutritional status and pancreatic function; confirmation may not always require pancreatic function tests in patients with a high likelihood of the condition (e.g., pancreatic cancer or pancreatectomy) • Direct, invasive pancreatic function tests should not be used for the diagnosis of in clinical practice • Non-invasive tests such as the fecal elastase and the 13C-mixed triglyceride breath test are recommended • If a diagnosis cannot be established, assessment of the clinical response to empiric pancreatic enzyme replacement may be useful • Initial doses may vary depending on the patient's age, disease severity, and the fat content of the meal • Successful treatment may be defined as the resolution of nutritional deficiencies and symptomatic relief

*Organizations included: United European Gastroenterology, European Pancreatic Club, European Digestive Surgery, European Society for Clinical Nutrition and Metabolism, European Society for Pediatric Gastroenterology, Hepatology and Nutrition, European Society of Digestive Oncology, and European Society for Primary Care Gastroenterology. Authors are from multiple countries including Spain, Sweden, the Netherlands, Italy, Ukraine, Hungary, Germany, the United Kingdom, France, and Belgium.
**The same organizations were involved but there are fewer authors (from Sweden and Spain).

See end of presentation for references

Guidelines and Expert Review Updates

Guidelines/Expert Review	Recommendations
European Society for Clinical Nutrition and Metabolism guideline: Cystic fibrosis (2024)	• Although pancreatic insufficiency is diagnosed by low levels of fecal elastase-1, pancreatic enzyme replacement therapy is required in patients with cystic fibrosis; a range of initial doses is recommended since 'optimal dosing' cannot be determined • Dose titration is based on symptomatic relief; tests such as the coefficient of fat absorption/fecal fat content or nutritional biomarkers may be used to measure treatment effectiveness; however, these tests are time consuming and bothersome to patients
American Gastroenterological Association practice update/expert review: Exocrine pancreatic insufficiency (2023)	• After a positive fecal elastase test (which is the most appropriate test to conduct initially), recommends that pancreatic enzyme replacement therapy be initiated at a dose of at least 40,000 USP units of lipase per meal and half that amount for snacks • Asserts that fecal fat testing (i.e., coefficient of fat absorption) is rarely required and requires a high-fat diet • Dose titration is based on symptomatic relief of steatorrhea and maldigestion • Asserts that measures of successful treatment include a reduction in steatorrhea and gastrointestinal symptoms, weight gain, and improvement in fat-soluble vitamin levels
American College of Gastroenterology guideline: Chronic pancreatitis (2020)	• Suggests use of pancreatic enzyme replacement treatment for patients with pancreatitis and exocrine pancreatic insufficiency to improve malnutrition • Asserts that the fecal elastase test is the most commonly used pancreatic function test to diagnose exocrine pancreatic insufficiency • Treatment include an "adequate dosage" pancreatic enzymes of at least 40,000-50,000 USP units of lipase with each meal

See end of presentation for references

New York State Medicaid Coverage – NYRx Program

- Creon® and Zenpep® are preferred
- Pertzye® and Viokace® are non-preferred
- Quantity limits required for Creon® and Zenpep®: 1,200 units per 30 days

Comparator State Medicaid Coverage

- Comparator states: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington
- Among the 9 programs, 6 require prior authorization for some products (most commonly for Pertzye® and Viokace®)
- Additional limits regarding quantity, age, or days' supply were unavailable

See end of presentation for references

Drug Utilization Data: Overview of Analyses

- A retrospective analysis of claims was conducted
- Members enrolled in the New York State Medicaid Program with ≥1 pharmacy claim for a pancreatic enzyme replacement product during State Fiscal Years 2024, 2025, and 2026 were included
  - State Fiscal Year 2024: April 1, 2023 – March 31, 2024
  - State Fiscal Year 2025: April 1, 2024 – March 31, 2025
  - State Fiscal Year 2026: April 1, 2025 – March 31, 2026
  - The diagnosis lookback timeframe was State Fiscal Years 2024, 2025, and 2026
- Data source: Medicaid Data Warehouse
- Dual eligible members (members eligible for both Medicare and Medicaid) were excluded from the analyses

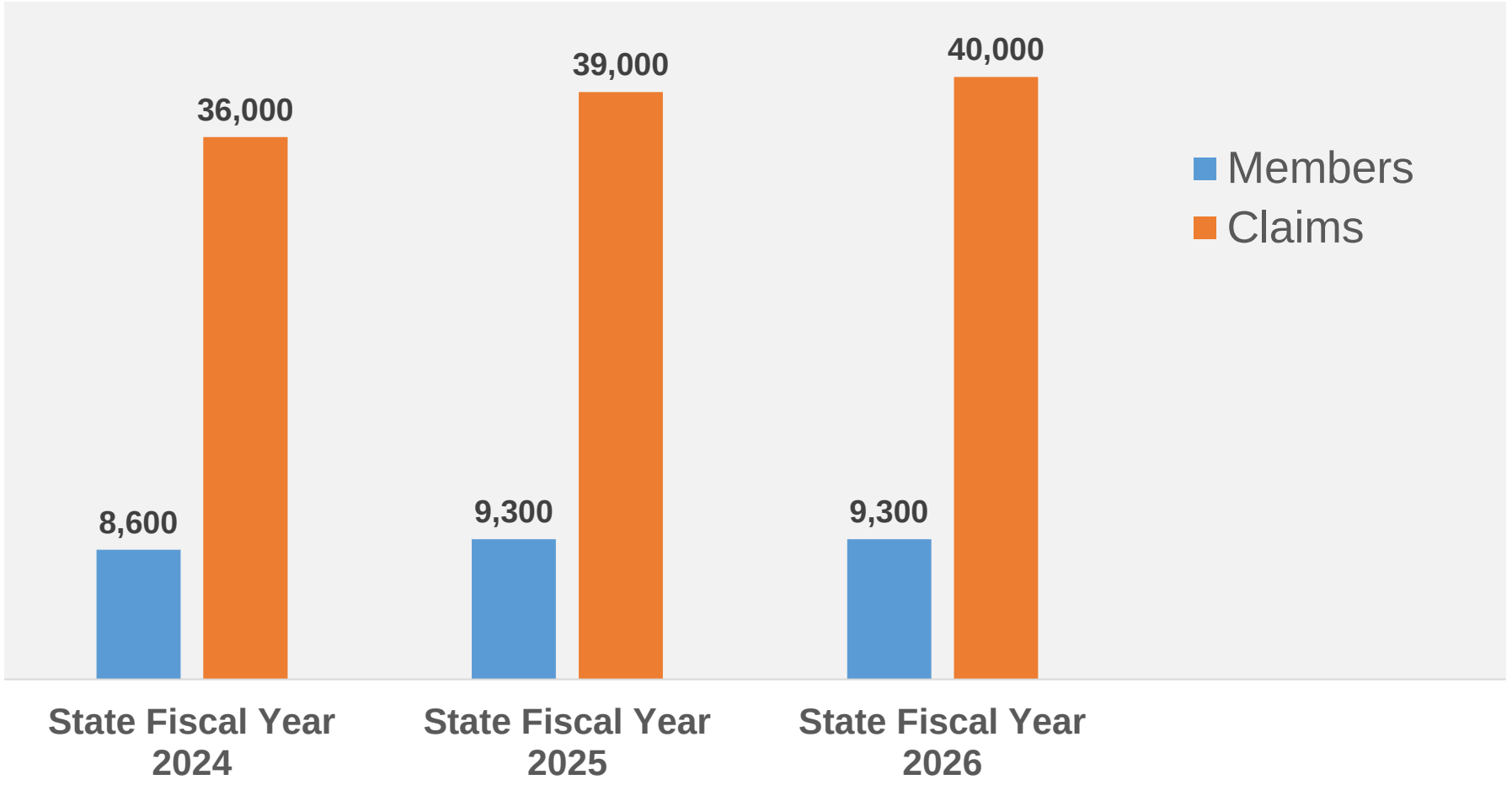
Drug Utilization Data: Disclaimers

- Medicaid Confidential Data Cell Size Policy (OHIP-0001)
  - Requires that no cell containing a value of 1 to 30 be reported; such values must be reported as ≤30 in all public-facing documents
- The following limitations should also be considered:
  - While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete

Objectives

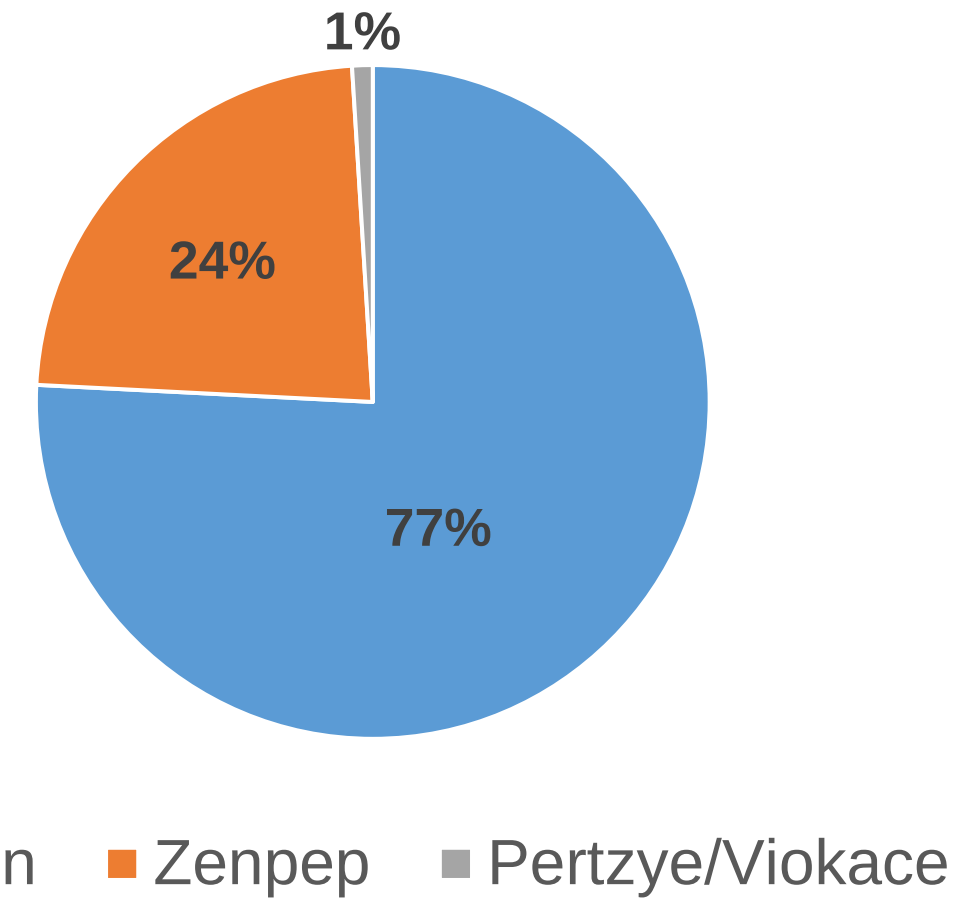
1. Evaluate the overall utilization of pancreatic enzyme replacement products (pancrelipase) for State Fiscal Years 2024, 2025, and 2026 (April 1, 2023 through March 31, 2026)
2. Determine the number of members who received pancrelipase enzymes with an appropriate diagnosis and those who lacked evidence of an appropriate diagnosis
3. Determine the gender and age of members who received pancrelipase enzymes
4. Determine the number of members who had evidence of fecal elastase testing
5. Determine the number of members who exceeded the recommended quantity limit

Objective 1 - Overall Utilization Per State Fiscal Year



Members are not additive
Data source: Medicaid Data Warehouse; date range: 04/01/2023 - 03/31/2026; extract date: 06/03/2026

Objective 1: Utilization of Members by Product in State Fiscal Year 2026 (n=9,342)



Members are not additive.
Data source: Medicaid Data Warehouse; date range: 04/01/2025 - 03/31/2026; extract date: 06/03/2026

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Objective 2: Top 5 Pancreas-Specific Diagnoses – State Fiscal Year 2026

ICD-10	Diagnosis Description	% of Members (n=9,342)
K8689	Other specified diseases of pancreas	23%
K8681	Exocrine pancreatic insufficiency	20%
K861	Other chronic pancreatitis	16%
K8590	Acute pancreatitis without necrosis or infection, unspecified	11%
K860	Alcohol-induced chronic pancreatitis	7%

Members are not additive.
Data source: Medicaid Data Warehouse; date range: 04/01/2024 - 03/31/2026; extract date: 06/03/2026

Objective 2: Top 5 Other Diagnoses – State Fiscal Year 2026

ICD-10	Diagnosis Description	% of Members (n=9,342)
E11*	Type 2 diabetes	40%
K58*	Irritable bowel syndrome	13%
E10*	Type 1 diabetes	6%
E84*	Cystic fibrosis	5%
K51*	Ulcerative colitis	2%

Members are not additive.
Data source: Medicaid Data Warehouse; date range: 04/01/2024 - 03/31/2026; extract date: 06/03/2026

Objective 2: Members Without an Appropriate Diagnosis

Diagnosis Summary For Selected Diagnoses		
Diagnosis	**Description**	**% of Members (N=9,342)**
List A*		
K8681	Exocrine pancreatic insufficiency	20%
Other (no K8681)	Other pancreas diagnoses (List A)	25%
None	**No List A diagnoses (pancreas-specific)**	**55%**
List B**		
Any code	Code from List B (no list A)	54%
Any code + K8681	Code from List B and K8681	13%
Any code + other List A code and no K8681	Code from List B and List A and NO K8681	15%
None	**No List B diagnoses**	**46%**
No diagnosis from List A or List B		**29%**

Members are not additive.
Data source: Medicaid Data Warehouse; date range: 04/01/2024 - 03/31/2026; extract date: 06/03/2026

***List A Diagnosis Codes:** Other specified diseases of pancreas, other chronic pancreatitis, acute pancreatitis without necrosis, alcohol-induced chronic pancreatitis, cyst of pancreas, malignant neoplasm of pancreas unspecific, disease of pancreas unspecified, alcohol induced acute pancreatitis, pseudocyst of pancreas, malignant neoplasm of head of pancreas, acquired partial absence of pancreas, acquired total absence of pancreas, other acute pancreatitis without necrosis, acute pancreatitis with uninfected necrosis

****List B Diagnosis Codes:** Shwachman-Diamond syndrome, type 1 diabetes, type 2 diabetes, Zollinger-Ellison syndrome, cystic fibrosis, Crohn's disease, ulcerative colitis, irritable bowel syndrome, Celiac's disease, Johanson-Blizzard syndrome

Objective 2: Members Without an Appropriate Diagnosis – Cont.

- Of the members who received pancrelipase enzymes in State Fiscal Year 2026, 20% and 25% had an exocrine pancreatic insufficiency or other pancreas-specific diagnoses (List A), respectively; 54% had a List B diagnosis code

- Members who lacked an appropriate diagnosis:
  - **55% did not have a List A diagnosis**
  - **46% did not have a List B diagnosis**
  - **29% of members had no diagnosis from List A or List B**

Members are not additive.
Data source: Medicaid Data Warehouse; date range: 04/01/2024 - 03/31/2026; extract date: 06/03/2026

Objective 3: Age and Gender in State Fiscal Year 2026

- 96% of members were ≥18 years of age
- 59% were female

Members are not additive.
Data source: Medicaid Data Warehouse; date range: 04/01/2025 - 03/31/2026; extract date: 06/03/2026

Objective 4: Fecal Elastase Testing

CPT Code Summary for Members Receiving Pancreatic Enzymes in State Fiscal Year 2026 Procedure Claims Data – State Fiscal Years 2025 or 2026		
Procedure Code	**Procedure Code Description**	**% of Members (N=9,342)**
82653	Measurement of pancreatic elastase (enzyme) in stool	11%
82656	Detection of pancreatic elastase (enzyme) in stool	3%
Total		**13%**

Members are not additive.
Data source: Medicaid Data Warehouse; date range: 04/01/2024 - 03/31/2026; extract date: 06/03/2026

Note: Fecal elastase testing is commonly only used for **diagnosis** of exocrine pancreatic insufficiency

Objective 5 – Quantity Limit

- The maximum recommended limit is based on the maximum bottle size of 250 units (maximum of 8 units per day or 1,500 units per 6 months)
  - The current quantity limit is 1,200 units per 30 days for Creon® and Zenpep®
  - Products should be dispensed in their original bottles due to extreme sensitivity to moisture and humidity
- 9% (n=1,661) of members exceeded the recommended quantity limit of 1,500 units per 6 months for State Fiscal Years 2024 – 2026

Conclusions

- Per treatment guidelines and expert review updates, pancreatic enzyme replacement therapy is recommended for all patients with exocrine pancreatic insufficiency
- Dosing and titration should be individualized based on patient response
- A fecal elastase test is typically used for diagnosis, while fecal fat content and/or adequate nutrition (in the form of weight gain) can be used as a sign of efficacy

See end of presentation for references

Conclusions

- In State Fiscal Year 2026, there were ~9,300 members and ~40,000 claims for pancreatic enzyme replacement products
  - The top 5 pancreas-specific diagnoses in State Fiscal Year 2026 were other specified diseases of the pancreas (23%), exocrine pancreatic insufficiency (20%), other chronic pancreatitis (16%), acute pancreatitis without necrosis or infection, unspecified (11%), and alcohol-induced chronic pancreatitis (7%)
  - The top 5 other diagnoses in State Fiscal Year 2026 included type 2 diabetes, irritable bowel syndrome, type 1 diabetes, cystic fibrosis, and ulcerative colitis
  - 29% of members lacked evidence of an appropriate diagnosis
  - 96% of members were ≥18 years of age and 59% were female in State Fiscal Year 2026
  - 9% of members exceeded the quantity limit of 1,500 units per 6 months for State Fiscal Years 2024 – 2026

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Onasemnogene abeparvovec-brve (Itvisma®)

November 2026
Drug Utilization Review Board Meeting

NEW YORK STATE | Department of Health | Office of Health Insurance Programs
SUNY The State University of New York

Purpose

- The aim of this review is to examine onasemnogene abeparvovec-brve (Itvisma®) and its potential utilization across the entire New York State Medicaid population
- Recommendations on Itvisma® will be provided based on a review of the available literature and results from utilization data analyses

Background

- Onasemnogene abeparvovec-brve (**Itvisma®**): gene therapy approved by the Food and Drug Administration in November 2025
  - Treatment of spinal muscular atrophy in adult and pediatric patients **≥2 years of age** with confirmed mutation in the survival motor neuron 1 (*SMN1*) gene
- Onasemnogene abeparvovec-xioi (**Zolgensma®**): gene therapy approved in 2019
  - Treatment of spinal muscular atrophy in pediatric patients **<2 years of age** with bi-allelic mutations in the *SMN1* gene

Food and Drug Administration. Center for Biologics Evaluation and Research. Itvisma. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/itvisma
Food and Drug Administration. Center for Biologics Evaluation and Research. Zolgensma. https://www.fda.gov/vaccines-blood-biologics/zolgensma

Spinal Muscular Atrophy

- Rare and progressive disease characterized by loss of motor neurons leading to muscle weakness and atrophy
- Most common form: mutations in *SMN1* gene resulting in reduced production of functional survival motor neuron protein
- Reduced production can be partially offset by *SMN2* genes
  - Larger number of *SMN2* copies → greater availability of functional protein
- Disease presentation varies in age of onset, life expectancy, and level of motor function

GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026. https://www.ncbi.nlm.nih.gov/books/NBK1352/
Food and Drug Administration. Center for Biologic Evaluation and Research. Summary basis for regulatory action – Itvisma. https://www.fda.gov/media/190313/download?attachment
National Organization for Rare Disorders. Spinal Muscular Atrophy. https://rarediseases.org/rare-diseases/spinal-muscular-atrophy/

Spinal Muscular Atrophy Phenotypes

Phenotype	*SMN2* copies	Age at onset	Life expectancy*	Motor milestones*
0 – prenatal	1	Prenatal	A few weeks to <6 months	None achieved
I – infantile	1-3	<6 months	Median survival 8-10 months	Some head control; sitting with support only
II – intermediate	2-3	6-18 months	70% alive at age 25 years	Independent sitting when placed
III – juvenile	3-4	>18 months	Normal	Independent ambulation
IV – late onset	≥4	Adulthood	Normal	Normal

*Based on observations of patients who received supportive care and no other treatment for spinal muscular atrophy

SMN2=survival motor neuron 2 gene

GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026. https://www.ncbi.nlm.nih.gov/books/NBK1352/
National Organization for Rare Disorders. Spinal Muscular Atrophy. https://rarediseases.org/rare-diseases/spinal-muscular-atrophy/

Treatment Options

- **Small molecule drugs** - messenger ribonucleic acid splicing modulators
  - Nusinersen (Spinraza®) – December 2016
  - Risdiplam (Evrysdi®) – August 2020
- **Gene therapy** – adeno-associated virus vector-based therapy; transduce a copy of the survival motor neuron gene to increase expression of the protein
  - Onasemnogene abeparvovec-xioi (Zolgensma®) – May 2019
  - Onasemnogene abeparvovec-brve (Itvisma®) – November 2025
  - **Key differences are in the indicated age range, route of administration, vector genome concentration, and dosing**

Spinraza®. Prescribing information. Biogen Inc.; 2026.
Evrysdi®. Prescribing information. Genentech, Inc.; 2026.
Zolgensma®. Prescribing information. Novartis Gene Therapies, Inc.; 2025.
Itvisma®. Prescribing information. Novartis Gene Therapies, Inc.; 2025.

Gene Therapy Comparison

Characteristic	Onasemnogene abeparvovec-xioi (Zolgensma®)	Onasemnogene abeparvovec-brve (Itvisma®)
Manufacturer	Novartis Gene Therapies, Inc.	
Approved use	Treatment of spinal muscular atrophy in pediatric patients <2 years of age with bi-allelic mutations in the *SMN1* gene	Treatment of spinal muscular atrophy in adult and pediatric patients **≥2 years of age** with confirmed mutation in the *SMN1* gene
Route of administration	Intravenous; infusion over 60 minutes	**Intrathecal**; bolus over 1-2 minutes
Concentration	2 x 10^{13} vector genomes/mL	**4 x 10^{13}** vector genomes/mL
Manufacturing	Identical active ingredient formulated using the same process in the same facility **Difference lies in the dilution process** to meet a higher target titer in the intrathecal product (Itvisma®)	
Recommended dose	1.1 x 10^{14} vector genomes per kg body weight	1.2 x 10^{14} vector genomes – **flat dose, not weight-based**
How supplied	Injection suspension in single-use vials in a kit	Injection suspension in single-dose vials
Wholesale acquisition cost	$2,586,630 per kit or single-dose vial	

Zolgensma®. Prescribing information.
Itvisma®. Prescribing information.

Gene Therapy Comparison, continued

Characteristic	Onasemnogene abeparvovec-xioi (Zolgensma®)	Onasemnogene abeparvovec-brve (Itvisma®)
Contraindications	None	
Boxed warnings	Serious liver injury and acute liver failure • Cases with fatal outcomes have been reported	Serious liver injury
Other warnings and precautions	• Systemic immune response • Thrombocytopenia • Thrombotic microangiopathy • Elevated troponin I • Tumorigenicity (theoretical) • Infusion-related reactions	• **Peripheral sensory neuropathy** • Thrombocytopenia • Thrombotic microangiopathy • Elevated troponin I • Tumorigenicity (theoretical)
Adverse events	Most common (≥5%): elevated aminotransferases and vomiting	Most common (≥10%): upper respiratory tract infection, upper gastrointestinal symptoms, pyrexia, headache
Monitoring parameters	• Liver function • Platelet counts • Infusion-related reactions	• Liver function • Platelet counts • **Neurologic function**

Zolgensma®. Prescribing information.
Itvisma®. Prescribing information.

Guidelines and Consensus Statements

- Guidelines and consensus statements have been published on treatment of spinal muscular atrophy
- Most were authored by organizations outside of the US
- **No guidelines were identified addressing place in therapy of onasemnogene abeparvovec or qualifications for use of gene therapy for spinal muscular atrophy**

Pitarch Castellano I. *Neurologia (Engl Ed)*. 2022;37(3):216-228.
Finkel RS. *Neuromuscul Disord*. 2018;28(3):197-207.
Brazilian Medical Association. *Rev Assoc Med Bras (1992)*. 2018;64(6):484-491.
Canadian Agency for Drugs and Technologies in Health (CADTH). ®). https://www.cadth.ca/sites/default/files/DRR/2022/SR0713-Spinraza-Reassessment.pdf. https://www.cadth.ca/sites/default/files/DRR/2021/SR0661%20Evrysdi%20Recommendation%20Final.pdf.
National Institute for Health and Care Excellence (NICE). https://www.nice.org.uk/guidance/ta588/resources/nusinersen-for-treating-spinal-muscular-atrophy-pdf-82607209989829. https://www.nice.org.uk/guidance/ta755/resources/risdiplam-for-treating-spinal-muscular-atrophy-pdf-82611377117125.

Literature on Itvisma®

- Itvisma® was approved based on data from 3 studies
  - STEER: phase 3 trial (pivotal)
  - STRONG: phase 1/2 trial
  - STRENGTH: phase 3b trial
- The Food and Drug Administration noted that they exercised regulatory flexibility in their review of the biologics license application due to the rarity, seriousness, and life-threatening nature of spinal muscular atrophy
  - Example: indication was extended beyond the age range of the pivotal study population to include adults

Food and Drug Administration. Center for Biologic Evaluation and Research. Summary basis for regulatory action – Itvisma. https://www.fda.gov/media/190313/download?attachment

Key Selection Criteria and Study Populations: STRONG (phase 1/2)

Inclusion criteria	Exclusion criteria	Baseline characteristics
• **Age ≥6 months and up to 60 months** at time of dosing • **Spinal muscular atrophy with proven mutation of the *SMN1* gene and 3 copies of the *SMN2* gene** • Able to sit unassisted for ≥10 seconds but unable to stand or walk independently • Onset of disease prior to 12 months of age	• Current or historical ability to stand or walk independently • Use of invasive ventilatory support or pulse oximetry <95% saturation • Medical necessity for gastric feeding tube or weight-for-age below the third percentile based on World Health Organization Child Growth Standards • Anti-AAV9 antibody titers >1:50 • Active viral infection • Serious infection within 4 weeks prior to screening • Clinically significant abnormalities in selected laboratory values	n=32 • Median age (range): 20.3 months (7-55) • Median age at symptom onset: 8.0 months • Median gestational age at birth (range): 39 weeks (35-42) • Median weight: 10.0 kg • Sex (male/female): 56.3%/43.8% • Race (white/other): 71.9%/28.1% • Median HFMSE score – reported only for participants 24 to <60 months (n=12): 12.0

AAV9=adeno-associated virus serotype 9; HFMSE=Hammersmith Functional Motor Scale-Expanded; SMN=survival motor neuron

Finkel RS et al. *J Neuromuscul Dis*. 2023;10(3):389-404. doi:10.3233/JND-221560

Key Selection Criteria and Study Populations: STEER (phase 3; pivotal)

Inclusion criteria	Exclusion criteria	Baseline characteristics
• **Age 2 to <18 years** at time of screening • **Treatment-naïve for all SMN-targeting therapies** • Spinal muscular atrophy with diagnostic confirmation • Able to sit unassisted for ≥10 seconds but unable to walk independently • Onset of disease at ≥6 months of age • Estimated life expectancy ≥2 years from screening in the opinion of the Investigator	• Hepatic dysfunction at screening • Platelet count <lower limit of normal at screening • Anti-AAV9 antibody titers >1:50 • Active infection within 30 days prior to screening • Clinically significant comorbidities that could affect overall interpretation of safety or efficacy data • Clinically significant abnormalities in selected laboratory values • History of gene therapy or hematopoietic/solid organ transplantation	n=126 overall Gene therapy (n=75) Sham procedure (n=51) Gene therapy vs. sham: • Mean age (range): 5.89 years (2.1-16.6) vs. 5.87 years (2.4-14.2); overall 5.88 years (2.1-16.6) • Mean age at onset of symptoms: 12.7 months vs. 12.6 months; overall 12.7 months • **Copies of *SMN2* gene:** o **2 copies: 1.3% vs. 7.8%; overall 4.0%** o **3 copies: 97.3% vs. 90.2%; overall 94.4%** o ≥4 copies: 1.3% vs. 2.0%; overall 1.6% • Sex (male/female): overall 49.2%/50.8% • Mean HFMSE score: 17.97 vs. 18.17

AAV9=adeno-associated virus serotype 9; HFMSE=Hammersmith Functional Motor Scale-Expanded; SMN=survival motor neuron

Proud CM et al. *Nat Med*. 2026;32(2):481-487. doi:10.1038/s41591-025-04103-w

Key Selection Criteria and Study Populations: STRENGTH (phase 3b)

Inclusion criteria	Exclusion criteria	Baseline characteristics
• **Age 2 to <18 years** at time of screening • **Experience with nusinersen or risdiplam prior to screening** • Spinal muscular atrophy with bi-allelic mutations in the *SMN1* gene and any number of *SMN2* gene copies • Able to sit unassisted for ≥10 seconds but unable to walk independently • Onset of disease at <18 months of age	• **Receipt of nusinersen within 4 months or risdiplam within 15 days of baseline** • Hepatic dysfunction at screening • Platelet count <lower limit of normal at screening • Anti-AAV9 antibody titers >1:50 • Active infection within 30 days prior to screening • Clinically significant comorbidities that could affect overall interpretation of safety or efficacy data • Clinically significant abnormalities in selected laboratory values • History of gene therapy or hematopoietic/solid organ transplantation	n=27 • Mean age (range): 7.4 years (2.4-17.7) • Mean age at onset of symptoms: 0.8 years • **Copies of *SMN2* gene:** o **2 copies: 14.8%** o **3 copies: 85.2%** • Prior use and mean duration of SMN-targeted therapy: o Nusinersen: 77.8%, 4.3 years o Risdiplam: 14.8%, 3.0 years o Either: 7.4% • Sex (male/female): 55.6%/44.4% • Mean HFMSE score: 24.31

AAV9=adeno-associated virus serotype 9; HFMSE=Hammersmith Functional Motor Scale-Expanded; SMN=survival motor neuron

Kwon JM et al. *Nat Med*. 2026;32(2):488-493. doi:10.1038/s41591-025-04119-2

Primary Endpoints and Outcomes

Study	Primary endpoint	Results
Phase 1/2 trial (STRONG)	• Proportion of patients who achieved the ability to stand without support for ≥3 seconds, or • Change from baseline in Hammersmith Functional Motor Scale Expanded score at 12 months	n=32 • 1 of 13 patients (7.7%) of medium-dose group, 1 of 3 (33.3%) of low-dose group • Least squares mean change: 6.0 (95% confidence interval 3.7-8.3)
Phase 3 trial (STEER – pivotal)	• Change from baseline in Hammersmith Functional Motor Scale Expanded score at 52 weeks	n=126 Gene therapy (n=75) vs. sham (n=51) • 2.39 vs. 0.51 (least squares mean difference 1.88, 95% confidence interval 0.51-3.25)
Phase 3b trial (STRENGTH)	• Safety	n=27 • All experienced ≥1 adverse event; 13 of 27 (48.1%) experienced treatment-related adverse events • Serious adverse events reported for 4 of 27 patients (14.8%) • No adverse events leading to death or study discontinuation

Finkel RS et al. *J Neuromuscul Dis*. 2023;10(3):389-404. doi:10.3233/JND-221560
Proud CM et al. *Nat Med*. 2026;32(2):481-487. doi:10.1038/s41591-025-04103-w
Kwon JM et al. *Nat Med*. 2026;32(2):488-493. doi:10.1038/s41591-025-04119-2

New York State Medicaid Coverage

- Itvisma® will be covered as a practitioner-administered drug

Food and Drug Administration. Center for Biologics Evaluation and Research. Itvisma. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/itvisma

Comparator State Medicaid Coverage

- Coverage of Itvisma® reviewed in 9 comparator state Medicaid programs
  - As of June 23, 2026: six of the 9 programs offered coverage; all required prior authorization
  - Clinical criteria identified for 2 of the 6 programs; product-specific criteria identified for 1 program

Product-specific prior authorization criteria	
• Appropriate diagnosis • Prescriber is a neuromuscular specialist • Member age ≥2 years and <18 years • Genetic testing confirming bi-allelic mutation of the *SMN1* gene • Onset of disease at ≥6 months of age • Baseline adeno-associated virus vector serotype 9 antibody titers <1:50	• Baseline Hammersmith Function Motor Scale Expanded score documented • Member does not require ventilation • Member can sit independently and has never been able to walk independently • Member has not previously received gene therapy for spinal muscular atrophy • Appropriate dose

Mass.gov. MassHealth Drug List. Table 76: Neuromuscular Agents – Duchenne Muscular Dystrophy and Spinal Muscular Atrophy. https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=373

Utilization Data: Overview of Analyses

- Retrospective analysis conducted to evaluate utilization of Zolgensma® and potential utilization of Itvisma®
- Data source: Medicaid Data Warehouse
  - Claims for members with service dates between May 1, 2019 and March 31, 2026 with focus on state fiscal years (SFY) 2025 and 2026
    - SFY 2025: April 1, 2024 – March 31, 2025
    - SFY 2026: April 1, 2025 – March 31, 2026
- Diagnoses of spinal muscular atrophy identified using International Classification of Diseases, tenth revision (ICD-10) codes
- **Members with third party liability on any claim with the ICD-10 codes of interest during the analysis period were excluded**

Utilization Data: Considerations

- Medicaid Confidential Data Cell Size Policy (OHIP-0001)
  - Requires that no cell containing a value of 1 to 30 be reported; such values must be reported as ≤30 in all public-facing documents
  - No cell can be reported that allows a value of 1 to 30 to be derived from other reported cells or information
- While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete

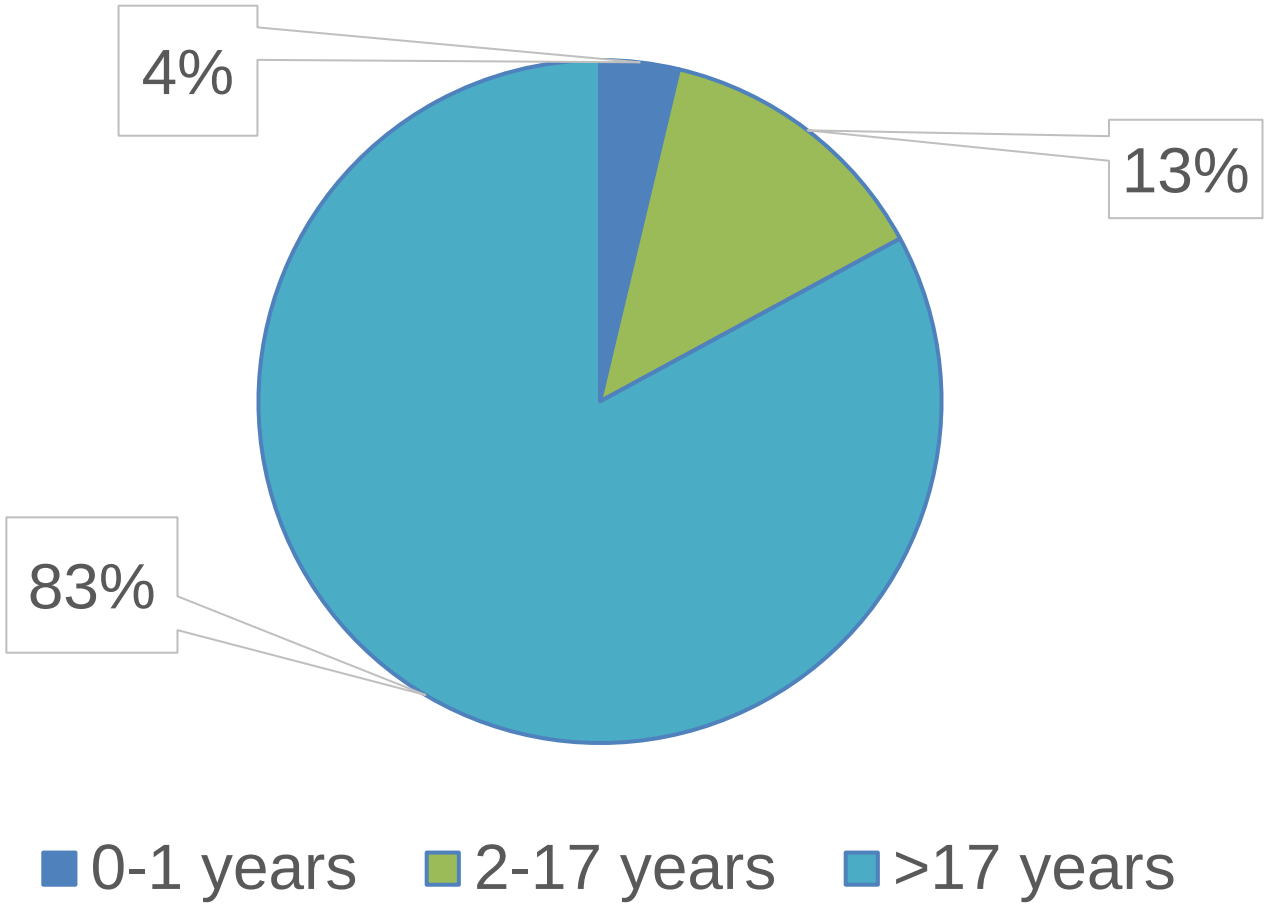
Summary Utilization

- From May 1, 2019 through March 31, 2026, there were 36 members with claims for Zolgensma®
  - 37 claims with estimated total cost of $72.5M

- From April 1, 2024 through March 31, 2026 (SFY 2025 and 2026), there were 1,077 members with a diagnosis of spinal muscular atrophy

Medicaid Data Warehouse; May 1, 2019 - March 31, 2026

Age Distribution of Members with Spinal Muscular Atrophy in SFY 2025 and 2026 (n=1,077)



Medicaid Data Warehouse; April 1, 2024 - March 31, 2026

NEW YORK STATE Department of Health | Office of Health Insurance Programs

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Diagnosis Breakdown of Members with Spinal Muscular Atrophy and 2-17 Years of Age (n=144)

ICD-10 code	ICD-10 code description	% Members*
G12.9	Spinal muscular atrophy, unspecified	88%
G12.1	Other inherited spinal muscular atrophy	35%
G12.0	Infantile spinal muscular atrophy, type I	31%
G12.8	Other spinal muscular atrophies and related syndromes	≤21%
G12.25	Progressive spinal muscle atrophy	≤21%

*Percentage members not additive
ICD-10=International Classification of Diseases, tenth revision; SFY=state fiscal year

Medicaid Data Warehouse; April 1, 2024 - March 31, 2026

Members with Spinal Muscular Atrophy: Utilization of Approved Therapy

- Among members with spinal muscular atrophy and 2 to 17 years of age in SFY 2025 or 2026:
  - ≤21% received Zolgensma®
  - 39% received nusinersen and/or risdiplam

Medicaid Data Warehouse; April 1, 2024 - March 31, 2026

Conclusions

- Spinal muscular atrophy is a rare and progressive neurogenerative disease that leads to muscle weakness and atrophy
- Most common form involves mutations in *SMN1* gene
- Disease presentation varies in age of onset, life expectancy, and level of motor function
- Treatment options are limited with 2 small molecule drugs (nusinersen, risdiplam) and gene therapy (onasemnogene abeparvovec [Zolgensma®, Itvisma®])
- Both gene therapies are adeno-associated virus vector-based and intended to transduce a copy of the human survival motor neuron gene and increase expression of the protein

GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026. https://www.ncbi.nlm.nih.gov/books/NBK1352/
Food and Drug Administration. Center for Biologic Evaluation and Research. Summary basis for regulatory action – Itvisma. https://www.fda.gov/media/190313/download?attachment
National Organization for Rare Disorders. Spinal Muscular Atrophy. https://rarediseases.org/rare-diseases/spinal-muscular-atrophy/

Conclusions, continued

- Key differences between Itvisma® and Zolgensma® lie in the indicated age range, route of administration, vector genome concentration, and dosing
  - Itvisma® is approved for treatment of adults and children ≥2 years of age
  - The product is intended for intrathecal administration and has a higher concentration of vector genomes per mL; dosing is not weight-based
- Itvisma® was approved based on data from 3 studies. Though the age range of participants in the pivotal trial was 2 to <18 years, the Food and Drug Administration exercised regulatory flexibility and extended the age range in the indication

Food and Drug Administration. Center for Biologic Evaluation and Research. Summary basis for regulatory action – Itvisma. https://www.fda.gov/media/190313/download?attachment

Conclusions, continued

- A retrospective analysis of claims data from the Medicaid Data Warehouse was performed to identify utilization of Zolgensma® and assess potential utilization of Itvisma®
  - From May 1, 2019 through March 31, 2026, there were 36 members with claims for Zolgensma®
  - In SFY 2025 and 2026, there were 1,077 members with a diagnosis of spinal muscular atrophy
    - 13% were 2 to 17 years of age
    - 4% were <2 years of age
    - 83% were >17 years of age

Medicaid Data Warehouse; May 1, 2019 - March 31, 2026

Tradipitant (Nereus®) Evaluation

Drug Utilization Review Board Meeting
November 6, 2026

NEW YORK STATE | Department of Health | Office of Health Insurance Programs
SUNY The State University of New York

Objective

- Review tradipitant (Nereus®) for the prevention of vomiting associated with motion sickness in adults.
- Tradipitant has not been reviewed by the Drug Utilization Review Board and is not included on the NYRx Preferred Drug Program.
- No utilization data are available.

Background

- The primary symptoms of motion sickness are nausea and vomiting.
- Motion sickness results from a mismatch between vestibular and visual sensory input.
- Motion sickness occurs more frequently in pediatric patients between 7 and 12 years of age and declines in adulthood, as some adults develop coping mechanisms.
- The Centers for Disease Control and Prevention Yellow Book (2026): Health Information for International Travel recommends the following products before traveling to prevent motion sickness:
  - Short-term travel ≤6 hours
    - Mild to moderate stimulus: meclizine or dimenhydrinate
    - Intense stimulus: promethazine
  - Long-term travel >6 hours
    - Mild stimulus: meclizine or dimenhydrinate
    - Moderate to intense stimulus: scopolamine patch

Golding, JF. Centers for Disease Control and Prevention Yellow Book: Health Information for International Travel. Motion Sickness. Revised April 23, 2025. Available at Motion Sickness | Yellow Book | CDC. Accessed June 2026.

Tradipitant (Nereus®)

- Food and Drug Administration (FDA) approval in December 2025 for the prevention of vomiting induced by motion in adults.

- A substance P/neurokinin-1 receptor antagonist.

- The recommended dose is either 85 mg or 170 mg, as a single oral dose taken 60 minutes before travel is expected.
  - Currently, only the 85 mg capsules are available.
  - Wholesale acquisition cost is $255 for the 85 mg capsule.

- The lifetime limit is 90 doses, as the safety of >90 doses has not been established in clinical trials.

- Most common adverse events associated with tradipitant in clinical trials were somnolence, headache, and fatigue.

Nereus® [package insert]. Washington D.C.: Vanda Pharmaceuticals, Inc.; March 2026.

Clinical Trials

Study National Clinical Trial (NCT)	Design and Sample	Inclusion/ Exclusion	Primary Outcome	Results	Adverse Events
Motion Serifos NCT05903924	Phase 3, randomized, double-blind, placebo-controlled 4-hour boat trip. The sea conditions were not described. 316 patients assigned to: 170 mg group=106 patients 85 mg group=104 patients Placebo group= 106 patients	<u>Inclusion:</u> History of motion sickness Age 18-75 years <u>Exclusion:</u> Nausea-inducing disorder other than motion sickness Body mass index>40 kg/m^2 History of intolerance and/or hypersensitivity to neurokinin-1 receptor antagonists	Prevention of vomiting as measured by Vomiting Assessment (VA). The VA is a 1-question questionnaire indicating whether or not the patient vomited during the day of travel.	170 mg group 10.4% (11/106) vomited (p=0.00002) 85 mg group 18.3% (19/104) vomited (p=0.0014) Placebo group 37.7% (40/106) vomited	<u>170 mg group (n=106)</u> Fatigue= 11.32% Headache= 9.43% Somnolence= 8.49% <u>85 mg group</u> Fatigue= 8.65% Headache= 8.65% Somnolence= 5.77% <u>Placebo group</u> Fatigue= 5.66% Headache= 8.49% Somnolence= 7.55%
Motion Syros NCT04327661	Phase 3, randomized, double-blind, placebo-controlled 2 to 5-hour boat trip with peak wave heights of 0.5 meters (1.6 feet) to 2.1 meters (8.2 feet), and the average wind speed between 2.0 (~2.3 miles per hour) and 26.1 (~30.0 miles per hour) knots 365 patients assigned to: 170 mg group= 120 patients 85 mg group= 123 patients Placebo group= 122 patients			170 mg group=18.3% (22/120) vomited (p<0.0001) 85 mg group= 19.5% (24/123) vomited (p<0.0001) Placebo group= 44.3% (54/122)	<u>170 mg dose group (n=120)</u> Fatigue= 8.3% Headache= 8.3% Somnolence= 8.33% (9/106) <u>85 mg group (n=123)</u> Fatigue= 4.07% Headache= 5.69% Somnolence= 6.50% <u>Placebo group (n=120)</u> Fatigue= 0 Headache= 2.46% Somnolence= 0.82%

Frontiers in Neurology. 2025 Mar 4;16:1550670. doi:10.3389/fneur.2025.1550670.
American Journal of Therapeutics. 2026,00(00):1-5.

National Institute of Health, National Library of Medicine, National Center for Biotechnology Information. ClinicalTrials.gov. Available at Home | ClinicalTrials.gov. Accessed June 2026

Summary

- Nereus® (tradipitant) is a substance P/neurokinin-1 receptor antagonist approved by the FDA for the prevention of vomiting associated with motion sickness in adults.

- Current guidelines recommend first-generation antihistamines (meclizine, dimenhydrinate, and promethazine) and scopolamine for the prevention of motion sickness.
  - The estimated average cost of a single dose of a first-generation antihistamine is $0.02, and $4.40 for a 1 mg scopolamine 3-day patch.

- The recommended tradipitant dose is either 85 mg or 170 mg, as a single oral dose 60 minutes before travel, which may cause motion-induced vomiting.
  - The wholesale acquisition cost is $255 for the 85 mg and $510 for the 170 mg single dose.

Nereus® [package insert]. Washington D.C.: Vanda Pharmaceuticals, Inc.; March 2026.
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