NEW COST OPTIMIZATION PROGRAM: TARGETS HIGH-COST FORMULATIONS/DOSAGES OF DRUG PRODUCTS

NYRx, the Medicaid Pharmacy Program, is initiating a new cost optimization program to help address increasing drug costs.

- **Program Focus:**
  - Manufacturing of new formulations and dosages of older drug products with substantially higher launch prices than equally efficacious, cost-effective alternatives.
  - These new formulations are **lacking *additional clinical utility* while others lack clear *medical necessity* for those specific formulations and dosages.**
- Pursuant to Title 18 of the New York Codes, Rules, and Regulations (NYCRR) Section 513.4(d), the ordering practitioner and dispensing pharmacy are responsible for assuring that adequate and less expensive alternatives to meet the member's medical needs have been explored and, where appropriate and cost effective, are prescribed and dispensed.
  - The use of affected formulations and dosages for convenience of the member or prescriber is not considered medically necessary.
  - NYRx covers most medically necessary Food and Drug Administration (FDA) approved drugs when used for Medicaid-covered indications.

NEW YORK STATE | Department of Health

NEW COST OPTIMIZATION PROGRAM: TARGETS HIGH-COST FORMULATIONS/DOSAGES OF DRUG PRODUCTS

Effective December 18, 2025, the following drugs require a Manual Review by NYRx for coverage approval:

Carbinoxamine Maleate 6mg Tablet	Meloxicam 5 and 10mg Capsule
Chlorzoxazone 250mg Tab	Metformin HCl 750mg (IR) Tablets
Diclofenac Potassium 25mg Tablets	Relafen DS 1,000mg Tablet
Dolobid 250mg Tablets	Tetracycline 250mg Tablet
Halcinonide 0.1% Solution	Tolectin 600mg Tablet
Hydrocortisone 2.5% Solution	Tolmetin Sodium 400mg Capsule

Note: D*rugs in the above list have FDA-approved, safe and effective alternatives for their common uses. Prescribers may consider alternatives using the Medicaid Pharmacy List of Reimbursable Drugs found here:* https://www.emedny.org/info/formfile.aspx

NEW YORK STATE | Department of Health

Effective February 19, 2026, the following drugs require a Manual Review by NYRx for coverage approval:

Amcinonide 0.1% Cream	Lurbiro 100mg Tablet
Dicyclomine 40mg Tablet	Metformin 625mg Tablet
Dolobid 375mg Tablet	Oxaprozin 300mg Capsule
Econzaole Nitrate 1% Foam	Pokonza 15Meq Packet
Ergomar 2mg Tablet	Prednisone (DR) 1mg, 2mg, Tablet
Escitalopram 15mg Capsule	Tonmya 2.8mg Tablet
Ibuprofen 300mg Tablet	Ultravate 0.05% Lotion
Javadin 0.02mg/ml Solution	Zanaflex 8mg Capsule

NEW COST OPTIMIZATION PROGRAM: TARGETS HIGH-COST FORMULATIONS/DOSAGES OF DRUG PRODUCTS

- If a prescriber has determined that one of these drugs is the only appropriate treatment for a Medicaid member, they may submit a letter of medical necessity and supporting documentation to NYRx@health.ny.gov for a review of coverage.
- **Supporting documentation must include peer-reviewed literature and chart notes that justify why the prescribed formulation/dosage is medically necessary.**

NEW YORK STATE | Department of Health

Drug Utilization Review: Atopic Dermatitis

New York State Medicaid Drug Utilization Review Board
February 26, 2026

Purpose

- This review examines topical and systemic therapies for the treatment of atopic dermatitis and their utilization across the entire New York State (NYS) 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.

Background

- Atopic (i.e., allergic) dermatitis is the most common type of eczema, a group of inflammatory skin conditions caused by genetic and environmental factors.
- Pathogenesis is driven by an exaggerated immune response to common environmental allergens, and affected individuals may be predisposed to other atopic comorbidities (e.g., food allergies, allergic asthma, allergic rhinoconjunctivitis, eosinophilic esophagitis).
- Diagnosis is primarily based on patient history and clinical signs, including eczematous rash with intense itch, which follow a chronic relapsing-remitting pattern.

National Eczema Association. https://nationaleczema.org/types-of-eczema/. Accessed 5/8/2025.
Guttman-Yassky E et al. *Lancet*. 2025;405(10478):583-596.

Background

- Globally, atopic dermatitis cases rose from 107 million in 1990 to 129 million in 2021, and forecasting models predict a further increase to 148 million cases by 2050.
- A meta-analysis published in 2025 estimated worldwide prevalence at 11.1% in children and adolescents and 6.3% in adults.
  - Prevalence in children and adolescents decreased as age increased: 16.0% in ages 0 – 5 years, 9.7% in ages 6 – 11 years, and 8.6% in ages 12 – 17 years.
  - Proportions of severe cases were up to 7.2% in children and adolescents and up to 15.6% in adults, depending on assessment criteria used.

GBD 2021 Asthma and Allergic Diseases Collaborators. *Lancet Respir Med*. 2025;13(5):425-446
Migliavaca CB et al. *Dermatitis*. 2025 Nov-Dec;36(6):575-582.

Background

- Prevalence of atopic dermatitis in the United States (US) is estimated at approximately 5 – 10% of adults and 15 – 24% of children under 18 years of age.
- Approximately 60% of adults with atopic dermatitis in the US have mild disease, 29% have moderate disease, and 11% have severe disease.
- Annual costs, direct and indirect, of atopic dermatitis have been conservatively estimated at $5.3 billion based on 2015 US dollars.

Silverberg JI et al. *Arch Dermatol Res*. 2025;317(1):556
Chiesa Fuxench ZC et al. *J Invest Dermatol*. 2019;139(3):583-590.
Drucker AM et al. *J Invest Dermatol*. 2017;137(1):26-30.

Background

- Conventional topical therapies for atopic dermatitis include moisturizers, topical corticosteroids, and topical calcineurin inhibitors. Conventional systemic therapies include primarily oral corticosteroids and off-label use of other immunosuppressants.
- In 2017, newer therapies with novel mechanisms of action began to receive Food and Drug Administration (FDA) approval, including: systemic biological agents, topical phosphodiesterase-4 inhibitors, topical and systemic Janus kinase inhibitors, and most recently a first-in-class topical aryl hydrocarbon receptor agonist.
- Evidence-based guidance for optimizing treatment in a patient-centered approach and considering all stakeholders continues to evolve.

Guttman-Yassky E et al. *Lancet*. 2025;405(10478):583-596.

Topical agents FDA-approved for atopic dermatitis

Generic (Brand) Drug Name / FDA Approval Date	Formulation(s)	FDA indication(s) and limitations for atopic dermatitis	Additional FDA indication(s)
Topical Corticosteroids			
Numerous brand and generic products approved since 1950s	Low-, medium-, high-, and very high-potency creams, gels, lotions, ointments, solutions, and sprays	• Inflammatory and pruritic corticosteroid-responsive dermatoses, and/or mild to moderate atopic dermatitis, and/or moderate to severe atopic dermatitis o Higher potency products have age and duration limits	• Plaque psoriasis
Topical Immunomodulators			
Calcineurin inhibitors			
Pimecrolimus 2001	1% cream	• Mild to moderate atopic dermatitis o Second-line therapy for short-term non-continuous chronic treatment in non-immunocompromised patients ≥2 years of age who have failed other topical prescription therapies or when such are not advised	• None
Tacrolimus 2000	0.03% and 0.1% ointments	• Moderate to severe atopic dermatitis o Second-line therapy for short-term non-continuous chronic treatment in non-immunocompromised patients who have failed other topical prescription therapies or when such are not advised o Only 0.03% is indicated for children 2 – 15 years of age	• None

Topical agents FDA-approved for atopic dermatitis, continued

Generic (Brand) Drug Name / FDA Approval Date	Formulation(s)	FDA indication(s) and limitations for atopic dermatitis	Additional FDA indication(s)
Topical Immunomodulators, continued			
Phosphodiesterase-4 inhibitors			
Crisaborole (Eucrisa®) 2016	2% ointment	• Mild to moderate atopic dermatitis o Patients ≥3 months of age	• None
Roflumilast (Zoryve®) 2024	0.05% and 0.15% creams	• Mild to moderate atopic dermatitis o 0.05% cream is indicated for patients 2 – 5 years of age o 0.15% cream is indicated for patients ≥6 years of age	• None
Janus kinase inhibitors			
Ruxolitinib (Opzelura®) 2021	1.5% cream	• Mild to moderate atopic dermatitis o Short-term non-continuous chronic treatment in non-immunocompromised patients ≥2 years of age who have failed other topical prescription therapies or when such are not advised o Not recommended in combination with therapeutic biologics, other Janus kinase inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) o Only apply to ≤20% of body surface area twice daily o Use no more than 60 g per week or 100 g per 2 weeks in ages ≥12 years and no more than 60 g per 2 weeks in ages 2 – 11 years	• Nonsegmental vitiligo (not a NYS Medicaid-covered indication)
Delgocitinib (Anzupgo®) 2025	20 mg/g cream	• Moderate to severe chronic hand eczema o Adults who have failed topical corticosteroids or in whom are not advised o Not recommended in combination with other Janus kinase inhibitors or potent immunosuppressants o Apply only on affected areas of hands/wrists twice daily o Use no more than 30 g per 2 weeks or 60 g per month	• None

Topical agents FDA-approved for atopic dermatitis, continued

Generic (Brand) Drug Name / FDA Approval Date	Formulation(s)	FDA indication(s) and limitations for atopic dermatitis	Additional FDA indication(s)
Topical Immunomodulators, continued			
Aryl hydrocarbon receptor agonist			
Tapinarof (Vtama®) 2024	1% cream	• Atopic dermatitis o Patients ≥2 years of age	• Plaque psoriasis
Topical Antihistamine			
Doxepin (Zonalon®, Prudoxin®) 1994	5% cream	• Moderate pruritus due to atopic dermatitis o Limited to adults and for short-term use up to 8 days	• Moderate pruritus due to lichen simplex chronicus

Systemic agents FDA-approved or compendia-supported for atopic dermatitis

Generic (Brand) Drug Name / FDA Approval Date	Formulation(s)	FDA indication(s) and limitations for atopic dermatitis	Additional FDA indication(s)
Systemic Immunomodulators			
Interleukin inhibitors (biologics)			
Dupilumab (Dupixent®) 2017	200 mg and 300 mg single-dose pens and syringes for subcutaneous injection	• Moderate to severe atopic dermatitis o Patients ≥6 months of age who have failed topical prescription therapies or when such are not advised o May be used with or without topical corticosteroids	• Asthma • Chronic obstructive pulmonary disease • Chronic rhinosinusitis with nasal polyps • Eosinophilic esophagitis • Prurigo nodularis
Lebrikizumab (Ebglyss®) 2024	250 mg single-dose pens and syringes for subcutaneous injection	• Moderate to severe atopic dermatitis o Patients ≥12 years of age and weigh ≥40 kg who have failed topical prescription therapies or when such are not advised o May be used with or without topical corticosteroids	• None
Nemolizumab (Nemluvio®) 2024	30 mg single-dose pen for subcutaneous injection	• Moderate to severe atopic dermatitis o Patients ≥12 years of age who have failed topical prescription therapies o Indicated in combination with topical corticosteroids or topical calcineurin inhibitors	• Prurigo nodularis
Tralokinumab (Adbry®) 2021	150 mg single-dose syringe and 300 mg single-dose autoinjector for subcutaneous injection	• Moderate to severe atopic dermatitis o Patients ≥12 years of age who have failed topical prescription therapies or when such are not advised o May be used with or without topical corticosteroids	• None

Systemic agents FDA-approved or compendia-supported for atopic dermatitis, continued

Generic (Brand) Drug Name / FDA Approval Date	Formulation(s)	FDA indication(s) and limitations for atopic dermatitis	Additional FDA indication(s)
Systemic Immunomodulators, continued			
Janus kinase inhibitors			
Abrocitinib (Cibinqo®) 2022	50 mg, 100 mg, 200 mg oral tablets	• Refractory, moderate to severe atopic dermatitis o Patients ≥12 years of age who have failed other systemic drug products, including biologics, or when such are not advised o Not recommended with other Janus kinase inhibitors, biologic immunomodulators, or other immunosuppressants	• None
Baricitinib (Olumiant®) – not FDA approved for atopic dermatitis	1 mg, 2 mg, 4 mg oral tablets	• †Refractory, moderate to severe atopic dermatitis o Evidence favors efficacy in adults for whom conventional treatment is ineffective o Not recommended with other Janus kinase inhibitors, biologic immunomodulators, or other immunosuppressants	• Alopecia areata • COVID-19 • Rheumatoid arthritis
Upadacitinib (Rinvoq®) 2022	15 mg, 30 mg, 45 mg extended-release tablets	• Refractory, moderate to severe atopic dermatitis o Patients ≥12 years of age who have failed other systemic drug products, including biologics, or when such are not advised o Not recommended with other Janus kinase inhibitors, biologic immunomodulators, or other immunosuppressants o Initiate treatment with 15 mg dose; may increase to 30 mg dose but if response is inadequate with 30 mg, discontinue	• Ankylosing spondylitis • Crohn's disease • Giant cell arteritis • Non-radiographic axial spondyloarthritis • Polyarticular juvenile idiopathic arthritis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis

† Denotes off-label, compendia-supported use

Systemic agents FDA-approved or compendia-supported for atopic dermatitis, continued

Generic (Brand) Drug Name / FDA Approval Date	Formulation(s)	FDA indication(s) and limitations for atopic dermatitis	Additional FDA indication(s)
Systemic Immunosuppressants			
Azathioprine	Oral tablets	• †Atopic dermatitis o Evidence favors efficacy in adult and pediatric patients	• Renal transplant rejection prophylaxis • Rheumatoid arthritis
Cyclosporine	Oral capsules, oral solution	• †Refractory or chronic severe atopic dermatitis o Evidence favors efficacy in adults	• Cardiac, liver, renal transplant rejection prophylaxis • Plaque psoriasis • Rheumatoid arthritis
Mycophenolate mofetil	Oral capsules, oral tablets, oral suspension	• †Atopic dermatitis o Evidence favors efficacy in adults	• Cardiac, liver, renal transplant rejection prophylaxis
Systemic Corticosteroids			
Dexamethasone, hydrocortisone, methylprednisolone prednisolone, prednisone, triamcinolone	Oral tablets, solutions, and/or elixirs; solutions and/or suspensions for injection	• Severe allergic conditions, including atopic dermatitis, intractable to adequate trials of conventional treatment o Adult and pediatric patients	• Many other conditions, diseases, and disorders

† Denotes off-label, compendia-supported use

Place in Therapy: Clinical Guidance

- American Academy of Allergy, Asthma, and Immunology / American College of Allergy, Asthma, and Immunology Joint Task Force on Practice Parameters
  - Atopic dermatitis (eczema) guidelines: 2023 GRADE- and Institute of Medicine-based recommendations
- American Academy of Dermatology
  - Management of atopic dermatitis in adults with topical therapies (2023)
  - Management of atopic dermatitis in adults with phototherapy and systemic therapies (2024)
  - Focused update: Guidelines of care for the management of atopic dermatitis in adults (2025)
- US expert consensus on managing childhood and adolescent atopic dermatitis in primary care (2024)
- US expert consensus on systemic therapy for atopic dermatitis in children and adolescents (2024)
- American Academy of Pediatrics clinical report on updated skin-directed management of atopic dermatitis (2025)

Place in Therapy: Clinical Guidance

Baseline Management of Atopic Dermatitis for All Severity Levels

- Assess signs, symptoms, and comorbidities for appropriate diagnosis and disease severity
- Identify triggers and counsel on trigger avoidance
- Educate on adherence to an individualized action plan using shared decision making
- Encourage daily use of emollient moisturizers

Management of Mild to Severe Atopic Dermatitis with Topical Pharmacologic Therapies

Use as needed to optimize control of inflamed sites and/or proactively for maintenance of control on sites prone to recurrent inflammation

Drugs / FDA Label Information	Guideline Recommendations	Additional Comments
Topical corticosteroids • Low-potency • Medium-potency • High-potency • Very high-potency FDA-approved agents for use in mild to severe disease. Most high- and very high-potency formulations have age and/or frequency/quantity/duration limits in FDA labeling.	Joint Task Force 2023 guidelines: Strong recommendation, high certainty of evidence, for ages ≥3 months with mild, moderate, or severe disease. American Academy of Dermatology 2023–2025 adult guidelines: Strong recommendation, high certainty of evidence, for treating all disease severities and also for use of medium-potency agents for maintenance therapy twice weekly to reduce flares and relapse. 2024 US expert consensus for children and adolescents: “The choice of topical anti-inflammatory for adolescents and children aged ≥2 years should balance efficacy and safety, be used for at least a few weeks or until the affected areas look clear, and tapered as tolerated to maintain disease control.”	Topical corticosteroids are the most commonly used FDA-approved therapy for atopic dermatitis and are typically used first-line for all severities and affected areas. Choice of potency and formulation should consider patient age, treatment history and application site. • High- / very high-potency agents should only be used short-term (no more than 4 weeks/no more than 2 weeks in younger children) for severe disease and/or controlling flares in non-sensitive areas. • Medium-potency agents have lower risk of adverse effects (e.g. skin atrophy) and are recommended intermittently for maintenance therapy.

Place in Therapy: Clinical Guidance

Management of Mild to Severe Atopic Dermatitis with Topical Pharmacologic Therapies, continued		
Drugs / FDA Label Information	Guideline Recommendations	Additional Comments
Topical calcineurin inhibitors • Pimecrolimus • Tacrolimus Pimecrolimus is FDA-approved for mild to moderate atopic dermatitis in ages ≥2 years. Tacrolimus is FDA-approved for moderate to severe atopic dermatitis in ages ≥2 years.	Joint Task Force 2023 guidelines: Strong recommendation, high certainty of evidence, for ages ≥3 months with mild, moderate, or severe disease. American Academy of Dermatology 2023–2025 adult guidelines: Strong recommendation, high certainty of evidence, for use of tacrolimus for mild, moderate, or severe disease, and for use of pimecrolimus for mild to moderate disease. 2024 US expert consensus for children and adolescents: "Topical calcineurin inhibitors have an excellent safety profile with no evidence of increased cancer risk, despite the theoretical risk that originally led to a boxed warning."	Topical calcineurin inhibitors are a safe anti-inflammatory option used primarily as steroid-sparing, intermittent maintenance therapy and for treating sensitive areas (e.g., face and groin), when there is concern for adverse steroid effects. Efficacy of pimecrolimus and tacrolimus 0.03% is comparable to low-potency topical corticosteroids, while efficacy of tacrolimus 0.1% is comparable to medium-potency topical corticosteroids.

Place in Therapy: Clinical Guidance

Management of Mild to Severe Atopic Dermatitis with Topical Pharmacologic Therapies, continued		
Drugs / FDA Label Information	Guideline Recommendations	Additional Comments
Phosphodiesterase-4 inhibitors • Crisaborole (Eucrisa®) • Roflumilast (Zoryve®) Both agents are FDA-approved for treatment of mild to moderate atopic dermatitis. Crisaborole is approved for ages ≥3 months. Roflumilast is approved for ages ≥2 years.	Joint Task Force 2023 guidelines: Conditional recommendation, moderate certainty of evidence, for crisaborole ointment in ages ≥3 months with mild to moderate disease; roflumilast is mentioned as a possible option for future review. American Academy of Dermatology 2023, 2024 adult guidelines: Strong recommendation, high certainty of evidence, for use of crisaborole ointment for mild to moderate disease. American Academy of Dermatology 2025 update to adult guidelines: Adds a strong recommendation, high certainty of evidence, for use of roflumilast 0.15% cream for mild to moderate disease. 2024 US expert consensus for children and adolescents: Crisaborole and roflumilast are listed with other topical nonsteroidal treatment options which “may be appropriate, particularly to maintain disease control.”	Crisaborole was the first FDA-approved non-steroidal, non-calcineurin inhibitor topical therapy for atopic dermatitis. Due to the lack of head-to-head comparisons with topical corticosteroids or topical calcineurin inhibitors, small to moderate improvements compared to vehicle, and favorable safety profiles, these agents are considered alternatives for treatment of mild to moderate disease.

Place in Therapy: Clinical Guidance

Management of Mild to Severe Atopic Dermatitis with Topical Pharmacologic Therapies, continued		
Drugs / FDA Label Information	Guideline Recommendations	Additional Comments
Topical Janus kinase inhibitors • Ruxolitinib (Opzelura®) • Delgocitinib (Anzupgo®) Ruxolitinib is FDA-approved for mild to moderate atopic dermatitis in ages ≥2 years. Class Boxed Warning: Serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis. Delgocitinib is FDA-approved for moderate to severe chronic hand eczema in adults. The class boxed warning is not included in FDA labeling for delgocitinib, but the same parameters are listed in the warnings section.	Joint Task Force 2023 guidelines: Conditional recommendation, low certainty of evidence, **against** use of topical ruxolitinib. American Academy of Dermatology 2023–2025 adult guidelines: Strong recommendation, moderate certainty of evidence, favoring treatment with ruxolitinib for mild to moderate disease. 2024 US expert consensus for children and adolescents: Ruxolitinib is listed with other topical nonsteroidal treatment options which “may be appropriate, particularly to maintain disease control.” Delgocitinib was approved in July 2025 and is not included in the above treatment guidelines and consensus statements.	The rationale for the Joint Task Force conditional recommendation against use of topical ruxolitinib was the modest benefit and uncertain risk of serious harms associated with systemic Janus kinase inhibitors (resulting in the class boxed warning), considering other topical options have higher certainty of safety. The American Academy of Dermatology noted there was enough short-term safety and efficacy data to warrant a strong recommendation for use of ruxolitinib, however, longer term safety data are needed to better elucidate risks from systemic absorption.

Place in Therapy: Clinical Guidance

Management of Mild to Severe Atopic Dermatitis with Topical Pharmacologic Therapies, continued		
Drugs / FDA Label Information	Guideline Recommendations	Additional Comments
Aryl hydrocarbon receptor agonist • Tapinarof (Vtama®) Tapinarof 1% cream is FDA-approved for treatment of atopic dermatitis in ages ≥2 years.	Joint Task Force 2023 guidelines: Tapinarof is mentioned as a possible option for future review. American Academy of Dermatology 2025 update to adult guidelines: Strong recommendation, high certainty of evidence, for use of tapinarof in adults with moderate to severe disease. 2024 US expert consensus for children and adolescents: Tapinarof is not mentioned.	Tapinarof was FDA approved for atopic dermatitis in December 2024 and was only reviewed for the 2025 American Academy of Dermatology guideline update. The work group noted the rationale for the strong recommendation is based on short-term evidence demonstrating moderate improvements in disease severity and pruritus with a favorable safety profile.
Topical antihistamine • Doxepin (Zonalon®) Doxepin 5% cream is FDA-approved for short-term use (up to 8 days) for moderate pruritus in adults with atopic dermatitis.	Joint Task Force 2023 guidelines: Neither topical antihistamines nor doxepin is mentioned. American Academy of Dermatology 2023 adult guidelines: Conditional recommendation, low certainty of evidence, **against** use of topical antihistamines, including doxepin.	The American Academy of Dermatology guidelines identified only one study of doxepin for atopic dermatitis and noted withdrawal due to adverse events was significantly (5-fold) higher with doxepin compared to vehicle. FDA labeling notes significant systemic absorption with topical application, leading to central nervous system and anticholinergic side effects, and also cites more than 25 documented post-marketing reports of allergic contact dermatitis attributed to topical doxepin.

Place in Therapy: Clinical Guidance

Management of Moderate to Severe Atopic Dermatitis with Systemic Pharmacologic Therapies

When control is inadequate with optimized topical therapy, these agents may be added and used concurrently with topical therapies for maintenance, rescue, or treatment of flares

Drugs / FDA Label Information	Guideline Recommendations	Additional Comments

Biologics (monoclonal antibodies)
 	
• Dupilumab (Dupixent®)
  o Interleukin-4 alpha antagonist
• Tralokinumab (Adbry®)
  o Interleukin-13 antagonist
• Lebrikizumab (Ebglyss®)
  o Interleukin-13 antagonist
• Nemolizumab (Nemluvio®)
  o Interleukin-31 antagonist
 	
All 4 agents are FDA-approved for treating moderate to severe atopic dermatitis
 	
Dupilumab is approved for ages ≥6 months and the other 3 agents are approved for ages ≥12 years.
	Joint Task Force 2023 guidelines:
	
	Strong recommendation, high certainty of evidence, for adding dupilumab (ages ≥6 months) or tralokinumab (ages ≥12 years).
	
	American Academy of Dermatology 2024 adult guidelines:
	
	Strong recommendation, moderate certainty of evidence, for adding either dupilumab or tralokinumab for adults with moderate to severe atopic dermatitis.
	
	American Academy of Dermatology 2025 update to adult guidelines:
	
	Added a strong recommendation with high certainty of evidence for both lebrikizumab and nemolizumab for adults with moderate to severe disease, with the condition that nemolizumab be used with concomitant topical therapy.
	
	2024 US expert consensus on use of systemic therapies in children and adolescents:
	
	“Biologics should be considered first-line systemic therapy in most patients unless contraindicated.”
		The Joint Task Force notes that the optimal timeframe for defining a patient’s atopic dermatitis as refractory to topical treatment is unclear, but clinical trials and experts typically expect response to mid- or high-potency topical therapy within 2-6 weeks.
		
		Dupilumab has been favored as a first-line systemic agent due to well-established safety and efficacy. It is also FDA approved for treating other atopic comorbid conditions, so this should be considered when choosing systemic therapy.
		
		The American Academy of Dermatology gave the strong recommendation for each of these agents based on the large magnitude of benefit and favorable safety profiles demonstrated in clinical trials, noting that long-term safety and efficacy data, patient-reported outcomes in real-world settings, and comparative studies are needed to provide a better understanding of the place in therapy of the newer agents.

Place in Therapy: Clinical Guidance

Management of Moderate to Severe Atopic Dermatitis with Systemic Pharmacologic Therapies, continued		
Drugs / FDA Label Information	Guideline Recommendations	Additional Comments
Systemic Janus kinase inhibitors • Abrocitinib (Cibinqo®) • Upadacitinib (Rinvoq®) • Baricitinib (Olumiant®) Abrocitinib and upadacitinib are FDA-approved for moderate to severe atopic dermatitis in ages ≥12 years. Baricitinib is compendia-supported for moderate to severe atopic dermatitis in adults. FDA labeling of all 3 agents carries the class boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.	Joint Task Force 2023 guidelines: Conditional recommendation, low certainty of evidence, for adding 1 of these 3 agents for adults and adolescents to replace previous systemic treatment (including biologics) when response is inadequate. American Academy of Dermatology 2024, 2025 adult guidelines: Strong recommendation, moderate certainty of evidence, for adding 1 of these 3 agents for adults with moderate to severe atopic dermatitis who have failed other systemic therapies, including biologics, or when those therapies are inadvisable. 2024 US expert consensus on use of systemic therapies in children and adolescents: "Biologic drugs or Janus kinase inhibitors [currently, abrocitinib and upadacitinib, indicated for ages ≥12 years] should be considered as first-line systemic treatment for moderate-to-severe atopic dermatitis unless contraindicated, in instances where standard topical therapies have proven insufficient/inadequate for disease control."	The American Academy of Dermatology adult guidelines note that in most circumstances these Janus kinase inhibitors are not considered first-line systemic therapy based on FDA indication. In addition to the boxed warning, other warnings and precautions for these agents include laboratory monitoring for changes in platelets, lymphocytes, and lipids with abrocitinib and lymphocytes, neutrophils, hemoglobin, liver enzymes, and lipids with upadacitinib and baricitinib. Baseline testing for hepatitis, tuberculosis, and pregnancy should also be completed. Clinicians must discuss risks vs benefits of Janus kinase inhibitor therapy with all potential candidates prior to initiation of treatment and perform appropriate screening and lab monitoring. Of note: International Eczema Council guidance on use of systemic Janus kinase inhibitors is consistent with the considerations above and notes that studies are needed to assess the durability and safety of continuous and episodic long-term use and combination regimens in patients with atopic dermatitis.

Place in Therapy: Clinical Guidance

Management of Moderate to Severe Atopic Dermatitis with Systemic Pharmacologic Therapies, continued		
Drugs / FDA Label Information	Guideline Recommendations	Additional Comments
Systemic immunosuppressants • Azathioprine • Cyclosporine • Mycophenolate mofetil • Methotrexate Azathioprine, cyclosporine, and mycophenolate mofetil are not FDA-approved for atopic dermatitis but all 3 are compendia-supported for use in adults; azathioprine and cyclosporine are also compendia-supported for use in pediatric patients. Methotrexate is neither FDA-approved nor compendia-supported for atopic dermatitis.	Joint Task Force 2023 guidelines: Conditional recommendation with low certainty of evidence for adding cyclosporine as a replacement for other systemic treatment (including biologics) when response is inadequate, but **against** adding azathioprine, mycophenolate mofetil, or methotrexate. American Academy of Dermatology 2024 adult guidelines: Conditional recommendation, based on low or very low certainty of evidence, favoring use of these agents with proper monitoring in adults with refractory moderate to severe atopic dermatitis. 2024 US expert consensus on use of systemic therapies in children and adolescents: "…Careful consideration should be given to when these agents should be used, such as when there are concomitant conditions (e.g., juvenile arthritis, inflammatory bowel disease) that could be managed by these drugs."	All of these guidelines and statements note that atopic dermatitis is an off-label use for these conventional immunosuppressants. Though they are less costly than newer systemic therapies and have been used off-label for decades to treat refractory disease, they are associated with safety concerns and require laboratory monitoring. Consensus guidelines which support use of oral and parenteral methotrexate for inflammatory skin disease, including atopic dermatitis, in pediatric patients were published in 2023.

Place in Therapy: Clinical Guidance

Management of Moderate to Severe Atopic Dermatitis with Systemic Pharmacologic Therapies, continued		
Drugs / FDA Label Information	Guideline Recommendations	Additional Comments
Systemic corticosteroids • Examples: dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone, triamcinolone FDA-approved uses for oral and injectable formulations of the above corticosteroids include atopic dermatitis as one of several allergic conditions, with the indication for controlling severe or incapacitating symptoms when conventional treatments fail.	Joint Task Force 2023 guidelines: Conditional recommendation **against** systemic corticosteroids for all patients. American Academy of Dermatology 2024 adult guidelines: Conditional recommendation **against** systemic corticosteroids. 2024 US expert consensus on use of systemic therapies in children and adolescents: Systemic corticosteroid use is generally **not recommended** for pediatric patients.	Due to the potential for significant harms and burdens compared to transient benefit, systemic corticosteroids should be reserved for acute, severe exacerbations and as a short-term bridge to other non-corticosteroid systemic therapies.

Potential sequence/overlap of prescription topical and systemic treatments recommended for atopic dermatitis

Mild to severe atopic dermatitis: Topical corticosteroid as needed and/or proactively to control inflammation

Topical corticosteroids:

<u>High/very high potency</u>

Short-term only, up to 4 weeks (2 weeks for younger children), in severe disease or to control flares in non-sensitive areas

<u>Medium potency</u>

Recommended for intermittent (e.g., twice weekly) maintenance to reduce flares and relapse

Additional/alternate therapy: Topical immunomodulators

Topical calcineurin inhibitors:

Recommended steroid-sparing option for sensitive areas and intermittent maintenance therapy in mild to severe disease

Phosphodiesterase-4 inhibitors:

Alternate option for mild to moderate disease

Topical Janus kinase inhibitor:*

Alternate option for mild to moderate disease

Aryl hydrocarbon receptor agonist:

Alternate option for any severity; recommended for moderate to severe disease

Moderate to severe atopic dermatitis: Systemic immunomodulators

Biologics (monoclonal antibodies):

Recommended first-line systemic therapy for moderate to severe disease when topical prescription treatments are inadequate or not advised; may be used with topical corticosteroids or topical calcineurin inhibitors

Systemic Janus kinase inhibitors:

Recommended for refractory moderate to severe disease not adequately controlled with other systemic agents, including biologics, or when they are not advised; should not be combined with biologics or with topical Janus kinase inhibitors

*Refers to ruxolitinib; delgocitinib is only FDA-approved for moderate to severe hand eczema.

Additional Literature

- 2024 Cochrane review and network meta-analysis of topical anti-inflammatory therapies for eczema
  - Most effective = potent topical corticosteroids, tacrolimus, Janus kinase inhibitors
  - Least effective = phosphodiesterase-4 inhibitors, mild topical corticosteroids, tapinarof
  - Safety: topical calcineurin inhibitors and crisaborole most likely to cause application site reactions, topical corticosteroids least likely; no skin thinning observed with ≤16 weeks of topical corticosteroid use but increased with >16 weeks of use
- 2024 Living systematic review and network meta-analysis of systemic immunomodulatory treatments for atopic dermatitis
  - Main objective was to compare lebrikizumab to other systemic immunomodulators, however all agents (biologics and Janus kinase inhibitors) were compared to dupilumab based on 4 outcome measures
  - Mixed results depending on measure and dose; most commonly the other agents were comparable or associated with less improvement compared to dupilumab; on 3 measures higher doses of a Janus kinase inhibitor were associated with more improvement than dupilumab.

Lax SJ et al. Cochrane Database of Systematic Reviews 2024, Issue 8.
Drucker AM et al. *JAMA Dermatol*. 2024;160(9):936-944.

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 for nonpreferred agents, the following selected criteria were identified:
  - 6 programs manage atopic dermatitis as separate therapeutic category.
  - For topical corticosteroids, 1 program requires prior authorization for >4 weeks of all high potency agents and >2 weeks of all very high potency agents.
  - For topical immunomodulators, all 9 programs have age, diagnosis, and frequency/quantity/duration limits, 5 programs require step therapy with trials of preferred topical corticosteroids and topical calcineurin inhibitors prior to other topical immunomodulators.
  - For systemic immunomodulators, all 9 programs have age, diagnosis, and frequency/quantity/duration limits, 6 programs require step therapy with trials of preferred topical corticosteroids and topical calcineurin inhibitors for all systemic agents and 6 programs additionally require a trial of 1 or more biologics prior to systemic Janus kinase inhibitors. Additionally, 2 programs do not allow combinations of systemic immunomodulators or combinations of Janus kinase inhibitors (systemic or topical).

Methodology

- A retrospective analysis of pharmacy and medical claims was conducted to evaluate the utilization of atopic dermatitis drugs among NYS Medicaid members with a diagnosis of atopic dermatitis.
- Diagnoses were identified using International Classification of Diseases-tenth revision (ICD-10) codes. The ICD-10 L20 category classifies atopic dermatitis diagnoses. ICD-10 L40 category classifies psoriasis diagnoses.
  - Inclusion criteria:
    - Members with ≥2 distinct dates of service with any L20 diagnosis code during the analysis period AND with ≥1 pharmacy claim for an atopic dermatitis drug during the analysis period
  - Exclusion criteria:
    - Members who also had an ICD-10 L40 diagnosis code during the analysis period

Methodology

- Atopic dermatitis drugs included in the analysis (listed in previous tables) were grouped as follows:
  - Topical therapies
    - Topical corticosteroids
    - Topical immunomodulators
    - Doxepin cream
  - Systemic therapies
    - Systemic immunomodulators
    - Systemic immunosuppressants
    - Systemic corticosteroids

Methodology

- Analysis period: April 1, 2023 – March 31, 2025 (2 years)
  - State Fiscal Year 2024: April 1, 2023 – March 31, 2024
  - State Fiscal Year 2025: April 1, 2024 – March 31, 2025
- Data source: Medicaid Data Warehouse
- The Medicaid Confidential Data Cell Size Policy (OHIP-0001) requires that no cell containing a value of 1 to 30 be reported.
- While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete.
- Results for number of members and claims are reported to the nearest 100 and results for percentages are reported to the nearest percent.

Methodology

- Objectives: To evaluate utilization of atopic dermatitis drugs during State Fiscal Years 2024 and 2025 in members with a diagnosis of atopic dermatitis, and assess the following:
  - Overall utilization and utilization of drugs in each therapeutic drug category
  - Utilization of topical and other systemic agents in members receiving systemic immunomodulators
  - Utilization of topical and other systemic agents in members NOT receiving systemic immunomodulators

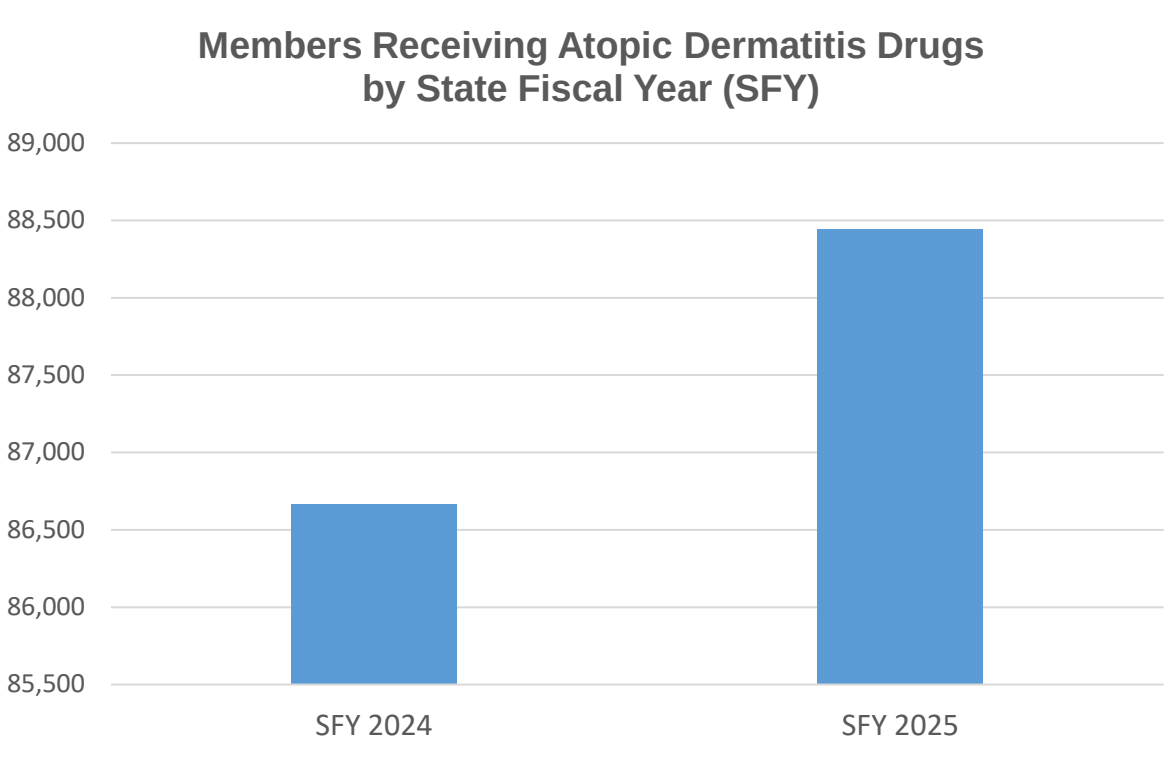
NYS Medicaid members with atopic dermatitis diagnosis during State Fiscal Years 2024 and 2025

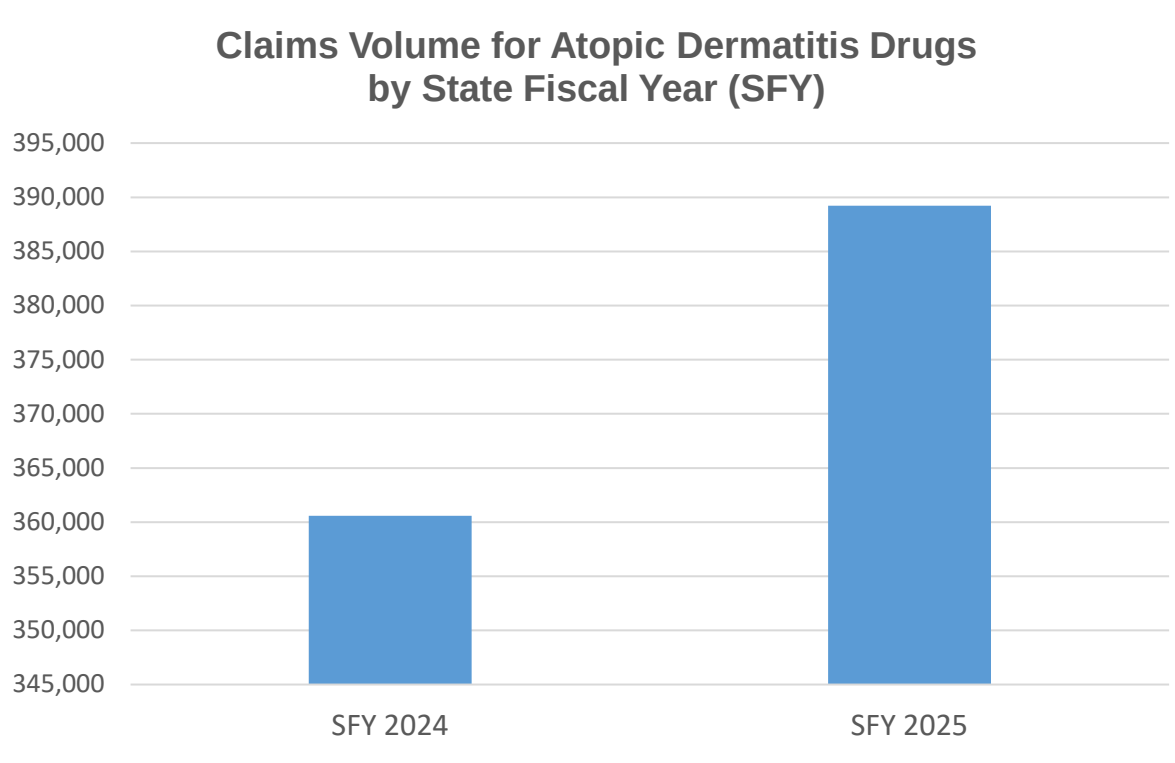
State Fiscal Years 2024-2025	Unique members with ≥2 distinct dates of service for any atopic dermatitis diagnosis*	138,200	%
	Unique members with ≥2 distinct dates of service for any atopic dermatitis diagnosis* AND received atopic dermatitis drug(s)	114,700	83%
	Unique members with ≥2 distinct dates of service for any atopic dermatitis diagnosis* and DID NOT receive atopic dermatitis drug(s)	23,500	17%

Data source: Medicaid Data Warehouse Date range: 4/1/2023 – 3/31/2025 *Excludes members with a diagnosis of psoriasis

- A total of 114,700 members with a diagnosis of atopic dermatitis received a total of 749,800 claims for atopic dermatitis drugs during the 2-year analysis period.
- These members comprise the overall analysis population for the remainder of this review.

Overall utilization of atopic dermatitis drugs in State Fiscal Years 2024 and 2025





Data source: Medicaid Data Warehouse. Date range: 4/1/2023 – 3/31/2025. Members had atopic dermatitis diagnosis on ≥2 dates of service during the analysis period. Members are not additive.

- Between State Fiscal Years 2024 and 2025:
  - Number of members who received atopic dermatitis drugs increased by 2%.
  - Number of claims for atopic dermatitis drugs increased by 8%.

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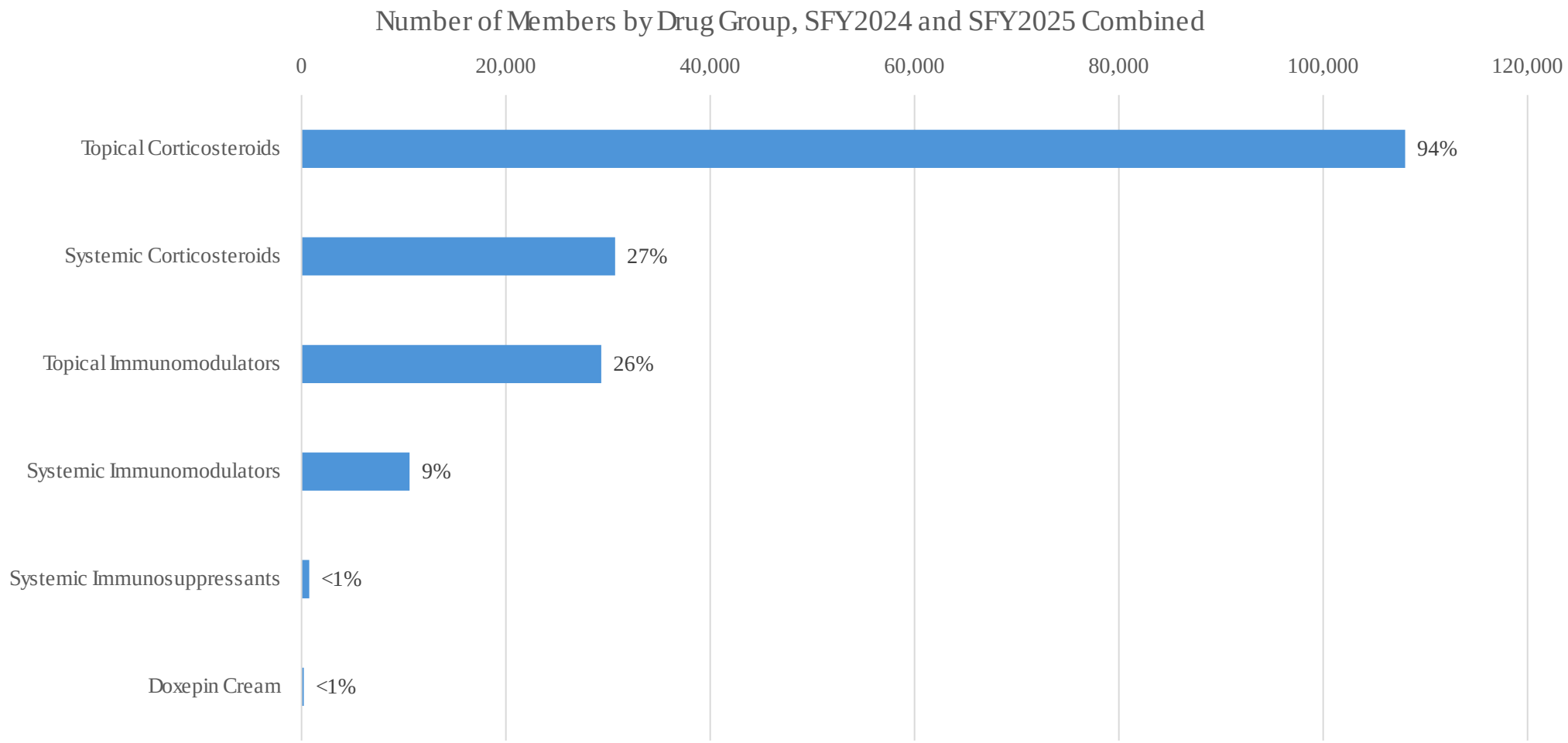
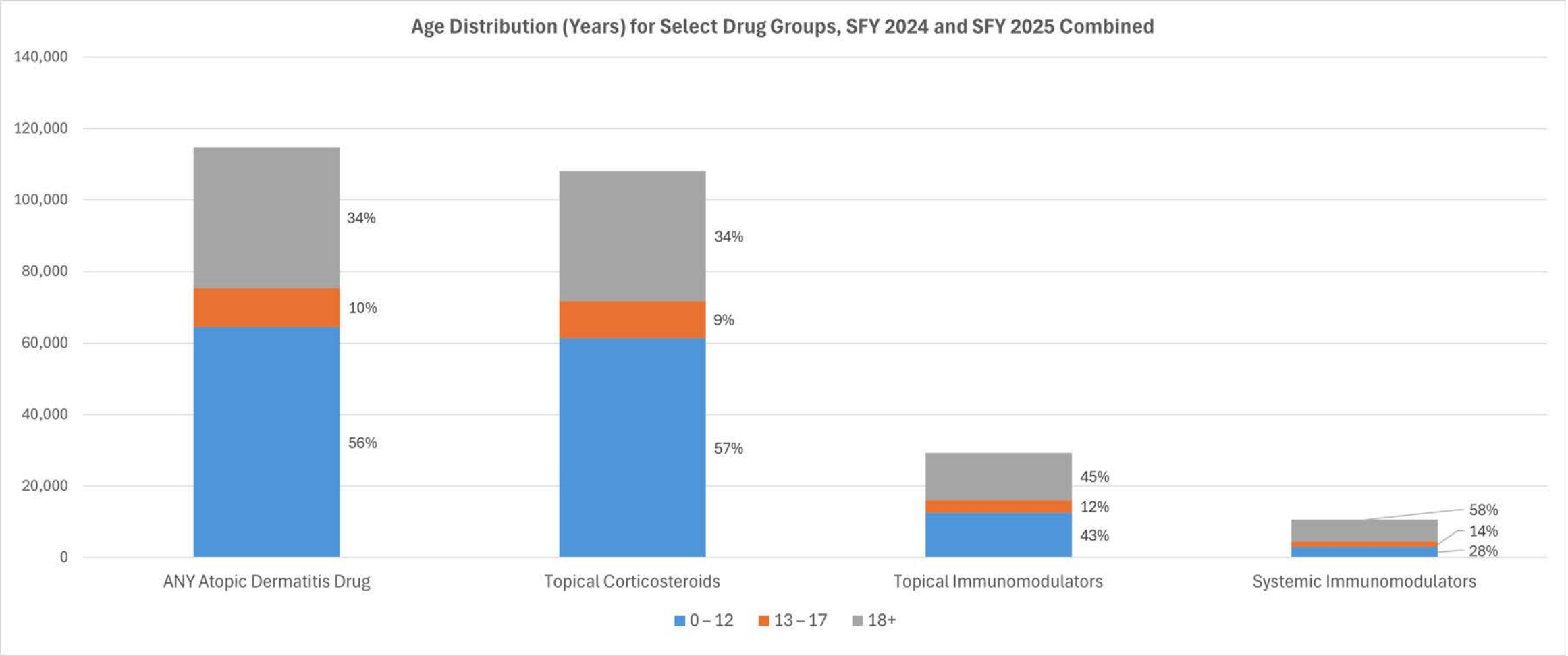
Overall utilization of atopic dermatitis drug groups



Data source: Medicaid Data Warehouse. Date range: 4/1/2023 – 3/31/2025. Members had atopic dermatitis diagnosis on ≥2 dates of service during the analysis period. Percentages are not additive.

Overall age distribution for select drug groups



Data source: Medicaid Data Warehouse. Date range: 4/1/2023 – 3/31/2025. Members had atopic dermatitis diagnosis on ≥2 dates of service during the analysis period.

- More pediatric/adolescent members received treatment compared to adults (66% vs 34%), but more adults received treatment for moderate to severe disease with systemic immunomodulators (58% vs 42%).

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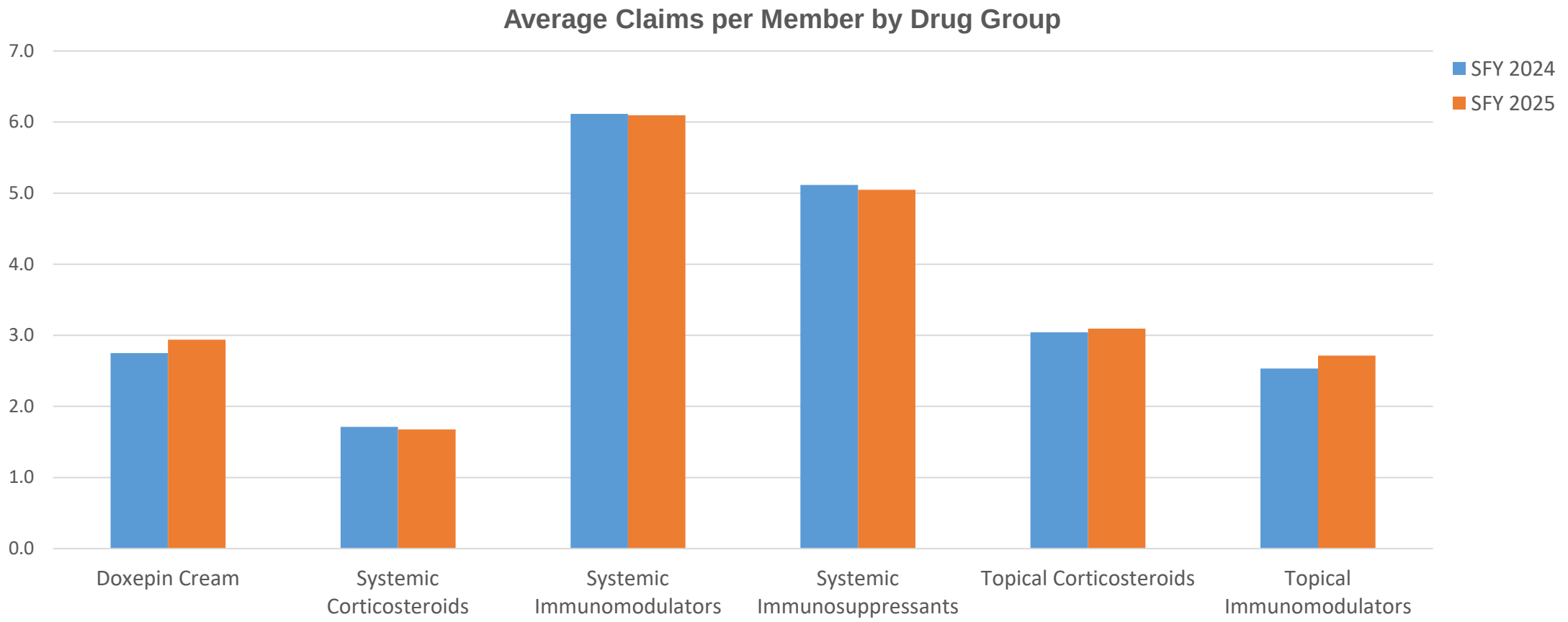
Average claims per member in State Fiscal Years 2024 and 2025



Data source: Medicaid Data Warehouse. Date range: 4/1/2023 – 3/31/2025. Members had atopic dermatitis diagnosis on ≥2 dates of service during the analysis period.

- Average claims per member stayed relatively consistent between State Fiscal Years 2024 and 2025 in each drug group.
- Average claims per member was highest for systemic immunomodulators (6) and lowest for systemic corticosteroids (<2); topical drug groups averaged between 2 and 3 claims per member per year.

Utilization of other drug groups in members WITHOUT systemic immunomodulators during State Fiscal Years 2024 and 2025

Members without systemic immunomodulators (n=104,100) who received topical and/or other systemic drug groups during the 2-year period		
Atopic dermatitis drug groups	**Members**	**%**
Topical corticosteroids AND/OR topical immunomodulators	100,500	
• Topical corticosteroids and NO topical immunomodulators	77,100	77%
• Topical immunomodulators and NO topical corticosteroids	1,800	2%
• BOTH topical corticosteroids AND topical immunomodulators	21,600	21%
Other systemic agents (immunosuppressants AND/OR corticosteroids)	23,700*	

Data source: Medicaid Data Warehouse. Date range: 4/1/2023 – 3/31/2025. Members had atopic dermatitis diagnosis on ≥2 dates of service during the analysis period.
*Members with other systemic agents are not additive to those with topical agents

- 100,500 / 104,100 (97%) members who did not receive systemic immunomodulators during the 2-year analysis period received topical corticosteroids and/or topical immunomodulators.
- 23,700 / 104,100 (23%) members without systemic immunomodulators received conventional systemic agents which may or may not have been prescribed for atopic dermatitis.

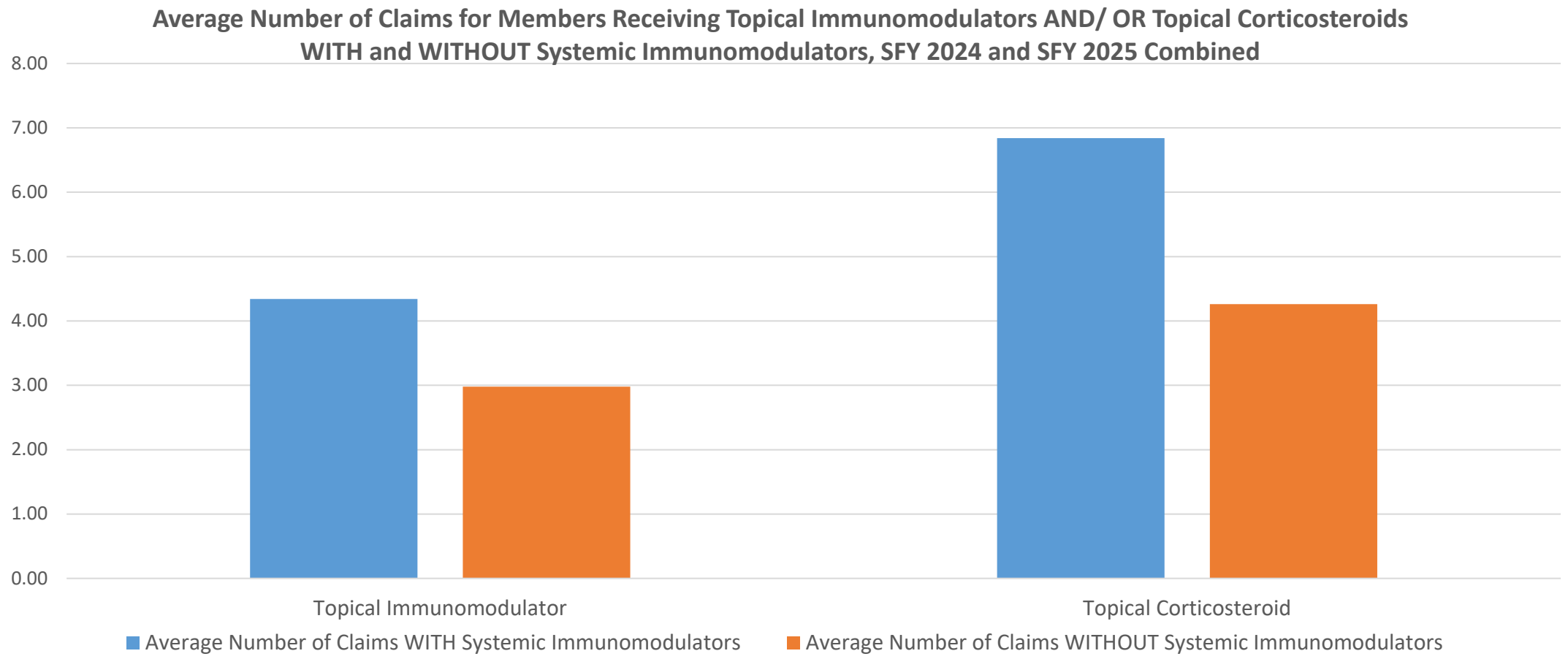
Overlapping utilization of other drug groups in members WITH systemic immunomodulators during State Fiscal Years 2024 and 2025

Members who received systemic immunomodulators (n=10,600) with topical and/or other systemic agents within 90 days of systemic immunomodulator fill date during 2-year period		
Drugs concurrent with systemic immunomodulators	**Members**	**%**
Topical corticosteroids AND/OR topical immunomodulators	9,200	
• Topical corticosteroids and NO topical immunomodulators	4,000	43%
• Topical immunomodulators and NO topical corticosteroids	600	7%
• BOTH topical corticosteroids AND topical immunomodulators	4,600	50%
Other systemic agents (immunosuppressants AND/OR corticosteroids) with or without topical agents	2,900*	

Data source: Medicaid Data Warehouse. Date range: 4/1/2023 – 3/31/2025. Members had atopic dermatitis diagnosis on ≥2 dates of service during the analysis period.
*Members with other systemic agents are not additive to those with topical agents

- 9,200 /10,600 (87%) members who received systemic immunomodulators received topical corticosteroids and/or topical immunomodulators within 90 days.
- Of note, among members who received a topical immunomodulator with a systemic immunomodulator, more than 100 members received a topical Janus kinase inhibitor (ruxolitinib), including 55% who received ruxolitinib with a systemic Janus kinase inhibitor. FDA labeling recommends against these combinations.
- Also, among the 2,900 members who received conventional systemic agents with systemic immunomodulators, nearly 200 members received a systemic Janus kinase inhibitor. FDA labeling recommends against these combinations as well.

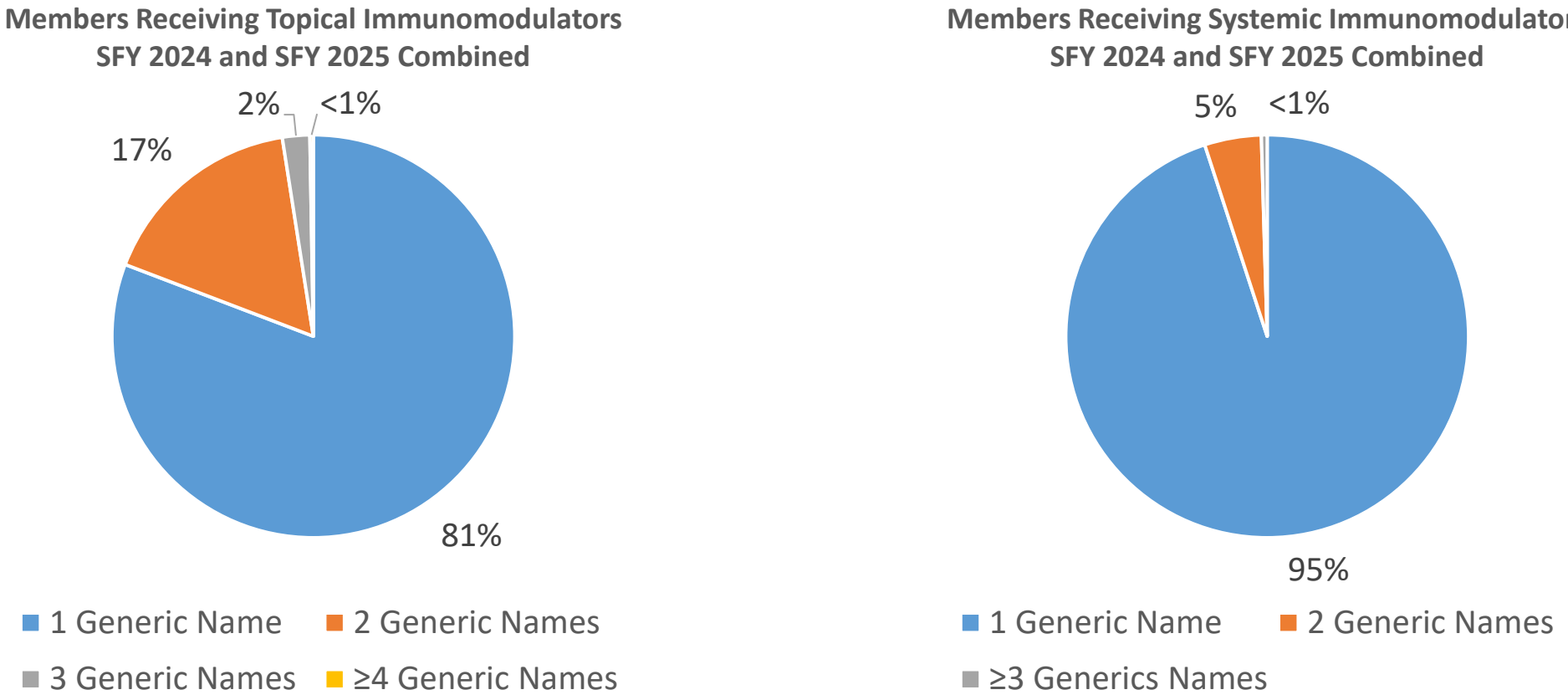
Utilization of topical drug groups in members with and without systemic immunomodulators



Data source: Medicaid Data Warehouse. Date range: 4/1/2023 – 3/31/2025. Members had atopic dermatitis diagnosis on ≥2 dates of service during the analysis period.

- Utilization of topical immunomodulators and/or topical corticosteroids (average claims per member) was higher in members who utilized systemic immunomodulators compared to members who did not.

Number of topical or systemic immunomodulators per member by generic drug name



Data source: Medicaid Data Warehouse. Date range: 4/1/2023 – 3/31/2025. Members had atopic dermatitis diagnosis on ≥2 dates of service during the analysis period. Percentages add up to slightly more than 100% due to rounding.

- The vast majority of members who received topical or systemic immunomodulators received only 1 distinct agent based on generic drug name during the 2-year analysis period.
- Members receiving more than 1 distinct agent may have switched and/or used multiple agents concurrently.

Conclusions

- Atopic dermatitis is a common chronic allergic inflammatory skin condition affecting individuals of all ages and with varying degrees of severity.
- Treatment focuses on management of symptoms and there are several topical and systemic agents with FDA-approved or compendia-supported use for atopic dermatitis.
- Evidence-based guidelines and consensus statements in the US continue to evolve, but all describe a stepwise patient-centered treatment approach starting with baseline use of emollient moisturizers for all individuals and use of topical prescription therapies for symptom control, progressing to systemic therapy when topical treatment is inadequate.

Conclusions

- **Topical corticosteroids** are recommended as first-line therapy for mild to severe disease as needed and/or to proactively control inflammation.
  - High- and very high-potency agents should only be used short-term in severe disease or to control flares in non-sensitive areas; medium-potency agents are recommended for intermittent maintenance to reduce flares and relapse.
- **Topical immunomodulators:**
  - **Calcineurin inhibitors** are recommended as a first-line steroid-sparing option for sensitive areas and intermittent maintenance therapy in mild to severe disease.
  - **Phosphodiesterase-4 inhibitors, Janus kinase inhibitors, and aryl hydrocarbon receptor agonist** are recommended as alternative steroid-sparing options for mild to moderate disease and/or moderate to severe disease.
- **Doxepin cream**, a topical antihistamine, is not recommended due to risk of adverse effects outweighing any benefit

Conclusions

- **Systemic immunomodulators:**
  - **Interleukin inhibitors** (aka, biologics) are recommended as first-line systemic therapy for moderate to severe disease and may be used with topical corticosteroids or calcineurin inhibitors.
  - **Janus kinase inhibitors** are recommended for refractory moderate to severe disease not adequately controlled with other systemic agents, including biologics, and should not be combined with biologics or other Janus kinase inhibitors, including topical agents.
- Comparator state Medicaid programs have implemented multiple clinical criteria, step criteria, and frequency/quantity/duration limits for atopic dermatitis drugs which are consistent with guideline recommendations and FDA labeling.

Conclusions

- A retrospective analysis encompassing State Fiscal Years 2024 and 2025, identified the following utilization trends among NYS Medicaid members with a diagnosis of atopic dermatitis:
  - 114,700 members with a diagnosis of atopic dermatitis received 749,800 claims for atopic dermatitis drugs
  - The number of members who received atopic dermatitis drugs increased 2% and the number of claims increased 8% between State Fiscal Years 2024 and 2025.
  - Topical corticosteroids were the most used agents (94% of members) and doxepin cream was least used (<1%) during the 2-year period. Average claims per member per year was approximately 3 for topical corticosteroids and <3 for doxepin cream.
  - **Of note, a separate analysis identified much higher utilization rates of both topical corticosteroids and doxepin cream among members WITHOUT a diagnosis of atopic dermatitis during this time frame. Therefore, those findings along with the recommendations for topical corticosteroids and doxepin cream will be presented separately.**

Conclusions

- Utilization trends in State Fiscal Years 2024 and 2025, continued:
  - The age distribution of members receiving any atopic dermatitis treatment was skewed toward younger members (66% children/adolescents vs 34% adults), while treatment for moderate to severe disease with systemic immunomodulators was skewed toward adults (42% vs 58%, respectively)
  - Overall, more than 90% of members did not receive a systemic immunomodulator during the 2-year period, and almost all these members received topical corticosteroids and/or topical immunomodulators. This may represent treatment of mild to moderate disease in most members, however approximately 20% of them received conventional systemic agents, which may or may not have been prescribed for atopic dermatitis.
  - Fewer than 10% of members received systemic immunomodulators and most of these members received overlapping claims for topical corticosteroids and/or topical immunomodulators.
    - A small proportion of members had overlapping claims for a topical Janus kinase inhibitor and a systemic immunomodulator, including systemic Janus kinase inhibitors. Also, some members had overlapping claims for systemic Janus kinase inhibitors and conventional systemic agents. FDA labeling recommends against these combinations.

Conclusions

- Utilization trends in State Fiscal Years 2024 and 2025, continued:
  - Overall, utilization of systemic immunomodulators was more consistent and utilization of topical corticosteroids and topical immunomodulators was more intermittent (6 and ≤3 claims per member per year, respectively).
  - Utilization of topical corticosteroids and topical immunomodulators was higher in members with systemic immunomodulators compared to members without systemic immunomodulators. This may be another marker of more severe disease, however, future analysis is needed to assess utilization of topical agents before and after initiating systemic immunomodulators.
  - The vast majority of members who received topical or systemic immunomodulators persisted with the same agent during the 2-year period, 81% and 95%, respectively. This indicates a low incidence of switching or concurrent use of multiple drugs from the same drug group. While it is possible some members may be prescribed more than 1 topical immunomodulator to use at different times or on different areas of the body as part of a steroid-sparing regimen, FDA labeling recommends against concurrent use of multiple systemic immunomodulators.

NYRx Preferred Drug List Criteria

Topical Immunomodulators for Atopic Dermatitis

Dermatologic Agents		
Immunomodulators & Related Agents – Topical[cc]		
Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
Eucrisa® pimecrolimus tacrolimus	Anzupgo® Opzelura® Vtama® Zoryve®	Clinical Criteria (CC): • Confirm diagnosis of FDA-approved, compendia-supported, and Medicaid-covered indication

Source: NYRx, the New York Medicaid Pharmacy Program Preferred Drug List. https://newyork.fhsc.com/downloads/providers/nyrx_pdp_pdl.pdf. Revised: 1/20/26. Accessed: 1/21/26.

NYRx Preferred Drug List Criteria

Systemic Immunomodulators for Atopic Dermatitis

Immunologic Agents		
Immunomodulators – Systemic CC, ST		
Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
Interleukin Inhibitors		Clinical Criteria (CC): • Confirm diagnosis for FDA-approved or compendia-supported indication and Medicaid-covered indication Step Therapy (ST) Indication-Specific Requirements: • Atopic dermatitis - Trial with a topical prescription product for a duration of at least 3 months. - For JAK inhibitors: Trial of topical prescription product and systemic product for a combined duration of at least 6 months.
Dupixent® Ebglyss®	Adbry® Nemluvio®	
JAK Inhibitors		
	Cibinqo® Olumiant® Rinvoq® ER	

Source: NYRx, the New York Medicaid Pharmacy Program Preferred Drug List. https://newyork.fhsc.com/downloads/providers/nyrx_pdp_pdl.pdf. Revised: 1/20/26. Accessed: 1/21/26.

Recommendations

Based on the available clinical guidance, and analysis of utilization in the NYRx program, the following recommendations may be considered:

1. For topical immunomodulators, in addition to the current diagnosis requirement, add the following criteria for atopic dermatitis:
   - Age edits for all agents, consistent with FDA labeling
   - Step Therapy for nonpreferred agents: Trial of a preferred medium or higher potency topical corticosteroid or preferred topical immunomodulator for a duration of at least 3 months
   - For Janus kinase inhibitors:
     - Frequency/quantity/duration limits:
       - Anzupgo® 30 g with 2 refills per year
       - Opzelura® 60 g with 2 refills per year
     - No concurrent use of Janus kinase inhibitors, topical or systemic
     - No concurrent use of topical Janus kinase inhibitors with any systemic immunomodulators

Recommendations

2. For systemic immunomodulators, in addition to the current diagnosis requirement, add the following criteria for atopic dermatitis:
   - Age edits for all agents, consistent with FDA labeling
   - Step Therapy for preferred and nonpreferred agents: Trial of preferred medium or higher potency topical corticosteroid or preferred topical immunomodulator for a duration of at least 3 months
   - For Janus kinase inhibitors: Trial of preferred medium or higher potency topical corticosteroid or preferred topical immunomodulator AND trial of a preferred systemic immunomodulator for a combined duration of at least 6 months
   - No concurrent use of more than 1 systemic immunomodulator
   - No concurrent use of systemic immunomodulators with topical Janus kinase inhibitors

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NEW YORK STATE | Department of Health

High-Cost Drug / Drug Cap Overview

NYS MEDICAID DRUG UTILIZATION REVIEW BOARD

February 26, 2026

HIGH-COST DRUG AND DRUG CAP OVERVIEW

	High-Cost Drug	Drug Cap
Authorizing Statute	NYS Social Services Law §367-a	NYS Public Health Law §280
Applicable	Newly launched high-cost drugs	Overall drug expenditures
Criteria for Identification of Drugs	Meets one of the following conditions: • Brand name drug/biologic with launch wholesale acquisition cost (WAC) >$30,000/year or course of treatment. • Biosimilar drug with launch WAC that is not at least 15% lower than the referenced brand biologic at time of launch. • Generic drug with WAC >$100 for a 30-day supply or recommended dosage approved for labeling by FDA. • Brand name drug/biologic with a WAC increase of >$3,000 in any 12-month period, or course of treatment <12 months.	Meets one of the following conditions: • 80th percentile or higher of total spend, net of rebate. • 80th percentile or higher based on cost per claim, net of rebate.
Overview of Process	Step 1: Voluntary Supplemental Rebate Agreement Step 2: Request for Confidential Financial Information Step 3: DUR Board Referral	

NEW YORK STATE | Department of Health

DRUG IDENTIFICATION & DUR BOARD REFERRAL

High-Cost Drug

The commissioner may identify and refer high-cost drugs to the drug utilization review board for a recommendation as to whether a target supplemental rebate should be paid by the manufacturer and the target amount of the rebate.

Drug Cap

The commissioner may identify and refer drugs (in the 80th percentile or higher of total spend, net of rebate or in the 80th percentile or higher based on cost per claim, net of rebate) to the drug utilization review board for a recommendation as to whether a target supplemental rebate should be paid by the manufacturer and the target amount of the rebate.

DAYBUE - CRITERIA FOR IDENTIFICATION

High-Cost Drug

Brand name drug or biologic with launch wholesale acquisition cost (WAC) greater than $30,000 per year or course of treatment.

Drug Cap

Eightieth percentile or higher based on cost per claim, net of rebate.

NEW YORK STATE | Department of Health

DAYBUE – MANUFACTURER CORRESPONDENCE

Correspondence	High-Cost Drug	Drug Cap
DOH notified manufacturer and attempted to reach a supplemental rebate agreement.	August 2023	October 2024
The manufacturer declined to offer DOH a supplemental rebate.	September 2023	December 2024
DOH requested confidential financial information from the manufacturer.	October 2023	December 2024
Manufacturer submitted confidential financial information to DOH.	October 2023	January 2025

NEW YORK STATE | Department of Health

DUR Board Member Questions

Value Assessment of Trofinetide (Daybue®)

February 26, 2026 – New York State Medicaid Drug Utilization Review Board Meeting

Presentation Overview

Executive Summary

Clinical Overview

- Rett Syndrome: Clinical Background
- Trofinetide Background and Dosing
- Trofinetide Clinical Trial Results
- Trofinetide Safety Profile
- Regulatory Assessment

Utilization & Pricing

- Trofinetide Utilization Trends
- Economic Input: Cost Overview

Pricing Strategy and Recommendation

- Pricing Methodology & Model Assumptions
- Trofinetide Clinical Efficacy
- Key Limitations
- Target Price Methodology - Summary
- Primary Target Price: Responder-Weighted Clinical Global Impression – Improvement (CGI-I) Scale Method
- Target Price Calculation
- Alternative Target Price Benchmark
- Trofinetide Recommendation

Q&A

Executive Summary

Trofinetide (Daybue®) Value & Pricing Assessment – Rett Syndrome

Daybue® (trofinetide) is the first and only Food and Drug Administration-approved therapy for Rett syndrome. The available evidence indicates statistically significant changes on caregiver-reported and clinician global measures, but the clinical meaningfulness and the durability of benefit remain uncertain. In New York Medicaid, utilization has remained in the 30 unique user range annually, with high discontinuation consistent with trial experience.

- Clinical Endpoints: Rett Syndrome Behavior Questionnaire (RSBQ) improved 4.9 points vs 1.7 on placebo (3.2-point difference); Clinical Global Impression – Improvement (CGI-I) Scale averaged 3.5 (between no change and minimally improved); there is no established threshold for clinically meaningful improvement.
- Cost is the dominant budget driver: trofinetide's average annual wholesale acquisition cost of $518,154 exceeds the high-cost drug pricing legislation threshold of New York State, and, published total Rett syndrome health care costs ($45,387 per year).
- An efficacy-adjusted cost-offset model yields a target net cost of $112,587 per year or a unit net price of $5.13, implying a total rebate of 78.3%.

1

Clinical Overview

Rett Syndrome: Clinical Background

Incidence: Estimated 1 in every 10,000 – 15,000 females by age 12 in the United States

Clinical Presentation

- Normal development in first 6-18 months
- Progressive loss of hand function and spoken language
- Gait abnormalities and stereotyped hand movements

Genetic Cause

- 90-95% of classic Rett syndrome caused by spontaneous Methyl-CpG-Binding Protein 2 mutation
- Located on X chromosome
- Almost exclusively affects females

Disease Progression

- Multisystem clinical manifestations evolve throughout lifespan
- Neurological, gastrointestinal, cardiac complications
- Endocrine and orthopedic disorders

Current Treatment Landscape

- No cure currently available
- Symptom management and support for daily activities
- Lifelong care from multiple subspecialty providers required
- Trofinetide is currently the only Food and Drug Administration approved therapy for Rett Syndrome

May D, Kponee-Shovein K, Mahendran M, et al. Epidemiology and patient journey of Rett syndrome in the United States: a real-world evidence study. *BMC Neurol*. 2023;23(1):141. Published 2023 Apr 4. doi:10.1186/s12883-023-03181-y

Trofinetide Background and Dosing

Background

Drug: Trofinetide (synthetic analog of glycine-proline-glutamate)

Indication: Treatment of Rett syndrome in adults and pediatric patients at least 2 years of age or older

Approval: Food and Drug Administration approved March 2023

Dosing and Administration

Route: Oral solution (200 milligram/milliliter)

Frequency: Twice daily (morning and evening)

Pricing

Unit Wholesale Acquisition Cost: $23.66 (As of Quarter 3, 2025)

Weight-based dosing:	Annual WAC
9 to less than 12 kilograms: 5,000 milligrams (25 milliliter) twice daily	$431,795
12 to less than 20 kilograms: 6,000 milligrams (30 milliliter) twice daily	$518,154
20 to less than 35 kilograms: 8,000 milligrams (40 milliliter) twice daily	$690,872
35 to less than 50 kilograms: 10,000 milligrams (50 milliliter) twice daily	$863,590
Greater than or equal to 50 kilograms: 12,000 milligrams (60 milliliter) twice daily	$1,036,308

Trofinetide Clinical Trial Results

Rett Syndrome Behavior Questionnaire (RSBQ)

Trofinetide: -4.9 points | Placebo: -1.7 points

Difference: -3.2 (p=0.018)

No established threshold for clinically meaningful improvement

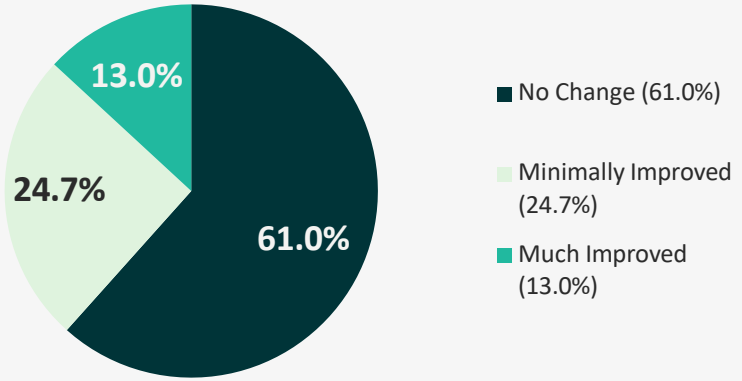
Clinical Global Impression – Improvement (CGI-I) Scale

Trofinetide: 3.5 | Placebo: 3.8

Difference -0.3 (p=0.003)

Halfway between "no change" and minimal improvement

Trofinetide Clinical Global Impression-Improvement Clinical Trial Results



Statistically significant does not equal clinically meaningful benefit

Neul JL, Percy AK, Benke TA, et al. Trofinetide for the treatment of Rett syndrome: a randomized phase 3 study. *Nat Med*. 2023;29(6):1468-1475. doi:10.1038/s41591-023-02398-1

Trofinetide Safety Profile

Most Common Side Effect

82%

experienced diarrhea

Vomiting

29%

of patients

High Discontinuation

19% withdrew due to side effects in randomized control trial at week 12; 45.5% in open-label study at week 40

Neul JL, Percy AK, Benke TA, et al. Trofinetide for the treatment of Rett syndrome: a randomized phase 3 study. *Nat Med*. 2023;29(6):1468-1475. doi:10.1038/s41591-023-02398-1
Open-label extension study of trofinetide for the treatment of girls and women with Rett syndrome (LILAC). ClinicalTrials.gov identifier: NCT04279314. Accessed May 22, 2025. https://clinicaltrials.gov/ct2/show/NCT04279314

Regulatory Assessment

Canadian Drug Expert Committee (CDEC)

DOES NOT RECOMMEND reimbursement for trofinetide

Key Concerns

- Uncertain clinical meaningfulness
- No established minimal important differences
- Limited Rett Syndrome Behavior Questionnaire measurement validity

Outcome Uncertainty

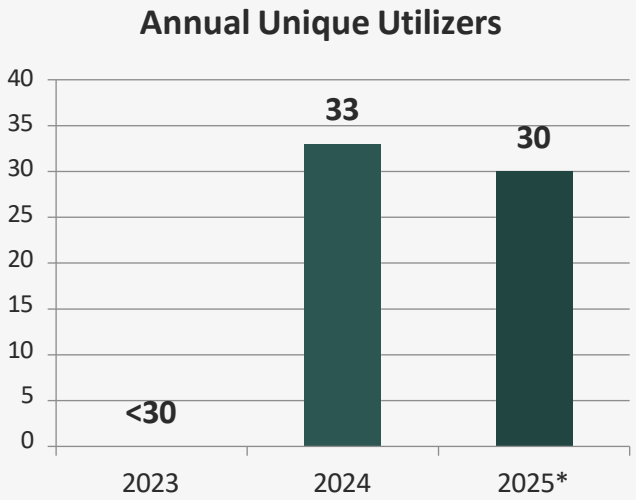
- No direct primary outcome to track related to Rett Syndrome
- Motor skills benefits uncertain
- Caregiver burden impact unknown

Absence of standardized outcomes contributes to evidence uncertainty

2

Utilization & Pricing

Trofinetide Utilization Trends



* Data as of September 2025 obtained from New York State Medicaid Data Warehouse

49% Discontinuation Rate

^ Nearly half of all New York State Medicaid members who initiated trofinetide discontinued therapy

^ Discontinuation defined as greater than or equal to a 60-day gap in claims history with no restart observed

Key Observations:

- 49% real-world discontinuation rate aligns with 45.5% rate in open-label clinical trial
- High discontinuation driven by side effects and modest efficacy (61% showed no improvement)

Economic Input: Cost Overview

Trofinetide Unit Wholesale Acquisition Cost (As of Quarter 3, 2025)

$23.66

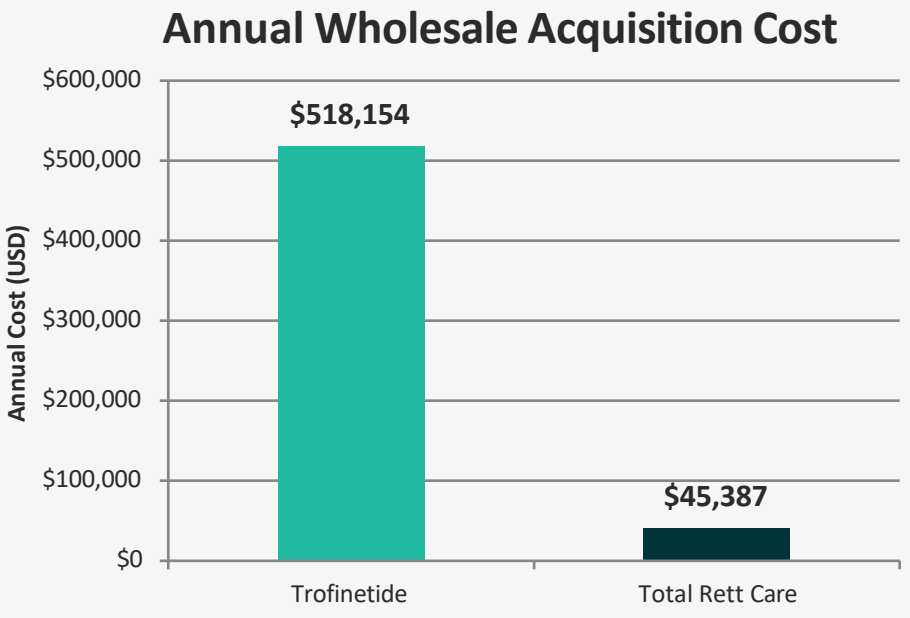
Trofinetide Average Annual Wholesale Acquisition Cost (2025)
Based on a 15-kilogram Individual

$518,154

Total Healthcare Costs*

$45,387

Trofinetide costs 11 times more than all other Rett Syndrome care combined



*May D, Kponee-Shovein K, Mahendran M, et al. Epidemiology and patient journey of Rett syndrome in the United States: a real-world evidence study. *BMC Neurol*. 2023;23(1):141. Published 2023 Apr 4. doi:10.1186/s12883-023-03181-y

3

Pricing Strategy and Recommendation

Pricing Methodology & Model Assumptions

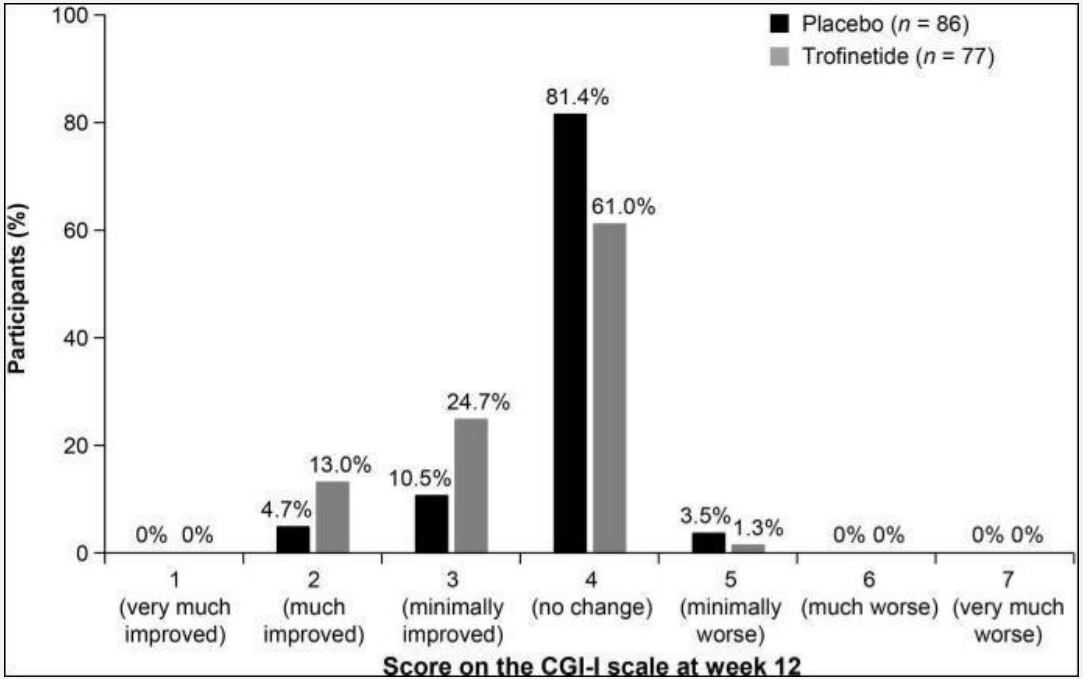
Introduction to the Model:

- Efficacy-Adjusted Cost-Offset Model
- Value-Based Pricing methodology that determines a reasonable price for a treatment based on its clinical efficacy and economic impact
- Objective: Align the price of the new treatment with the clinical outcomes and economic savings it generates, given the drug's modest effect size

Key Assumptions:

- Clinical Efficacy: Derived from trial data, where efficacy is represented by the percent of patients showing improvement (e.g., 13.0% much improved, 24.7% minimally improved)
- Base Cost of Standard Care: Current treatment costs for the disease (e.g., $45,387 for Rett syndrome care)
- Treatment Price: List price of the treatment (e.g., $518,154 for trofinetide) adjusted by the efficacy factor

Trofinetide Clinical Efficacy



Neul JL, Percy AK, Benke TA, et al. Trofinetide for the treatment of Rett syndrome: a randomized phase 3 study. *Nat Med*. 2023;29(6):1468-1475. doi:10.1038/s41591-023-02398-1

Key Limitations

Clinical Evidence

- No established minimal important difference for Clinical Global Impression – Improvement scale /Rett Syndrome Behavior Questionnaire in Rett; clinical meaning of a -0.3 Clinical Global Impression – Improvement shift is uncertain.
- Short clinical trial duration (12 weeks) limits confidence in durability and long-run functional impact.
- Benefit is heterogeneous: majority show no change; average effects may not reflect individual-level value.
- Open-label extension data are subject to selection/attrition bias and do not establish comparative effectiveness.

Economic & Data Limitations

- Claims-based discontinuation (greater than or equal to a 60-day gap, no restart) is a proxy and can misclassify temporary interruptions or data lags.
- Model does not quantify caregiver burden, education services, or long-term supportive care impacts (potential benefits and costs).
- Rebate illustrations simplify statutory dynamics (e.g., inflationary penalties, best price) and are intended for directional guidance only.

Target Price Methodology - Summary

- **Objective:** recommend an annual net price aligned to observed benefit and real-world persistence
- **Key inputs:**
  - Trofinetide annual wholesale acquisition cost (Quarter 3, 2025): $518,154
  - Baseline annual Rett syndrome healthcare costs: $45,387
  - Trial Clinical Global Impression – Improvement Scale distribution: 61.0% no change; 24.7% minimally improved; 13.0% much improved
- **Primary method:** responder-weighted Clinical Global Impression – Improvement Scale efficacy factor applied to WAC
- **Result:** target annual net = $112,587 (78.3% total rebate)

Primary Target Price: Responder-Weighted CGI-I Method

Step 1: Define improvement categories (Clinical Global Impression – Improvement Scale):

- Minimally improved (3) and much improved (2); no change = (4)

Step 2: Map categories to normalized improvement weights (relative to 3-step distance 4→1):

- Minimally improved: 1/3 (0.33); Much improved: 2/3 (0.66)

Step 3: Compute efficacy adjustment factor:

- Efficacy = ((24.7×0.33) + (13.0×0.66)) / 77 = 0.217

Step 4: Apply to annual wholesale acquisition cost to derive target annual net price:

- Target annual net = $518,154 × 0.217 = $112,587

Interpretation: Pay for the weighted share of patients achieving improvement on Clinical Global Impression – Improvement, recognizing heterogeneous response.

Target Price Calculation:

Efficacy Adjustment Factor

((24.7×0.33) + (13×0.66)) / 77 = 0.217

Calculation Formula

Target = (Trofinetide Price × Efficacy)

Average Annual Trofinetide Price: $518,154

Efficacy Factor: 0.217 (21.7% improvement rate)

Target Price Calculation

($518,154 × 0.217) = $112,587

Target Annual Net = $112,587 / year (78.3% total rebate)

Alternative Target Price Benchmark

Methodology

Step 1 — Baseline
Total annual Rett syndrome healthcare costs = **$45,387**

Step 2 — Efficacy Estimand
Clinical Global Impression – Improvement Scale
difference: 3.8 (placebo) − 3.5 (trofinetide) = **0.3**

Step 3 — Normalize
0.3 ≈ 30% of one Clinical Global Impression – Improvement Scale step (4='no change' → 3='minimally improved')

Step 4 — Incremental Value of Trofinetide
$45,387 × 30% = **$13,616 per year**
Standard of Care costs of $45,387 continue regardless of trofinetide use

Trofinetide Net Target Price

$13,616

per year (incremental value only)

Implied Total Rebate off Wholesale Acquisition Costs

97.4%

($518,154 – $13,616) ÷ $518,154

Q&A

Doxepin 5% Cream
Additional Information

February 26, 2026

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

Objectives

1. Evaluate the utilization of doxepin 5% cream for both State Fiscal Years 2024 and 2025.

2. Determine if the product is being used for the Food and Drug Administration-approved indications of atopic dermatitis or lichen simplex chronicus.

Background

- Food and Drug Administration-approved for the short-term use of up to 8 days for the management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

- Atopic dermatitis is a chronic pruritic inflammatory skin disease affecting approximately 7% to 10% of adults in the United States.

- Lichen simplex chronicus is a chronic, pruritic skin disorder characterized by well-demarcated, thickened, leathery plaques, which are the result of persistent rubbing or scratching. It is estimated to affect approximately 12% of adults in the United States.

- Doxepin 5% cream is not recommended as first-line therapy for atopic dermatitis or lichen simplex chronicus.

- Doxepin 5% cream [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; 2017.
- National Library of Medicine. Available at Atopic dermatitis: MedlinePlus Genetics. Accessed October 2025.
- *American Journal of Clinical Dermatology*. August 25, 2025. DOI:10.1007/s40257-025-00979-z.

Adverse Events

- Systemic absorption of doxepin 5% cream can result in drug levels comparable to oral doxepin.
- Patients have reported experiencing drowsiness, dry mouth, dizziness, headache, edema, and mental and emotional changes.
- The most common adverse event reported was local site irritation (e.g., burning or stinging at the site of application).
- 26 cases of allergic contact dermatitis were reported, and 20 of those cases were confirmed by positive patch tests to be the result doxepin 5% cream use.
- The drug should not be used in patients with narrow-angle glaucoma or urinary retention.

Doxepin 5% cream [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; 2017.

NYRx Status

- There are no compendia-supported indications for doxepin 5% cream.
- Not included in the NYRx Preferred Drug Program.
- The generic product is available in 45-gram tubes. The current quantity limit is 45 grams/ claim, with a days-supply of 30 days.

Comparator State Medicaid Coverage

- Comparator states: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington

- 5/9 of state Medicaid programs had established clinical criteria.
  - Three of the state Medicaid programs had quantity limits, and two of the state Medicaid programs have a monthly total claim quantity limit.
  - One of the state Medicaid programs requires a trial of a topical corticosteroid and immunomodulator.

Methodology

- A retrospective analysis of pharmacy claims was conducted for:
  - April 1, 2023 through March 31, 2024 (State Fiscal Year 2024) and
  - April 1, 2024 through March 31, 2025 (State Fiscal Year 2025).

- The data source was the New York State Medicaid Data Warehouse.

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

- Limitations:
  - The quantity limit allows for 45 grams to be dispensed per claim, with a days-supply of 30 days, which was implemented in April 2025. The impact of the quantity limit on utilization was not captured in this dataset.
  - While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete.

Results

Overall Estimated Doxepin 5% Cream Utilization					
State Fiscal Year (SFY)	Members*	Claims	Estimated Total Spend ($)	Quantity	Days Supply
SFY 2024	1,700	5,400	$4,100,000	378,000	152,200
SFY 2025	10,300	27,400	$26,300,000	3,200,000	802,100
Total	11,100	32,800	$30,400,000	3,570,000	954,300

*Member counts are not additive.
Data source= Medicaid Data Warehouse; Extract date: October 2025

From State Fiscal Year 2024 to State Fiscal Year 2025, there were increases of:

- 83.1% in members,
- 405.6% in claims, and
- 744.5% in the estimated total spend.

Results

- Demographics for State Fiscal Year 2025:
    - 99.5% of members were ≥18 years of age.
    - 56.4% of members were female.

Results:
Utilization for Members with Atopic Dermatitis or Lichen Simplex Chronicus

Timeframe State Fiscal Year 2025	Quantity Dispensed (grams)	Members (Not Additive)	Claims	Estimated Total Spend
Members with a Food and Drug Administration-approved diagnosis of atopic dermatitis and/or lichen simplex chronicus	45	280	890	$342,900
	90	260	810	$604,300
	135	1,100	2,800	$3,100,000
TOTAL		1,500	4,500	$4,000,000

Data source= Medicaid Data Warehouse Extract date: October 2025

- 14.8% of members had a diagnosis of atopic dermatitis and/or lichen simplex chronicus, resulting in 4,500 claims at an estimated spend of $4,000,000.
- The average number of claims annually per members was 3.0 claims.
- 20.0%, 18.0%, and 62.0% of claims were for quantities of ≤60 grams, 90 grams, or 135 grams, respectively.

Results:
Utilization for Members Without a Food and Drug Administration Approved Diagnosis

Timeframe State Fiscal Year 2025	Quantity Dispensed (grams)	Members (Not Additive)	Claims	Estimated Total Spend ($)
Members withOUT a Food and Drug Administration-approved diagnosis, but WITH a PAIN diagnosis (e.g., low back pain, chronic pain, dorsalgia, unspecified, or cervicalgia)	30	≤30	≤30	Not Applicable
	45	730	2,700	$966,100
	60	≤30	≤30	Not Applicable
	90	820	2,400	$1,800,000
	135	6,900	16,500	$18,300,00
TOTAL		8,205	21,500	$21,100,000
Members withOUT a Food and Drug Administration-approved diagnosis, and no relatable diagnosis	45	80	330	$124,700
	90	90	190	$134,500
	135	400	840	$949,900
TOTAL		560	1,700	$1,200,000

Data source= Medicaid Data Warehouse Extract date: October 2025

Results:
Utilization for Members Without a Food and Drug Administration Approved Diagnosis

- Doxepin 3.3% cream, a compounded product that is not commercially available, is compendia-supported in one source, based on level B evidence, for the treatment of neuropathic pain.

- 85.2% of members were not using the drug for a Food and Drug Administration-approved indication, which resulted in 22,900 claims at an estimated total spend of $22,300,000.
  - 79.7% of members had a pain diagnosis (e.g., low back pain, chronic pain, dorsalgia, unspecified, or cervicalgia), which is not a compendia-supported indication for doxepin 5% cream.
  - 5.4% of members did not have a diagnosis that related to the use of doxepin cream.
  - 13.1%, 11.3%, and 75.6% of claims were for quantities of ≤60 grams, 90 grams, or 135 grams, respectively.

Summary

- Doxepin 5% cream is Food and Drug Administration-approved for the short-term use of up to 8 days for the management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.
- Doxepin 5% cream systemic absorption can result in drug levels comparable to oral doxepin.
- There are no compendia-supported indications for doxepin 5% cream.
- 14.8% of members were utilizing doxepin 5% cream for the Food and Drug Administration-approved indication of atopic dermatitis and/or lichen simplex chronicus, which resulted in approximately 4,500 claims at an estimated spend of $4,000,000.
- 85.2% of members were not using the product for a Food and Drug Administration-approved indication, resulting in an estimated 22,900 claims at an estimated total spend of $22,300,000.

Doxepin 5% cream [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; 2017.

Recommendations

- Based on the available guidelines and literature, the following recommendations should be considered:
  1. Confirmation of a Food and Drug Administration-approved or compendia-supported indication.
  2. Require a trial of a topical corticosteroid or immunomodulator before the use of doxepin 5% cream.
  3. Maintain the current quantity limit of 45 grams/ claim with a days-supply of 30 days and consider implementing a refill limit of 1/ claim.
  4. Allow for a total of 4 claims annually, allowing the member to receive 2 regimens for a total of 180 grams.

Topical Corticosteroids Additional Information

February 26, 2026

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

Objectives

1. Evaluate the utilization of topical corticosteroids from State Fiscal Year 2022 through State Fiscal Year 2025.

2. Evaluate the use of low-, medium-, high-, and very-high-potency topical corticosteroids for State Fiscal Year 2025.

Background

- Topical corticosteroids are Food and Drug Administration-approved for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatosis.

- Commonly used for inflammatory conditions such as atopic dermatitis (eczema), dermatitis-unspecified, and psoriasis.

- Included in the NYRx Preferred Drug Program in the following therapeutic categories:
  - Low-Potency Topical Corticosteroids,
  - Medium-Potency Topical Corticosteroids,
  - High-Potency Topical Corticosteroids, and
  - Very-High-Potency Topical Corticosteroids.

NYRx Preferred Drug Program. Revised January 20, 2025. Available at NYRx, the Medicaid Pharmacy Program | Preferred Drug Program. Accessed January 2026.
Food and Drug Administration Approved Drug Products. Available at https://www.accessdata.fda.gov/. Accessed January 2026.

NYRx Preferred Drug Program

Steroids, Topical – Low Potency	
Preferred	Non-Preferred
hydrocortisone acetate (Over the Counter) hydrocortisone acetate (Prescription)	alclometasone Capex® shampoo Derma-Smoothe/FS® desonide fluocinolone oil hydrocortisone 2.5% solution (Cost Optimization Program)

Steroids, Topical – Medium Potency	
Preferred	Non-Preferred
fluocinolone acetonide solution fluticasone propionate cream, ointment hydrocortisone valerate cream mometasone furoate cream, ointment, solution	Beser lotion betamethasone valerate foam clocortolone fluocinolone acetonide cream, ointment flurandrenolide fluticasone propionate lotion hydrocortisone butyrate cream, lotion, ointment, solution hydrocortisone valerate ointment Pandel® prednicarbate ointment Synalar®

Steroids, Topical – High Potency	
Preferred	Non-Preferred
betamethasone dipropionate lotion, cream, ointment betamethasone dipropionate augmented cream betamethasone valerate cream, ointment fluocinonide cream, ointment, solution triamcinolone acetonide	amcinonide cream ApexiCon-E® betamethasone dipropionate augmented gel, ointment, lotion betamethasone valerate lotion clobetasol 0.025% cream desoximetasone diflorasone Diprolene® fluocinonide gel, emollient halcinonide cream halcinonide 0.1% solution (generic Halog®/ Cost Optimization Program) Halog® cream, solution, ointment Kenalog® Topicort® triamcinolone spray

Steroids, Topical – Very High Potency	
Preferred	Non-Preferred
clobetasol cream, emollient, gel, ointment, solution halobetasol cream, ointment	clobetasol foam, lotion, spray, shampoo Clobex® halobetasol foam Olux® Ultravate®

Preferred Drug Program status as of January 20, 2026.

Topical Corticosteroid Usage

- Selection depends on the potency and formulation of the product, site of application, the patient's age, skin pigmentation, the frequency of administration, the total body surface area to be treated, and the duration of treatment.

- Low-potency agents are used in pediatric patients, when a large body surface area is involved, or on intertriginous area.

- Medium- to high-potency agents can be used on most areas of the body in pediatric and adult patients.

- Very-high-potency agents are used on thick skin in patients ≥12 years of age.
  - These products are not Food and Drug Administration-approved for use in patients <12 years of age.

American Family Physician. 2021;103(6):337-343. Available at Topical Corticosteroids: Choice and Application | AAFP. Accessed February 2026.
Journal of the Academy of Dermatology. 2014 July; 71(1): 116-132. Doi: 10.1016/j.aad.2024.03.023

Duration of Use of Topical Corticosteroids

- Suggested maximum duration of therapy for:
  - Low-potency agents - not often specified,
  - Medium- to high-potency agents - short-term use is recommended (e.g., <12 weeks), and
  - Very high-potency agents – use for 2 to 4 weeks.

- If longer durations are needed with a more potent topical corticosteroid, the product may be applied intermittently and should be transitioned to a less potent agent when possible.

- It is advisable to treat lesions on the face, groin, and skinfolds at 1- to 2-week intervals, and once the lesions have cleared, the therapy should be discontinued.

American Family Physician. 2021;103(6):337-343. Available at Topical Corticosteroids: Choice and Application | AAFP. Accessed February 2026.
Journal of the Academy of Dermatology. 2014 July; 71(1): 116-132. Doi: 10.1016/j.aad.2024.03.023.

Potential Adverse Effects

- The use of topical corticosteroids can be associated with cutaneous adverse effects such as hypopigmentation, purpura, telangiectasias, and allergic contact dermatitis.

- Of concern is the potential for skin atrophy, which has been associated with higher-potency formulations, long-term continuous use, the use of occlusive coverings, use on thinner skin and in intertriginous areas, and use in older patients.

- Atrophy of the skin compromises the ability of the skin to act as a barrier.

- To reduce the potential for skin atrophy:
  - A lower potency product can be used and
  - A reduction in the frequency and duration of application can be implemented.

Drugs@FDA. Available at https://www.accessdata.fda.gov/. Accessed January 2026.
American Family Physician. 2021;103(6):337-343. Available at Topical Corticosteroids: Choice and Application | AAFP. Accessed February 2026.
Journal of the Academy of Dermatology. 2014 July; 71(1): 116-132. Doi: 10.1016/j.aad.2024.03.023.

Comparator State Medicaid Program Coverage

- Comparator states: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington

- All the comparator state Medicaid Programs included topical corticosteroids in their Preferred Drug Program.

- One comparator state Medicaid program had established quantity limits based on the product's potency.

Methodology

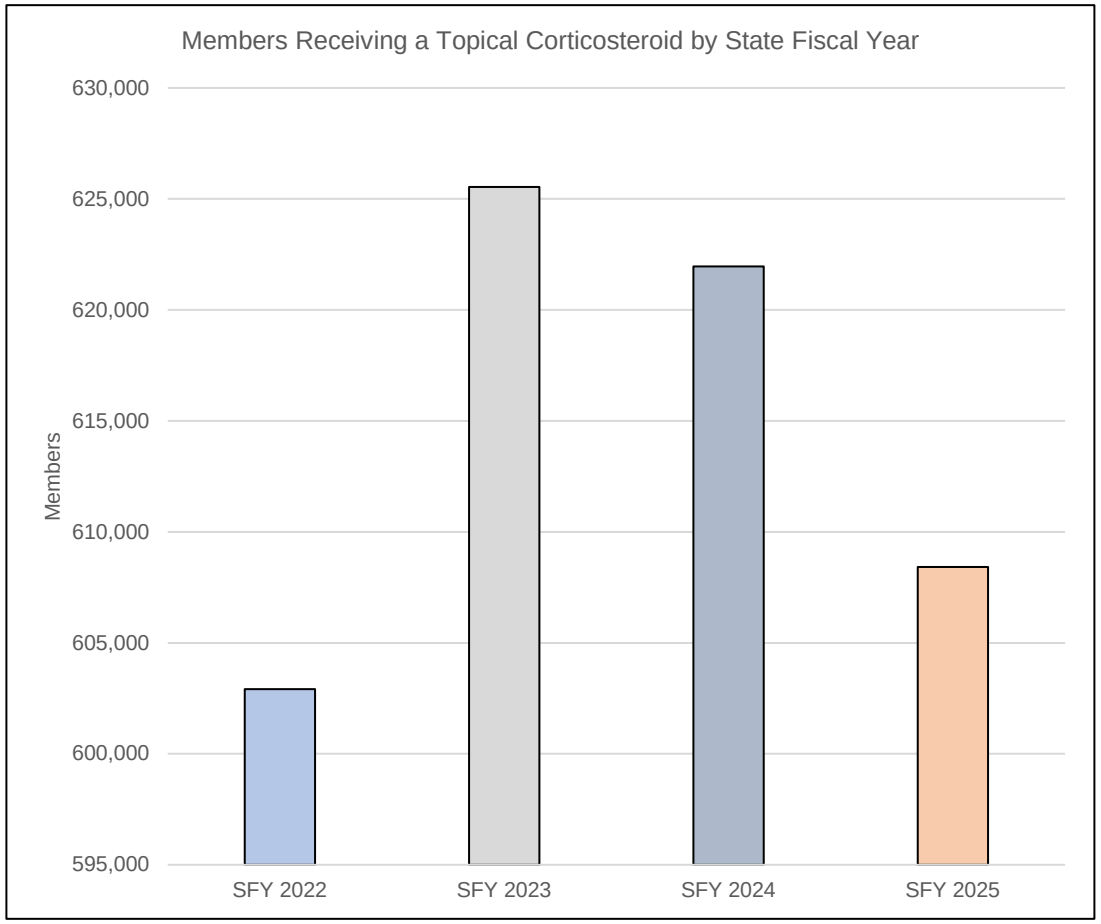
- A retrospective analysis of claims was conducted for the following timeframes:
  - State Fiscal Year 2022: April 1, 2021 through March 31, 2022
  - State Fiscal Year 2023: April 1, 2022 through March 31, 2023
  - State Fiscal Year 2024: April 1, 2023 through March 31, 2024
  - State Fiscal Year 2025: April 1, 2024 through March 31, 2025

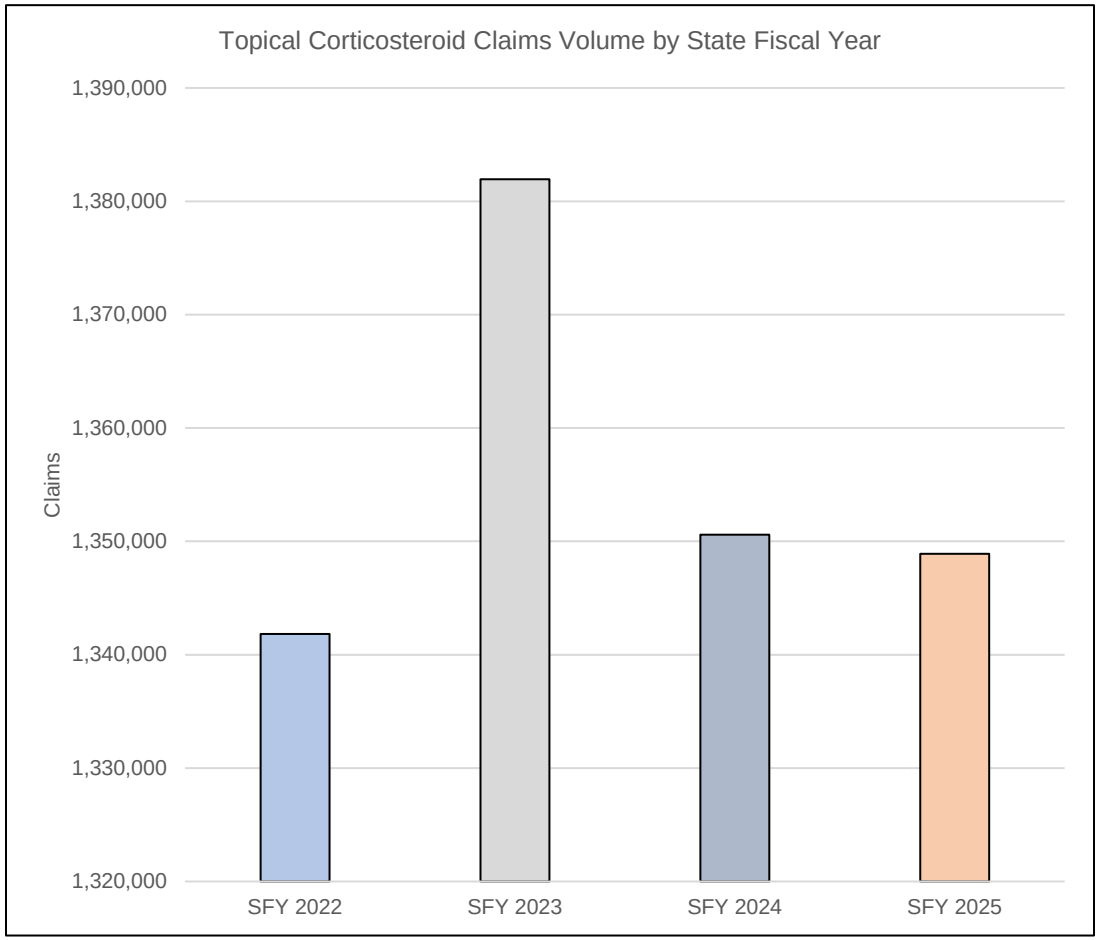
- The data source was the Medicaid Data Warehouse (MDW).

Limitations:

- The Medicaid Confidential Data Cell Size Policy (OHIP-0001) requires that no cell containing a value of 1 to 30 be reported.
- Information regarding how the members are using the agent is not available in the Medicaid Data Warehouse, and without that information, it is difficult to determine the exact quantity of topical corticosteroids the member would require.

Results:
Utilization of Topical Corticosteroids by State Fiscal Year

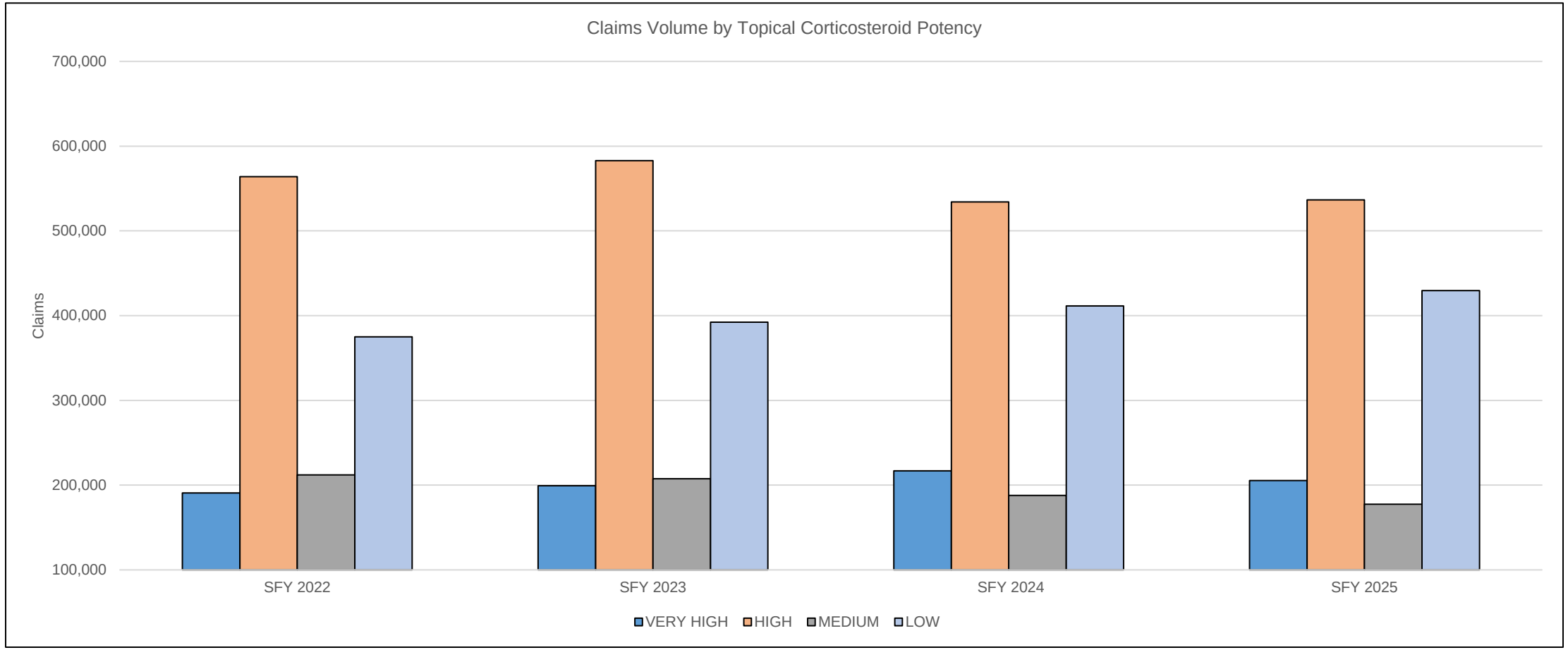




Data source= Medicaid Data Warehouse; Extract date= December 2025

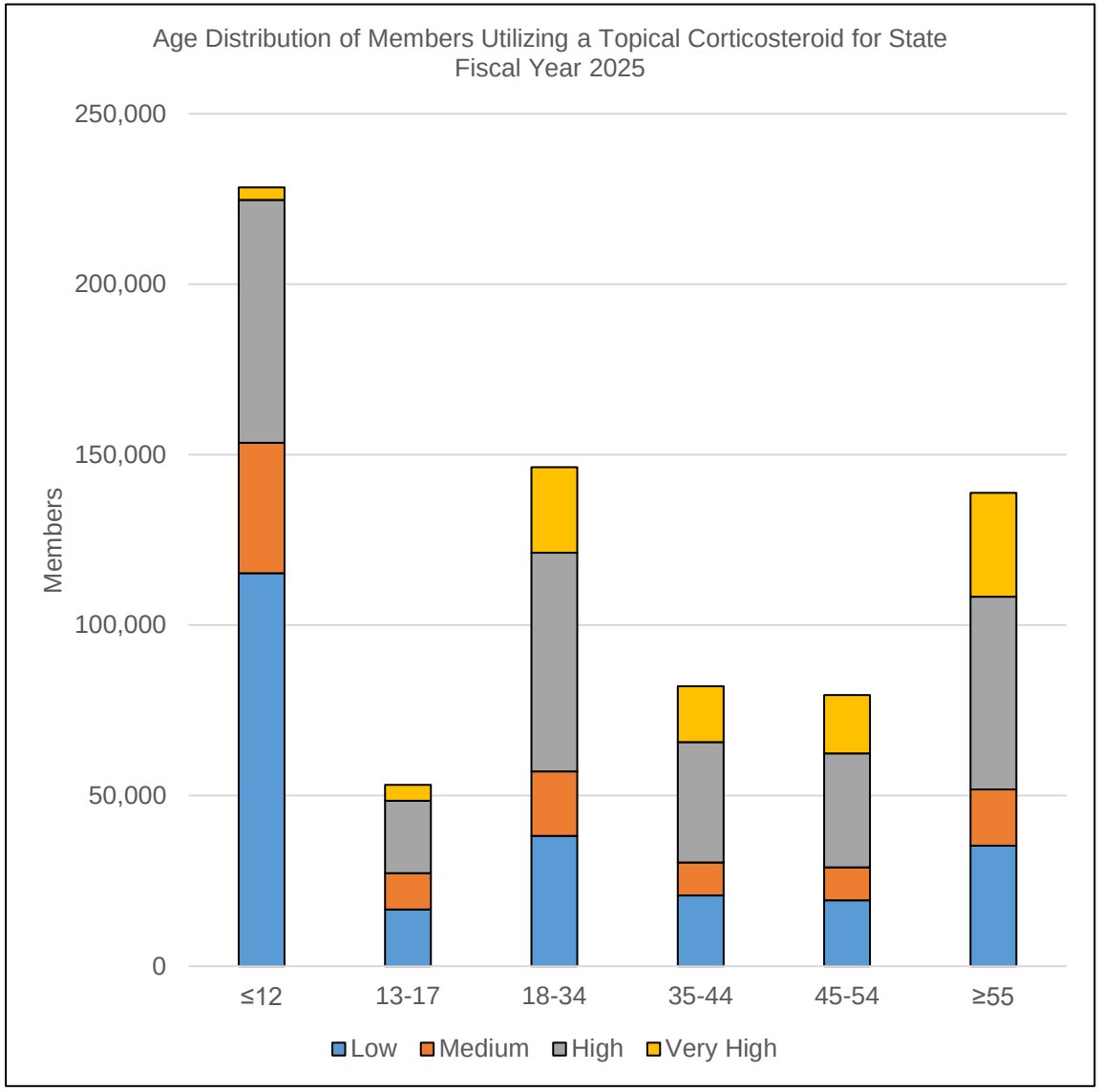
From State Fiscal Year 2022 through State Fiscal Year 2025, 1,620,000 unique members had a pharmacy claim for a topical corticosteroid, which resulted in 5,420,000 claims.

Results:
Claims Volume by Topical Corticosteroid Potency



Data source= Medicaid Data Warehouse; Extract date= December 2025

Results:
State Fiscal Year 2025 Utilization



Data source= Medicaid Data Warehouse; Extract date= December 2025

- 608,400 unique members received a topical corticosteroid.
- 90.9% of claims were for preferred agents.
- 59.0% of members were female.
- 59.6% of members were <35 years of age
  - 32.2% of members were ≤12 years of age.
  - 7.4% of members were 13 to 17 years of age.
  - 20.0% of members were 18 to 34 years of age.

Results:
Diagnosis of Members Receiving a Topical Corticosteroid in State Fiscal Year 2025

Diagnosis	LOW		MEDIUM		HIGH		VERY-HIGH	
	Percentage of Members	Percentage of Claims	Percentage of Members	Percentage of Claims	Percentage of Members	Percentage of Claims	Percentage of Members	Percentage of Claims
Atopic Dermatitis, Dermatitis, Unspecified, or Psoriasis Diagnosis	45.6%	49.0%	54.8%	56.5%	51.6%	55.2%	50.7%	54.9%
NO Atopic Dermatitis, Dermatitis, Unspecified, or Psoriasis Diagnosis	54.4%	51.0%	45.2%	43.5%	48.4%	44.8%	49.3%	45.1%

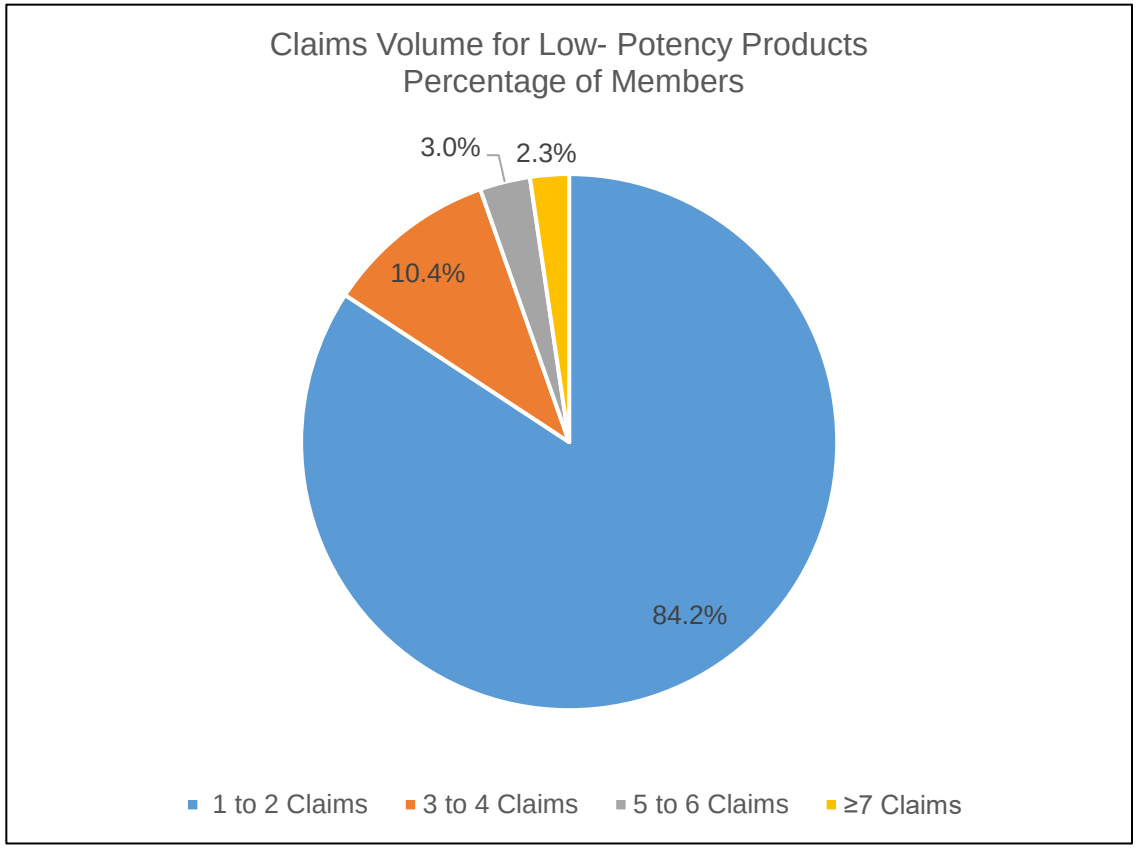
Data source= Medicaid Data Warehouse; Extract date= December 2025

- 608,400 members received a topical corticosteroid which resulted in approximately 1,350,000 claims.

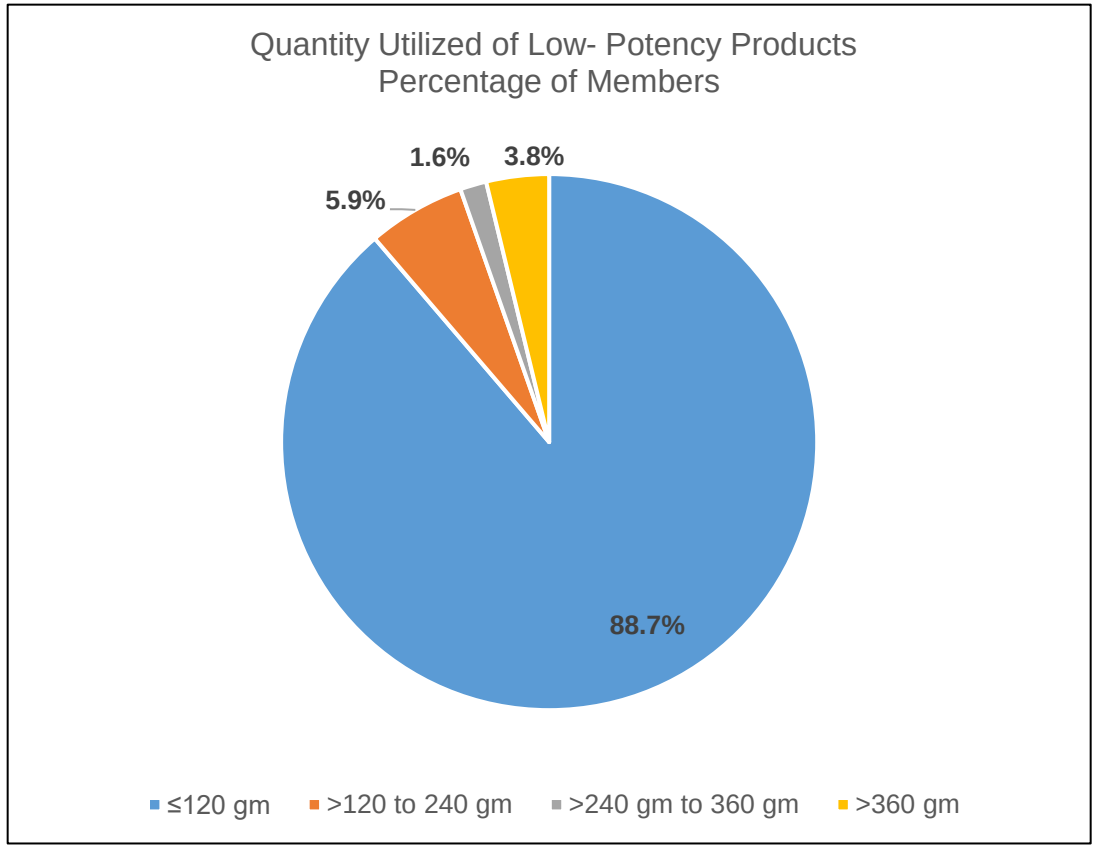
- 53.7% of members utilizing a topical corticosteroid did not have a Food and Drug Administration-approved diagnosis.

Results:
Low-Potency Topical Corticosteroids Utilization for State Fiscal Year 2025

Claims Volume



Quantity Utilized

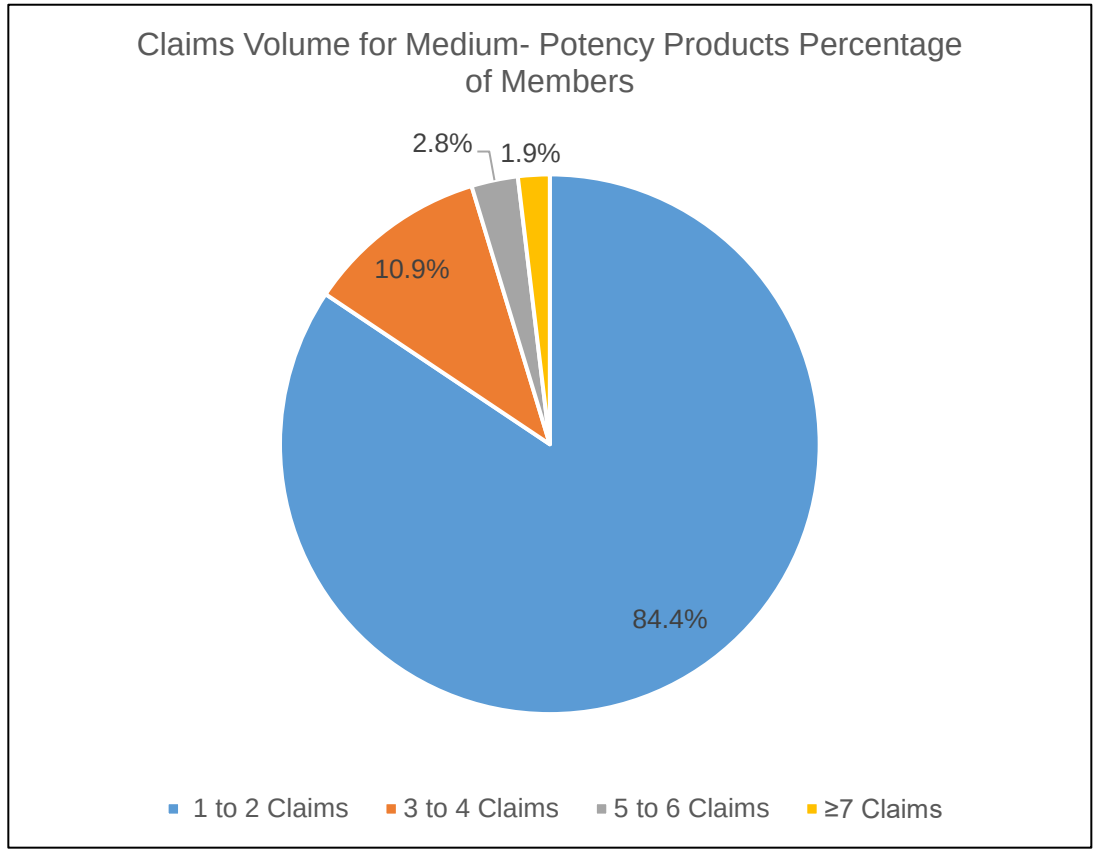


N= 245,700 members (not additive)

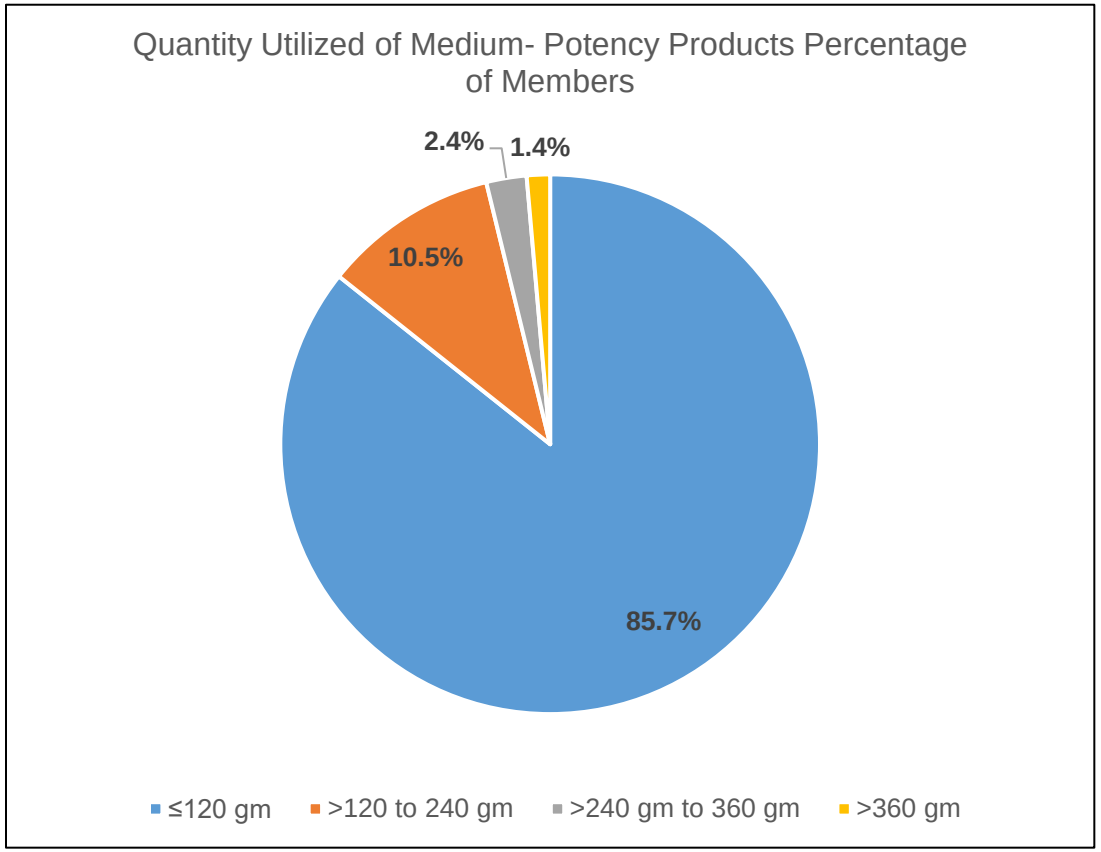
Data source= Medicaid Data Warehouse; Extract date= December 2025

Results:
Medium-Potency Topical Corticosteroids Utilization for State Fiscal Year 2025

Claims Volume



Quantity Utilized

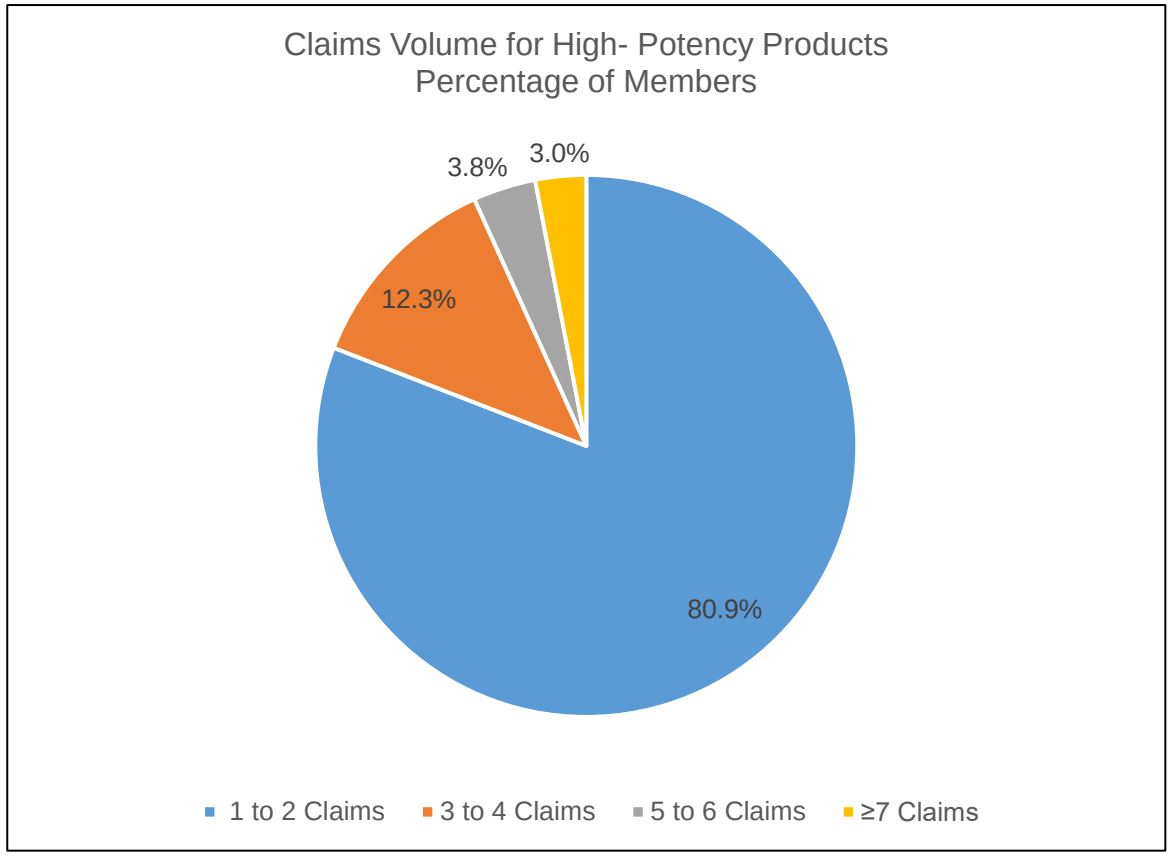


N= 103,500 members (not additive)

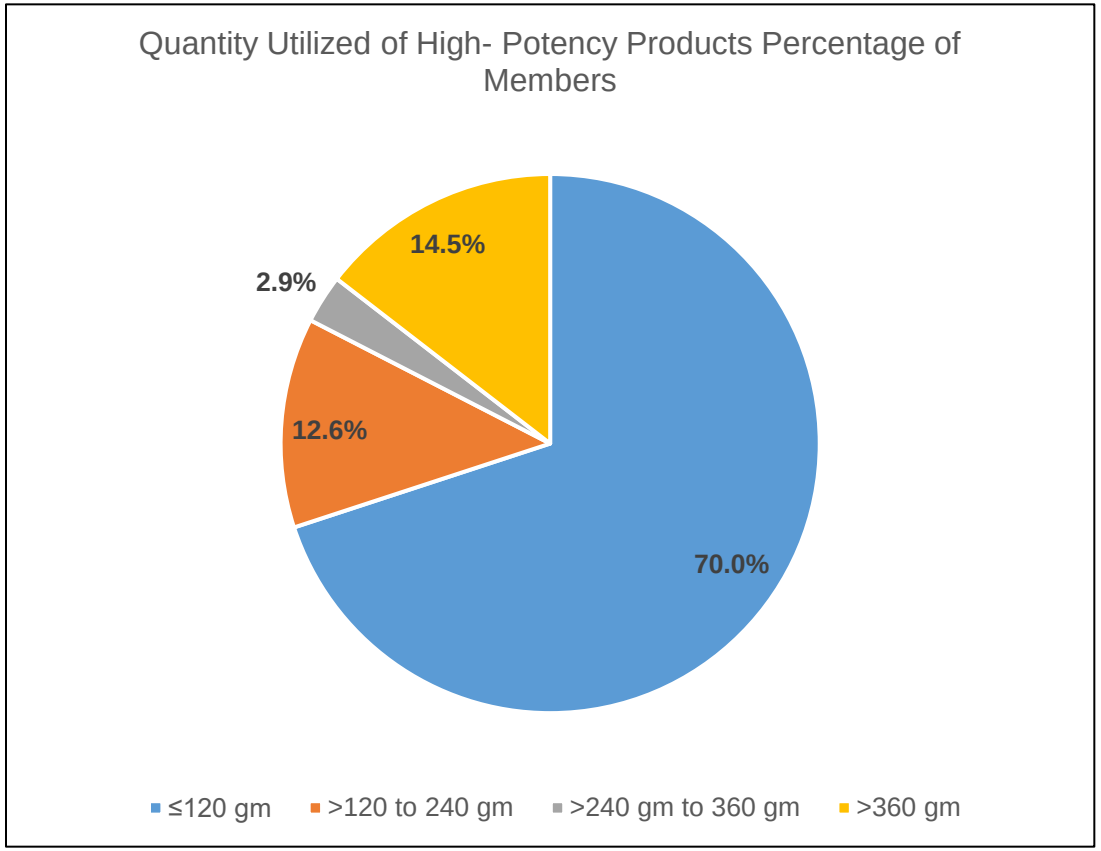
Data source= Medicaid Data Warehouse; Extract date= December 2025

Results:
High-Potency Topical Corticosteroids Utilization for State Fiscal Year 2025

Claims Volume



Quantity Utilized

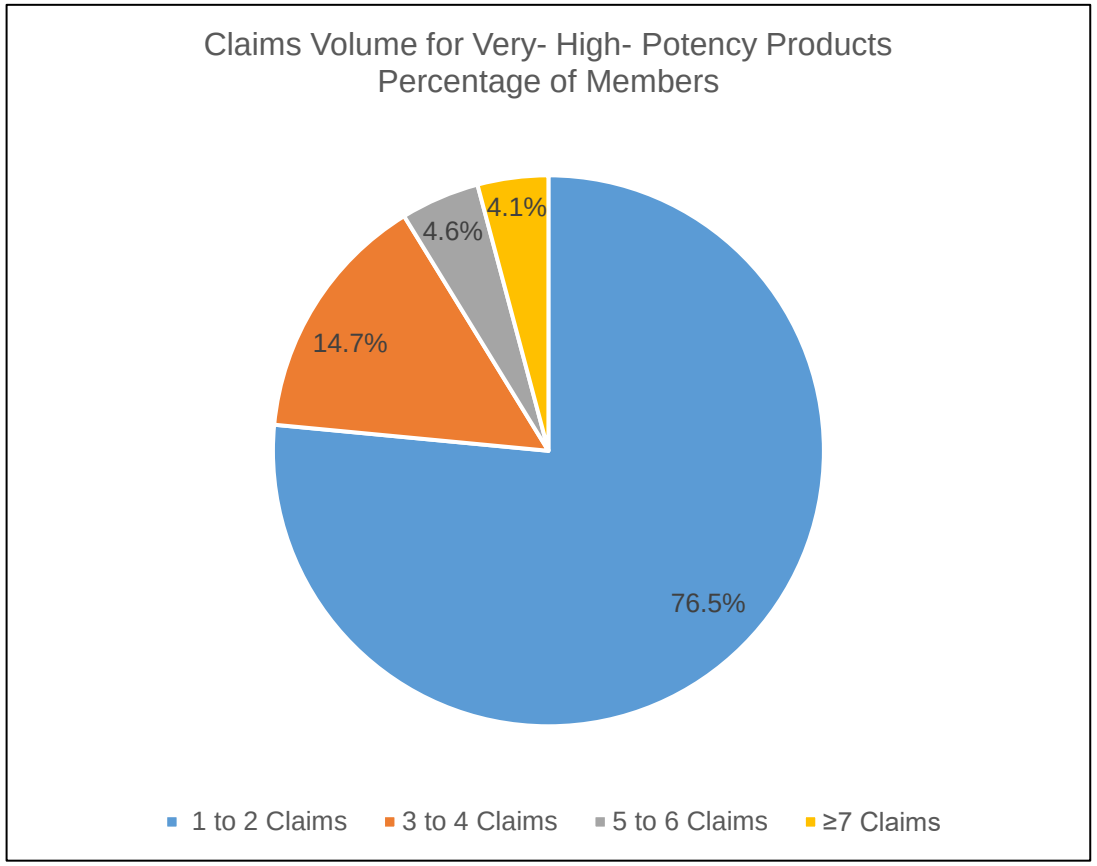


N= 282,000 members (not additive)

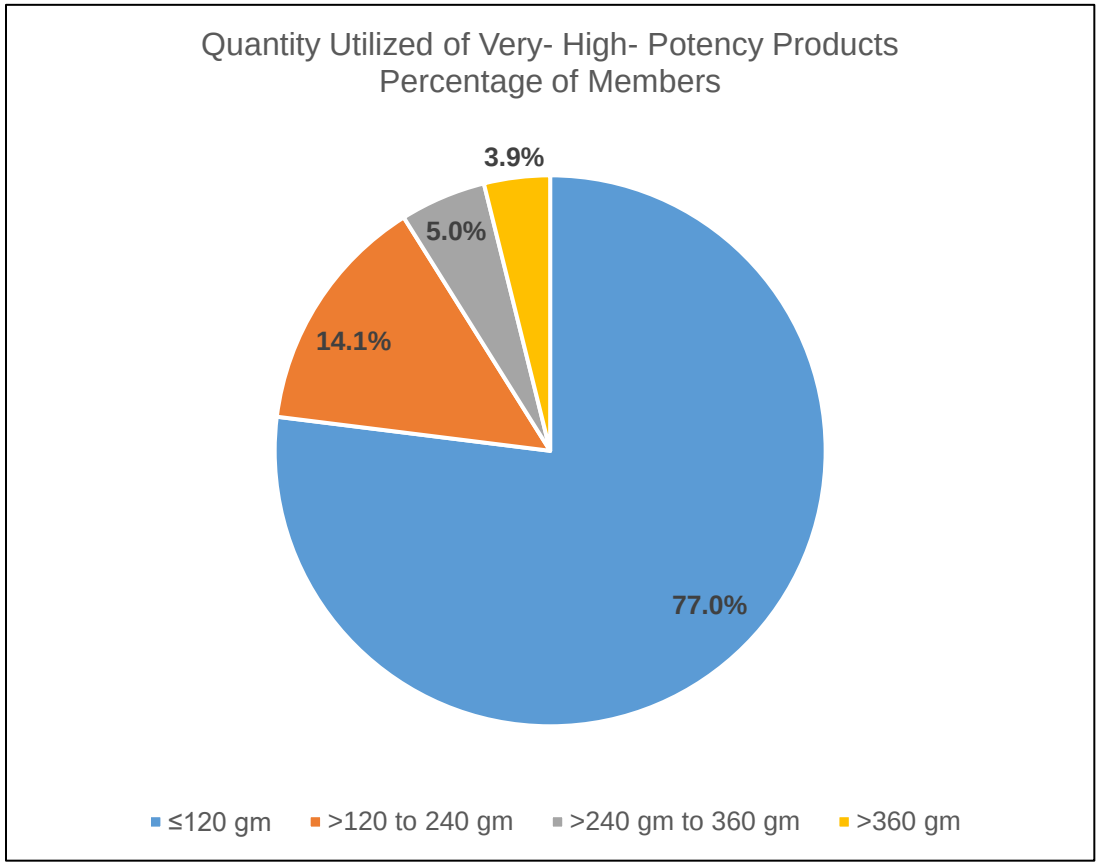
Data source= Medicaid Data Warehouse; Extract date= December 2025

Results:
Very-High-Potency Topical Corticosteroids Utilization for State Fiscal Year 2025

Claims Volume



Quantity Utilized



N= 97,500 members (not additive)

Data source= Medicaid Data Warehouse; Extract date= December 2025

Conclusions

- The selection of a topical corticosteroid depends on the potency and formulation of the product, site of application, the patient's age, skin pigmentation, the frequency of administration, the total body surface area to be treated, and the duration of treatment.

- The duration of therapy depends on the potency of the agent selected, the patient's diagnosis, and the application site.

- To minimize the potential for skin atrophy, it is recommended to use lower potency agents and reduce the frequency and duration of application.

Conclusions

- For the therapeutic categories of topical corticosteroids included in the NYRx Preferred Drug Program, the utilization for State Fiscal Year 2025 is as follows:
  - Low-potency, 97.7% of members had ≤6 claims, and 96.2% of members utilized ≤360 grams,
  - Medium-potency, 98.1% of members had ≤6 claims, and 98.6% of members utilized ≤360 grams,
  - High-potency, 97.0% of the members had ≤6 claims, and 85.5% of members utilized ≤360 grams, and
  - Very high-potency, 95.9% of members have ≤6 claims, and 91.1% of members utilized ≤240 grams.

Recommendations

- Based on the available guidelines and literature, the following recommendations should be considered:

1. For each of the Low-, Medium-, and High-Potency Topical Corticosteroid therapeutic categories, allow a maximum quantity of 360 grams of creams and ointments annually.
2. For each of the Low-, Medium-, and High-Potency Topical Corticosteroid therapeutic categories, allow for a maximum of 12 claims annually.
3. For the Very-High-Potency Topical Corticosteroid therapeutic category, allow for a maximum quantity of 240 grams of creams and ointments annually.
4. For Very High-Potency Topical Corticosteroid therapeutic category, allow for a maximum of 6 claims annually.
5. For the Very High-Potency Topical Corticosteroid therapeutic category, require prior authorization for members <12 years of age.

Neurokinin Receptor Antagonists for Vasomotor Symptoms

February 26, 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 fezolinetant (Veozah®) and elinzanetant (Lynkuet®) and their potential 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

Menopause and Vasomotor Symptoms

- Menopause: permanent cessation of menstruation, occurring 12 months after the last menstrual period
  - Median age of occurrence in North America: 51 years
  - Typical range: 45 to 55 years
- Most women experience physiologic changes during menopause and perimenopause
- Vasomotor symptoms: sudden sensations of extreme heat in the upper body (e.g., face, neck, chest), usually lasting 1-5 minutes
  - Observed in up to 80% of menopausal women

DiPiro's Pharmacotherapy: A Pathophysiologic Approach. 13th ed. McGraw Hill; 2026.
ACOG Practice Bulletin No. 141. *Obstet Gynecol*. 2014;123(1):202-216.

Treatment of Vasomotor Symptoms: Hormone Therapy

- Multiple guidelines recommend hormone therapy as the most effective option for treatment of moderate-to-severe symptoms
- Supporting organizations:
  - International Menopause Society
  - North American Menopause Society
  - British Menopause Society/Royal College of Obstetricians and Gynecologists/Society for Endocrinology
  - Society of Obstetricians and Gynecologists of Canada
  - American Association of Clinical Endocrinologists/American College of Endocrinology
  - Endocrine Society
- Available options include combined formulations of estrogens and progestins, and estrogen- and progestin-only products, supplied in oral, transdermal, and vaginal forms
- All forms of systemic therapy thought to be similar in efficacy
  - Initial effects: within 2 weeks
  - Full effects: within 4-6 weeks
  - Optimal duration unknown but can be continued in patients ≥65 years of age

ACOG Practice Bulletin No. 141. *Obstet Gynecol*. 2014;123(1):202-216. *Menopause*. 2023;30(6):573-590. *Climacteric*. 2025;28(6):634-656. *Post Reprod Health*. 2022;28(3):123-125. *J Obstet Gynaecol Can*. 2021;43(10):1188-1204.e1. *Endocr Pract*. 2017;23(7):869-880. *J Clin Endocrinol Metab*. 2015;100(11):3975-4011.

Treatment of Vasomotor Symptoms: Hormone Therapy, continued

Absolute contraindications	Relative contraindications
• Undiagnosed abnormal genital bleeding • Known, suspected, or history of breast cancer • Known or suspected estrogen- or progesterone-dependent neoplasia • Active deep vein thrombosis or pulmonary embolism, or history of these conditions • Thrombophilic disorders, such as protein C, protein S, or antithrombin deficiency • Active or 1-year history of arterial thromboembolic disease, such as stroke or myocardial infarction • Liver dysfunction or disease	• Elevated blood pressure • Hypertriglyceridemia • Impaired liver function and history of cholestatic jaundice • Hypothyroidism • Fluid retention • Severe hypocalcemia • Ovarian cancer • Exacerbation of endometriosis, asthma, diabetes mellitus, migraine headaches, systemic lupus erythematosus, epilepsy, porphyria, hepatic hemangioma, or gallbladder disease

DiPiro's Pharmacotherapy: A Pathophysiologic Approach. 13th ed. McGraw Hill; 2026.

Treatment of Vasomotor Symptoms: Hormone Therapy, continued

- Historically, all of the hormone replacement therapies carried boxed warnings regarding cardiovascular disease, breast cancer, endometrial cancer, and dementia
- On November 10, 2025, the Food and Drug Administration announced a proposal to remove the boxed warnings from these products

Managing Vasomotor Menopause Symptoms. *Pharmacist's Letter/Pharmacy Technician's Letter/Prescriber Insights*. March 2025
FDA Requests Labeling Changes Related to Safety Information to Clarify the Benefit/Risk Considerations for Menopausal Hormone Therapies. https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-labeling-changes-related-safety-information-clarify-benefitrisk-considerations

Neurokinin Receptor Antagonists

- Newest class of non-hormonal medications approved for treatment of moderate to severe vasomotor symptoms due to menopause
  - Fezolinetant (Veozah®): neurokinin 3 receptor antagonist
  - Elinzanetant (Lynkuet®): neurokinin 1 and neurokinin 3 receptor antagonist
- No additional compendia-supported uses

Veozah®. Prescribing information. Astellas Pharma US, Inc.; 2024.
Lynkuet®. Prescribing information. Bayer HealthCare Pharmaceuticals Inc.; 2025.

Fezolinetant and Elinzanetant

Characteristics	Fezolinetant (Veozah®)	Elinzanetant (Lynkuet®)
Approval date	May 12, 2023	October 24, 2025
Manufacturer	Astellas Pharma US, Inc.	Bayer HealthCare Pharmaceuticals, Inc.
How supplied	45 mg oral tablets	60 mg oral capsules
Dosage and administration	45 mg (1 tablet) by mouth once daily, with or without food, at about the same time each day	120 mg (2 capsules) by mouth once daily at bedtime • If concurrently using a moderate cytochrome P450 3A4 inhibitor, reduce dose to 60 mg once daily
Wholesale acquisition cost	$567 for a 30-day supply	• $625 for a 30-day supply
Contraindications	• Known cirrhosis; aminotransferase levels ≥2 times the upper limit of normal or total bilirubin ≥2 times the upper limit of normal • Severe renal impairment or end-stage renal disease (estimated glomerular filtration rate 15 to 30 mL/min/1.73 m^2, or <15 mL/min/1.73 m^2, respectively) • Concurrent use with cytochrome P450 1A2 inhibitors	• Pregnancy • Relative contraindications: o Baseline alanine aminotransferase or aspartate aminotransferase levels ≥2 times the upper limit of normal, or total bilirubin ≥2 times the upper limit of normal o Use of a strong cytochrome P450 3A4 inhibitor and/or consumption of grapefruit juice o Use of strong and moderate cytochrome P450 3A4 inducers

Veozah®. Prescribing information. Astellas Pharma US, Inc.; 2024.
Lynkuet®. Prescribing information. Bayer HealthCare Pharmaceuticals Inc.; 2025.
Red Book. In: Merative Micromedex®. Merative US LP. www.micromedexsolutions.com

Fezolinetant and Elinzanetant, continued

Characteristics	Fezolinetant (Veozah®)	Elinzanetant (Lynkuet®)
Boxed warning	Hepatotoxicity has been reported in postmarketing surveillance • Liver function tests should be performed prior to initiation and at specified intervals • Discontinue if transaminase elevations are >5 times the upper limit of normal, or if transaminase levels are >3 times the upper limit of normal and total bilirubin is >2 times the upper limit of normal	None
Other warnings and precautions	None	• Central nervous system depression and daytime impairment • Elevations in hepatic transaminases ≥3 times the upper limit of normal o Discontinue if transaminase levels >5 times the upper limit of normal, or if transaminase levels >3 times the upper limit of normal and total bilirubin >2 times the upper limit of normal • Risk of pregnancy loss or stillbirth • Risk of seizures; cautious use advised in patients with a history of seizures or conditions lowering the seizure threshold

Veozah®. Prescribing information. Astellas Pharma US, Inc.; 2024.
Lynkuet®. Prescribing information. Bayer HealthCare Pharmaceuticals Inc.; 2025.

Fezolinetant and Elinzanetant, continued

Characteristics	Fezolinetant (Veozah®)	Elinzanetant (Lynkuet®)
Adverse events	Reactions reported in ≥2% of clinical trial participants who received fezolinetant: • Abdominal pain, diarrhea, insomnia, back pain, hot flush, elevations in hepatic transaminases In post-marketing surveillance, cases of serious drug-induced hepatotoxicity have been reported.	Reactions reported in ≥2% of clinical trial participants who received elinzanetant: • Headache, fatigue, dizziness, somnolence, abdominal pain, rash, diarrhea, muscle spasms
Monitoring parameters	**Prior to administration**: • Hepatic function – liver function tests, including transaminases and bilirubin • Renal impairment – estimated glomerular filtration rate **Following initiation**: • Hepatic function – monthly for first 3 months, at 6 months, and at 9 months. If transaminases >3 times the upper limit of normal, monitor liver function more often until transaminase levels decline	**Prior to administration**: • Pregnancy – rule out • Hepatic function – liver function tests, including serum alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, and bilirubin. **Following initiation**: • Hepatic function – perform follow-up monitoring 3 months after initiation of treatment

Veozah®. Prescribing information. Astellas Pharma US, Inc.; 2024.
Lynkuet®. Prescribing information. Bayer HealthCare Pharmaceuticals Inc.; 2025.

Fezolinetant

- Approved based on efficacy data from two phase 3 studies: SKYLIGHT 1 and SKYLIGHT 2
  - Additional supporting data from a phase 3b trial: DAYLIGHT
- Randomized, double-blind
  - Fezolinetant 30 mg/day*, 45 mg/day, or placebo
- Primary endpoint: change from baseline in frequency and severity of vasomotor symptoms
  - SKYLIGHT 1 and 2: weeks 4 and 12
  - DAYLIGHT: week 24

*Lower dose only included in SKYLIGHT trials

Lancet. 2023;401(10382):1091-1102.
J Clin Endocrinol Metab. 2023;108(8):1981-1997.
BMJ. 2024;387:e079525.

SKYLIGHT 1 and 2: Selection Criteria

Inclusion	Exclusion
•Age 40-65 years •Menopausal •≥7 moderate-to-severe hot flashes per day •Body mass index 18-38 kg/m^2	•Use of any other treatment for vasomotor symptoms •History of malignant tumor •Systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg •History of undiagnosed uterine bleeding •Active liver disease, jaundice, or elevated liver function markers •Serum creatinine >1.5 x upper limit of normal or estimated clearance ≤59 mL/min/1.73 m^2

Lancet. 2023;401(10382):1091-1102.
J Clin Endocrinol Metab. 2023;108(8):1981-1997.

Fezolinetant Study Results

Study	Baseline vasomotor symptoms	Outcomes (fezolinetant [30 mg, 45 mg] vs. placebo)
SKYLIGHT 1	n=522 • Frequency: 10.4 to 10.7 per day • Severity: 2.4	**Frequency**: Week 4: -5.19, -5.39 vs. -3.32 (p<0.001) Week 12: -6.28, -6.44 vs. -3.90 (p<0.001) **Severity**: Week 4: -0.42 (p=0.012), -0.46 (p=0.002) vs. -0.27 Week 12: -0.60 (p=0.002), -0.57 (p=0.007) vs. -0.37
SKYLIGHT 2	n=484 • Frequency: 11.23 to 11.79 per day • Severity: 2.41 to 2.44	**Frequency**: Week 4: -5.53, -6.26 vs. -3.72 (p<0.001) Week 12: -6.83, -7.50 vs. -4.97 (p<0.001) **Severity**: Week 4: -0.47 (p=0.021), -0.61 (p<0.001) vs. -0.32 Week 12: -0.64 (p<0.05), -0.77 (p<0.001) vs. -0.48
DAYLIGHT	n=452 • Frequency: 10.58 to 10.75 per day • Severity: 2.41 to 2.43	**Frequency**: Week 24: -8.13 vs. -6.20 (p<0.001) **Severity**: Week 24: -1.01 vs. -0.62 (p<0.001)

Lancet. 2023;401(10382):1091-1102.
J Clin Endocrinol Metab. 2023;108(8):1981-1997.
BMJ. 2024;387:e079525.

Elinzanetant

- Efficacy and safety evaluated in three phase 3 trials: OASIS 1, 2, and 3
- Randomized, double-blind
  - Elinzanetant 120 mg/day or placebo
- Primary endpoint: change from baseline in frequency and severity of vasomotor symptoms
  - OASIS 1 and 2: weeks 4 and 12
  - OASIS 3: week 12

Menopause. 2024;31(6):522-529.
JAMA. 2024; epub ahead of print. doi:10.1001/jama.2024.14618
JAMA Intern Med. 2025;185(11):1319-1327.

OASIS 1 and 2: Selection Criteria

Inclusion	Exclusion
•Age 40-65 years •Menopausal •≥50 moderate-to-severe hot flashes for 7 days during screening	•Use of any other treatment for vasomotor symptoms •History of malignancy •Uncontrolled or treatment-resistant hypertension •History of cardiac arrhythmias •Abnormal liver parameters •Endometrial or breast abnormalities •History of thyroid disorders •Unexplained postmenopausal bleeding

Menopause. 2024;31(6):522-529.
JAMA. 2024; epub ahead of print. doi:10.1001/jama.2024.14618

Elinzanetant Study Results

Study	Baseline vasomotor symptoms	Outcomes (elinzanetant 120 mg vs. placebo)
OASIS 1	n=396 • Frequency: 13.4 to 14.3 per day • Severity: 2.5 to 2.6	**Frequency**: Week 4: -7.5 vs. -4.4 Week 12: -8.7 vs. 5.5 **Severity**: Week 4: -0.73 vs. -0.39 Week 12: -0.95 vs. -0.55 (p not reported for above values)
OASIS 2	n=400 • Frequency: 14.7 to 16.2 per day • Severity: 2.5	**Frequency**: Week 4: -8.6 vs. -6.1 Week 12: -10.0 vs. -7.2 **Severity**: Week 4: -0.75 vs. -0.53 Week 12: -0.97 vs. -0.65 (p not reported for above values)
OASIS 3	n=628 • Frequency: 6.7 to 6.8 • Severity: 2.3	**Frequency**: Week 12: -5.4 vs. -3.5 (p<0.001) **Severity**: Week 12: -1.2 vs. -0.8 (p=not reported)

Menopause. 2024;31(6):522-529.
JAMA. 2024; epub ahead of print. doi:10.1001/jama.2024.14618
JAMA Intern Med. 2025;185(11):1319-1327.

New York State Medicaid Coverage

- Fezolinetant is included in the New York State Medicaid Pharmacy List of Reimbursable Drugs
- Fezolinetant and elinzanetant are not subject to the NYRx Preferred Drug Program at this time

Comparator State Medicaid Coverage

- 9 states: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington
- As of December 2025:

Fezolinetant	Elinzanetant
•8/9 programs include on formulary •7/9 require prior authorization o 4/9 have drug-specific clinical criteria ▪ 3/9 require a trial of hormone therapy ▪ 1/9 requires trials of hormone therapy and other non-hormone therapy	•1/9 includes on formulary •Requires prior authorization

Drug Utilization Data: Overview of Analyses

- A retrospective analysis was conducted to evaluate utilization of fezolinetant and potential utilization of elinzanetant
- **Data source**: Medicaid Data Warehouse
- **Sample**: members with ≥1 pharmacy claim for fezolinetant during the analysis period
- **Analysis period**: April 1, 2023 – September 30, 2025 (2 years and 6 months)
  - State Fiscal Year 2024: April 1, 2023 – March 31, 2024
  - State Fiscal Year 2025: April 1, 2024 – March 31, 2025
  - Partial State Fiscal Year 2026: April 1, 2025 – September 30, 2025

Drug Utilization Data: Disclaimers

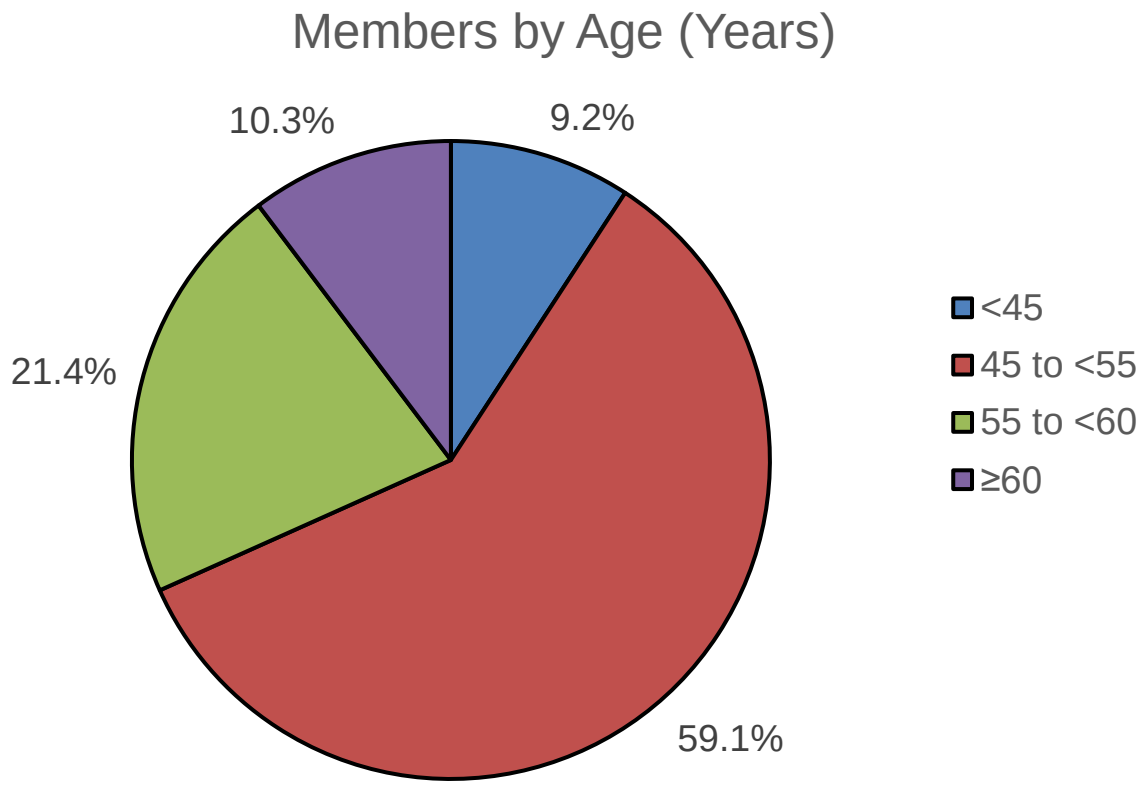
- Medicaid Confidential Data Cell Size Policy (OHIP-0001)
  - Requires that no cell containing a value of 1 to 30 be reported; such values must be reported as ≤ 30 in all public-facing documents
- The following limitation should also be considered:
  - While time periods analyzed take into account inherent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

Overall Utilization of Fezolinetant

Period	Members*	Claims	Claims/ Member
State Fiscal Year 2024 (12 months)	1,062	2,554	2
State Fiscal Year 2025 (12 months)	2,966	11,964	4
Partial State Fiscal Year 2026 (6 months)	2,535	8,144	3
Total (2 years and 6 months)	4,515	22,662	5

Data source: Medicaid Data Warehouse; 4/1/2023 – 9/30/2025; extracted 1/8/2026
*Members not additive

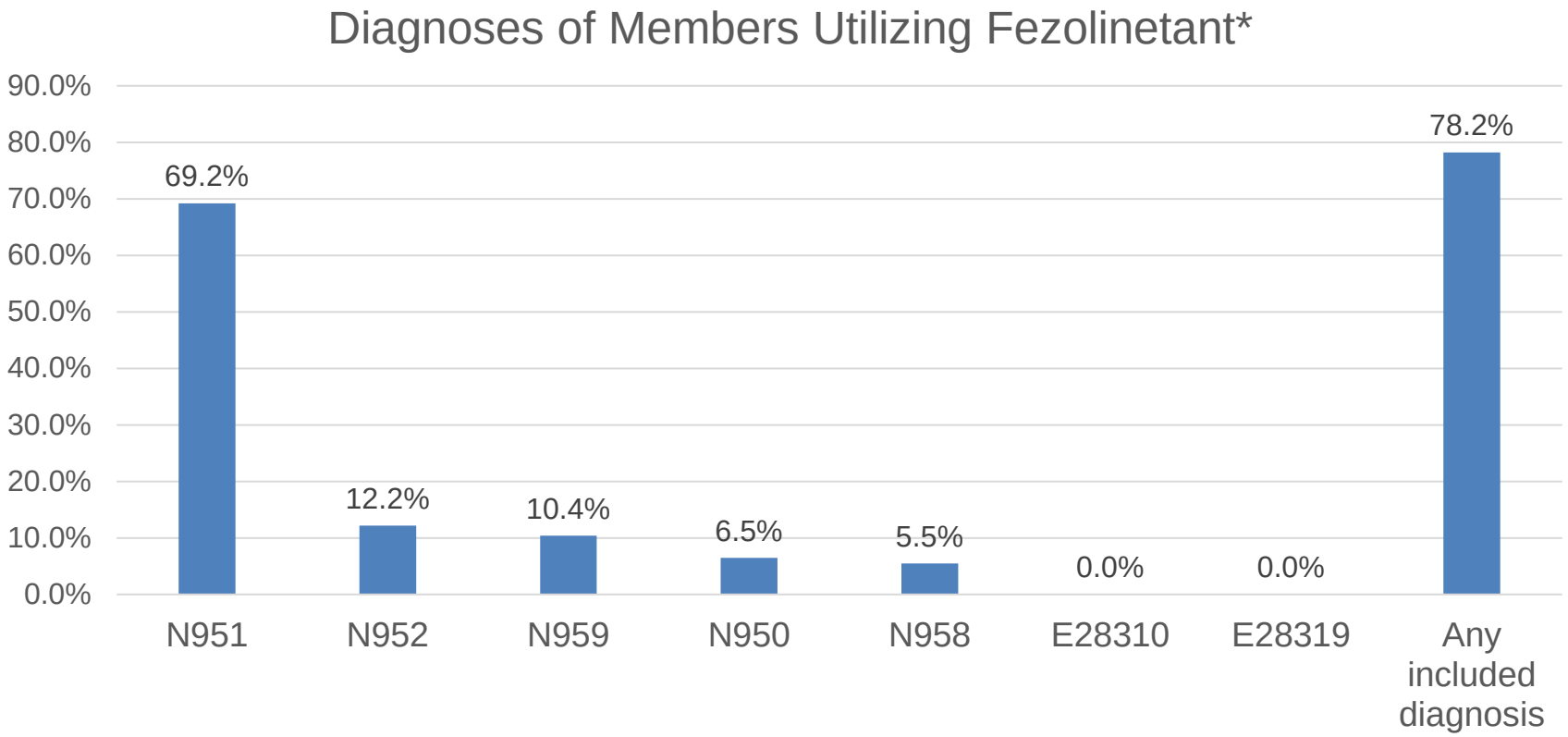
Age Distribution in State Fiscal Year 2025



- Over 80% of members utilizing fezolinetant in State Fiscal Year 2025 were 45 to <60 years of age

Data source: Medicaid Data Warehouse; 4/1/2024 – 3/31/2025; extracted 1/8/2026

Diagnoses in State Fiscal Year 2025



International Classification of Diseases-tenth revision codes:

N951: Menopausal and female climacteric states; N952: Postmenopausal atrophic vaginitis; N959: Unspecified menopausal and perimenopausal; N950: Postmenopausal bleeding; N958: Other specified menopausal and perimenopausal; E28310: Symptomatic premature menopause; E28319: Asymptomatic premature menopause

Data source: Medicaid Data Warehouse; 4/1/2024 – 3/31/2025; extracted 1/8/2026

*Members not additive

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

SUNY The State University of New York

Utilization of Hormone Therapy Prior to Fezolinetant

- Identified members newly starting fezolinetant in State Fiscal Year 2025
  - Defined as ≥1 claim for fezolinetant in State Fiscal Year 2025 and no claims for fezolinetant in State Fiscal Year 2024
- Date of first claim for fezolinetant considered the index date
- Reviewed pharmacy claims occurring between April 1, 2023 and the index date to identify prior utilization of hormone therapy

Utilization of Hormone Therapy Prior to Fezolinetant, continued

- There were 2,966 members with ≥1 claim for fezolinetant in State Fiscal Year 2025
- Of these, 2,329 members had no claims for fezolinetant in State Fiscal Year 2024
- **Among the 2,329 members who started fezolinetant in State Fiscal Year 2025:**
  - **1,796 members (77.1% [1,796 / 2,329]) did NOT have prior use of hormone therapy**
  - 533 members (22.9% [533 / 2,329]) had prior claims for hormone therapy
- For the 533 members who had prior use of hormone therapy, the associated costs were as follows:
  - Hormone therapy: $424,879 ($113 per claim)
  - Fezolinetant: $1,588,232 ($539 per claim)

Data source: Medicaid Data Warehouse; 4/1/2023 – 9/30/2025; extracted 1/8/2026

Utilization Among Members Starting Fezolinetant in State Fiscal Year 2025

Period	Hormone Therapy		Fezolinetant	
	Members*	Claims	Members*	Claims
State Fiscal Year 2024 (12 months)	405	1,747	0	0
State Fiscal Year 2025 (12 months)	374	1,485	533	1,930
Partial State Fiscal Year 2026 (6 months)	191	518	268	1,019
Total (2 years and 6 months)	533	3,750	533	2,949

Data source: Medicaid Data Warehouse; 4/1/2023 – 9/30/2025; extracted 1/8/2026
*Members not additive

Conclusions

- During menopause and in the years preceding, women commonly experience vasomotor symptoms
- Vasomotor symptoms vary in frequency and duration but can be disruptive and chronic
- Unless contraindicated, hormone therapy is considered the most effective option for vasomotor symptoms and is recommended for treatment of moderate-to-severe symptoms
- Nonhormonal medications are available for treatment of vasomotor symptoms. Among these, neurokinin receptor antagonists represent the most recently approved agents
- Randomized placebo-controlled trials have demonstrated efficacy of fezolinetant and elinzanetant in reducing the frequency and severity of vasomotor symptoms in postmenopausal women

DiPiro's Pharmacotherapy: A Pathophysiologic Approach. 13th ed. McGraw Hill; 2026. ACOG Practice Bulletin No. 141. *Obstet Gynecol*. 2014;123(1):202-216. Veozah®. Prescribing information. Astellas Pharma US, Inc.; 2024. Lynkuet®. Prescribing information. Bayer HealthCare Pharmaceuticals Inc.; 2025.

Conclusions, continued

- Based on data from the Medicaid Data Warehouse, during the period of April 1, 2023 – September 30, 2025 (2.5 years), there were 4,515 members in the New York State Medicaid program with 22,662 claims for fezolinetant, with an estimated total cost of $12,156,547
- In State Fiscal Year 2025, there were 2,966 members with ≥1 claim for fezolinetant
  - Over 80% were 45 to <60 years of age
  - Over 78% had a diagnosis related to menopause
- Among the 2,966 members, 2,329 were identified as new starts for fezolinetant
  - 1,796 (77%) did not have prior utilization of hormone therapy
- For the remaining 533 members who had prior use of hormone therapy, the associated costs were as follows:
  - Hormone therapy: $424,879 ($113 per claim)
  - Fezolinetant: $1,588,232 ($539 per claim)

Data source: Medicaid Data Warehouse; 4/1/2023 – 9/30/2025; extracted 1/8/2026

UB Recommendation

- Consider implementation of step therapy for fezolinetant and elinzanetant – require a trial with at least one hormone replacement therapy unless contraindicated