

**New York State Medicaid Drug Utilization Review Board Meeting – February 27, 2025**  
**Preferred Drug Program – Drug Class Review**

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
<b>Fluoroquinolones, Oral</b>		
ciprofloxacin suspension, tablet levofloxacin tablet	Baxdela® Cipro® suspension, tablet levofloxacin solution moxifloxacin ofloxacin tablet	N/A

# Wegovy® (semaglutide) – Addendum

February 27, 2025  
Drug Utilization Review Board (DURB)  
Meeting

# Purpose

- In October 2024, a review of the semaglutide product Wegovy® was presented to the DURB with a focus on the supplemental indication:
  - Use for reduction in the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight
- Coverage criteria were discussed; the Board voted unanimously to defer the development of Wegovy® clinical criteria to allow for further assessment of various items
- The purpose of this addendum is to provide additional information and modified recommendations for Wegovy® coverage criteria



Department  
of Health

Office of  
Health Insurance  
Programs



# Key Questions

1. What were the inclusion and exclusion criteria in the study leading to approval of the supplemental indication for Wegovy®?
2. Should there be a lead-in period of lifestyle change(s) to establish member readiness for Wegovy®?
3. Should patients be on cardiovascular treatment prior to starting Wegovy® for the supplemental indication?
4. What are the criteria for bariatric surgery in the New York State Medicaid program?
5. Have members in the New York State Medicaid program utilizing semaglutide (Ozempic®) been adherent?



Department  
of Health

Office of  
Health Insurance  
Programs



# 1. Eligibility Criteria for Wegovy® in the SELECT trial



Department  
of Health

Office of  
Health Insurance  
Programs



# Background: Wegovy®

- Supplemental indication approved by the Food and Drug Administration in March 2024:
  - Adjunct to diet and exercise to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight
    - Events: cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke

Wegovy®. Prescribing information. Novo Nordisk Inc.; 2024. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/215256s011lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215256s011lbl.pdf)



**Department  
of Health**

Office of  
Health Insurance  
Programs



# Literature – Supplemental Indication

## SELECT trial

**Design:** Multicenter, double-blind, randomized, event-driven study

**Objective:** To determine whether addition of semaglutide to standard care would be superior to standard care alone in reducing the risk of major adverse cardiovascular events in patients who did not have diabetes

### Interventions:

- Semaglutide: injected subcutaneously once weekly, initiated at 0.24 mg once weekly, increased every 4 weeks to target of 2.4 mg once weekly
- Placebo: injected subcutaneously once weekly
- Standard care: medical treatment and healthy lifestyle counseling in accordance with treatment guidelines or local clinical practice (choice at discretion of investigators)

**Primary endpoint:** Composite of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke

# SELECT Trial – Eligibility Criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>• <b>Male or female</b></li> <li>• <b>Age <math>\geq 45</math> years</b></li> <li>• <b>Body mass index <math>\geq 27</math> kg/m<sup>2</sup></b></li> <li>• <b>Established cardiovascular disease</b>, as evidenced by 1 of the following:               <ul style="list-style-type: none"> <li>- Prior myocardial infarction</li> <li>- Prior ischemic or hemorrhagic stroke</li> <li>- Symptomatic peripheral arterial disease*</li> </ul> </li> </ul>	<p><b>Cardiovascular</b></p> <ul style="list-style-type: none"> <li>• Myocardial infarction, stroke, hospitalization for unstable angina or transient ischemic attack within 60 days before screening</li> <li>• Planned coronary, carotid, or peripheral artery revascularization</li> <li>• New York Heart Association Class IV**</li> </ul> <p><b>Glycemic</b></p> <ul style="list-style-type: none"> <li>• Hemoglobin A1c <math>\geq 6.5\%</math></li> <li>• History of type 1 or type 2 diabetes</li> <li>• Treatment with glucose-lowering agents including glucagon-like peptide-1 receptor agonists within 90 days before screening</li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>• History or presence of chronic pancreatitis</li> <li>• Acute pancreatitis within 180 days before screening</li> <li>• First-degree relative history of multiple endocrine neoplasia syndrome type 2 or medullary thyroid carcinoma</li> <li>• End-stage renal disease, chronic or intermittent hemodialysis, or peritoneal dialysis</li> <li>• Severe psychiatric disorder</li> <li>• Known or suspected hypersensitivity</li> </ul>

\* Intermittent claudication with ankle-brachial index  $< 0.85$ , or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease

\*\* Symptoms at rest, discomfort with any physical activity in patients with heart failure

Lincoff AM et al. *N Engl J Med*. 2023;389(24):2221-2232.



**Department  
of Health**

Office of  
Health Insurance  
Programs





# 2 and 3. Lifestyle Change(s) and Cardiovascular Treatment Prior to Initiation of Wegovy®



Department  
of Health

Office of  
Health Insurance  
Programs



# SELECT Trial

## Lifestyle Modifications

- There was no lead-in period of lifestyle modifications
- Individualized healthy lifestyle counseling was offered to participants at randomization and at every visit throughout the study

## Cardiovascular Treatment

- Use of cardiovascular medications prior to enrollment was NOT required for participation
- Study interventions included standard care
  - Aligned with guideline recommendations

Lincoff AM et al. *N Engl J Med*. 2023;389(24):2221-2232.



**Department  
of Health**

Office of  
Health Insurance  
Programs



# Guideline Recommendations – Lifestyle Modifications

Organization, Year of Publication	Population	Recommendations
ACC/AHA multisociety, 2024	Adults with lower extremity PAD	<ul style="list-style-type: none"> <li>• Healthy diet is recommended for cardiovascular risk reduction</li> <li>• Structured exercise programs are recommended to improve functional status, walking performance, and quality of life</li> </ul>
European Society of Cardiology, 2024	Adults with peripheral arterial and aortic diseases	<ul style="list-style-type: none"> <li>• Patients should strive to maintain a healthy lifestyle, because lifestyle factors are strongly related to ASCVD</li> <li>• Behavioral counseling to promote healthy diet, smoking cessation, and physical activity is recommended to improve the cardiovascular risk profile</li> <li>• Web- or app-based secondary prevention risk calculators should be considered to improve patient adherence to treatment and lifestyle changes</li> </ul>

ACC=American College of Cardiology; AHA=American Heart Association; ASCVD=atherosclerotic cardiovascular disease

# Guideline Recommendations, Continued – Lifestyle Modifications

Organization, Year of Publication	Population	Recommendations
ACC/AHA/ACCP/ASPC/NLA/PCNA, 2023	Adults with chronic coronary disease	<ul style="list-style-type: none"> <li>Assess for adherence to and adequacy of recommended lifestyle interventions; includes physical activity, nutrition, weight management, and stress reduction</li> <li>Patients should receive ongoing individualized education on symptom management, lifestyle changes, and SDOH</li> </ul>
AHA/ASA, 2021	Adults post-stroke	<ul style="list-style-type: none"> <li>Recommended lifestyle practices include regular physical activity, weight management, smoking cessation, avoidance of passive tobacco smoke, avoidance of excessive alcohol use and certain substances; adherence to Mediterranean diet and sodium restriction</li> </ul>
Canadian Cardiovascular Society, 2021	Adults at risk for ASCVD event	<ul style="list-style-type: none"> <li>Health behavior interventions recommended to optimize cardiovascular health; includes smoking cessation, limited alcohol consumption, healthy dietary pattern, moderate-vigorous aerobic physical activity</li> </ul>
Veterans Affairs, Dept of Defense	Prevention of CVD	<ul style="list-style-type: none"> <li>Recommends structured exercise-based rehabilitation</li> <li>Dietitian-led Mediterranean diet is recommended</li> </ul>

ACC=American College of Cardiology; ACCP=American College of Clinical Pharmacy; AHA=American Heart Association; ASA=American Stroke Association; ASCVD=atherosclerotic cardiovascular disease; ASPC=American Society for Preventive Cardiology; NLA=National Lipid Association; PCNA=Preventive Cardiology; SDOH=social determinants of health

*J Am Coll Cardiol.* 2023;82:833-955.

*Stroke.* 2021;52:e558-e571.

*Can J Cardiol.* 2021;37:1129-1150. *Ann Intern Med.* 2020;173:822-829.



**Department  
of Health**

Office of  
Health Insurance  
Programs



# Lifestyle Modifications – Summary

- All of the identified organizations recommend counseling on and monitoring of adherence to lifestyle modifications
  - Includes adoption of a healthy diet and increased physical activity

*J Am Coll Cardiol.* 2024;83:2497-2604.

*Eur Heart J.* 2024;45:3538-3700.

*J Am Coll Cardiol.* 2023;82:833-955.

*Stroke.* 2021;52:e558-e571.

*Can J Cardiol.* 2021;37:1129-1150.

*Ann Intern Med.* 2020;173:822-829.



**Department  
of Health**

**Office of  
Health Insurance  
Programs**



# Guideline Recommendations – Pharmacologic Therapy

Organization(s), Year of Publication	Antiplatelet	Anticoagulant	Lipid-lowering	Antihypertensive	Antidiabetic	Other
PAD						
ACC/AHA/Multisociety, 2024	√	√	√	√	√	Drugs for smoking cessation, weight management
European Society of Cardiology, 2024	√	√	√	√	√	--
Chronic coronary disease						
AHA/ACC/ACCP/SPC/NLA/PCNA, 2023	√	√	√	√	√	Antianginal therapy, immunizations, weight management
Stroke						
AHA/ASA, 2021	√	√	√	√	√	Weight management
ASCVD						
Canadian Cardiovascular Society, 2021	--	--	√	--	--	--
VA/DoD, 2020	--	--	√	--	--	--

# Pharmacologic Therapy – Summary

- Despite differences in cardiovascular conditions, there are similarities among guideline recommendations
- All recommend lipid-lowering therapy with high-intensity statins
- Several also recommend antiplatelet therapy and antihypertensive therapy

*J Am Coll Cardiol.* 2024;83:2497-2604.

*Eur Heart J.* 2024;45:3538-3700.

*J Am Coll Cardiol.* 2023;82:833-955.

*Stroke.* 2021;52:e558-e571.

*Can J Cardiol.* 2021;37:1129-1150.

*Ann Intern Med.* 2020;173:822-829.



**Department  
of Health**

**Office of  
Health Insurance  
Programs**



# 4. Coverage Criteria for Bariatric Surgery



**Department  
of Health**

**Office of  
Health Insurance  
Programs**





# CMS Coverage Criteria for Bariatric Surgery

Requirements	Comorbidities
<ul style="list-style-type: none"> <li>• <b>BMI <math>\geq 35</math> kg/m<sup>2</sup> at the time of surgery and at least 1 comorbidity</b></li> <li>• Patient provided with knowledge and tools needed to achieve lifelong lifestyle modifications, <b>exhibits understanding, and has demonstrated willingness and capability to undergo these modifications</b></li> <li>• Patient has made <b>diligent effort to achieve healthy body weight</b>; efforts must be described in the medical record and certified by the clinician</li> <li>• <b>Adequate participation in a structured dietary program overseen</b> by a recognized specialist</li> <li>• <b>Objective evaluation by mental health professional</b> in patients with history of psychiatric disorder or psychotropic medications</li> <li>• Other medically reasonable or necessary preoperative evaluation(s) based on comorbidities and medical/surgical history</li> </ul>	<ul style="list-style-type: none"> <li>• Type 2 diabetes mellitus</li> <li>• Refractory hypertension despite medical treatment with maximal doses of 3 antihypertensive medications.</li> <li>• Refractory hyperlipidemia</li> <li>• Obesity-induced cardiomyopathy</li> <li>• Clinically significant obstructive sleep apnea</li> <li>• Obesity-related hypoventilation</li> <li>• Pseudotumor cerebri</li> <li>• Severe arthropathy of spine and/or weight-bearing joints</li> <li>• Hepatic steatosis without prior evidence of active inflammation</li> </ul> <p>All conditions must be of sufficient severity as to pose considerable short- or long-term risk to function and/or survival</p>

# 5. Utilization of Glucagon-Like Peptide-1 Receptor Agonists in New York State Medicaid

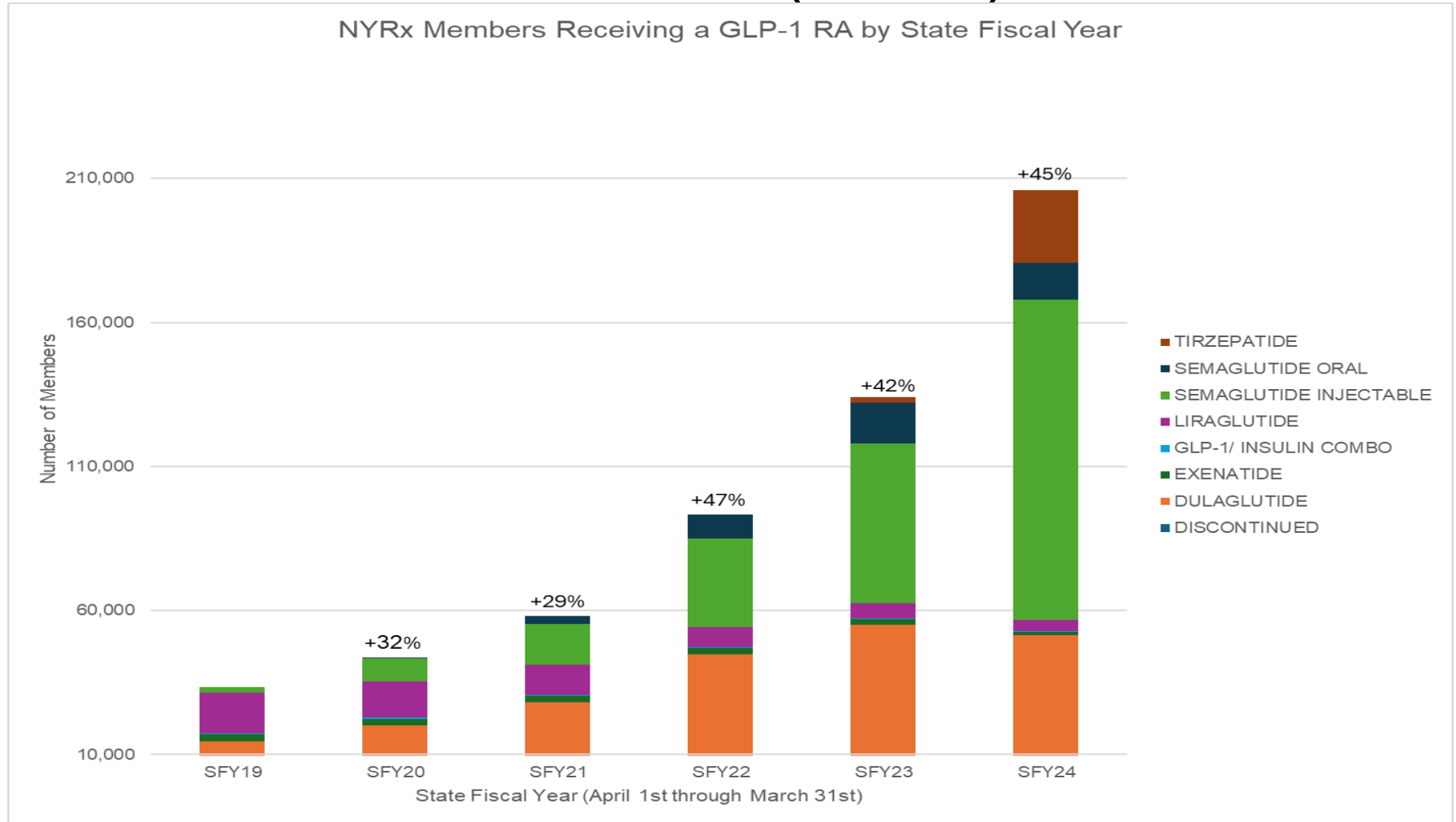


Department  
of Health

Office of  
Health Insurance  
Programs



# NYRx GLP-1 Receptor Agonist Utilization: Members (207 K)



Source: Medicaid Data Warehouse (MDW)  
Extract date: December 2024

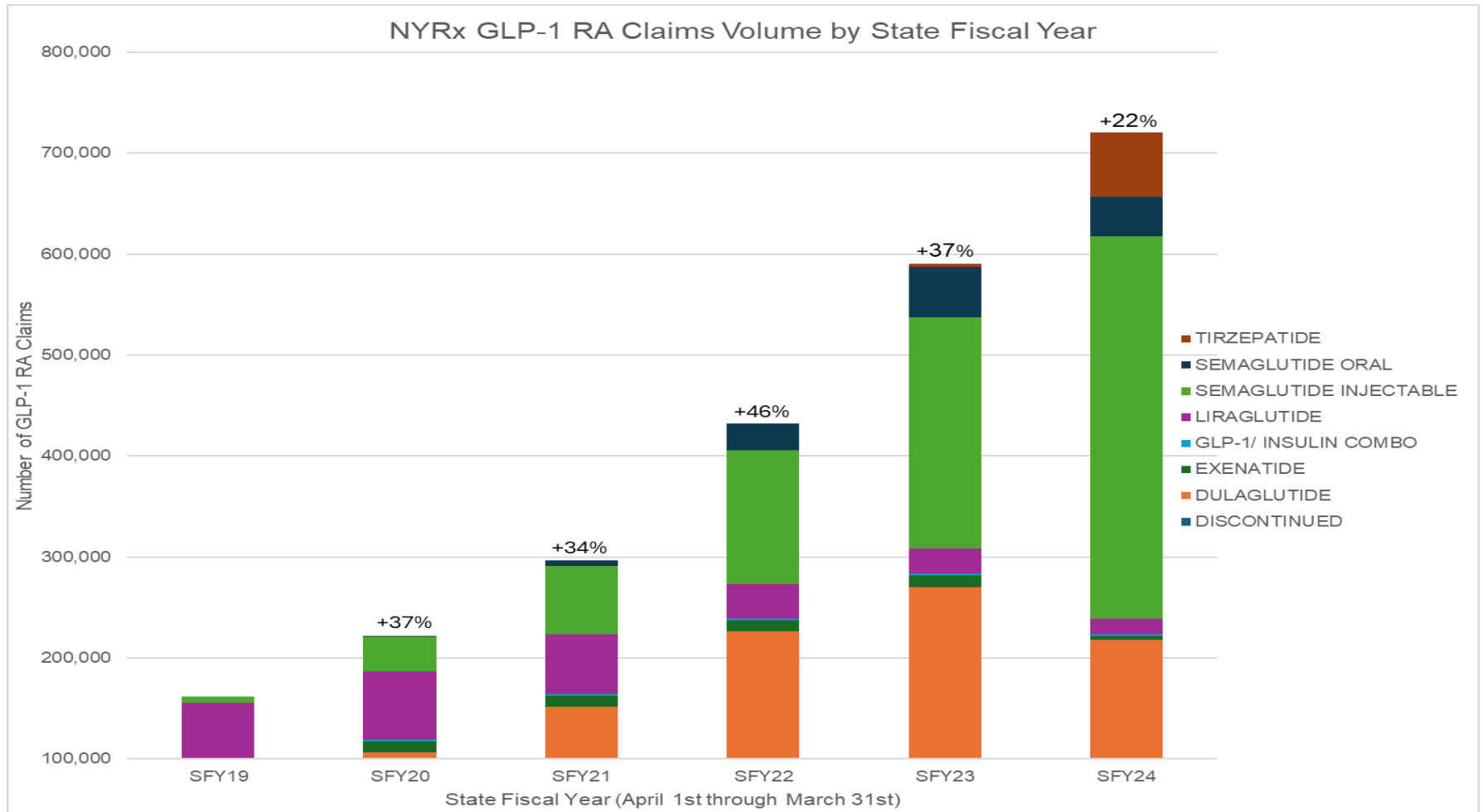


Department  
of Health

Office of  
Health Insurance  
Programs



# NYRx GLP-1 Receptor Agonist Utilization: Claims (2.8 M)



Source: Medicaid Data Warehouse (MDW)  
Extract date: December 2024



Department  
of Health

Office of  
Health Insurance  
Programs



# Calculation of Discontinuation Rates

- Step 1: Identify members initiating GLP-1 receptor agonist therapy in 2023
- Step 2: Confirm members are continuously enrolled in state fiscal year (SFY) 2022, 2023, and 2024
- Step 3: Calculate discontinuation rate for members initiating GLP-1 receptor agonist therapy in 2023
  - Discontinuation defined as >110-day gap between 2 consecutive claims for GLP-1 receptor agonist

SFY 2022  
Lookback  
period

- Continuously enrolled
- Lookback period

SFY 2023  
Initiated  
GLP-1  
receptor  
agonist

- Continuously enrolled
- Lookback 91 days for prior use

SFY 2024  
Continuation

- Continuously enrolled
- Evaluate continuation of therapy as a measure of adherence

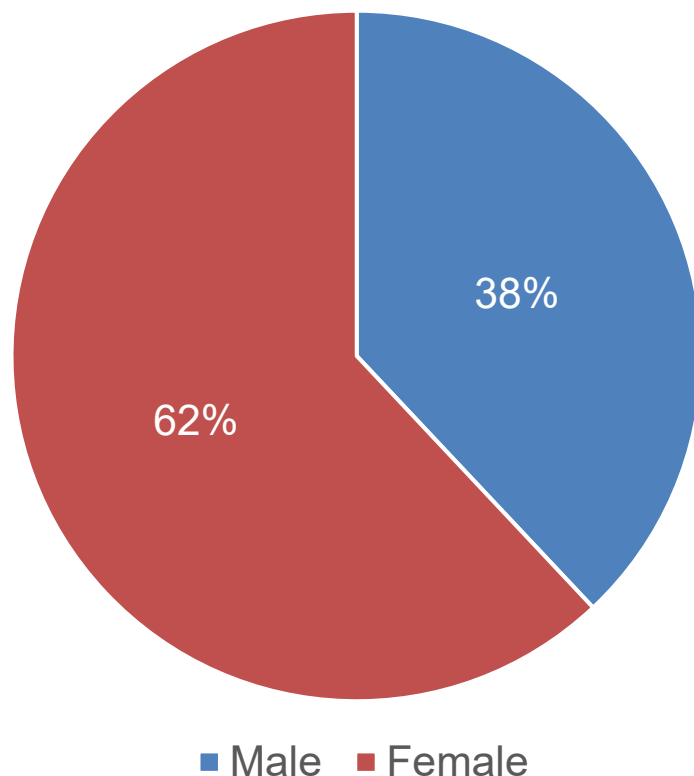


# Discontinuation Rates: Sample for Analysis

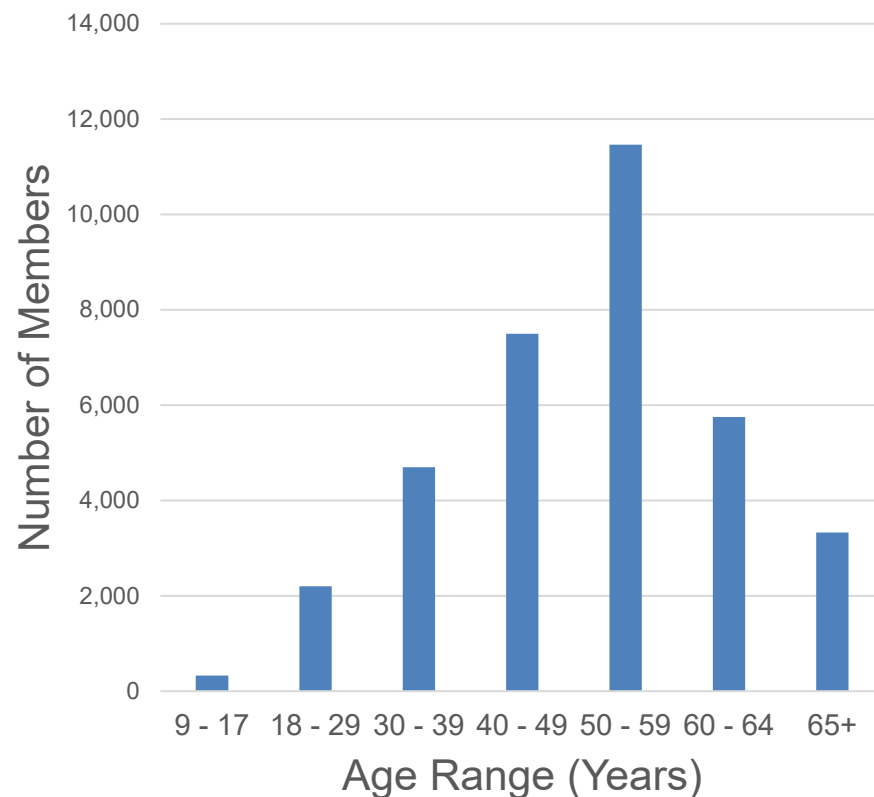
Number of Members	Percent of Members	Criteria
91 K	100%	Members with GLP1 claims for SFY 2023. (Index claim is first GLP1 claim in SFY 2023.)
	45%	Exclude members with prior GLP1 with claim with service date within 91 days of SFY2023 index claim
	10%	Exclude members without continuous enrollment for SFY 2024
	2%	Exclude members without continuous enrollment for SFY 2023
	4%	Exclude members without continuous enrollment for SFY 2022
	1%	Exclude members with $\geq 2$ claims on same service date
<b>35 K</b>	<b>38%</b>	<b>Members included in the sample for remainder of analysis</b>

# Sample Demographics (n=35 K)

Gender

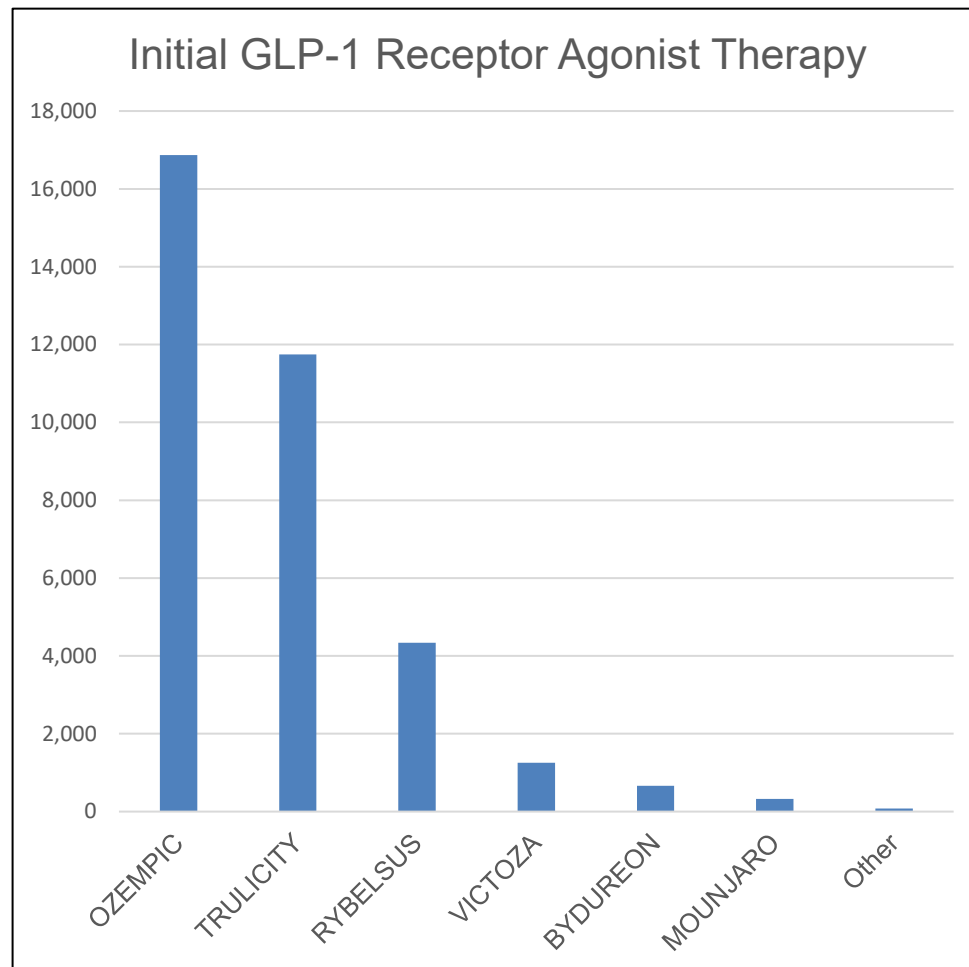


Age Distribution



# Initial Therapy in Sample (n=35 K)

- 48% of members started on Ozempic® (semaglutide injection)
  - 86% of members initiating therapy with Ozempic® started on 0.25-0.5 mg dose pen





# Discontinuation Rates

SFY 2022		SFY 2023		Variable
Number of Members	Percentage of Members	Number of Members	Percentage of Members	
26 K	100%	35 K	100%	Members starting GLP-1 receptor agonist in SFY 2023 (No GLP-1 receptor agonist in priors 91 days)
12 K	56%	19 K	53%	Members <b><u>discontinued</u></b> GLP-1 receptor agonist* therapy
14 K	44%	16 K	47%	Members continued GLP-1 receptor agonist therapy

\*Discontinuation defined as >110-day gap between 2 consecutive GLP-1 receptor agonist claims

# Questions?



**Department  
of Health**

**Office of  
Health Insurance  
Programs**





Department  
of Health

# Over-the-Counter (OTC) Bismuth Subsalicylate

NYS MEDICAID DRUG UTILIZATION REVIEW BOARD

February 27, 2025

# GENERAL OVERVIEW

## NYS Medicaid-covered OTC formulations

- Chewable tablets, 262 mg
- Oral suspension, 525 mg/30 mL

## Food & Drug Administration OTC monograph for antidiarrheal drug products

### ▪ Indications

- Control or relief of diarrhea and/or traveler's diarrhea; reduction in number of bowel movements; or firming of stool
- Dose: 525 mg every 30 minutes to hour or 1,050 mg every hour as needed; do not exceed 4,200 mg in 24 hours; use until diarrhea stops but not more than 2 days

### ▪ Warnings

- Do not use if stool is bloody or black, if allergic to salicylates or taking other salicylate products, or if there is an ulcer or bleeding problem

# GENERAL OVERVIEW

## Compendia

### ▪ FDA uses

- Micromedex® – Control of diarrhea, relief of heartburn, treatment of indigestion, relief of nausea, and treatment of upset stomach associated with nausea or caused by excess food and drink; in adults and children  $\geq 12$  years of age
- Clinical Pharmacology® – Treatment of nonspecific diarrhea, relief of gastric distress and related symptoms; in adults and children  $\geq 12$  years of age

### ▪ Non-FDA uses

- Micromedex® – Eradication of *Helicobacter pylori* (*H. pylori*) gastrointestinal tract infection in adults, as part of a quadruple therapy regimen (category B evidence); prophylaxis and treatment of traveler's diarrhea in adults (evidence rating not specified)
- Clinical Pharmacology® – Eradication of *H. pylori*, as part of initial, salvage, or alternative bismuth-based quadruple therapy in adults and children  $\geq 1$  year of age; treatment of traveler's diarrhea in adults and children  $\geq 3$  years of age; prevention of traveler's diarrhea in adults

### ▪ Mechanism of action

- Stimulates absorption of fluid and electrolytes; inhibits synthesis of prostaglandins responsible for intestinal inflammation and hypermotility; binds toxins produced by *Escherichia coli*



Department  
of Health

Bismuth subsalicylate monograph. In Merative Micromedex®. [www.micromedexsolutions.com](http://www.micromedexsolutions.com). Monograph last revised 10/17/2024. Accessed 1/10/25.  
Bismuth subsalicylate monograph. In Clinical Pharmacology powered by ClinicalKey®. <https://www-clinicalkey-com.gate.lib.buffalo.edu/pharmacology/>.  
Monograph last updated 1/3/25. Accessed 1/10/25.

# LITERATURE REVIEW

- **2021 meta-analysis on prevention and treatment of traveler's diarrhea / infectious diarrhea**

- Objective: to evaluate the efficacy of bismuth subsalicylate for prevention and treatment of diarrhea
- Inclusion criteria: randomized, placebo-controlled trials evaluating use of bismuth subsalicylate for prevention or treatment of traveler's diarrhea and infectious diarrhea
- Results (odds ratios and 95% confidence intervals):
  - Prevention of traveler's diarrhea (3 trials): 3.5 (2.1 to 5.9)
  - Treatment of traveler's diarrhea (5 trials): 3.1 (1.9 to 5.0)
  - Treatment of infectious diarrhea (11 trials): 3.7 (2.1 to 6.3)
- Authors' conclusions: bismuth subsalicylate can be beneficial for prevention or treatment of traveler's or infectious diarrhea

# LITERATURE REVIEW

## Guidelines

- **Centers for Disease Control and Prevention Yellow Book 2024: For acute traveler's diarrhea**
  - Mild: consider treatment with bismuth subsalicylate or loperamide
  - Moderate or severe: consider loperamide, unless patients have bloody diarrhea or are febrile
  - Contraindications include aspirin allergy, gout, or renal insufficiency, and those taking anticoagulants (including aspirin), methotrexate, or probenecid.
  - In travelers taking aspirin or salicylates for other reasons, concomitant use of bismuth can increase the risk of developing salicylate toxicity.
  - Studies have not established the safety of bismuth use for >3 weeks.
- **UpToDate®: Treatment and Prevention**
  - Bismuth is not commonly used as TD treatment nor prophylaxis due to number of OTC tablets required, increasing toxicity risk



**Department  
of Health**

Centers for Disease Control and Prevention (CDC). Traveler's diarrhea. CDC Yellow Book 2024. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/travelers-diarrhea>.

UpToDate®. Travelers' diarrhea: Treatment and prevention. Available at: <https://www.uptodate.com/contents/travelers-diarrhea-treatment-and-prevention>

# LITERATURE REVIEW

## Guidelines: American College of Gastroenterology 2024 guideline for treatment of *H. pylori*

- For treatment-naïve patients with *H. pylori* infection
  - Optimized bismuth quadruple therapy recommended as first-line treatment
    - Bismuth subsalicylate 300 mg or bismuth subcitrate 120-300 mg, 4 times daily
    - Metronidazole 500 mg, 3 or 4 times daily
    - Tetracycline 500 mg, 4 times daily
    - Proton pump inhibitor at standard dose, 2 times daily
  - Note: recommended dose of bismuth subsalicylate not achievable with OTC preparation
  - Avoidance of bismuth subsalicylate recommended in patients with salicylate allergy







**Department  
of Health**



**Department  
of Health**

# **Over-the-Counter (OTC) Carbamide Peroxide Ear Drops**

**NYS MEDICAID DRUG UTILIZATION REVIEW BOARD**

**February 27, 2025**

# GENERAL OVERVIEW

## NYS Medicaid-covered OTC formulations

- Carbamide peroxide 6.5% ear wax removal drops and kits

## Food & Drug Administration OTC monograph

### ▪ Indications

- Occasional use as an aid to soften, loosen, and remove excessive earwax in adults and children  $\geq 12$  years of age
- Dose: 5 to 10 drops in affected ear twice daily up to 4 days, if needed, or as directed by a doctor
- For use in children under 12 years of age, consult a doctor

### ▪ Warnings

- Do not use and consult a doctor if there is ear drainage or discharge, ear pain, irritation, rash in the ear, dizziness, injury, or perforated ear drum

# GENERAL OVERVIEW

## Compendia

### ▪ FDA uses

- Micromedex® – None
- Clinical Pharmacology® – Cerumen removal in adults and children  $\geq 12$  years of age

### ▪ Non-FDA uses

- Micromedex® – Ear wax removal (effective in adults and pediatrics; category B evidence for adults; category C evidence for pediatrics)
- Clinical Pharmacology® – Cerumen removal in children  $< 12$  years of age

### ▪ Mechanism of action

- Carbamide peroxide is a loose complex of urea and hydrogen peroxide, slowly dissociating in contact with moisture in the ear; hydrogen peroxide is reduced to water and urea acts as a mild keratolytic, aiding in disintegration of keratin debris



# LITERATURE REVIEW

## Guidelines: 2017 American Academy of Otolaryngology cerumen impaction guidelines

### ▪ For clinicians treating impaction

- Cerumenolytic (wax-softening) agents, irrigation, and/or manual removal of ear wax with instrumentation may be appropriate options
- No cerumenolytic agent is superior to any another (e.g., docusate sodium, hydrogen peroxide, sodium bicarbonate, sterile saline, almond oil, mineral oil, olive oil, carbamide peroxide)
- Patients susceptible to impaction may use cerumenolytic drops and/or irrigation at home to control accumulation

### ▪ Precautions

- Instilling cerumenolytics may result in discomfort, transient hearing loss, dizziness, and skin irritation, and should not be used in patients with active ear infections



# LITERATURE REVIEW

## Additional literature

- **2018 Cochrane systematic review and meta-analysis**

- 10 randomized controlled trials, 9 were >15 years old; comparisons included oil-based drops, water-based drops, saline or water alone, or no treatment; only 1 trial included carbamide peroxide
- Authors concluded there was no high-quality evidence to determine if one cerumenolytic was more effective than another or if water or saline alone was better or worse than commercial cerumenolytics or better than no treatment

- **2021 systematic review and network meta-analysis**

- 25 randomized trials were included in the meta-analysis; 3 trials included carbamide peroxide
- Authors concluded very low-grade strength of evidence was observed for all interventions; several cerumenolytics (including oils) showed significant benefit over normal saline for ear wax removal but carbamide peroxide did not

- **2024 study not included in above meta-analyses**

- 29 patients with bilateral cerumen impaction served as their own controls comparing carbamide peroxide in one ear to phenol glycerin in the other; there was no significant difference in time to removal of ear wax

Aaron K, Cooper TE, Warner L, Burton MJ. Ear drops for the removal of ear wax. *Cochrane Database Syst Rev*. 2018;7(7):CD012171. Published 2018 Jul 25.

Sridharan K, Sivaramakrishnan G. Cerumenolytics with or without manual extraction for impacted earwax: A network meta-analysis of randomised clinical trials. *Clin Otolaryngol*. 2021;46(3):464-473.

Asgari AR, Asgari HR, Ghorbanlou M, Dobakhti F, Ghorbanian MA. Cerumenolytic effects of carbamide peroxide in patients with ear wax obstruction. *Iran J Otorhinolaryngol*. 2024;36(2):415-420.



**Department  
of Health**



**Department  
of Health**



Department  
of Health

# Over-the-Counter (OTC) Topical Menthol Products

NYS MEDICAID DRUG UTILIZATION REVIEW BOARD

February 27, 2025



# GENERAL OVERVIEW

## NYS Medicaid-covered OTC formulations

- Menthol patch
- Menthol/methyl salicylate cream

## Mechanism of action

- Menthol: Exact mechanism is not well defined, but involves analgesia, cooling sensation, irritant/counter-irritant effects, and vasodilation (via alteration of calcium efflux from nerve cells and activation of kappa-opioid receptors, cold thermoreceptors, and nociceptors)
- Methyl salicylate: Acts as a topical analgesic with anti-inflammatory, rubefacient/counter-irritant, and vasodilatory effects (increases blood flow and temperature)

## Food and Drug Administration (FDA)-approved uses

- Minor arthralgia or myalgia associated with arthritis, bruises, simple backaches, sprains, and strains

Medicaid Pharmacy List of Reimbursable Drugs. Available at: <https://www.emedny.org/info/formfile.aspx>. Accessed 12/17/24.

Methyl salicylate and menthol monographs. In UpToDate® Lexidrug™. Available at: <https://online-lexi-com.gate.lib.buffalo.edu/lco/action/home>. Accessed 12/17/2024.

Methyl salicylate and menthol monographs. In Clinical Pharmacology powered by ClinicalKey. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed 12/17/2024.

# LITERATURE REVIEW

Cochrane Systematic Review (2014) – Salicylate-containing rubefacients for acute and chronic musculoskeletal pain

- Evidence does not support use of these products for acute injuries or chronic conditions
- Products are well-tolerated
- Did not directly address menthol



**Department  
of Health**

Derry et al. *Cochrane Database Syst Rev.* 2014;2014(11):1-51.  
Derry et al. *Cochrane Database Syst Rev.* 2017;5(5):1-32.

# LITERATURE REVIEW

Cochrane Systematic Review (2017) – Topical analgesics for acute and chronic pain

- Addressed use of salicylate-containing rubefacients, capsaicin, and other topical agents (e.g., NSAIDs, lidocaine)
- Noted there are no Cochrane or non-Cochrane systematic reviews with menthol
- Only found evidence that topical NSAIDs have good and limited efficacy in treating strains/sprains and hand/knee osteoarthritis, respectively
- Evidence was limited for use of salicylates for chronic pain



**Department  
of Health**