



Department  
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# **Drug Utilization Review (DUR) Board Meeting**

## **October 25, 2024**

### **Medicaid Pharmacy Program Updates**

October 25, 2024

# Medicaid Pharmacy Program Updates

- Medicaid Pharmacy SFY 2024-2025 Budget Initiatives
- Clinical Criteria Modifications

October 25, 2024

# Medicaid Pharmacy Budget Initiatives SFY 2024-2025

- Supplemental Rebate Program Changes
- Over-the-Counter (OTC) Drug Coverage Modifications
- Others
  - Reimbursement Methodology Changes
  - Maintenance Medications and 90 Day Supplies

Legislation effective date: October 1, 2024

October 25, 2024

# Supplemental Rebate Program Changes

## NYS Public Health Law 280 – Drug Cap

New method for identifying drugs for possible Drug Utilization Review (DUR) Board referral:

“The commissioner shall review at least annually the department of health state funds Medicaid drug expenditures to identify drugs in the eightieth percentile or higher of total spend net of rebate or in the eightieth percentile or higher based on cost per claim net of rebate.”

October 25, 2024

# Supplemental Rebate Program Changes

## NYS Social Services Law 367-A - Payments; insurance

New language related to drugs that come to market by way of the accelerated approval pathway - “accelerated approval” drugs.

“Accelerated approval” is defined as a drug or labeled indication of a drug authorized by the Federal Food, Drug and Cosmetic Act for drugs approved under Subpart H of 21 CFR Part 314 and Subpart E of 21 CFR Part 601 for serious conditions that fill an unmet medical need based on whether the drug has an effect on a surrogate clinical end point and is pending verification of clinical benefit in confirmatory trials.

October 25, 2024

# Supplemental Rebate Program Changes

## Drug Cap - NYS Public Health Law 280

Manufacturer notifications - October 2024.

## Accelerated approval drugs - NYS Social Services Law 367-A

Manufacturer notifications will be integrated into the semi-annual high-cost drug and gene therapy notification process.

October 25, 2024

# Over-the-Counter (OTC) Drug Coverage Modifications

## NYS Social Services Law 365-A - Character and adequacy of assistance

“Modifications to the list of drugs reimbursable under this paragraph may be filed as regulations by the commissioner of health without prior notice and comment; provided, however, that the department will notify enrollees of any eliminations to the list of drugs reimbursable under this paragraph at least sixty days prior to the removal of such drug. Such eliminations shall be referred to the drug utilization review board.....”

# Over-the-Counter (OTC) Drug Coverage Modifications

**During today's meeting:**

**The DUR Board will review the following drugs / drug categories, that may be dispensed without a prescription (i.e., over-the-counter drugs that are dispensed with a fiscal order) and, if applicable, recommend coverage changes:**

- Cough and Cold Products: Oxymetazoline nasal, Phenylephrine
- Gastrointestinal Products: Simethicone
- Anti-hypoglycemics: Glucose tablets
- Dermatologicals: Bacitracin, Neomycin
- Vitamins and Minerals: Multivitamins

October 25, 2024



# Other Budget Initiatives

## Reimbursement Methodology Changes:

NYS Social Services Law 367-A - Payments; insurance

- Single source brand name drugs without a NADAC
- Physician/Prescriber Administered Drugs (PADs)

## Maintenance Medications and 90 Day Supplies

October 25, 2024

# Clinical Criteria Modifications

## Step therapy modifications:

- Metformin
- Anti-migraine agents indicated for migraine prevention



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# Questions?

October 25, 2024

**New York State Medicaid Drug Utilization Review Board Meeting – October 25, 2024**  
**Preferred Drug Program – Drug Class Review**

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
<b>Insulin – Long-Acting</b>		
insulin glargine solostar, vial (gen Lantus® Solostar®, vial) Lantus® Solostar®, vial Levemir®	Basaglar® Basaglar® Tempo™ insulin degludec vial, pen (gen Tresiba) insulin glargine max solostar (gen Toujeo® Max Solostar®) insulin glargine solostar (gen Toujeo® Solostar®) insulin glargine-YFGN: vial, pen Rezvoglar™ Semglee®-YFGN: vial, pen Toujeo® Solostar® Toujeo® Max Solostar® Tresiba®	N/A

**New York State Medicaid Drug Utilization Review Board Meeting – October 25, 2024**  
**Preferred Drug Program – Drug Class Review**

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
<b>Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors</b>		
Farxiga® <a href="#">BLTG</a> Invokamet® Invokamet® XR Invokana® Jardiance® Synjardy® Synjardy® XR Trijardy® XR Xigduo® XR <a href="#">BLTG</a>	dapagliflozin (gen Farxiga®) dapagliflozin/metformin (gen Xigduo® XR) Inpefa™ Segluromet® Steglatro®	N/A

# Wegovy® (semaglutide)

October 25, 2024  
DURB Meeting

# Purpose

- The aim of this review is to examine the semaglutide product Wegovy® and its potential utilization in the New York State Medicaid population
  - Focus: use for reduction in the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight
- Recommendations will be provided based on a review of the literature and results from utilization data analyses



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# Glucagon-like Peptide-1 Receptor Agonists

- Analogs of glucagon-like peptide-1
  - Enhance insulin secretion, delay gastric emptying, reduce food intake
- Semaglutide is one of several agents available in the United States
  - Most agents were initially approved for glycemic control in patients with type 2 diabetes mellitus
  - **Other** indications:
    - Reduction in risk of major adverse cardiovascular events in patients with type 2 diabetes mellitus\*
    - Management of obesity or overweight with weight-related morbidity\*\*
      - Body mass index  $\geq 30$  kg/m<sup>2</sup> or  $\geq 27$  kg/m<sup>2</sup>

Exenatide
<ul style="list-style-type: none"> <li>• Byetta® (2005)</li> <li>• Bydureon Bcise® (2017)</li> </ul>

Liraglutide
<ul style="list-style-type: none"> <li>• <b>Victoza® (2010, 2017)*</b></li> <li>• <b>Saxenda® (2014)**</b></li> <li>• Xultophy® (2016)</li> </ul>

Albiglutide
<ul style="list-style-type: none"> <li>• Tanzeum® (2014)</li> </ul>

Dulaglutide
<ul style="list-style-type: none"> <li>• <b>Trulicity® (2014, 2020)*</b></li> </ul>

Lixisenatide
<ul style="list-style-type: none"> <li>• Adlyxin® (2016)</li> <li>• Soliqua® (2016)</li> </ul>

Semaglutide
<ul style="list-style-type: none"> <li>• <b>Ozempic® (2017, 2020)*</b></li> <li>• Rybelsus® (2019)</li> <li>• <b>Wegovy® (2021, 2024)**</b></li> </ul>

Tirzepatide
<ul style="list-style-type: none"> <li>• Mounjaro® (2022)</li> <li>• <b>Zepbound® (2023)**</b></li> </ul>

Glucagon-like Peptide-1 Receptor Agonists. In: Clinical Pharmacology powered by ClinicalKey®.  
 Food and Drug Administration. Drugs@FDA: FDA-Approved Drugs. <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.  
 Product labels – please see end of presentation for references



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# 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

# Overview of Semaglutide-Containing Products

Characteristics	Wegovy®	Ozempic®	Rybelsus®
Approved uses*	<ul style="list-style-type: none"> <li>Weight reduction and maintenance in patients with obesity or overweight with <math>\geq 1</math> weight-related morbidity (age <math>\geq 12</math> years)</li> <li>Reduction in risk of major adverse cardiovascular events in patients with established cardiovascular disease and either obesity or overweight (age <math>\geq 18</math> years)</li> </ul>	<ul style="list-style-type: none"> <li>Improvement in glycemic control in patients with type 2 diabetes mellitus (age <math>\geq 18</math> years)</li> <li>Reduction in risk of major adverse cardiovascular events in patients with type 2 diabetes mellitus with established cardiovascular disease (age <math>\geq 18</math> years)</li> </ul>	<ul style="list-style-type: none"> <li>Improvement in glycemic control in patients with type 2 diabetes mellitus (age <math>\geq 18</math> years)</li> </ul>
Compendia-supported uses	<ul style="list-style-type: none"> <li>Symptomatic improvement of heart failure with preserved ejection fraction in patients with obesity (age <math>\geq 18</math> years)</li> </ul>		<ul style="list-style-type: none"> <li>No additional uses</li> </ul>
Manufacturer	<ul style="list-style-type: none"> <li>Novo Nordisk Inc.</li> </ul>		
Limitations of use	<ul style="list-style-type: none"> <li>Concomitant use with other semaglutide-containing products or any other glucagon-like peptide-1 receptor agonist is not recommended</li> </ul>	<ul style="list-style-type: none"> <li>These products have not been studied in patients with a history of pancreatitis</li> <li>These products are not intended for treatment of type 1 diabetes mellitus</li> </ul>	
Dosing regimen	<p>Adults:</p> <ul style="list-style-type: none"> <li>Weeks 1-4: 0.25 mg once weekly</li> <li>Weeks 5-8: 0.5 mg once weekly</li> <li>Weeks 9-12: 1 mg once weekly</li> <li>Weeks 13-16: 1.7 mg once weekly</li> <li>Weeks 17 and onward: 1.7 mg or 2.4 mg once weekly</li> <li>If intolerance occurs, delay dose escalation for 4 weeks</li> </ul> <p>Pediatric: same as above; discontinue if 1.7 mg once weekly not tolerated</p>	<p>(Adults only)</p> <ul style="list-style-type: none"> <li>Weeks 1-4: 0.25 mg once weekly</li> <li>Weeks 5-8: 0.5 mg once weekly</li> <li>Weeks 9-12: increase to 1 mg once weekly if additional glycemic control is needed</li> <li>Weeks 13 and onward: increase to 2 mg once weekly if additional glycemic control is needed</li> <li>Maximum: 2 mg once weekly</li> </ul>	<p>(Adults only)</p> <ul style="list-style-type: none"> <li>Days 1-30: 3 mg once daily</li> <li>Days 31-60: 7 mg once daily</li> <li>Days 61 and onward: increase to 14 mg once daily if additional glycemic control is needed</li> </ul>
Administration	<ul style="list-style-type: none"> <li>Inject subcutaneously on the same day each week, at any time of day, with or without meals</li> <li>Site and time of day can change without dose adjustment</li> </ul>		<ul style="list-style-type: none"> <li>Administer orally <math>\geq 30</math> minutes before the first food, drink or other oral medications, with <math>\leq 4</math> oz of plain water only</li> </ul>
How supplied	<ul style="list-style-type: none"> <li>Single-dose pen</li> <li>0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL, 2.4 mg/0.75 mL</li> </ul>	<ul style="list-style-type: none"> <li>Multi-dose pen</li> <li>2 mg/3 mL, 4 mg/3 mL, 8 mg/3 mL</li> </ul>	<ul style="list-style-type: none"> <li>Oral tablet</li> <li>3 mg, 7 mg, 14 mg</li> </ul>

\*Adjunct to diet and exercise



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Wegovy®, Ozempic®, and Rybelsus®. Prescribing information. Novo Nordisk Inc.; revised 2024, 2023, and 2024, respectively.

# Overview, continued

Characteristics	Wegovy®	Ozempic®	Rybelsus®
Contra-indications	<ul style="list-style-type: none"><li>• Personal or family history of medullary thyroid carcinoma</li><li>• Diagnosis of multiple endocrine neoplasia syndrome type 2</li><li>• Serious hypersensitivity reactions to semaglutide or excipients</li></ul>		
Warnings and precautions	<ul style="list-style-type: none"><li>• <b>Risk of thyroid C-cell tumors (boxed warning)</b></li><li>• Acute pancreatitis, acute gallbladder disease, acute kidney injury/worsening renal failure</li><li>• Hypoglycemia (particularly with concurrent insulin or insulin secretagogues)</li><li>• Serious hypersensitivity reactions, including anaphylaxis and angioedema</li><li>• Diabetic retinopathy complications in patients with type 2 diabetes mellitus</li></ul>		
Additional warnings	<ul style="list-style-type: none"><li>• Increased resting heart rate</li><li>• Suicidal behavior and ideation</li></ul>	<ul style="list-style-type: none"><li>• Pens should not be shared among patients, even if the needle is changed</li></ul>	<ul style="list-style-type: none"><li>• None</li></ul>
Specific populations	<ul style="list-style-type: none"><li>• <b>Pregnancy</b> – if using product for weight loss, discontinuation during pregnancy is advised</li><li>• <b>Lactation</b> – potential benefits and risks should be assessed</li><li>• <b>Pediatric</b> – safety and effectiveness have not been established in patients &lt;12 years of age</li><li>• <b>Geriatric</b> – no difference in efficacy were observed between patients ≥65 years of age and those &lt;65 years of age; serious adverse reactions were reported more commonly in adults ≥75 years compared to younger adults</li></ul>	<ul style="list-style-type: none"><li>• <b>Pregnancy/lactation</b> – potential benefits and risks should be assessed</li><li>• <b>Pediatric</b> – safety and effectiveness have not been established in patients &lt;18 years of age</li><li>• <b>Geriatric</b> – no overall differences in safety or efficacy were observed between patients ≥65 years of age and those &lt;65 years of age</li><li>• <b>Pregnancy/lactation</b> – potential benefits and risks should be assessed</li><li>• <b>Pediatric</b> – safety and effectiveness have not been established in patients &lt;18 years of age</li><li>• <b>Geriatric</b> – no overall differences in safety or efficacy were observed between patients ≥65 years of age and those &lt;65 years of age</li></ul>	
	<ul style="list-style-type: none"><li>• <b>Renal impairment</b> (including end-stage) or <b>hepatic impairment</b> – no dose adjustment is recommended</li></ul>		
Monitoring parameters	<ul style="list-style-type: none"><li>• Renal function, when initiating treatment or increasing doses, and in patients with renal impairment reporting any adverse reactions that could lead to volume depletion</li><li>• Blood glucose in patients with type 2 diabetes mellitus, complications in patients with diabetic retinopathy</li></ul>		
Cost / month	<ul style="list-style-type: none"><li>• \$1349 per package of 4 pens</li></ul>	<ul style="list-style-type: none"><li>• \$969 per pen</li></ul>	<ul style="list-style-type: none"><li>• \$969 per package</li></ul>

# 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.



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# SELECT Trial – Participant Characteristics

Trial period: October 2018 – March 2021  
Mean duration of follow-up: **39.8 ( $\pm 9.4$ ) months**

Total of 17,604 participants  
Semaglutide + standard care: n=8,803  
Placebo + standard care: n=8,801

Mean **age**:  $61.6 \pm 8.9$   
years

Male sex: 72.3%  
(n=12,732)

Mean **body mass index**:  
 $33.3 \pm 5.0$  kg/m<sup>2</sup>

71.5% (n=12,580) had  
body mass index  $\geq 30$  kg/m<sup>2</sup>

Mean **A1c**:  $5.8 \pm 0.3\%$

66.4% (n=11,696) had  
A1c of 5.7 to 6.4%

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



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# SELECT Trial – Participant Characteristics, continued

Characteristic	Semaglutide (n=8,803)	Placebo (n=8,801)
<b>History of cardiovascular disease</b>		
Coronary heart disease	82.2% (n=7,234)	82.0% (n=7,218)
Myocardial infarction	76.4% (n=6,729)	76.2% (n=6,709)
Coronary revascularization	67.4% (n=5,933)	67.2% (n=5,916)
Stroke	23.4% (n=2,058)	23.3% (n=2,052)
Symptomatic peripheral arterial disease	8.6% (n=754)	8.8% (n=771)
Chronic heart failure	24.5% (n=2,155)	24.2% (n=2,131)
Hypertension	81.9% (n=7,206)	81.6% (n=7,186)
<b>Cardiovascular medications at baseline</b>		
Platelet aggregation inhibitors	86.5% (n=7,612)	86.0% (n=7,569)
Antithrombotic medications	12.3% (n=1,086)	13.1% (n=1,150)
Lipid-lowering drugs	90.1% (n=7,928)	90.1% (n=7,929)
Beta-blockers	70.2% (n=6,182)	70.2% (n=6,175)
Angiotensin-converting enzyme inhibitors	45.0% (n=3,963)	45.1% (n=3,966)
Angiotensin receptor blockers	29.7% (n=2,618)	29.2% (n=2,569)
Calcium channel blockers	27.3% (n=2,407)	26.5% (n=2,331)

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



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# SELECT Trial – Outcomes

Endpoint	Semaglutide (n=8,803)	Placebo (n=8,801)	Hazard Ratio (95% Confidence Interval)
Primary composite*	6.5% (n=569)	8.0% (n=701)	0.80 (0.72 to 0.90)
• Death from cardiovascular causes	2.5% (n=223)	3.0% (n=262)	0.85 (0.71 to 1.01)
• Nonfatal myocardial infarction	2.7% (n=234)	3.7% (n=322)	0.72 (0.61 to 0.85)
• Nonfatal stroke	1.7% (n=154)	1.9% (n=165)	0.93 (0.74 to 1.15)
Heart failure composite	3.4% (n=300)	4.1% (n=361)	0.82 (0.71 to 0.96)
Nephropathy composite	1.8% (n=155)	2.2% (n=198)	0.78 (0.63 to 0.96)
Death from any cause	4.3% (n=375)	5.2% (n=458)	0.81 (0.71 to 0.93)
Coronary revascularization	5.4% (n=473)	6.9% (n=608)	0.77 (0.68 to 0.87)
A1c ≥6.5%	3.5% (n=306)	12.0% (n=1,059)	0.27 (0.24 to 0.31)
A1c ≥5.7% in patients with baseline A1c <5.7%	21.3% (n=623)	50.4% (n=1,501)	0.33 (0.30 to 0.36)

\*Death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke

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



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# New York State Medicaid Coverage

- Wegovy® is not currently covered in the New York State Medicaid program
  - Per New York Codes, Rules and Regulations, Title: Section 505.3, no payment will be made for any drug which has weight reduction as its sole clinical use
- Glucagon-like peptide-1 receptor agonists are subject to clinical criteria: **confirm diagnosis of FDA-approved, compendia-supported, and Medicaid-covered indication**

Glucagon-like Peptide-1 Receptor Agonist Coverage	
Preferred	Non-preferred
Byetta® (exenatide) Ozempic® (semaglutide) Trulicity® (dulaglutide) Victoza® (liraglutide)	Bydureon BCise® (exenatide) Liraglutide (generic Victoza®) Mounjaro® (tirzepatide) Rybelsus® (semaglutide) Soliqua® 100/33 (insulin glargine/lixisenatide) Xultophy® 100/3.6 (insulin degludec/liraglutide)

New York State Department of Health. New York Codes, Rules and Regulations. Title: Section 505.3 – Drugs.

<https://regs.health.ny.gov/content/section-5053-drugs>



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# Comparator State Medicaid Coverage

- Comparator states: CA, CO, FL, IL, MA, MI, PA, TX, WA
- Among the 9 programs, 6 offer restricted coverage of Wegovy®
  - Five of the 6 programs require prior authorization
  - Most also have quantity limits
- All 9 programs offer restricted coverage of Ozempic®, with quantity limits and/or prior authorization requirements



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# Drug Utilization Data: Overview of Analyses

- Members with selected international classification of diseases, 10<sup>th</sup> revision, codes present on  $\geq 1$  claim during the analysis period were identified
  - Overweight: body mass index between 25 and  $<30$  kg/m<sup>2</sup>
  - Obesity: body mass index  $\geq 30$  kg/m<sup>2</sup>
  - Type 2 diabetes mellitus
  - Cardiovascular conditions
- Data source: Medicaid Data Warehouse (MDW)
- Timeframe: April 1, 2023 – March 31, 2024



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# 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  $\leq 30$  in all public-facing documents
- The following limitations should also be considered:
  - While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete
  - Per a memo issued September 23, 2022, by the MDW Customer Care Center, the MDW Encounters Intake System (EIS) is rejecting Pharmacy/National Council for Prescription Drug Programs (NCPDP)
    - Encounters for a subset of national drug codes (NDC) are missing from its reference data
    - Encounters containing NDCs added to the approved formulary since December 2021 are being rejected and this could potentially result in incorrect data analytics/reporting



# Diagnoses of Interest

- Total enrollment in the New York State Medicaid program: 7.7 million members
- Population for analysis: 1.26 million members with overweight or obesity and WITHOUT a diagnosis of type 2 diabetes mellitus
- 16% of these members had a diagnosis of cardiovascular disease

Data source: MDW, April 1, 2023 - March 31, 2024



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# Age and Gender Distributions

Age Range (years)	Percentage of Members (n=1.26 million)
<12	8%
12 to 17	6%
≥18	86%
Unidentifiable	0%

Gender	Percentage of Members (n=1.26 million)
Female	38%
Male	62%
Unknown	0%

Data source: MDW, April 1, 2023 - March 31, 2024



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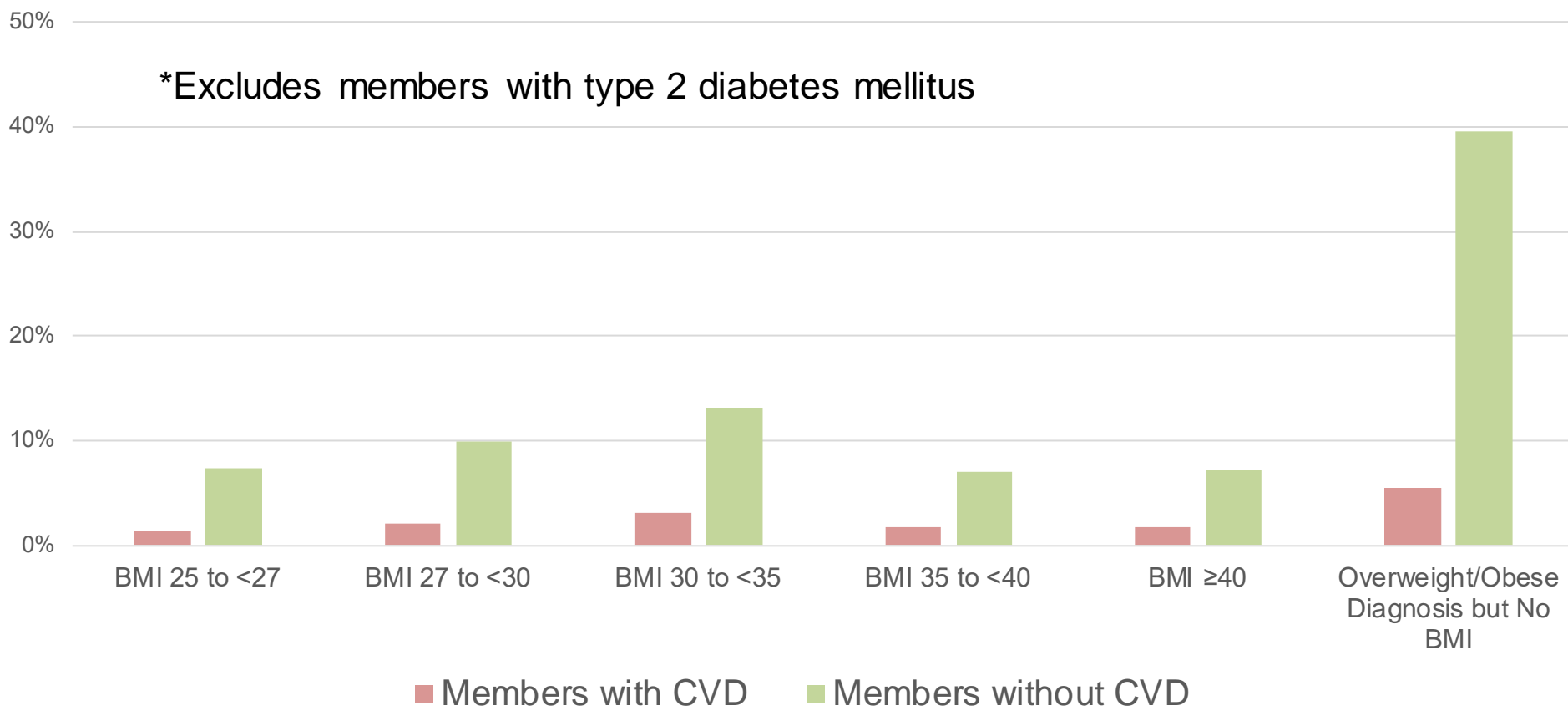
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# Body Mass Index Distributions

Percentages of Members Overweight or Obese, with or without Cardiovascular Disease (CVD)\* (overall n=1.26 million)

\*Excludes members with type 2 diabetes mellitus



Data source: MDW, April 1, 2023 - March 31, 2024



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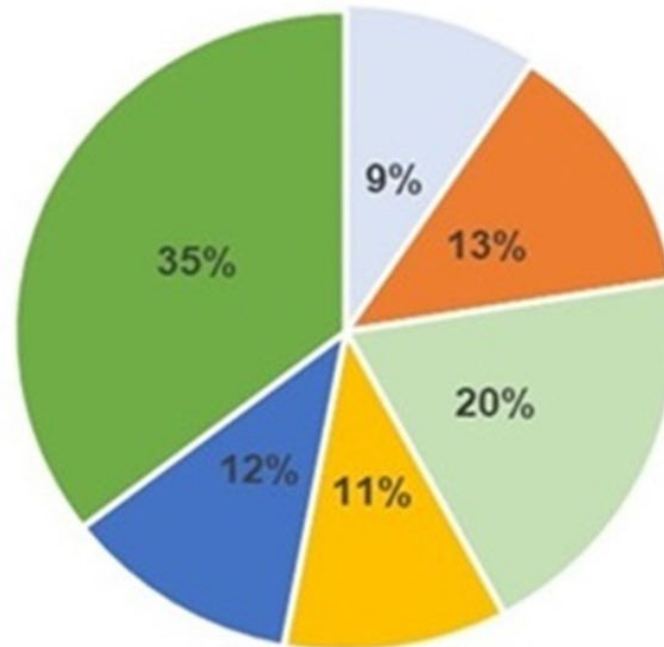
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# Body Mass Index Distribution – Subset of Analysis Population

Members with cardiovascular disease\*

\*Approximately 200,000;  
excludes members with  
type 2 diabetes mellitus



■ BMI 25 to <27 ■ BMI 27 to <30 ■ BMI 30 to <35 ■ BMI 35 to <40 ■ BMI ≥40 ■ Overweight/Obese Diagnosis but No BMI

Data source: MDW, April 1, 2023 - March 31, 2024



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# Utilization of Cardiovascular Medications

Medication	Number and percentage of members* with $\geq 1$ pharmacy claim	
	Overall population (n=1.26 million)	Members with cardiovascular disease (n=200,000)
Lipid-lowering therapy	14%	30%
Beta-blockers	6%	17%
ACE inhibitors/ARBs	10%	23%
Calcium channel blockers	8%	18%
Anticoagulants	7%	25%
GLP-1 RAs	1%	2%
SGLT-2 inhibitors	0.3%	2%
Use of $\geq 1$ medication listed above	27%	54%
Use of medications from $\geq 2$ different classes listed above	12%	32%
None of the above medications	73%	46%

\*Members were overweight or obese and without type 2 diabetes mellitus

ACE=angiotensin-converting enzyme; ARB=angiotensin receptor blocker; GLP-1 RA=glucagon-like peptide-1 receptor agonist; SGLT-2=sodium-glucose cotransporter-2

Data source: MDW, April 1, 2023 - March 31, 2024



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# Conclusions

- Semaglutide-containing products: Wegovy®, Ozempic®, Rybelsus®
  - Primary differences in formulations and indications
- In 2021, Wegovy® was approved for weight loss and weight maintenance in adults and pediatric patients  $\geq 12$  years of age with obesity and adults with overweight and  $\geq 1$  weight-related comorbidity
- In 2024, Wegovy® was approved for reduction in the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight
  - Supported by findings from SELECT trial
    - Included adults with body mass index  $\geq 27$  kg/m<sup>2</sup> and established cardiovascular disease
    - Excluded patients with diabetes
    - Significant reduction in composite of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke

Food and Drug Administration. Drugs@FDA: FDA-Approved Drugs. <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.

Product labels – please see end of presentation for references

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



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# Conclusions, continued

- A retrospective analysis of claims data from the Medicaid Data Warehouse was conducted to evaluate potential utilization of Wegovy®
- During the analysis period of April 1, 2023 to March 31, 2024, approximately 1.26 million members had diagnosis codes corresponding to overweight or obesity and did not have diagnoses of type 2 diabetes mellitus
  - Among these, 200,000 members had a diagnosis of cardiovascular disease
  - Of the members with cardiovascular disease, 54% had  $\geq 1$  claim for a cardiovascular drug during the analysis period

Data source: MDW, April 1, 2023 - March 31, 2024



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# UB Recommendations

- Consider implementation of prior authorization for Wegovy® with the following clinical criteria:
  - Presence of these diagnoses: overweight or obese and cardiovascular disease
  - Absence of diabetes (type 1 or 2)
  - Utilization of  $\geq 1$  cardiovascular medication in the past 30 days
  - No concurrent utilization of other semaglutide-containing products and non-semaglutide glucagon-like peptide-1 receptor agonists
  - Initial dose of 0.25 mg once weekly



# References – Product Labels

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# Review of Over-The-Counter (OTC) Products

NYS Medicaid Drug Utilization Review Board  
October 25, 2024



# Agenda

## A. Cough and Cold Products

- Oxymetazoline nasal
- Phenylephrine

## B. Gastrointestinal Products

- Simethicone

## C. Anti-hypoglycemics

- Glucose tablets

## D. Dermatologicals

Bacitracin  
Neomycin

## E. Vitamins and Minerals

Multivitamins



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# Objectives

- Provide a general overview of the OTC products
- Conduct a literature review for the OTC products



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# Cough and Cold Products

## Oxymetazoline Nasal and Phenylephrine



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# General Overview: Oxymetazoline Nasal Spray

NYS Medicaid covered OTC formulation

- Oxymetazoline 0.05% nasal spray

Mechanism of action

- Alpha-adrenergic agonist associated with vasoconstriction in the nasal mucosa, thereby reducing nasal edema for up to 10 hours.

Food and Drug Administration (FDA)-approved use

- Provides temporary symptomatic relief of sinus/nasal congestion due to colds, hay fever, upper respiratory allergies, and sinusitis.

# General Overview: Oxymetazoline Nasal Spray

## Directions

- Instill 2 to 3 sprays into each nostril twice daily in members  $\geq 6$  years of age for 3 to 5 consecutive days.

## Warnings

- Do not use this product for more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

# Guideline Review: Oxymetazoline Nasal Spray

- Rhinitis 2020: A Practice Parameter Update recommends short-term use of nasal decongestants for the following scenarios:

Recommendations	Strength of Recommendations	Certainty of the Evidence
Intermittent or episodic nasal congestion	Conditional	Low
Severe nasal mucosal edema that impairs the delivery of other intranasal agents	Conditional	Ungraded*
Persistent nasal congestion unresponsive to an intranasal corticosteroid (INCS) and/or intranasal antihistamine (INAH) therapies. An intranasal decongestant can be used in combination with the INCS and/or INAH for up to 4 weeks	Conditional	Low

\*The certainty of the evidence was ungraded because of the lack of studies but the guideline committee unanimously voted in favor of the recommendation.



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# Literature Review: Oxymetazoline Nasal Spray

2016 meta-analysis evaluated the use of oral and nasal decongestants for monotherapy for the common cold

- 15 randomized controlled trials (RCTs) were included in the analysis (n=1838 participants)
  - 3 RCTs compared oxymetazoline to placebo
- The authors concluded that the effectiveness of nasal decongestants following multiple doses for the common cold was uncertain
  - It was unclear the clinical relevance of the small benefit observed in the 3 RCTs



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# General Overview: Phenylephrine Containing Oral Products

## NYS Medicaid covered OTC formulations

- Phenylephrine tablets (10 mg)
- Guaifenesin/ phenylephrine tablets
- Brompheniramine/ phenylephrine/ dextromethorphan liquid

## Food and Drug Administration (FDA) approved uses for phenylephrine

- Temporarily relieves sinus congestion and pressure
- Temporarily relieves nasal congestion due to common cold, hay fever or other upper respiratory allergies

# General Overview: Phenylephrine Containing Oral Products

## Uses

- Oral nasal decongestant

## Mechanism of action

- Alpha-adrenergic agonist associated with vasoconstriction

## Pharmacokinetics

- Low oral bioavailability with the drug extensively metabolized in the gut wall, which reduces the therapeutic effectiveness of the drug



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# Guideline Review: Phenylephrine Containing Oral Products

In September 2023, the Food and Drug Administration (FDA) Nonprescription Drug Advisory Committee met to review new data on the effectiveness of oral phenylephrine.

- The FDA Committee concluded that oral phenylephrine was not an effective oral decongestant
- No safety concerns were identified by the FDA Committee



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# Gastrointestinal Products

## Simethicone



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# General Overview: Simethicone

## Mechanism of action

- Decreases surface tension of gas bubbles by forming a thin layer on their surface, leading to an anti-foaming effect and dispersal of gas pockets in the gastrointestinal tract

## NYS Medicaid covered OTC formulations

- Chewable tablets and infant drops

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

- Treatment of gas retention in adults, children, and infants

## Additional uses

- Preparation for endoscopy (gastroscopy and colonoscopy)
- Immediate post-prandial upper abdominal distress
- Gastroesophageal reflux disease (GERD)
- Infantile colic

# Literature Review: Simethicone

## European Society of Gastrointestinal Endoscopy (2019)

- Suggests adding simethicone to bowel preparation for colonoscopy – Weak recommendation; moderate-quality evidence
- Potential benefits include reduction in amount of bubbles/improved visibility, improvement in bowel cleanliness, and improvement in tolerance

No other guidelines identified addressing use of simethicone



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# Literature Review: Simethicone

There are multiple published clinical trials evaluating the effectiveness of simethicone, but most focus on its use for bowel preparation prior to endoscopy

- Infantile colic – 3 clinical trials identified with mixed results
- GERD – 2 clinical trials identified, both demonstrating no significant improvement in symptoms

Compendia designate the evidence for these conditions as **inconclusive**

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# Anti-Hypoglycemics

## Glucose Tablets



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# General Overview: Glucose Tablets

## NYS Medicaid covered OTC formulations

- Glucose 3.75 gram chewable tablet
- Glucose 4 gram chewable tablet

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

- Treatment of hypoglycemia

## An FDA-approved OTC monograph is unavailable.

- Per an FDA communication, glucose tablets are a food product regulated by the Center for Food Safety and Applied Nutrition (CFSAN).

# Literature Review: Glucose Tablets

If the patient can ingest glucose orally:

- 15-15 Rule
  - 15 grams of fast-acting carbohydrates and recheck blood glucose in 15 minutes to determine if it is  $\geq 70$  mg/dL.

Pure glucose is the preferred treatment, but any form of carbohydrate that contains glucose will raise blood glucose and is also recommended.

Examples are:

- Glucose tablets/ gel tube,
- 4 ounces (1/2 cup) of juice or regular soda (not diet),
- 1 tablespoon of sugar, honey, or corn syrup, and
- Hard candies, jellybeans, or gumdrops.



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# Dermatologicals

## Bacitracin and Neomycin



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# General Overview: Topical Bacitracin and Neomycin

## Mechanism of action

- Bacitracin inhibits bacterial growth by interfering with cell wall synthesis; it exhibits activity against several gram-positive and few gram-negative bacteria; clinical usefulness is restricted to staphylococcal infections
- Neomycin is an aminoglycoside antibiotic which interferes with bacterial protein synthesis; it is effective against gram-negative bacilli and some gram-positive microorganisms

## NYS Medicaid covered OTC formulations

- Bacitracin, bacitracin zinc, neomycin/bacitracin/polymyxin B

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

- First aid to help prevent infection in minor cuts, scrapes, and burns
  - Topical bacitracin and bacitracin zinc: Infants, children, adolescents, adults
  - Topical neomycin/bacitracin/polymyxin B: Ages  $\geq 2$  years

# Literature Review: Topical Bacitracin and Neomycin

## CDC guideline for prevention of surgical site infection (2017)

- Do not apply topical antimicrobial agents (i.e., ointments, solutions, or powders) to surgical incisions to prevent infection – Category 1B: strong recommendation; low-quality evidence

## Subsequent meta-analyses evaluating topical antibiotics for prevention of surgical/procedural site infection have yielded mixed results

- Few studies included bacitracin or bacitracin/neomycin/polymyxin B, also with mixed results
- Conclusions were limited by small number of studies with small sample sizes

## Comparative efficacy reported in compendia does not favor topical bacitracin

- White petrolatum was superior for healing of surgical site wounds and similar for preventing infections
- Triple dye was more effective in reducing bacterial colonization of umbilical cord stumps

CDC=Centers for Disease Control and Prevention

Berrios-Torres et al. *JAMA Surg* 2017.

Zhang et al, *Int Wound J* 2023.

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Tong et al, *Infect Drug Resist* 2018.

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Andrich & Golden. *Clin Pediatr* 1984.



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# Literature Review: Topical Bacitracin and Neomycin

Bacitracin and neomycin are among the top 10 allergens associated with allergic contact dermatitis (ACD), a delayed hypersensitivity reaction

- Top 2 allergens from topical medication sources

American Contact Dermatitis Society named bacitracin and neomycin “Allergen of the Year” in 2003 and 2010, respectively

- To draw attention to relatively high rates of ACD and other adverse effects

Several case reports of anaphylaxis associated with topical bacitracin and/or bacitracin/neomycin/polymyxin B have been published

Marks et al. *J Am Acad Dermatol* 1998.  
Zawawi et al. *Dermatitis* 2023.  
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Militello et al. *Dermatol Clin* 2020.  
Saryan et al. *Am J Emerg Med* 1998.  
Schoer et al. *Ann Allergy Asthma Immunol* 2008.  
Cronin et al. *Cutis* 2009.  
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# Literature Review: Topical Bacitracin and Neomycin

American Academy of Dermatology guidance for consumers on what to do for minor cuts, scrapes, and first-degree burns:

- Use of topical antibiotics to prevent infection is discouraged due to risk of adverse skin reactions and increasing antibiotic resistance
- General first aid care is recommended
  - Keep area clean
  - “Do not apply topical antibiotics”



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# **Vitamins and Minerals**

## **Multivitamins**



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# General Overview: Multivitamins

An adequate amount of vitamins and minerals is typically obtained from a well-balanced diet

- A multivitamin is **defined as 3 or more vitamins or minerals**

Dietary supplementation may be considered for:

- Patients with poor dietary habits
- Patients with temporarily increased demand (e.g., pregnancy, lactation)
- Proper growth in pediatric patients

Treatment of vitamin and mineral deficiencies - may be indicated in certain pathologic conditions, including:

- Increased nutritional requirements (e.g., severe illness, cachexia, hyperthyroidism, alcoholism)
- Abnormal absorption, utilization, or excretion of vitamins (e.g., malabsorption syndromes, hemodialysis)

\*For full list of multivitamin products: <https://www.emedny.org/info/formfile.aspx>

# Literature Review: Multivitamins

Products	Notes
Multivitamins/multivitamins with minerals (multiple products)*	<ul style="list-style-type: none"> <li>• <b>Defined as 3 or more vitamins or minerals</b></li> <li>• USPSTF guidelines/systematic review (Grade I recommendation) and statements from AHA and DHHS recommend that most patients receive nutritional support from their diet rather than nutritional supplementation</li> <li>• USPSTF guidelines: insufficient evidence on the benefits/harms to support the use of multivitamins for prevention of cardiovascular disease or cancer</li> <li>• CMS/EPSTD requires that “nutritional supplements” be covered for children when “medically necessary” (&lt;21 years of age)</li> </ul>

\*For full list of multivitamin products: <https://www.emedny.org/info/formfile.aspx>

AHA=American Heart Association; CMS=Centers for Medicare & Medicaid Services; DHHS=Department of Health and Human Services; EPSTD=Early and Periodic Screening, Diagnostic, and Treatment; USPSTF=United States Preventive Services Task Force

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O'Connor EA, et al. USPSTF; 2021. <https://www.ncbi.nlm.nih.gov/books/NBK581645/>

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