Prime THERAPEUTICS™

Antibiotics, Vaginal

Therapeutic Class Review

Antibiotics, Vaginal

New Drugs	
Cleocin ovules (clindamycin phosphate) vaginal suppositories	Nuvessa (Metronidazole 1.3%) vaginal gel
Xaciato (clindamycin phosphate) vaginal gel	Vandazole (metronidazole 0.75%) vaginal gel
Cleocin (clindamycin phosphate 2%) vaginal cream	Metronidazole 0.75% vaginal gel
Clindamycin 2% vaginal cream	
Clindesse (clindamycin phosphate 2%) vaginal cream	

Cleocin® (clindamycin phosphate) vaginal ovules

Clinical Information

Indications:

Clindamycin Vaginal Ovules are indicated for the treatment of bacterial vaginosis in non-pregnant adults.

Dosage and Administration:

- Dose: One vaginal ovule intravaginally once daily, preferably at bedtime
- Duration: 3 consecutive days
- Route: For intravaginal use only; not for oral use
- Patients should be advised to avoid vaginal intercourse and not use tampons or douches during treatment.

Adverse Reactions (>1%):

- Vaginal candidiasis
- Vaginitis
- Vulvovaginal irritation or pruritus
- Fungal infections

Drug Interactions:

- Clindamycin may enhance the effects of neuromuscular blocking agents; use caution with concomitant administration.
- Vaginal ovules contain components that may weaken latex or rubber contraceptives; condoms or diaphragms should not be relied upon during treatment and for at least 72 hours after therapy.

https://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=553

Cleocin® (clindamycin phosphate) vaginal ovules

Clinical Information, continued

Contraindications:

Clindamycin phosphate vaginal suppositories (Vaginal Ovules) are contraindicated in patients with:

- A history of hypersensitivity to clindamycin or lincomycin
- A history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis

Warning and Precautions:

Pseudomembranous colitis may occur; patients should be advised to report severe or persistent diarrhea.

Avoid use of intravaginal products (tampons, douches) and vaginal intercourse during treatment.

Use may result in overgrowth of non-susceptible organisms, including fungi.

Special Populations:

Pregnancy: Clindamycin vaginal ovules should be used during the first trimester of pregnancy only if clearly needed and the benefits outweigh the risks. There are no adequate and well-controlled studies of clindamycin vaginal ovules in pregnant women during the first trimester of pregnancy. In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters, has not been associated with an increased frequency of congenital abnormalities.

Lactation: Limited published data based on breast milk sampling reports that clindamycin appears in human breast milk. It is not known if clindamycin is excreted in human breast milk following the use of vaginally administered clindamycin phosphate.

Pediatric patients: Safety and effectiveness have not been established in pre-menarchal patients.

Geriatric patients: Clinical studies did not include sufficient numbers of patients aged 65 and older to determine whether response differs from younger adults.

https://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=553

Xaciato® (clindamycin phosphate) vaginal gel

Clinical Information

Indications:

Clindamycin phosphate vaginal gel is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older.

Dosage and Administration:

- Dose: One applicatorful (5 g of vaginal gel containing 100 mg clindamycin)
- Frequency: Single intravaginal dose
- Timing: May be administered at any time of day
- Route: Intravaginal only (not for ophthalmic, dermal, or oral use)

Clindamycin phosphate vaginal gel is formulated to increase viscosity at body temperature, allowing localized drug release without repeat dosing.

Adverse Reactions (>2%):

- Vulvovaginal candidiasis
- Vulvovaginal discomfort

Drug Interactions:

Clindamycin may enhance the effects of neuromuscular blocking agents; use caution with concomitant administration.

https://www.organon.com/product/usa/pi_circulars/x/xaciato/xaciato_pi.pdf

Xaciato® (clindamycin phosphate) vaginal gel

Clinical Information, continued

Contraindications:

Clindamycin phosphate vaginal gel is contraindicated in patients with a prior history to clindamycin or lincomycin.

Warning and Precautions:

Clostridioides difficile–associated diarrhea (CDAD): Has been reported with clindamycin use; discontinue and evaluate if diarrhea occurs.
Use with polyurethane condoms: Polyurethane condoms are not recommended during treatment and for 7 days after dosing, as they may not be reliable for pregnancy or sexually transmitted infection (STI) protection. Latex or polyisoprene condoms should be used instead.
Vaginal Candida overgrowth: Treatment may result in Candida overgrowth requiring antifungal therapy.

Special Populations:

Pregnancy: Clindamycin phosphate vaginal gel has not been studied in pregnant women. However, based on the low systemic absorption following the intravaginal route of administration in nonpregnant women, maternal use is not likely to result in significant fetal exposure to the drug.
Lactation: Systemic absorption following intravaginal administration of clindamycin is low; therefore, transfer of clindamycin into breastmilk is likely to be low and adverse effects on the breastfed infant are not expected.
Pediatric patients: The safety and effectiveness of XACIATO have not been established in pediatric patients younger than 12 years of age for the treatment of bacterial vaginosis.
Geriatric patients: Clinical studies did not include any subjects 65 years of age or older to determine whether they respond differently than younger subjects.

https://www.organon.com/product/usa/pi_circulars/x/xaciato/xaciato_pi.pdf

Metronidazole 0.75% vaginal gel

Clinical Information

Indications:

Metronidazole vaginal gel 0.75% is indicated for the treatment of bacterial vaginosis in non-pregnant women.

Dosage and Administration:

- Dose: One applicatorful (5 g of vaginal gel containing 37.5 mg metronidazole)
- Frequency: Once daily or twice daily intravaginally
- Duration: 5 consecutive days
- Route: For intravaginal use only (not for oral, dermal, or ophthalmic use)

Adverse Reactions (>1%):

- Fungal infection
- Headache
- Pruritis
- Abdominal pain
- Nausea
- Dysmenorrhea
- Pharyngitis
- Rash
- Infection
- Diarrhea
- Breast pain
- Metrorrhagia

Drug Interactions:

- Although systemic levels are low, disulfiram-like reactions with alcohol have been reported with oral metronidazole; caution is advised.
- Metronidazole may potentiate the effects of warfarin and other oral anticoagulants due to cytochrome-P450 mediated interactions when systemically absorbed.
- In patients stabilized on relatively high doses of lithium, short-term oral metronidazole therapy has been associated with elevation of serum lithium levels.
- Use of cimetidine with oral metronidazole may prolong the half-life and decrease plasma clearance of metronidazole.

IBM Micromedex® DRUGDEX®. Metronidazole [drug monograph]. Accessed Apr 2026.

Metronidazole 0.75% vaginal gel

Clinical Information, continued

Contraindications:

Metronidazole vaginal gel is contraindicated in patients with a prior history of hypersensitivity to metronidazole, parabens, other ingredients of the formulation, or other nitroimidazole derivatives.

Warning and Precautions:

Convulsive Seizures and Peripheral Neuropathy: Seizures and peripheral neuropathy have been reported with systemic metronidazole; discontinue therapy if neurologic symptoms occur.
Psychotic Reactions: Psychotic reactions have been reported in alcoholic patients who were using oral metronidazole and disulfiram concurrently. Metronidazole vaginal gel should not be administered to patients who have taken disulfiram within the last two weeks.

Special Populations:

Pregnancy: There is no data available regarding the use of metronidazole vaginal gel in pregnant women.

Lactation: Metronidazole is excreted in breast milk at concentrations similar to plasma. Caution is advised when administered to nursing individuals.

Pediatric patients: The safety and efficacy of metronidazole vaginal gel in pre-menarchal females have not been established.

Geriatric patients: Clinical studies with metronidazole vaginal gel did not include sufficient numbers of subjects 65 years of age or older to determine whether they respond differently than younger subjects.

IBM Micromedex® DRUGDEX®. Metronidazole [drug monograph]. Accessed Apr 2026.

Nuvessa® (Metronidazole 1.3%) vaginal gel

Clinical Information

Indications:

Metronidazole Vaginal Gel 1.3% is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in females 12 years of age and older.

Dosage and Administration:

- Dose: One single-dose, pre-filled disposable applicator
- Frequency: Once intravaginally
- Timing: Administer at bedtime
- Route: For intravaginal use only (not for oral, dermal, or ophthalmic use)

Adverse Reactions (>1%):

- Vulvovaginal candidiasis
- Headache
- Vulvovaginal pruritus
- Nausea
- Diarrhea
- Dysmenorrhea

Drug Interactions:

- **Warfarin and other coumarin anticoagulants:** Prolonged anticoagulant effects have been reported with oral metronidazole; caution is advised.
- **Lithium:** Elevated plasma lithium concentrations have been reported with oral metronidazole.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205223s002lbl.pdf

Nuvessa® (Metronidazole 1.3%) vaginal gel

Clinical Information, continued

Contraindications:

Metronidazole Vaginal Gel 1.3% is contraindicated in patients with:

- History of hypersensitivity to metronidazole, parabens, other formulation components, or other nitroimidazole derivatives
- Concomitant use of disulfiram or use within 2 weeks of disulfiram therapy
- Concomitant alcohol use

Warning and Precautions:

Convulsive Seizures and Peripheral Neuropathy: Seizures and peripheral neuropathy have been reported with systemic metronidazole; discontinue therapy if neurologic symptoms occur.
Interference with laboratory tests: Metronidazole may interfere with certain serum chemistry laboratory values.

Special Populations:

Pregnancy: There is no data available regarding the use of metronidazole vaginal gel in pregnant women.

Lactation: Some metronidazole is systemically absorbed following vaginal administration excretion in human milk following topical use is possible. A nursing mother may choose to pump and discard her milk during NUVESSA therapy and for 2 days after therapy ends, and feed her infant stored human milk or formula.

Pediatric patients: Approved for use in patients 12 years of age and older; safety and effectiveness have not been established in younger children.

Geriatric patients: Clinical studies did not include sufficient numbers of patients aged 65 and older to determine differences in response.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205223s002lbl.pdf

Cleocin® (clindamycin phosphate 2%) vaginal cream

Clinical Information

Indications:

Clindamycin phosphate 2% vaginal cream is indicated for the treatment of bacterial vaginosis in non-pregnant women.

Dosage and Administration:

- Dose: One applicatorful
- Frequency: Once daily intravaginally
- Duration: 3 to 7 consecutive days depending on clinical judgment
- Route: For intravaginal use only (not for oral, dermal, or ophthalmic use)

Adverse Reactions (>1%):

- Vaginal moniliasis
- Vulvovaginitis
- Vulvovaginal disorder
- Trichomonal vaginitis

Drug Interactions:

Neuromuscular blocking agents: Clindamycin may potentiate neuromuscular blockade; caution is advised with concomitant use.

https://labeling.pfizer.com/showlabeling.aspx?id=627

Cleocin® (clindamycin phosphate 2%) vaginal cream

Clinical Information, continued

Contraindications:

Clindamycin phosphate 2% vaginal cream is contraindicated in patients with:

- History of hypersensitivity to clindamycin, lincomycin, or any component of the formulation
- History of enteritis, ulcerative colitis, or antibiotic-associated colitis

Warning and Precautions:

Pseudomembranous colitis: Monitor patients for severe or persistent diarrhea; discontinue if suspected.

Special Populations:

Pregnancy: Clindamycin vaginal cream should be used during the first trimester of pregnancy only if clearly needed and the benefits outweigh the risks. There are no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy. In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters has not been associated with an increased frequency of congenital abnormalities.

Lactation: It is not known if clindamycin is excreted in human breast milk following the use of vaginally administered clindamycin phosphate.

Pediatric patients: Safety and effectiveness in pediatric patients have not been established.

Geriatric patients: Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

https://labeling.pfizer.com/showlabeling.aspx?id=627

Clindamycin phosphate 2% vaginal cream

Clinical Information

Indications:

Clindamycin phosphate 2% vaginal cream is indicated for the treatment of bacterial vaginosis in non-pregnant women.

Dosage and Administration:

- Dose: One applicatorful
- Frequency: Once daily intravaginally
- Duration: 3 to 7 consecutive days depending on clinical judgement
- Route: For intravaginal use only (not for oral, dermal, or ophthalmic use)

Adverse Reactions (>1%):

- Vaginal moniliasis
- Vulvovaginitis
- Vulvovaginal disorder
- Trichomonal vaginitis

Drug Interactions:

Neuromuscular blocking agents: Clindamycin may potentiate neuromuscular blockade; caution is advised with concomitant use.

Micromedex® (IBM). Clindamycin Phosphate [drug monograph]. Accessed Apr 2026.

Clindamycin phosphate 2% vaginal cream

Clinical Information, continued

Contraindications:

Clindamycin phosphate 2% vaginal cream is contraindicated in patients with:

- History of hypersensitivity to clindamycin, lincomycin, or any component of the formulation
- History of enteritis, ulcerative colitis, or antibiotic-associated colitis

Warning and Precautions:

Pseudomembranous colitis: Monitor patients for severe or persistent diarrhea; discontinue if suspected.

Special Populations:

Pregnancy: Clindamycin vaginal cream should be used during the first trimester of pregnancy only if clearly needed and the benefits outweigh the risks. There are no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy. In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters has not been associated with an increased frequency of congenital abnormalities.

Lactation: It is not known if clindamycin is excreted in human breast milk following the use of vaginally administered clindamycin phosphate.

Pediatric patients: Safety and effectiveness in pediatric patients have not been established.

Geriatric patients: Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Micromedex® (IBM). Clindamycin Phosphate [drug monograph]. Accessed Apr 2026.

Clindesse ® (clindamycin phosphate 2%) vaginal cream

Clinical Information

Indications:

Clindamycin phosphate 2% vaginal cream is indicated for the treatment of bacterial vaginosis in non-pregnant women.

Dosage and Administration:

- Dose: One applicatorful
- Frequency: Single intravaginal dose
- Route: For intravaginal use only (not for oral, dermal, or ophthalmic use)

Adverse Reactions (>2%):

- Vaginosis fungal
- Headache
- Back pain
- Constipation
- Urinary tract infection

Drug Interactions:

Neuromuscular blocking agents: Clindamycin may potentiate neuromuscular blockade; caution is advised with concomitant use.

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fe8bb204-f173-44fe-803b-b08f2ec5aa31&audience=professional

Clindesse ® (clindamycin phosphate 2%) vaginal cream

Clinical Information, continued

Contraindications:

Clindamycin phosphate 2% vaginal cream is contraindicated in patients with:

- History of hypersensitivity to clindamycin, lincomycin, or any component of the formulation.
- History of enteritis, ulcerative colitis, or antibiotic-associated colitis.

Warning and Precautions:

Clostridioides difficile-Associated Diarrhea: Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.
Use with Condoms and Vaginal Contraceptive Diaphragms: This cream contains mineral oil that may weaken latex or rubber products such as condoms or vaginal contraceptive diaphragms. Therefore, the use of such barrier contraceptives is not recommended concurrently or for 5 days following treatment with Clindesse. During this time period, condoms may not be reliable for preventing pregnancy or for protecting against transmission of human immunodeficiency virus (HIV) and other sexually transmitted diseases.

Special Populations:

Pregnancy: Clindesse was not studied in pregnant women.

Lactation: The systemic exposure of Clindesse is substantially lower than intravenous administration of clindamycin. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need.

Pediatric patients: The safety and efficacy of Clindesse in pre-menarchal females have not been established.

Geriatric patients: Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fe8bb204-f173-44fe-803b-b08f2ec5aa31&audience=professional

Vandazole ® (metronidazole 0.75%) vaginal gel

Clinical Information

Indications:

Metronidazole 0.75% vaginal gel is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in non-pregnant women.

Dosage and Administration:

- Dose: One applicatorful
- Frequency: Once daily intravaginally
- Duration: 5 consecutive days
- Route: For intravaginal use only (not for oral, dermal, or ophthalmic use)

Adverse Reactions (>2%):

- Fungal infection
- Headache
- Pruritis
- Abdominal pain
- Nausea
- Dysmenorrhea
- Pharyngitis
- Rash
- Infection
- Diarrhea
- Breast pain
- Metrorrhagia

Drug Interactions:

- Although systemic levels are low, disulfiram-like reactions with alcohol have been reported with oral metronidazole; caution is advised.
- Metronidazole may potentiate the effects of warfarin and other oral anticoagulants due to cytochrome-P450 mediated interactions when systemically absorbed.
- In patients stabilized on relatively high doses of lithium, short-term oral metronidazole therapy has been associated with elevation of serum lithium levels.
- Use of cimetidine with oral metronidazole may prolong the half-life and decrease plasma clearance of metronidazole.

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fe8bb204-f173-44fe-803b-b08f2ec5aa31&audience=professional

Vandazole ® (metronidazole 0.75%) vaginal gel

Clinical Information, continued

Contraindications:

- Metronidazole vaginal gel is contraindicated in patients with a prior history of hypersensitivity to metronidazole, parabens, other ingredients of the formulation, or other nitroimidazole derivatives.
- Disulfiram: Psychotic reactions have been reported with disulfiram and oral metronidazole; do not administer concurrently with or within the last 2 weeks of disulfiram.
- Alcohol: Disulfiram-like reactions to alcohol have been reported with oral metronidazole; do not consume alcohol during and for at least three days following treatment.

Warning and Precautions:

Convulsive Seizures and Peripheral Neuropathy: Seizures and peripheral neuropathy have been reported with systemic metronidazole; discontinue therapy if neurologic symptoms occur.
Psychotic Reactions: Psychotic reactions have been reported in alcoholic patients who were using oral metronidazole and disulfiram concurrently. Metronidazole vaginal gel should not be administered to patients who have taken disulfiram within the last two weeks.

Special Populations:

Pregnancy: Metronidazole 0.75% vaginal gel should be used during pregnancy only if clearly needed. There are no adequate and well-controlled studies in pregnant women.

Lactation: Metronidazole is excreted in breast milk at concentrations similar to plasma. Caution is advised when administered to nursing individuals.

Pediatric patients: The safety and efficacy of metronidazole vaginal gel in pre-menarchal females have not been established.

Geriatric patients: Clinical studies with metronidazole vaginal gel did not include sufficient numbers of subjects 65 years of age or older to determine whether they respond differently than younger subjects.

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fe8bb204-f173-44fe-803b-b08f2ec5aa31&audience=professional

Vaginal Antibiotics Drug Utilization Review

May 15, 2026

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

Objectives

- Evaluate the utilization of vaginal antibiotics for the treatment of bacterial vaginosis.

Centers for Disease Control and Prevention Recommendations for the Treatment of Bacterial Vaginosis

- The recommended initial treatment regimens for bacterial vaginosis are as follows:
  - Metronidazole 500 mg orally twice a day for 7 days or
  - Metronidazole gel 0.75% one applicatorful (5 grams) intravaginally once daily for 5 days or
  - Clindamycin cream 2% one applicatorful (5 grams) intravaginally at bedtime for 7 days.

- Alternative treatment regimens for bacterial vaginosis are as follows:
  - Clindamycin 300 mg orally twice a day for 7 days or
  - Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days or
  - Secnidazole 2 grams oral granules in a single dose or
  - Tinidazole 2 grams orally once daily for 2 days or
  - Tinidazole 1 gram orally once daily for 5 days.

- Single-dose regimens for bacterial vaginosis are not included in the Centers for Disease Control and Prevention recommendations.

Available at Sexually Transmitted Infections Treatment Guidelines, 2021 | MMWR. Accessed April 2026.

Centers for Disease Control and Prevention Recommendations for Recurrent Bacterial Vaginosis

- Recurrent bacterial vaginosis is defined as 3 episodes a year or 2 episodes in 6 months.

- Recommended treatment is metronidazole gel 0.75% one applicatorful (5 grams) intravaginally twice weekly for 3 months.

- Alternatives are:
  - Vaginal boric acid 600 mg daily for 14 days, which may be followed by twice weekly for 3 months, or
  - Metronidazole 750 mg vaginal suppositories daily for 7 days, or
  - Combination of oral and vaginal agent, given for 14 days (could be oral metronidazole and vaginal clindamycin, oral metronidazole and vaginal boric acid, oral tinidazole or secnidazole and vaginal boric acid).

Available at Sexually Transmitted Infections Treatment Guidelines, 2021 | MMWR. Accessed April 2026.

Methodology

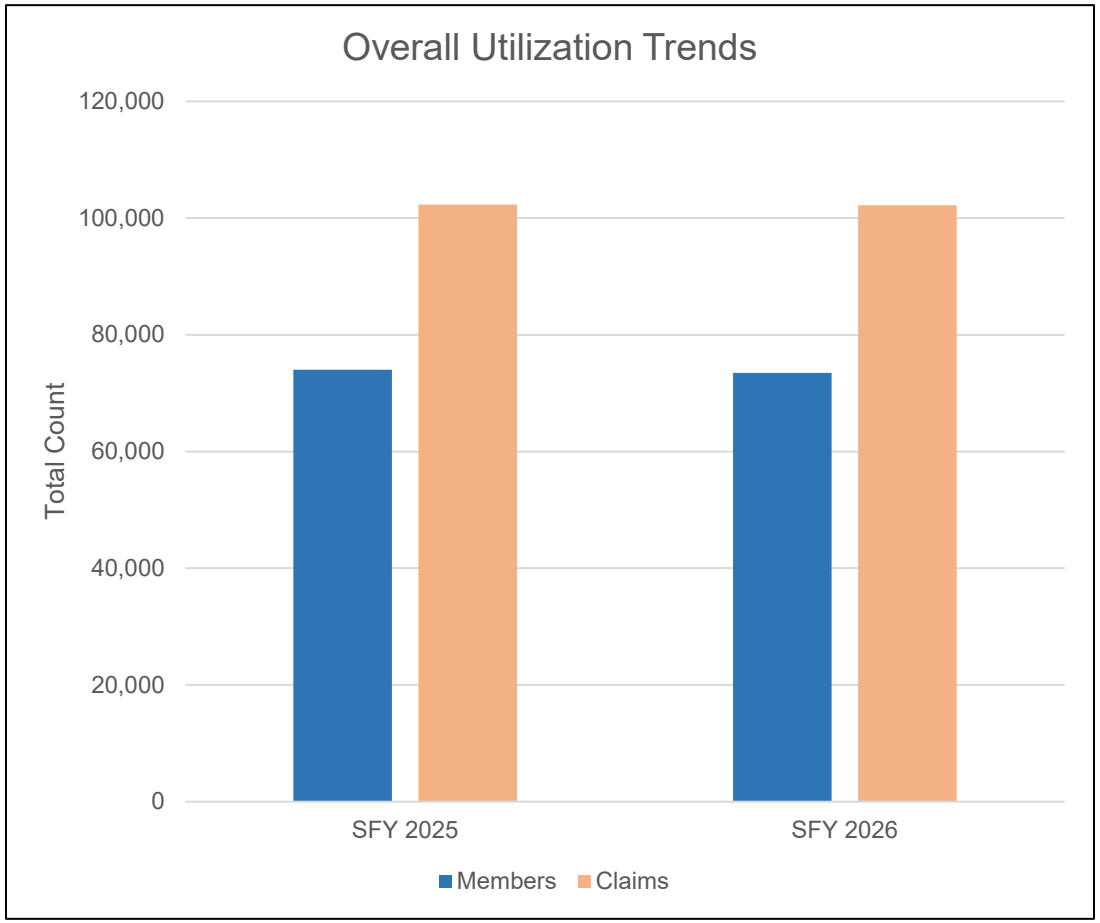
- Retrospective analysis of pharmacy claims was conducted for:
  - April 1, 2024 through March 31, 2025 (State Fiscal Year 2025) and
  - April 1, 2025 through March 31, 2026 (State Fiscal Year 2026).

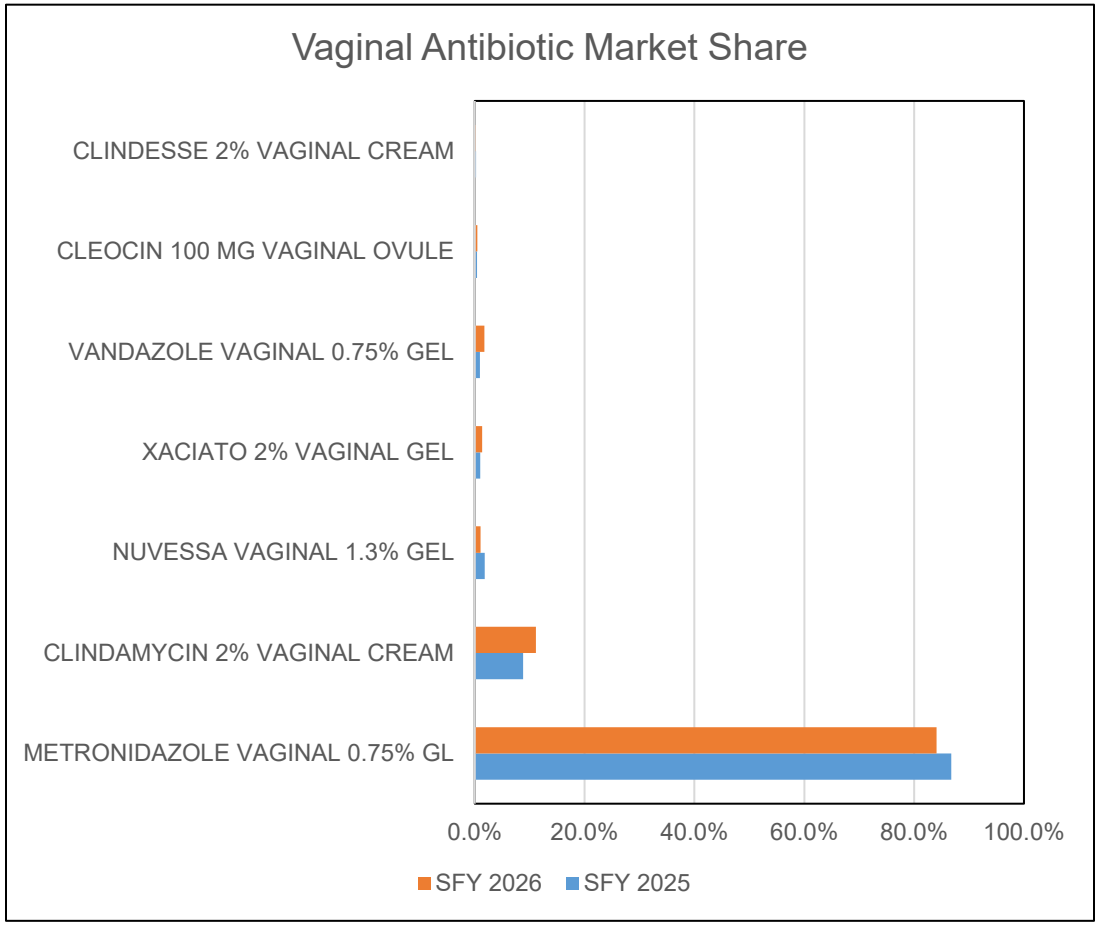
- The data source was the New York State Medicaid Data Warehouse.

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

- A possible limitation may be that while time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete.

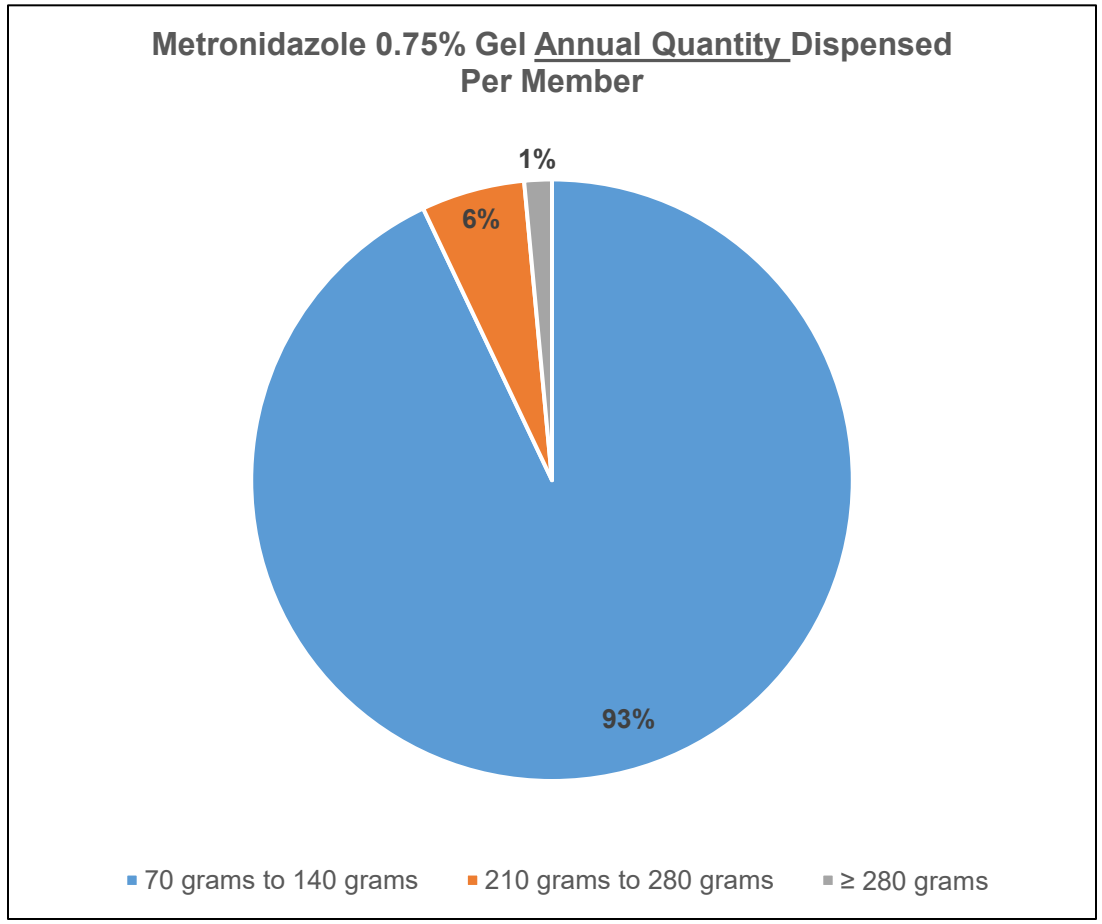
Overall Utilization

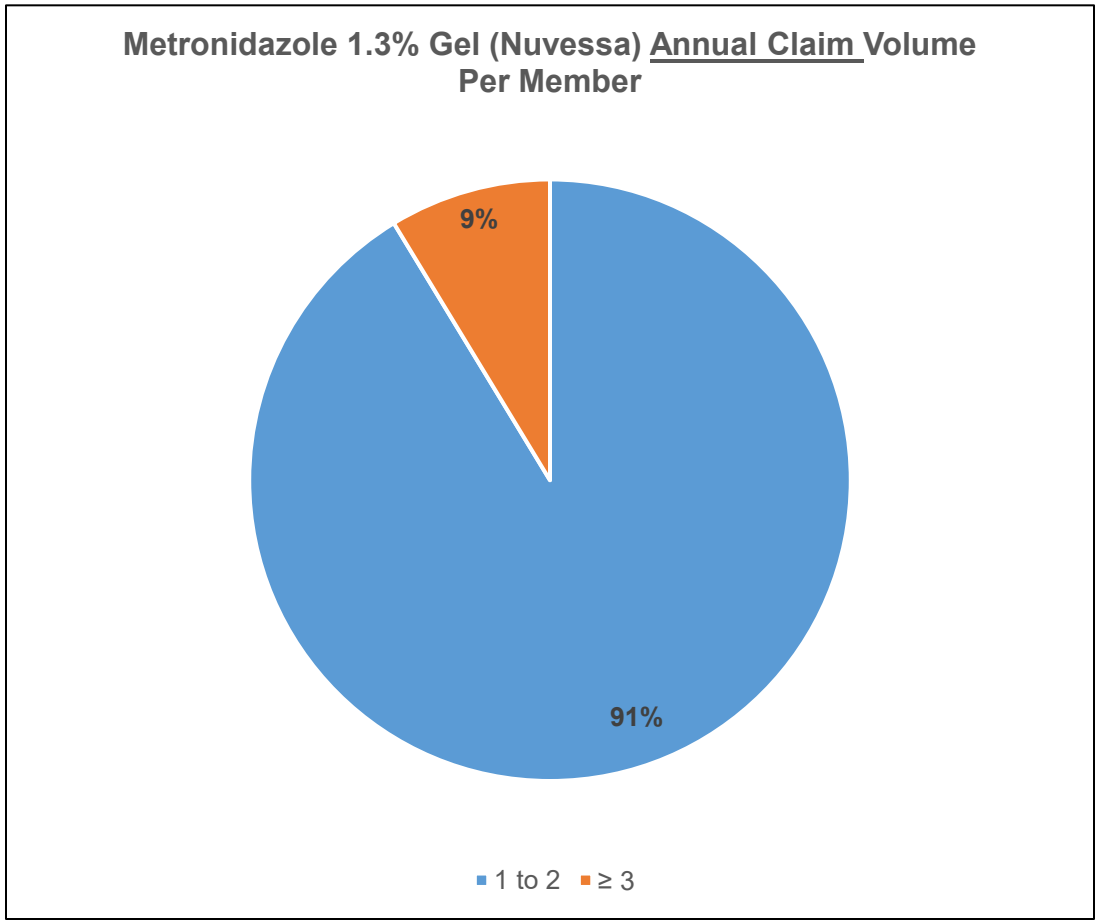




Source= Medicaid Data Warehouse Extract date= April 2026

Metronidazole Utilization for State Fiscal Year 2026





Source= Medicaid Data Warehouse Extract date= April 2026

Clindamycin Utilization for State Fiscal Year 2026

- Clindamycin 2% vaginal cream is available in 40-gram tubes and 98.4% of members utilized 1 to 3 tubes (40 grams to 120 grams) for a ≤3-month supply.

- Xaciato® and Clindesse® (clindamycin) 2% cream are single-dose regimens, and 93.6% of members had 1 to 2 claims.

- Cleocin® Ovule 100 mg is Food and Drug Administration approved for a 3-day regimen and 92.4% (340/ 368) of members had 1 to 2 claims.

Conclusions

- The Centers for Disease Control and Prevention recommends the following for initial treatment of bacterial vaginosis:
  - Metronidazole 500 mg orally twice a day for 7 days, or
  - Metronidazole gel 0.75% one applicatorful (5 grams) intravaginally once daily for 5 days, or
  - Clindamycin cream 2% one applicatorful (5 grams) intravaginally at bedtime for 7 days.

- Persistent or recurrent bacterial vaginosis is common, and the recommended initial treatment regimen is metronidazole gel 0.75% one applicatorful (5 grams) intravaginally twice weekly for 3 months.

- Routine chronic use of vaginal antibiotics is not recommended.

- Utilization remained relatively stable from State Fiscal Year 2025 through State Fiscal Year 2026.

- Metronidazole 0.75% gel had the largest market share of 86.8% and 84.1% for State Fiscal Year 2025 and State Fiscal Year 2026, respectively.

Available at Sexually Transmitted Infections Treatment Guidelines, 2021 | MMWR. Accessed April 2026.

Prime THERAPEUTICS™

Lipotropics, Other

Therapeutic Class Review

Lipotropics, Other

New Drugs
Praluent (alirocumab)
Repatha (evolocumab)
Redemplo (plozasiran)
Tryngolza (olezarsen)

Praluent® (alirocumab)

Clinical Information

Indications:

Alirocumab is indicated to reduce the risk of major adverse cardiovascular events in adults at increased cardiovascular risk, and as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol in:

- Adults with hypercholesterolemia
- Adults and pediatric patients 8 years of age and older with heterozygous familial hypercholesterolemia
- Adults with homozygous familial hypercholesterolemia

Dosage and Administration:

Alirocumab is administered as a subcutaneous injection:

- Adults with hypercholesterolemia or heterozygous familial hypercholesterolemia: 75 milligrams every 2 weeks or 300 milligrams every 4 weeks; dose may be increased to 150 milligrams every 2 weeks if response is inadequate.
- Adults with heterozygous familial hypercholesterolemia undergoing low-density lipoprotein apheresis or adults with homozygous familial hypercholesterolemia: 150 milligrams every 2 weeks.
- Pediatric patients 8 years of age and older with heterozygous familial hypercholesterolemia: weight-based dosing every 4 weeks with adjustment if needed.
- Injections should be given in the thigh, abdomen, or upper arm, rotating sites.

Adverse Reactions (>5%):

Primary Hypercholesterolemia:

- Injection site reactions
- Influenza

Established Cardiovascular Disease:

- Myalgia

Drug Interactions:

No clinically significant drug-drug interactions have been identified. Alirocumab may be used in combination with statins and other lipid-lowering therapies.

https://www.regeneron.com/downloads/praluent_pi.pdf

Clinical Information, continued

Contraindications:

Alirocumab is contraindicated in patients with a history of serious hypersensitivity reactions to alirocumab or any excipient in the product.

Warning and Precautions:

Hypersensitivity reactions: including vasculitis, angioedema, and reactions requiring hospitalization, have been reported.

Alirocumab should be discontinued immediately if serious allergic reactions occur.

Special Populations:

Pregnancy: Available data from clinical trials and postmarketing reports on alirocumab use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. In animal reproduction studies, there were no effects on embryo-fetal development.

Lactation: It is unknown whether alirocumab is present in human milk; consider the benefits of breastfeeding along with maternal need for therapy.

Pediatric patients: Approved for use in patients 8 years of age and older with heterozygous familial hypercholesterolemia; safety and effectiveness have not been established in younger children.

Geriatric patients: No overall differences in safety or effectiveness compared with younger adults were observed.

https://www.regeneron.com/downloads/praluent_pi.pdf

Repatha ® (evolocumab)

Clinical Information

Indications:

Evolocumab is indicated to reduce the risk of major adverse cardiovascular events (myocardial infarction, stroke, and coronary revascularization) in adults with established cardiovascular disease. Repatha is also indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies, to reduce low-density lipoprotein cholesterol in:

- Adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia
- Pediatric patients 10 years of age and older with heterozygous familial hypercholesterolemia
- Adults and pediatric patients 10 years of age and older with homozygous familial hypercholesterolemia

Dosage and Administration:

Evolocumab is administered as a subcutaneous injection:

- Adults with cardiovascular disease or primary hyperlipidemia: 140 milligrams every 2 weeks or 420 milligrams once monthly.
- Pediatric patients 10 years of age and older with heterozygous familial hypercholesterolemia: 140 milligrams every 2 weeks or 420 milligrams once monthly.
- Adults and pediatric patients 10 years of age and older with homozygous familial hypercholesterolemia: 420 milligrams once monthly, with the option to increase to 420 milligrams every 2 weeks if response is inadequate.
- Evolocumab may be administered in the abdomen, thigh, or upper arm, and injection sites should be rotated.

Adverse Reactions (>5%):

Primary Hypercholesterolemia:

- Nasopharyngitis
- Upper respiratory tract infection
- Injection site reactions
- Influenza
- Back pain

Established Cardiovascular Disease:

- Diabetes Mellitus
- Nasopharyngitis
- Upper respiratory tract infection

Drug Interactions:

No clinically significant drug-drug interactions have been identified. Evolocumab may be used concomitantly with statins and other lipid-lowering therapies.

https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Repatha/repatha_pi_hcp_english_L.pdf

Repatha ® (evolocumab)

Clinical Information, continued

Contraindications:

Evolocumab is contraindicated in patients with a history of a serious hypersensitivity reaction to evolocumab or to any of the excipients.

Warning and Precautions:

Hypersensitivity reactions: angioedema has occurred. If signs or symptoms of serious hypersensitivity reactions occur, discontinue treatment with evolocumab, treat according to the standard of care and monitor until signs and symptoms resolve.

Latex Allergy: Patients with latex sensitivity should be aware that some product presentations contain dry natural rubber in the needle cover.

Special Populations:

Pregnancy: Available data from clinical trials and postmarketing reports on evolocumab use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. In animal reproduction studies, there were no effects on pregnancy or neonatal/infant development.

Lactation: It is unknown whether evolocumab is excreted in human milk; consider maternal need for therapy and potential effects on the breastfed infant.

Pediatric patients: Approved for patients 10 years of age and older with heterozygous or homozygous familial hypercholesterolemia; safety and effectiveness have not been established in younger children.

Geriatric patients: No overall differences in safety or effectiveness were observed between older and younger adults.

Redemplo ® (plozasiran)

Clinical Information

Indications:

Plozasiran is indicated as an adjunct to diet to reduce triglyceride levels in adults with familial chylomicronemia syndrome, a rare genetic disorder characterized by severe hypertriglyceridemia.

Dosage and Administration:

The recommended dosage of plozasiran is 25 milligrams administered by subcutaneous injection once every 3 months.

Patients should adhere to a very low-fat diet (≤20 grams of fat per day) during treatment. Injections may be administered in the front of the thigh or abdomen; the outer upper arm may be used if a caregiver administers the dose.

Adverse Reactions (>10%):

- Hyperglycemia
- Headache
- Nausea
- Injection site reactions

Drug Interactions:

No clinically meaningful drug-drug interactions have been identified in the prescribing information.

https://arrowheadpharma.com/en-us/redemplo/prescribing-information.pdf

Redemplo ® (plozasiran)

Clinical Information, continued

Contraindications:

Plozasiran has no listed contraindications.

Warning and Precautions:

The prescribing information does not list boxed warnings or specific safety warnings beyond routine monitoring and administration considerations.

Special Populations:

Pregnancy: There are insufficient data on plozasiran use in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal reproduction studies, no adverse drug-related developmental effects were observed in pregnant rats or rabbits.

Lactation: It is unknown whether plozasiran is present in human milk; consider the benefits of breastfeeding along with maternal need for therapy.

Pediatric patients: Safety and effectiveness have not been established in pediatric patients.

Geriatric patients: No clinically meaningful differences in safety or effectiveness were observed compared to younger adults.

https://arrowheadpharma.com/en-us/redemplo/prescribing-information.pdf

Tryngolza® (olezarsen)

Clinical Information

Indications:

Olezarsen is indicated as an adjunct to diet to reduce triglyceride levels in adults with familial chylomicronemia syndrome, a rare inherited disorder characterized by severely elevated triglycerides due to impaired fat metabolism.

Adverse Reactions (>5%):

- Injection site reactions
- Decreased platelet count
- Arthralgia

Dosage and Administration:

The recommended dosage of olezarsen is 80 milligrams administered subcutaneously once monthly. Injections should be given in the abdomen or front of the thigh, with the back of the upper arm an alternative site when administered by a healthcare provider or caregiver.

Drug Interactions:

No clinically significant drug-drug interactions are described in the prescribing information.

https://ionis.com/medicines/TRYNGOLZA/TRYNGOLZA-FPI.pdf

Tryngolza® (olezarsen)

Clinical Information, continued

Contraindications:

Olezarsen is contraindicated in patients with a history of serious hypersensitivity reactions to olezarsen or any of the excipients in the product.

Warning and Precautions:

Hypersensitivity reactions have been reported, including serious allergic reactions.

Patients should be counseled on recognizing signs and symptoms of hypersensitivity and instructed to discontinue olezarsen and seek immediate medical attention if these occur.

Special Populations:

Pregnancy: There are no available data on olezarsen use in pregnant women to inform drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation: It is unknown whether olezarsen is present in human milk; evaluate the benefits of breastfeeding alongside maternal need for therapy.

Pediatric patients: Safety and effectiveness have not been established in pediatric patients.

Geriatric patients: No clinically meaningful differences in safety or effectiveness were observed compared to younger adults.

https://ionis.com/medicines/TRYNGOLZA/TRYNGOLZA-FPI.pdf

Prime THERAPEUTICS™

Pulmonary Arterial Hypertension (PAH) Agents, Other

Therapeutic Class Review

Pulmonary Arterial Hypertension (PAH) Agents, Other

New Drug: Winrevair (sotatercept-csrk); Tyvaso (Treprostinil); Yutrepia (Treprostinil)

New Formulation: Yutrepia (treprostinil); Tyvaso (treprostinil)

Key Label Revisions: Winrevair (sotatercept-csrk); Tracleer (bosentan)

Winrevair® (sotatercept-csrk)

Clinical Information

Indications:

Sotatercept-csrk is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension.

Dosage and Administration:

- Administered by subcutaneous injection every three weeks; recommended starting dose is 0.3 milligrams per kilogram, titrated to a target dose of 0.7 milligrams per kilogram based on laboratory monitoring.
- Dosage modifications due to increased hemoglobin and decreased platelets may be necessary. Check hemoglobin and platelets before each dose for the first 5 doses, or longer if values are unstable, and monitor periodically thereafter.

Adverse Reactions (>10%):

- Infections
- Epistaxis
- Telangiectasia
- Diarrhea
- Headache
- Rash
- Increased Hemoglobin
- Dizziness
- Erythema
- Gingival bleeding

Drug Interactions:

- Serious bleeding risk may be increased when used concomitantly with prostacyclin therapies and or antithrombotic agents, particularly in patients with low platelet counts.
- No formal pharmacokinetic drug interaction studies have been conducted; use caution with therapies that increase bleeding risk.

https://www.merck.com/product/usa/pi_circulars/w/winrevair/winrevair_pi.pdf

Winrevair® (sotatercept-csrk)

Clinical Information, continued

Contraindications:
None

Warning and Precautions:
Erythrocytosis: Increases in hemoglobin may raise the risk of thromboembolic events and hyperviscosity; hemoglobin levels must be monitored prior to each dose initially and periodically thereafter.

Severe thrombocytopenia: Decreased platelet counts may increase bleeding risk; platelet monitoring is required prior to dosing during initiation and titration.

Serious bleeding events: Do not administer sotatercept-csrk in patients experiencing active serious bleeding.

Embryo-fetal toxicity: May cause fetal harm; patients of reproductive potential should use effective contraception during therapy.

Impaired fertility: May impair female and male fertility based on nonclinical findings.

Special Populations:

Pregnancy: Based on findings in animal reproduction studies, sotatercept-csrk may cause fetal harm when administered to a pregnant woman. There are no available data on sotatercept-csrk use in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation: Breastfeeding is not recommended during treatment and for at least four months after the final dose due to potential for serious adverse reactions in the breastfed infant.

Pediatric patients: Safety and effectiveness have not been established in patients younger than 18 years of age.

Geriatric patients: No overall differences in safety or effectiveness observed compared with younger adults. Studies did not include sufficient number of patients aged 75 and older to determine if they respond differently than younger patients.

https://www.merck.com/product/usa/pi_circulars/w/winrevair/winrevair_pi.pdf

Tyvaso ® (Treprostinil inhalation solution)

Clinical Information

Indications:

Treprostinil is a prostacyclin analog indicated for:
- Pulmonary arterial hypertension to improve exercise capacity
- Pulmonary hypertension associated with interstitial lung disease to improve exercise capacity

Dosage and Administration:

- Administration route: Inhalation using the TYVASO Inhalation System
- Starting dose: 3 breaths per treatment session
- Titration: Increase by 3 breaths per session at approximately 1- to 2-week intervals, as tolerated
- Target maintenance dose: 9 to 12 breaths per session
- Maximum dose: 12 breaths per session
- Dosing frequency: Four times daily, approximately 4 hours apart during waking hours

If adverse effects limit titration, maintain the highest tolerated dose.

Adverse Reactions (>4%):

- Headache
- Cough
- Nausea
- Dizziness
- Throat irritation
- Flushing
- Pharyngolaryngeal pain
- Diarrhea
- Syncope

Drug Interactions:

- Oral treprostinil is primarily metabolized by Cytochrome 2C8.
- It is unclear if the safety and efficacy of inhaled Treprostinil (Tyvaso) are altered by Cytochrome 2C8 inhibitors or inducers.

https://www.tyvaso.com/pdf/TYVASO-PI.pdf

Tyvaso ® (Treprostinil inhalation solution)

Clinical Information, continued

Contraindications:
None

Warning and Precautions:

Risk of hypotension: Treprostinil may cause symptomatic hypotension, particularly in patients with low systemic blood pressure

Bleeding risk: Inhibition of platelet aggregation may increase bleeding, especially in patients receiving anticoagulants

Bronchospasm: Use caution in patients with underlying reactive airway disease

Special Populations:

Pregnancy: Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes.

Lactation: There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric patients: Safety and effectiveness in pediatric patients have not been established.

Geriatric patients: No overall differences in safety or effectiveness observed, but dose selection for elderly patients should be cautious.

https://www.tyvaso.com/pdf/TYVASO-PI.pdf

Yutrepia ® (Treprostinil inhalation solution)

Clinical Information

Indications:

Treprostinil is a prostacyclin analog indicated for:
- Pulmonary arterial hypertension to improve exercise capacity
- Pulmonary hypertension associated with interstitial lung disease to improve exercise capacity

Dosage and Administration:

- Route: For oral inhalation only; do not swallow capsules
- Device: Use only with the supplied YUTREPIA inhaler
- Dosing frequency: 3–5 times daily
- Administration: Contents of each capsule inhaled in 2 breaths
- Dosing considerations: Specific starting, titration, and transition dosing are provided for treprostinil-naïve patients and for patients transitioning from inhaled treprostinil solution

Adverse Reactions (>4%):

- Headache
- Cough
- Throat irritation
- Dizziness

Drug Interactions:

- Oral treprostinil is primarily metabolized by Cytochrome 2C8.
- It is unclear if the safety and efficacy of inhaled Treprostinil (Tyvaso) are altered by Cytochrome 2C8 inhibitors or inducers.

https://www.yutrepiahcp.com/full-prescribing-information.pdf

Yutrepia ® (Treprostinil inhalation solution)

Clinical Information, continued

Contraindications:
None

Warning and Precautions:

Risk of hypotension: Treprostinil may cause symptomatic hypotension, particularly in patients with low systemic blood pressure

Bleeding risk: Inhibition of platelet aggregation may increase bleeding, especially in patients receiving anticoagulants

Bronchospasm: Use caution in patients with underlying reactive airway disease

Special Populations:

Pregnancy: Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes.

Lactation: There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric patients: Safety and effectiveness in pediatric patients have not been established.

Geriatric patients: No overall differences in safety or effectiveness observed, but dose selection for elderly patients should be cautious.

https://www.yutrepiahcp.com/full-prescribing-information.pdf

Pulmonary Arterial Hypertension (PAH) Agents, Other

Label Revisions

Winrevair (sotatercept-csrk): Postmarket Experience subsection has been added to the package insert to include pericardial effusion.

Tracleer (bosentan): Risk evaluation and mitigation strategy update to remove references to risk of embryo-fetal toxicity. Additional updates to Warnings/Precautions and Use in Specific Populations sections regarding use of this class of medications during pregnancy.

See references slide

Pulmonary Arterial Hypertension (PAH) Agents, Other

Formulations

	Orenitram (Treprostinil)	Tyvaso (Treprostinil)*	Yutrepia (Treprostinil)*
Formulation	Extended-release oral tablet	Inhalation solution (nebulized)	Dry powder inhalation
Route / Device	Oral	Inhalation via Tyvaso system	Capsule-based inhaler
Dosing Frequency	Two to three times daily	Four times daily	Three to five times daily
Approved Indications	Pulmonary arterial hypertension (World Health Organization Group 1)	Pulmonary arterial hypertension (Group 1) and pulmonary hypertension associated with interstitial lung disease (Group 3)	Pulmonary arterial hypertension (Group 1) and pulmonary hypertension associated with interstitial lung disease (Group 3)
Systemic Exposure	Systemic	Primarily pulmonary with systemic absorption	Primarily pulmonary with systemic absorption
Key Safety Information	Avoid abrupt discontinuation; hepatic impairment restrictions	Bronchospasm risk; inhalation-related cough	Bronchospasm risk; inhalation-related cough
Drug Interactions	Cytochrome P450 2C8 inhibitors or inducers	Cytochrome P450 2C8 inhibitors or inducers	Cytochrome P450 2C8 inhibitors or inducers

*These have not been previously reviewed and are considered new to the class

See references slide

Pulmonary Arterial Hypertension (PAH) Agents, Other– Current Status

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
III. Cardiovascular		
Pulmonary Arterial Hypertension (PAH) Agents, Other		
ambrisentan (gen Letairis) bosentan tablets (gen Tracleer®)	Adempas® bosentan tablets for susp (gen Tracleer®) Letairis® Opsumit® Orenitram® ER tablet, dosepack Tracleer® tablet for suspension, tablet Tyvaso® Uptravi® Winrevair™ Yutrepia™	

References

1. https://www.merck.com/product/usa/pi_circulars/w/winrevair/winrevair_pi.pdf’
2. https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TRACLEER-pi.pdf
3. https://www.orenitramhcp.com/media/content/files/Orenitram-Prescribing-Information.pdf
4. https://www.tyvaso.com/pdf/TYVASO-PI.pdf
5. https://www.yutrepiahcp.com/full-prescribing-information.pdf

Prime THERAPEUTICS™

Hemophilia Agents, Other

Therapeutic Class Review

Hemophilia Agents – Other

New Indication: Vonvendi [von Willebrand factor (recombinant)]

Hemophilia Agents – Other

New Indications

Vonvendi [von Willebrand factor (recombinant)] –
Food and Drug Administration has approved Vonvendi for:

1. Routine prophylactic use in adults with *all types* of von Willebrand disease and
2. On-demand treatment of bleeding episodes and perioperative use in *children* with von Willebrand Disease.

Previously, it was indicated for:

1. Preventative use only in adults with *Type 3* von Willebrand Disease, and
2. On-demand treatment of bleeding episodes and perioperative use in *adults*.

Recommended dosage for on-demand treatment and control of bleeding episodes is weight based and dependent on bleeding episode (minor versus major). For prophylactic treatment, the recommended dosage is 40 to 60 International Units per kilogram of body weight twice weekly.

Hemophilia Agents – Other – Current Status

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
VIII. Hematological Agents		
Hemophilia Agents – Other		
Alphanate® (von Willebrand factor/Factor VIII) Coagadex® (Factor X) Corifact® (Factor XIII) Feiba® NF (activated prothrombin complex) Hemlibra® (emicizumab-kxwh) Novoseven® RT (Factor VIIa) Sevenfact® (Factor VIIa-jncw) Tretten® (Factor XIII) Vonvendi® (von Willebrand factor) Wilate® (von Willebrand factor/Factor VIII)	Alhemo® Hympavzi™ Qfitlia®	

Prime THERAPEUTICS™

Immunomodulators Systemic

Therapeutic Class Review

Immunomodulators, Systemic: Summary

New Products: Rhapsido (remibrutinib)

New Indications (many)

Key Label Revisions (many)

Practice Guideline Updates

Rhapsido® (remibrutinib)

Clinical Information

Indications:

Remibrutinib is indicated for the treatment of **chronic spontaneous urticaria (CSU)** in adult patients who remain symptomatic despite H1 antihistamine treatment.

Dosage and Administration:

Dosing: 25 mg orally twice daily
- May be taken with or without food
- Tablets must be swallowed whole
- Do not split, crush, or chew

Missed Dose:
- Skip missed dose and resume at next scheduled dose
- Do not double dose

Temporary Interruption for Surgery
- Interrupt remibrutinib 3-7 days before and after surgery
- Duration depends on procedure type and bleeding risk

Adverse Reactions (>3%):

- Nasopharyngitis
- Bleeding
- Headache
- Nausea
- Abdominal pain

Drug Interactions:

Avoid concomitant use with:
- Strong or moderate Cytochrome (CYP) 3A4 inhibitors
- Strong or moderate Cytochrome (CYP) 3A4 inducers

Use caution with :
- P-glycoprotein (P-gp) Substrates**:** Monitor more frequently for adverse reactions when using remibrutinib with P-glycoprotein (P-gp) substrates where minimal concentration changes may lead to serious adverse reactions (e.g., digoxin).
- Antithrombic agents: Consider the risks and benefits of concomitant administration of antithrombotic agents with remibrutinib. No data are available on concomitant use of remibrutinib with anticoagulants.

https://www.novartis.com/us-en/sites/novartis_us/files/rhapsido.pdf

Rhapsido® (remibrutinib)

Clinical Information, continued

Contraindications:
None

Warning and Precautions:
Bleeding risk: Monitor for signs and symptoms of bleeding. Interrupt therapy if bleeding occurs. Concomitant use with antithrombic agents may increase risk of bleeding.

Live vaccines: Avoid administration of live or live-attenuated vaccines during treatment.

Special Populations:
Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to remibrutinib during pregnancy. Available data on the use of remibrutinib during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.
Lactation: No data are available regarding the presence of remibrutinib in either human or animal milk, its effects on the breastfed child, or on milk production.
Pediatric patients: The safety and effectiveness of RHAPSIDO have not been established in pediatric patients.
Geriatric patients: No overall differences in safety or effectiveness were observed between older adults and younger adults in clinical trials.

https://www.novartis.com/us-en/sites/novartis_us/files/rhapsido.pdf

Immunomodulators, Systemic

New Indications

Cosentyx (secukinumab): Food and Drug Administration approved subcutaneous secukinumab for moderate to severe hidradenitis suppurativa in patients 12 years of age and older, expanding use beyond adults; FDA also approved expansion of ankylosing spondylitis (AS) indication to include pts ≥ 12 yo; previously, indicated for active ankylosing spondylitis in adults only.
Sotyktu (deucravacitinib): Food and Drug Administration approved deucravacitinib for adults with active psoriatic arthritis; previously approved for plaque psoriasis.
Dupixent (dupilumab): Food and Drug Administration approved dupilumab for allergic fungal rhinosinusitis in adults and pediatric patients 6 years of age and older with prior sinonasal surgery; first approved therapy for this condition.
Idacio (adalimumab-aacf): Label expanded to include pediatric uveitis in patients 2 years of age and older and adolescent hidradenitis suppurativa in patients 12 years of age and older, aligning with reference adalimumab.
Tezspire (tezepelumab-ekko): Food and Drug Administration approved tezepelumab as add-on maintenance therapy for chronic rhinosinusitis with nasal polyps in adults and pediatric patients 12 years of age and older.
Xeljanz and Xeljanz Extended Release (tofacitinib): Psoriatic arthritis indication expanded to include pediatric patients 2 years of age and older with inadequate response or intolerance to tumor necrosis factor inhibitors.
Adalimumab Interchangeable Biosimilars (Amjevita, Cyltezo, Hyrimoz, Simlandi, Yuflyma): Food and Drug Administration expanded indications to include adolescent hidradenitis suppurativa (12 years of age and older) and pediatric uveitis (2 years of age and older); labeling updated to include rare autoimmune hepatitis risk.
Simponi (golimumab): Ulcerative colitis indication expanded to include adult and pediatric patients weighing at least 15 kilograms with moderately to severely active disease; labeling updated to reduce dispensing errors.

See references slide

Immunomodulators, Systemic

Label Revisions

Skyrizi (risankizumab-rzaa): Package insert updated with clinical trial data evaluating treatment of plaque psoriasis involving the genital and scalp areas.
Xeljanz (tofacitinib): Warnings and Precautions updated to include additional information on serious infections, with fracture data added to clinical safety studies in adults with rheumatoid arthritis.
Entyvio (vedolizumab): Warnings updated to include postmarketing reports of serious opportunistic infections; labeling now recommends assessing patients for tuberculosis prior to treatment initiation.
Enbrel (etanercept): Food and Drug Administration approved unbranded biological product labeling for etanercept across vial, prefilled syringe, and autoinjector presentations.
Otulfi (ustekinumab-aauz): Safety labeling updated to include information on serious hypersensitivity reactions, aligning with the reference ustekinumab product.
Avtozma (tocilizumab-anoh): Food and Drug Administration approved unbranded labeling across intravenous and subcutaneous presentations and approved interchangeability with reference tocilizumab for subcutaneous use.
Abrilada (adalimumab-afzb): Label revised to align with reference adalimumab, including addition of autoimmune hepatitis risk under Warnings and Precautions.
Humira (adalimumab): Package insert updated to remove discontinued vial and low-dose syringe presentations and associated product identifiers.
Adbry (tralokinumab-ldrm): Adverse reactions section updated based on long-term extension trial data in patients with atopic dermatitis.

See references slide

Immunomodulators, Systemic

Label Revisions, continued

Actemra (tocilizumab): Postmarketing adverse reaction section updated to include reports of low fibrinogen levels.
Ilumya (tildrakizumab-asmn): Label updated with efficacy and safety data for adults with moderate to severe nail psoriasis who are candidates for systemic therapy or phototherapy.
Steqeyma (ustekinumab-stba): Package insert updated to align with the reference ustekinumab product, including approval of unbranded biological product labeling.
Imuldosa (ustekinumab-srlf): Unbranded and branded labeling updated to align with recent reference ustekinumab labeling changes.
Selarsdi (ustekinumab-aekn): Label updated to align with reference ustekinumab regarding pregnancy information and serious hypersensitivity reactions.
Selarsdi (ustekinumab-aekn): Storage labeling updated to allow room temperature storage of intravenous vials for up to seven days under specified conditions.
Yusimry (adalimumab-aqvh): Warnings and Precautions updated to include risk of autoimmune hepatitis.
Stelara (ustekinumab): Warnings updated to clarify risk of serious hypersensitivity reactions occurring during clinical trials and postmarketing use, including with first intravenous dose.
Dupixent (dupilumab); Warning and precautions updated with new safety info on ocular infections, irritations & inflammation.

See references slide

Immunomodulators, Systemic

Practice Guideline Updates

The American Gastroenterological Association (AGA) has released a living clinical practice guideline on the pharmacologic management of moderately to severely active Crohn's disease. (December 2025)

- Recommends early use of advanced therapies rather than stepwise escalation with corticosteroids or immunomodulators in moderate to severe disease.
- In treatment-naïve patients, higher-efficacy biologic or small-molecule therapies are preferred over lower-efficacy options.
- In patients previously exposed to advanced therapies, therapy selection should be based on relative efficacy, with preference for higher or intermediate efficacy agents over lower efficacy agents.
- Recommends against thiopurine monotherapy for induction of remission, though it may be considered for maintenance in select patients.
- Supports combination therapy with infliximab and thiopurines in appropriate patients to improve efficacy, particularly in those not previously exposed to thiopurines.

https://www.gastrojournal.org/article/S0016-5085(25)06091-3/fulltext#xd_co_f=ZTNiNThkM2ItNTU0MS00NmZkLTg1NDEtY2ZhN2NiYTZjMTVm~

Immunomodulators, Systemic – Current Status

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic CC, ST		
Interleukin Inhibitors		**CLINICAL CRITERIA (CC)** • Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication **STEP THERAPY (ST)** For indications not specified below • Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a non-biologic disease-modifying anti-rheumatic drug (DMARD) • Trial of a TNF inhibitor prior to treatment with a JAK inhibitor **INDICATION-SPECIFIC REQUIREMENTS:** • Asthma: – history and concurrent use of a corticosteroid • Nasal polyps: – history and concurrent use of an intranasal corticosteroid • 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. • COPD: – History and concurrent use of a long acting beta agonist (LABA) + long acting muscarinic agonist (LAMA) + inhaled corticosteroid (ICS)
Cosentyx® Dupixent® Ebglyss™ 1 Fasenra® Nucala®	Actemra® SQ Adbry™ Avtozma® Bimzelx® Ilumya® Imuldosa® Kevzara® Kineret® Nemluvio® Omvoh™ SQ Otulfi™ Pyzchiva® Selarsdi™ Skyrizi® Skyrizi® On-Body Spevigo® Starjemza™ Stelara® Steqeyma® Taltz® Tremfya® Tyenne® ustekinumab Yesintek™	
JAK Inhibitors		
	Cibinqo™ Olumiant® Rinvoq™ ER Rinvoq® LQ Xeljanz®	

Immunomodulators, Systemic – Current Status

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IX. Immunologic Agents		
	Xeljanz® XR	
TNF Inhibitors		
adalimumab (Boehringer Ingelheim)[1] Enbrel® Humira®	Abrilada™ adalimumab Amjevita™ Cyltezo® Cimzia® Hadlima™ Hulio® Hyrimoz® Idacio® Simlandi® Simponi® Yuflyma® Yusimry™ Zymfentra™	
Miscellaneous		
Xolair®	Entyvio® SQ Orencia® SQ Otezla® Otezla XR™ Rhapsido® Sotyktu™ Tezspire® pen Velsipity™	

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20. https://labeling.pfizer.com/ShowLabeling.aspx?id=12780
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24. https://www.accordbiopharma.com/our-therapies/imuldosa/imuldosa_pi.pdf
25. https://www.selarsdi.com/globalassets/selarsdi/prescribing-information.pdf
26. https://cdn.prod.website-files.com/6483738bedd883892f331b8d/699f4c76201bbadadc1129df_proposed-PI-lbl-40mg-0.8ml-08.06.2025-00.pdf
27. https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf

NEW YORK STATE | Department of Health

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

NYS MEDICAID DRUG UTILIZATION REVIEW BOARD

May 15, 2026

CLINICAL CRITERIA FOR NON-PREFERRED PRODUCTS

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

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

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

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

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

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

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

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

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
II. Anti-Infectives		
Antibiotics – Inhaled CC, F/Q/D		
Bethkis® BLTG Cayston® Kitabis® Pak BLTG TOBI Podhaler™ tobramycin (gen TOBI®) solution	TOBI® solution tobramycin (gen Bethkis®, Kitabis®) solution	**CLINICAL CRITERIA (CC)** • Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Aztreonam (Cayston) – 3 ampules (3 mL) per day – 84 ampules (84 mL) per 56-day regimen (28 days on, 28 days off) • Tobramycin inhalation solution (Bethkis, TOBI, Kitabis Pak) – 2 ampules (8 mL Bethkis, 10 mL TOBI, Kitabis Pak) per day – 56 ampules (224 mL Bethkis, 280 mL TOBI, Kitabis Pak) per 56-day regimen (28 days on-28 days off) • Tobramycin capsules with inhalation powder (TOBI Podhaler) – 8 capsules per day 224 capsules per 56-day regimen (28 days on-28 days off)

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
III. Cardiovascular		
Pulmonary Arterial Hypertension (PAH) Agents, Other		
ambrisentan (gen Letairis) bosentan tablet (gen Tracleer®)	Adempas® bosentan tablet for susp (gen Tracleer®) Letairis® Opsumit® Orenitram® ER tablet, dosepack Tracleer® tablet for suspension, tablet Tyvaso® Uptravi® Winrevair™ Yutrepia™	

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
V. Dermatologic Agents		
Immunomodulators & Related Agents – Topical CC		
Eucrisa® pimecrolimus tacrolimus	Anzupgo® Opzelura® Vtama® Zoryve®	**CLINICAL CRITERIA (CC)** • Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication • Plaque psoriasis – Trial of a Preferred agent from the Psoriasis Agents, Topical class

New York State Medicaid Drug Utilization Review Board Meeting – May 15, 2026
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
VI. Endocrine and Metabolic Agents		
Glucagon Agents		
Baqsimi® glucagon vial glucagon HCl emergency kit (Fresenius, Amphastar) Zegalogue® pen, syringe	glucagon emergency kit (Mylan) Gvoke® pen, syringe, vial	

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
VI. Endocrine and Metabolic Agents		
Growth Hormones CC		
Genotropin® Norditropin®	Humatrope® Ngenla™ Nutropin AQ® NuSpin Omnitrope® Skytrofa® Sogroya® Zomacton®	**CLINICAL CRITERIA (CC)** • Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication • For Diagnosis of Growth Hormone Deficiency (GHD) or Short for Gestational Age (SGA): ○ Prior to initiating growth hormone treatment, documentation of a recommended GHD diagnostic and / or laboratory test (e.g., provocative test and / or IGF-1 test) • Continuation of GH treatment, documentation of a recommended GHD laboratory test annually (e.g., IGF-1 test) and documentation of positive treatment response

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
VI. Endocrine and Metabolic Agents		
Insulin, Rapid-Acting		
insulin aspart (gen Novolog®) cartridge, vial, pen insulin lispro (gen Humalog® U100) vial, pen insulin lispro junior (gen Humalog® Jr.)	Admelog® Afrezza® Apidra® Fiasp® Penfill, FlexTouch, Pumpcart, vial Humalog® Jr. 100 U/mL Kwikpen Humalog® 100 U/mL vial, pen, cartridge, Tempo™ Humalog® 200 U/mL Kirsty™ Lyumjev® Lyumjev® Tempo™ Merilog™ Solostar, vial Novolog® cartridge, vial, FlexPen	

New York State Medicaid Drug Utilization Review Board Meeting – May 15, 2026
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
VIII. Hematological Agents		
Hemophilia Agents, Other		
Alphanate® (von Willebrand factor/Factor VIII) Coagadex® (Factor X) Corifact® (Factor XIII) Feiba® NF (activated prothrombin complex) Hemlibra® (emicizumab-kxwh) Novoseven® RT (Factor VIIa) Sevenfact® (Factor VIIa-jncw) Tretten® (Factor XIII) Vonvendi® (von Willebrand factor) Wilate® (von Willebrand factor/Factor VIII)	Alhemo® Hympavzi™ Qfitlia®	

<table>
<tr><th>Preferred Drugs</th><th>Non-Preferred Drugs</th><th>Coverage Parameters</th></tr>
<tr><td colspan="3">IX. Immunologic Agents</td></tr>
<tr><td colspan="3">Immunomodulators – Systemic CC, ST</td></tr>
<tr><td colspan="2">Interleukin Inhibitors</td><td rowspan="4">CLINICAL CRITERIA (CC)
• Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication
STEP THERAPY (ST)
For indications not specified below
• Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a non-biologic disease-modifying anti-rheumatic drug (DMARD)
• Trial of a TNF inhibitor prior to treatment with a JAK inhibitor
INDICATION-SPECIFIC REQUIREMENTS:
• Asthma:
– history and concurrent use of a corticosteroid
• Nasal polyps:
– history and concurrent use of an intranasal corticosteroid
• 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.
• COPD:
– History and concurrent use of a long acting beta agonist (LABA) + long acting muscarinic agonist (LAMA) + inhaled corticosteroid (ICS)</td></tr>
<tr><td>Cosentyx®
Dupixent®
Ebglyss™
Fasenra®
Nucala®</td><td>Actemra® SQ
Adbry™
Avtozma®
Bimzelx®
Ilumya®
Imuldosa®
Kevzara®
Kineret®
Nemluvio®
Omvoh™ SQ
Otulfi™
Pyzchiva®
Selarsdi™
Skyrizi®
Skyrizi® On-Body
Spevigo®
Starjemza™
Stelara®
Steqeyma®
Taltz®
Tremfya®
Tyenne®
ustekinumab
Yesintek™</td></tr>
<tr><td colspan="2">JAK Inhibitors</td></tr>
<tr><td></td><td>Cibinqo™
Olumiant®</td></tr>
</table>

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IX. Immunologic Agents		
	Rinvoq™ ER Rinvoq® LQ Xeljanz® Xeljanz® XR	
TNF Inhibitors		
adalimumab (Boehringer Ingelheim) Enbrel® Humira®	Abrilada™ adalimumab Amjevita™ Cyltezo® Cimzia® Hadlima™ Hulio® Hyrimoz® Idacio® Simlandi® Simponi® Yuflyma® Yusimry™ Zymfentra™	
Miscellaneous		
Xolair®	Entyvio® SQ Orencia® SQ Otezla® Otezla XR™ Rhapsido® Sotyktu™ Tezspire® pen Velsipity™	

NEW YORK STATE | Department of Health

High-Cost Drug / Drug Cap Overview

NYS MEDICAID DRUG UTILIZATION REVIEW BOARD

May 15, 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 or biologic with launch wholesale acquisition cost (WAC) of $30,000 or more per 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 or 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.

ENTYVIO - CRITERIA FOR IDENTIFICATION

High-Cost Drug

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

Drug Cap

Eightieth percentile or higher based on total net spend, net of rebate.

NEW YORK STATE | Department of Health

ENTYVIO – MANUFACTURER CORRESPONDENCE

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

NEW YORK STATE | Department of Health

DUR Board Member Questions

Value Assessment of Vedolizumab (Entyvio®)

May 2026 — New York State Medicaid Drug Utilization Review Board Meeting

Presentation Overview

Clinical Overview

- Inflammatory Bowel Disease: Clinical Background
- Vedolizumab Background and Mechanism
- Clinical Evidence: GEMINI Trials and VARSITY
- Safety Profile
- Regulatory Assessment and Guidelines

Utilization and Pricing

- New York Medicaid Utilization Trends
- Economic Input: Cost Overview
- International Pricing Landscape

Pricing Strategy and Recommendation

- Pricing Methodology and Assumptions
- Primary Target: Ratio-Normalized (77%)
- Alternative Target: Direct Comparison — pen (84%) | vial (76%)
- Methodology Comparison
- Vedolizumab Recommendation

1

Clinical Overview

Inflammatory Bowel Disease: Clinical Background

Prevalence: 2.4—3.1 million Americans | ulcerative colitis: ~900,000—1,000,000 patients | Crohn's disease: ~700,000—800,000 patients

Ulcerative Colitis

Continuous mucosal inflammation starting in rectum and extending proximally. Characterized by bloody diarrhea, urgency, and cramping. Can involve the entire colon (pancolitis).

Crohn's Disease

Transmural inflammation affecting any segment of the gastrointestinal tract. Involves skip lesions, strictures, fistulas, and perianal disease. More heterogeneous presentation than ulcerative colitis.

Disease Course

Both are chronic, relapsing-remitting conditions requiring long-term advanced therapy in moderate-to-severe disease. Multisystem complications are common.

Genetic / Immune Cause

- Complex polygenic immune-mediated disorder — no single causative mutation
- Aberrant mucosal immune response to intestinal microbiota in genetically susceptible individuals
- Involves dysregulation of T-lymphocyte homing to the gut via alpha-4 beta-7 integrin / mucosal addressin cell adhesion molecule-1 pathway

Current Treatment Landscape

- No cure — therapy targets remission induction and maintenance
- Conventional treatment: aminosalicylates → thiopurines → corticosteroids
- Advanced therapy for moderate-to-severe: tumor necrosis factor inhibitors, vedolizumab, ustekinumab, interleukin-23 inhibitors, Janus kinase inhibitors
- Vedolizumab is the only gut-selective advanced therapy — no systemic immunosuppression

Guideline Position

- American Gastroenterological Association, American College of Gastroenterology, and European Crohn's and Colitis Organization guidelines uniformly endorse vedolizumab as a recommended advanced therapy option for both ulcerative colitis and Crohn's disease — with specific preference in patients where systemic immunosuppression is a concern.

Vedolizumab Clinical Trial Results

GEMINI Phase 3 Program — Pivotal Randomized Controlled Trials					
Trial	Indication	Endpoint	Vedolizumab	Placebo	p-value
GEMINI-1	Ulcerative colitis	Maintenance remission - every 8 weeks dosing (Week 52)	41.8%	15.9%	<0.001
GEMINI-1	Ulcerative colitis	Maintenance remission - every 4 weeks dosing (Week 52)	44.8%	15.9%	<0.001
GEMINI-1	Ulcerative colitis	Mucosal healing - every 8 weeks dosing (Week 52)	56.0%	27.4%	<0.001
GEMINI-2	Crohn's disease	Maintenance remission - every 8 weeks dosing (Week 52)	39.0%	21.6%	<0.001
GEMINI-2	Crohn's disease	Enhanced remission - every 8 weeks dosing (Week 52)	36.4%	12.1%	<0.001

Head-to-Head: VARSITY Trial (ulcerative colitis, Week 52, 769 participants) — Only Published Head-to-Head Biologic Trial in Inflammatory Bowel Disease			
Endpoint (Week 52)	Vedolizumab	Adalimumab	Favors
Clinical remission (primary)	31.3%	22.5%	vedolizumab (p<0.001)
Endoscopic improvement	39.7%	27.7%	vedolizumab (p<0.001)
Corticosteroid-free remission	12.6%	21.8%	adalimumab — see note

Note: VARSITY enrolled biologic-naive ulcerative colitis patients. Corticosteroid-free remission favored adalimumab — reflecting baseline patient differences. Results may differ in patients with prior tumor necrosis factor inhibitor exposure.

Vedolizumab Safety Profile

No increase in systemic infection versus placebo

Gut-Selective

No systemic immunosuppression established in clinical trials

Progressive multifocal leukoencephalopathy

1 case

Postmarketing — multiple contributory factors noted

High tolerability — no boxed warning

~94%

of patients complete induction without serious adverse event

Label Safety Items — Current Prescribing Information Position

Label Item	Current Label Position	Risk Category
Infusion/Hypersensitivity	Warning in label. Standard pre-medication and monitoring apply. Less common with subcutaneous formulation.	Monitor
Infections	Label advises against initiating in active serious infection. No established increase in systemic infection rate. Interrupt if serious infection develops.	Low systemic risk
Progressive multifocal leukoencephalopathy	Risk cannot be ruled out per label. One postmarketing case with multiple confounders.	Cannot rule out
Liver Injury	Transaminase/bilirubin elevations reported. Discontinue in jaundice or significant liver injury.	Monitor liver function tests
Immunizations	Update immunizations before initiation. Non-live vaccines permitted during treatment. Live vaccines require benefit-risk assessment.	Pre-screen

2

Utilization and Pricing

Vedolizumab Utilization Trends

Annual Prescription Claims — New York Medicaid (Intravenous + Subcutaneous)

Year	Total Claims	Year-over-Year Change
2022	7,022	—
2023	7,362	+340 (+4.8%)
2024	6,964	-398 (-5.4%)
2025	6,628	-336 (-4.8%)

Economic Input: Cost Overview

Vedolizumab Annual Wholesale Acquisition Cost (as of March 25, 2026)

$3,639

Vedolizumab Pen Unit wholesale acquisition cost per dose Based off Quarter 1, 2026

$10,109

Vedolizumab Vial Unit wholesale acquisition cost per dose Based off Quarter 1, 2026

Vedolizumab costs 76% - 84% more than the non-United States average across 7 comparator countries

Country	Vedolizumab Pen Annual Cost (United States dollars)	Percentage Below United States Wholesale Acquisition Cost	Vedolizumab Vial Annual Cost (United States dollars)	Percentage Below United States Wholesale Acquisition Cost
United States	$94,614		$60,654	
United Kingdom	$17,655	-81%	$17,918	-70%
France	$7,337	-92%	$7,317	-88%
Germany	$14,343	-85%	$14,435	-76%
Italy	$24,165	-74%	$17,068	-72%
Canada	$17,543	-81%	$17,764	-71%
Japan	$9,984	-89%	$10,018	-83%
Switzerland	$17,943	-81%	$17,993	-70%
Non-United States Average	**$15,567**	**-84%**	$14,658	**-76%**

All foreign prices are public list prices converted to United States dollars at March 2026 exchange rates and do not reflect confidential managed-entry agreements or net prices. Actual international net prices are likely lower — meaning the true United States premium may be larger.

3

Pricing Strategy and Recommendation

International Reference Pricing Methodology and Model Assumptions

Introduction to the Model: International Reference Pricing (International Reference Pricing)

International Reference Pricing benchmarks a drug's United States price against its price in high-income comparator countries. Rather than applying foreign prices directly, the primary approach uses a ratio-based methodology that normalizes each country's pricing environment using shared reference drugs — eliminating country-specific confounders and isolating the relative premium vedolizumab commands in the United States market.

Key Inputs	
Vedolizumab United States annual wholesale acquisition cost (March 25, 2026):	$94,614 for the subcutaneous pen and $60,654 for the intravenous vial
Comparator countries	United Kingdom, France, Germany, Italy, Canada, Japan, Switzerland
Anchor comparators:	Adalimumab, ustekinumab, infliximab — approved for both ulcerative colitis and Crohn's disease in all 8 countries
International Reference Pricing methods:	Primary: ratio-normalized international reference pricing, applied separately to each formulation Alternative: direct vedolizumab price comparison, applied separately to each formulation
Country selection criteria:	(a) Organization for Economic Co-operation and Development membership; (b) public list price data available; (c) anchor drugs approved for ulcerative colitis + Crohn's disease in all countries

Why the Ratio-Normalized Method is Preferred

The direct country price for vedolizumab may reflect drug-specific factors (earlier market entry, biosimilar dynamics, country-specific negotiations) rather than a generalized national pricing norm. The ratio-normalized approach removes this drug-specific noise by anchoring to the same country's pricing behavior across three independent inflammatory bowel disease biologics approved for both indications. It produces a target independently justified by the anchor-drug pricing landscape and is therefore more auditable and defensible in negotiations.

International Pricing Data Inputs

Annual Gross List Prices (United States dollars) — Vedolizumab and Anchor Comparators — All converted at March 2026 exchange rates

Country	Vedolizumab pen	Vedolizumab vial	Adalimumab	Ustekinumab	Infliximab	Note
United States (Reference)	$94,614	$60,654	$102,850	$196,772	$40,540	Reference country
United Kingdom	$17,655	$17,918	$14,031	$18,508	$19,533	British Pound → United States dollars
France	$7,337	$7,317	$5,705	$10,137	$8,186	Euro → United States dollars
Germany	$14,343	$14,435	$12,619	$35,033	$22,449	Euro → United States dollars
Italy	$24,165	$17,068	$18,407	$23,479	$20,673	Euro → United States dollars
Canada	$17,543	$17,764	$15,459	$21,508	$24,972	Canadian Dollar → United States dollars
Japan	$9,984	$10,108	$7,752	$14,232	$9,923	Japanese Yen → United States dollars
Switzerland	$17,943	$17,993	$15,273	$25,109	$22,327	Swiss Franc → United States dollars
Comparator Country Average	**$15,567**	**$14,658**	**$12,749**	**$21,144**	**$18,295**	**Unweighted average**
United States Premium over non-United States average	**84%**	**76%**	**88%**	**89%**	**55%**	

Anchor comparator rationale: Adalimumab, ustekinumab, and infliximab each hold confirmed regulatory approval for both ulcerative colitis and Crohn's disease across all 8 countries. Risankizumab, guselkumab, and others were evaluated but excluded due to incomplete approval footprints across all countries as of March 2026.

Ratio-Normalized International Reference Pricing Method

Step 1: Compute the Price Ratio for Each Anchor Drug in Each Country | Ratio = Country Annual Cost ÷ United States Annual Cost

Country	Adalimumab	adalimumab/United States	Ustekinumab	ustekinumab/United States	Infliximab	infliximab/United States
United States (Reference Country)	$102,850	1.00	$196,772	1.00	$40,540	1.00
United Kingdom	$14,031	0.14	$18,508	0.09	$19,533	0.49
France	$5,705	0.06	$10,137	0.05	$8,186	0.20
Germany	$12,619	0.12	$35,033	0.18	$22,449	0.55
Italy	$18,407	0.18	$23,479	0.12	$20,673	0.51
Canada	$15,459	0.15	$21,508	0.11	$24,972	0.62
Japan	$7,752	0.08	$14,232	0.07	$9,923	0.24
Switzerland	$15,273	0.15	$25,109	0.13	$22,327	0.55

Each ratio = what fraction of the United States price that country pays for that specific drug. Three ratios per country — one per anchor drug. These feed into Step 2.

Ratio-Normalized International Reference Pricing Method

Step 2: Average the Three Ratios for Each Country | Country Average Ratio = (adalimumab/United States + ustekinumab/United States + infliximab/United States) ÷ 3

Country	Calculation	Average Ratio	Interpretation
United Kingdom	(0.14+ 0.09 + 0.49) / 3	0.237	Pays about 23.7% of United States price on average
France	(0.06 + 0.05 + 0.20) / 3	0.103	Pays about 10.3% of United States price on average
Germany	(0.13+ 0.18 + 0.55) / 3	0.285	Pays about 28.5% of United States price on average
Italy	(0.18 + 0.12 + 0.51) / 3	0.269	Pays about 26.9% of United States price on average
Canada	(0.15 + 0.11+ 0.62) / 3	0.292	Pays about 29.2% of United States price on average
Japan	(0.08 + 0.07+ 0.24) / 3	0.131	Pays about 13.1% of United States price on average
Switzerland	(0.15 + 0.13 + 0.55) / 3	0.276	Pays about 27.6% of United States price on average

The average ratio represents each country's overall pricing level for established inflammatory bowel disease biologics relative to the United States — smoothing drug-specific dynamics. These ratios are applied to the United States vedolizumab wholesale acquisition cost in Step 3 to derive the implied price per country.

Target Price Calculation: Ratio-Normalized Method

Step 3 — Average Country Ratio (from Anchor Drug Ratios)

Country	Avg Ratio (vs. US)
United Kingdom	0.237
France	0.103
Germany	0.285
Italy	0.269
Canada	0.292
Japan	0.131
Switzerland	0.276

Step 4 — Average the 7 Ratios

(0.24 + 0.10 + 0.28 + 0.27 + 0.29 + 0.13 + 0.28) ÷ 7

= 0.2276

Average International Pricing Ratio

(applied to both formulations)

Step 5 — Apply Average Ratio × United States Wholesale Acquisition Cost → Ratio-Normalized Net Target Price

Subcutaneous Pen

$94,614 × 0.2276

$21,531

per patient per year

77% rebate off WAC

Intravenous Vial

$60,654 × 0.2276

$13,803

per patient per year

77% rebate off WAC

Direct Price Comparison

Methodology

1 Identify Annual Gross Cost by Formulation

Formulation	US WAC	Non-US Avg
SC pen	$94,614	$15,567
IV vial	$60,654	$14,658

2 Compute Non-US Average per Formulation

Pen:

$17,655 + $7,337 + $14,343 + $24,165 + $17,543 + $9,984 + $17,943 = $109,969 ÷ 7 = $15,567

Vial:

$17,918 + $7,317 + $14,435 + $17,068 + $17,764 + $10,108 + $17,993 = $102,603 ÷ 7 = $14,658

3 Implied Reduction from US WAC

Form.	Calculation	Rebate
Pen	($94,614 − $15,567) ÷ $94,614	84%
Vial	($60,654 − $14,658) ÷ $60,654	76%

Net Target Price — By Formulation

SUBCUTANEOUS PEN

$15,567

per patient per year

84% rebate off $94,614 WAC

INTRAVENOUS VIAL

$14,658

per patient per year

76% rebate off $60,654 WAC

Positioning vs. Ratio-Normalized Method

The direct comparison method uses vedolizumab's actual country prices without adjusting for each market's broader pricing environment. The pen (84%) yields a more aggressive leverage point than the vial (76%), reflecting the larger absolute gap between the US pen WAC and international prices.

Key Limitations

Pricing and Methodology

- All foreign prices represent publicly available annual list prices — they do not reflect confidential managed-entry agreements or actual net prices after national-level negotiations. Actual international net prices are likely lower, meaning the true United States premium may be larger than reported.
- Currency movements affect calculated ratios and implied prices at each update. Analysis should be refreshed annually or when material exchange rate movements occur.
- The ratio-normalized method assumes pricing norms established by adalimumab, ustekinumab, and infliximab are representative of vedolizumab's pricing behavior — a standard assumption in ratio-based International Reference Pricing.
- The direct comparison method is sensitive to country-specific factors (single-payer leverage, biosimilar entry timelines) not generalizable across the comparator set.

Clinical Evidence

- All efficacy figures are from published pivotal trials or prescribing information. Cross-trial comparisons are indirect and not head-to-head; patient populations, definitions, and designs vary materially.
- VARSITY enrolled biologic-naive ulcerative colitis patients — results may differ in tumor necrosis factor inhibitor-experienced populations.
- Open-label extension data are subject to selection/attrition bias and do not establish long-run comparative effectiveness.

Utilization and Economic Data

- 2025 New York Medicaid prescription count reflects the full calendar year (6,628 claims).
- No patient-level persistence, unique-patient count, or cost-of-care analysis has been conducted. Further claims analysis recommended before budget impact modeling.
- Rebate calculations simplify statutory dynamics (inflationary penalties, best price) and are intended for directional guidance only.

Questions and Discussion

Butalbital-Containing Products for the Treatment of Headaches

May 15, 2026

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

Objective

- To evaluate the utilization of butalbital-containing products used for the treatment of tension-type headaches.

Background

- Butalbital-containing products are Food and Drug Administration-approved for the treatment of tension-type (or muscle contraction) headaches and considered safe for use in patients ≥12 years of age and are compendia-supported for the management of migraine headaches.

- Butalbital is a short- to intermediate- acting barbiturate that is combined with acetaminophen or aspirin with or without caffeine or codeine for the treatment of tension-type headaches.
  - Note: Products containing codeine are excluded from this presentation.

The Journal of Head and Face Pain, (2001) 41: 953-967. https://doi.org/10.1046/j.1526-4610.2001.01189.
Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed November 9, 2025.

Available Products

Variable	Butalbital and Acetaminophen	Butalbital, Acetaminophen, and Caffeine	Butalbital, Aspirin, and Caffeine
Formulation/ Strength	**Capsule:** • Butalbital 50 mg and acetaminophen 300 mg **Tablet:** • Butalbital 25 mg and acetaminophen 325 mg • Butalbital 50 mg and acetaminophen 300 mg • Butalbital 50 mg and acetaminophen 325 mg	**Capsule:** • Butalbital 50 mg, acetaminophen 325 mg, and caffeine 40 mg • Butalbital 50 mg, acetaminophen 300 mg, and caffeine 40 mg **Tablet:** • Butalbital 50 mg, acetaminophen 325 mg, and caffeine 40 mg **Solution:** • Butalbital 50 mg, acetaminophen 325 mg, and caffeine 40 mg per 15 mL	**Capsule**: • Butalbital 50 mg, aspirin 325 mg, and caffeine 40 mg
Dosing regimen	**Capsules/ Tablets**: 1 to 2 capsules or tablets every 4 hours; not to exceed 6 capsules or tablets per day.	**Capsules/ Tablets**: 1 to 2 tablets or capsules every 4 hours as needed; not to exceed 6 tablets or capsules per day. **Solution:** 15 to 30 mL every 4 hours, as needed; not to exceed 90 mL per day.	**Capsules**: 1 to 2 capsules every 4 hours as needed; maximum: 6 capsules per day.
EMedNY Maximum Reimbursable Amount (MRA) and Quantity Limits*	MRA: $0.56 to $1.53 Maximum Quantity: Capsules/ Tablets: 180 units/ claim	MRA: $0.14 to $2.87 Maximum Quantity: Capsules/ Tablets: 180 units/ claim Solution: 900 mL/ claim	MRA: $ 0.56 to $ 0.62 Maximum Quantity: Capsules: 180 units/ claim

MRA= maximum reimbursable amount
*As of January 20, 2026

Butalbital and Acetaminophen [package insert]. Princeton, NJ: Nostrum Laboratories, Dr. Reddy's Laboratories Inc. July 2024.
Butalbital, Acetaminophen, and Caffeine [package insert]. Philadelphia, PA: Lannett, Inc.; July 2023.
Butalbital, Aspirin, and Caffeine [package insert]. Kansas City, MO: Nostrum Laboratories, Inc.; October 2021.

Tension-Type Headaches

Variable	Tension-Type Headache	Migraine Headache
Characteristic	Constant, dull ache that affects both sides of the head	Throbbing pain that affects one side of the head
Duration	30 minutes to 7 days	4 to 72 hours
Aura	Absent	May be present
At least 2 of the criteria must be met	• Bilateral location • Mild to moderate pain intensity* • Pain described as pressing or tightening (not pulsating) • Not aggravated by routine activity	• Unilateral location • Moderate to severe pain intensity* • Pain described as pulsating • Aggravated by routine activity
Other symptoms	• No sensitivity to light or sound, or sensitivity to only 1 of the 2 • Nausea and vomiting are not present	• Sensitivity to light and/or sound • OR • Nausea and/or vomiting.

*Pain intensity definitions:

- Mild: Patient is aware of the headache but able to continue daily routine with minimum alterations.
- Moderate: Headache inhibits daily activities, but the patient is able to perform activities of daily living.
- Severe: The patient is unable to perform activities of daily living.

Headache Classification Committee of the International Headache Society (IHS), The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018;38(1):1–211. https://doi.org/10.1177/0333102417738202.

Place in Therapy

- According to the World Health Organization and national headache guidelines:
  - Butalbital-containing analgesics are not recommended for the treatment of tension-type headaches and are reserved for patients for whom other therapies were ineffective or who are intolerant to other therapies.
  - For acute episodic tension-type headaches, treatment can begin with nonsteroidal anti-inflammatory drugs.
  - If the patient cannot tolerate or has a contraindication to a nonsteroidal anti-inflammatory drug, acetaminophen 500 mg to 1000 mg every 6 to 8 hours can be considered.
  - If the tension-type headache is refractory to nonsteroidal anti-inflammatory drugs, consider aspirin or acetaminophen with the addition of caffeine.
    - Caffeine has been shown to enhance the analgesic effects of aspirin and acetaminophen.

World Health Organization. Migraine and other headache disorders. Revised October 24, 2025. Available at Migraine and other headache disorders. Accessed December 2025.

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Outpatient primary care management of headaches: guidelines from the VA/DoD. September 2021. 104(3): 316-320. Available at Outpatient Primary Care Management of Headaches: Guidelines from the VA/DoD | AAFP. Accessed December 2025.

Risks Associated with the Use of Butalbital-Containing Products

- Risks associated with the use of butalbital-containing products include addiction, abuse, and dependence with long-term use.
- Additionally, these products can cause sedation and respiratory depression, especially when combined with other central nervous system depressants, and there is the potential for overdose.
- Chronic use is not recommended unless pain remains severe and other options are ineffective, as long-term use can result in tolerance, withdrawal symptoms, and medication-overuse headaches.
- Butalbital-containing products cannot be stopped abruptly, as abrupt cessation can cause withdrawal seizures.

Med Clin North Am. 2013 Mar;97(2):337-52. doi: 10.1016/j.mcna.2012.12.007.
Headache. 2008;48(8):1157-68. doi: 10.1111/j.1526-4610.2008.01217.x.

Examples of Coverage Parameters

- Comparator states: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington
  - Three of the state Medicaid programs have established step edit criteria and quantity limits.
    - The quantity limit parameters range from 120 units or 180 mL every 365 days to 18 to 20 units/ 30 days.

- The United States Department of Veterans Affairs/ Department of Defense Clinical Practice Guideline for Management of Headache defines butalbital overuse as ≥5 days/ month for >3 months.
  - Use beyond that threshold can result in medication overuse headache.
  - International Classification of Headache Disorders, 3rd Edition defines medication overuse headache as a secondary headache disorder that occurs when overuse of acute medications to treat other headache disorders results in an increased headache burden with attacks occurring ≥15 days per month for at least 3 months in a patient with a pre-existing primary headache disorder.

VA/DoD clinical practice guideline for the management of headache. Version 3.0 (2023). Available at Management of Headache (2023) - VA/DOD Clinical Practice Guidelines. Accessed December 2025.

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The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018;38(1):1–211. https://doi.org/10.1177/0333102417738202.

Methodology

- A retrospective analysis of butalbital-containing products was conducted from April 1, 2024, to March 31, 2025 (State Fiscal Year 2025).

- The data source was the 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:
  - While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete.
  - This dataset does not capture the reduction in the quantity limit from 240 units/ 30 days to 180 units/ 30 days implemented in July 2025.

Results:
State Fiscal Year 2025

Generic Drug Names	Members*	Claims	Average Number of Claims/ Member	Average Number of Units/ Claim
Butalbital, Acetaminophen, and Caffeine	12,100	34,400	2.8	57.0
Butalbital and Acetaminophen	910	3,200	3.6	103.0
Butalbital, Aspirin, and Caffeine	250	690	2.8	46.0
Totals	13,100	38,300	3.0	61.0

Source= Medicaid Data Warehouse; Extract date= July 2025
*Members are not additive

- 79.0% of members receiving a butalbital-containing product were female
- The age distributions of members receiving butalbital-containing products:
  - 1.0% were <18 years of age
  - 14.5% were 18 and 29 years of age
  - 22.2% were 30 and 39 years of age
  - 23.8% were 40 and 49 years of age
  - 24.4% were 50 and 59 years of age
  - 14.1% were ≥ 60 years of age

Results:
State Fiscal Year 2025

- The NYRx quantity limit was reduced from 240 units/ claim to 180 units/ claim in July 2025. The current quantity limit of 6 units/ day is the maximum daily dose.

- The number of units members received per claim was:
  - 56.2% received ≤60 units/ claim,
  - 25.9% received >60 units/ claim to 90 units/ claim,
  - 12.6% received >90 units/ claim to 120 units/ claim, and
  - 5.3% received >120 units/ claim.

- The number of members using the products long-term is described below:
  - 3.7% members had >12 claims.
    - Based on guideline recommendations, butalbital-containing products should be used for a short period of time.
    - The duration is not defined in the Food and Drug Administration-approved product information.
  - 0.8% members received >1800 units/ year.

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Source= Medicaid Data Warehouse; Extract date= July 2025

Summary

- Butalbital-containing products are Food and Drug Administration-approved for the treatment of tension-type (or muscle contraction) headaches and are considered safe for use in patients ≥12 years of age and are compendia-supported for the management of migraine headaches.

- These products have limited benefits for tension-type headaches and have significant risks, including dependence, abuse potential, and medication-overuse headaches.

- The products are not recommended as first-line treatment for tension-type headaches and are reserved for patients for whom other therapies are ineffective or who are intolerant of other therapies. Nonsteroidal anti-inflammatory drugs remain the preferred first-line treatment for tension-type headaches. Additionally, aspirin and acetaminophen with or without caffeine can be used.

- A total of 13,100 members received a butalbital-containing product that resulted in 38,300 claims. Most members (56.2%) received ≤60 units/ claim. Also, a low number of members (3.7%) had >12 claims.

Dihydroergotamine and Ergotamine Agents

May 15, 2026

Drug Utilization Review Board Meeting

Department of Health
Office of Health Insurance Programs

Purpose

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

Dihydroergotamine and Ergotamine Agents

Generic Drug Name (Trade Name)	Food and Drug-Approved Indications	Available Dosage Forms
Dihydroergotamine mesylate (Migranal®, Trudhesa®)*	Acute treatment of migraine with or without aura in adult patients	Migranal® nasal spray: 4 mg/mL (available in a package of 8 units) Trudhesa® nasal spray: 4 mg/mL (available in a package of 4 single-dose units)
Dihydroergotamine mesylate (DHE 45, Brekiya®*)	Acute treatment of migraine with or without aura in adult patients Acute treatment of cluster headaches	Single-dose autoinjector: 1 mg/mL solution
Ergotamine (Ergomar®)*	Acute treatment of migraine in adult patients	Sublingual tablets: 2 mg (available in a carton of 20 unit doses)
Ergotamine/caffeine (Migergot®)	Abort or prevent vascular migraine (migraine, migraine variants) in adult patients	Oral tablet (generic): 1 mg/100 mg Rectal suppository (Migergot®): 2 mg/100 mg (available in a box of 12 suppositories)

*Ergotamine tablets, dihydroergotamine nasal spray, and dihydroergotamine injection (Brekiya®) are listed on the eMedNY formulary

See end of presentation for product labeling references

Guidelines and Consensus Statements

Guidelines/consensus statements	Recommendations
American College of Physicians guidelines (2025)	• Calcitonin gene-related peptide antagonists (gepants) or ergotamines may be considered for treatment of moderate to severe acute migraines in adult patients who have an inadequate response or intolerance to a triptan, nonsteroidal anti-inflammatory agents, or acetaminophen.
International Headache Society practice recommendations (2024)	• Ergotamines are not considered an option for acute migraine treatment due to side effects, risk of serious drug interactions, overuse risk, and availability of better treatment options. Use may be considered in “exceptional cases” when all other available acute treatment options with better safety profiles are ineffective or contraindicated. • Notes a lack of evidence, but in patients with a migraine lasting >72 hours, suggests use of intramuscular or other dosage forms of nonsteroidal anti-inflammatory agents, subcutaneous sumatriptan, or oral/intranasal dihydroergotamine. • Dihydroergotamine and ergotamine should not be used in patients with a history of stroke, other vascular diseases, or uncontrolled hypertension.
European Academy of Neurology guidelines (2023)	• Asserts that there is very low evidence for dihydroergotamine nasal spray for the acute treatment of cluster headaches. • Strongly recommends oxygen and intranasal or injectable sumatriptan for the acute treatment of cluster headaches.

See end of presentation for references

Guidelines and Consensus Statements – Cont.

Guidelines/consensus statements	Recommendations
American Headache Society consensus statement (2021)	• Recommends that dihydroergotamines and triptans be considered for treatment of moderate/severe migraines or mild/moderate migraines that do not respond to “nonspecific” treatment.
European Academy of Neurology/European Headache Federation consensus statement (2021)	• Asserts that oral ergotamine should be avoided for treatment of acute migraines since they are not effective and potentially toxic and should not be used as a substitute for triptans. • The statement does not address other dosage formulations.
National Institute for Health and Care Excellence guidelines (2021)	• Does not recommend ergotamines for acute treatment of migraines or cluster headaches.

See end of presentation for references

New York State Medicaid Coverage

- These agents are not subject to the NYRx Preferred Drug Program
- Ergotamine tablets, dihydroergotamine nasal spray, and dihydroergotamine injection (Brekiya®) are listed on the eMedNY formulary
- Quantity limits:
  - Dihydroergotamine nasal spray: 8 units/30 days
  - Dihydroergotamine injection: 4 units/30 days
  - Ergotamine tablets: 20 units/30 days
- Prior authorization is required for members <18 years of age

See end of presentation for references

Comparator State Medicaid Coverage

- Comparator states: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington
- Among the 9 programs, 7 require prior authorization, 3 have quantity limits, and 2 limit the age to ≥18 years

See end of presentation for references

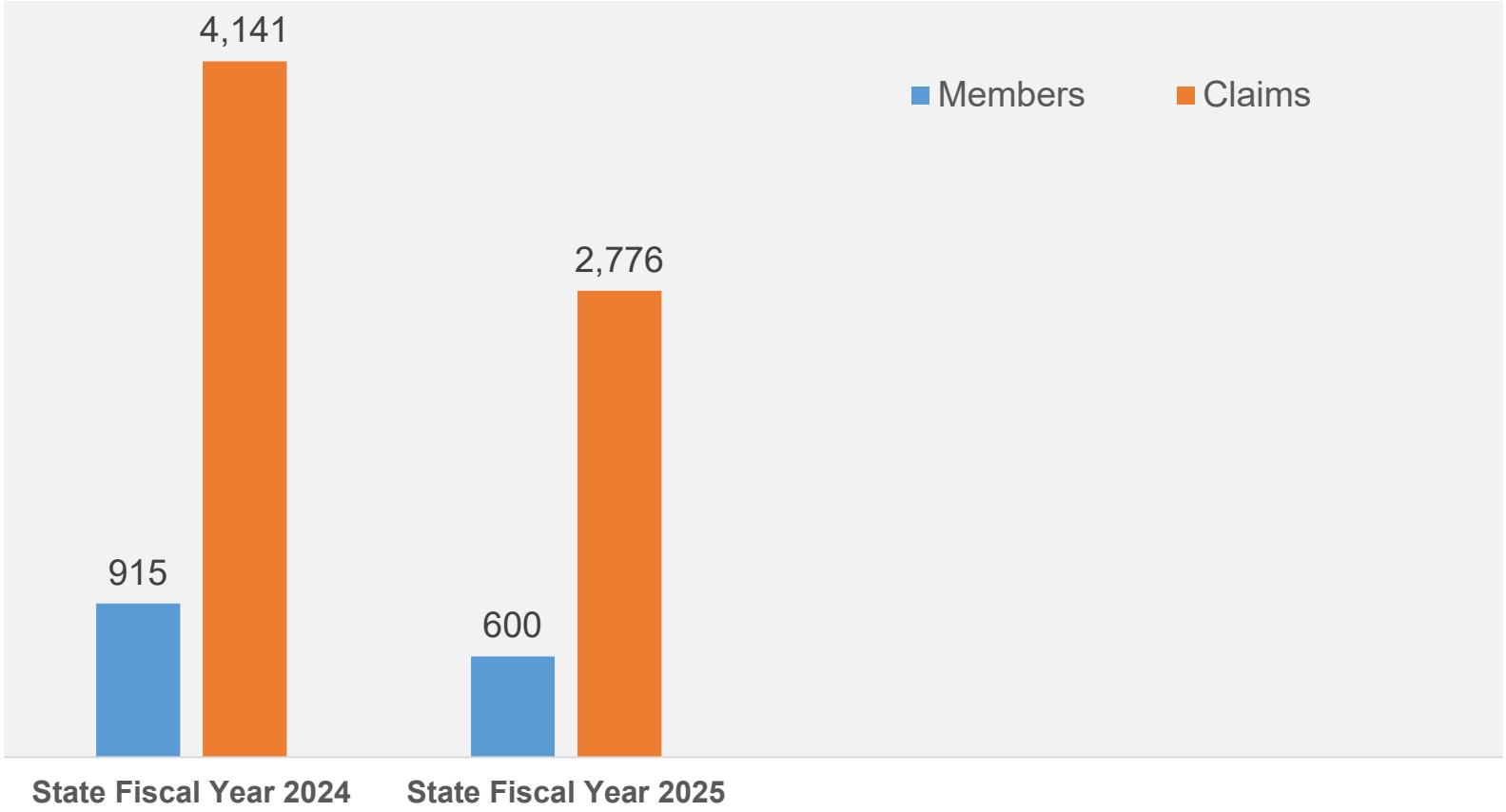
Drug Utilization Data: Overview of Analyses

- A retrospective analysis of claims was conducted
- Members enrolled in the New York State Medicaid Program with ≥1 pharmacy claim for a dihydroergotamine or ergotamine agent during State Fiscal Year 2024 and 2025 were included
  - State Fiscal Year 2024: April 1, 2023 – March 31, 2024
  - State Fiscal Year 2025: April 1, 2024 – March 31, 2025
  - The diagnosis lookback timeframe was State Fiscal Years 2024 and 2025
- Data source: Medicaid Data Warehouse

Drug Utilization Data: Disclaimers

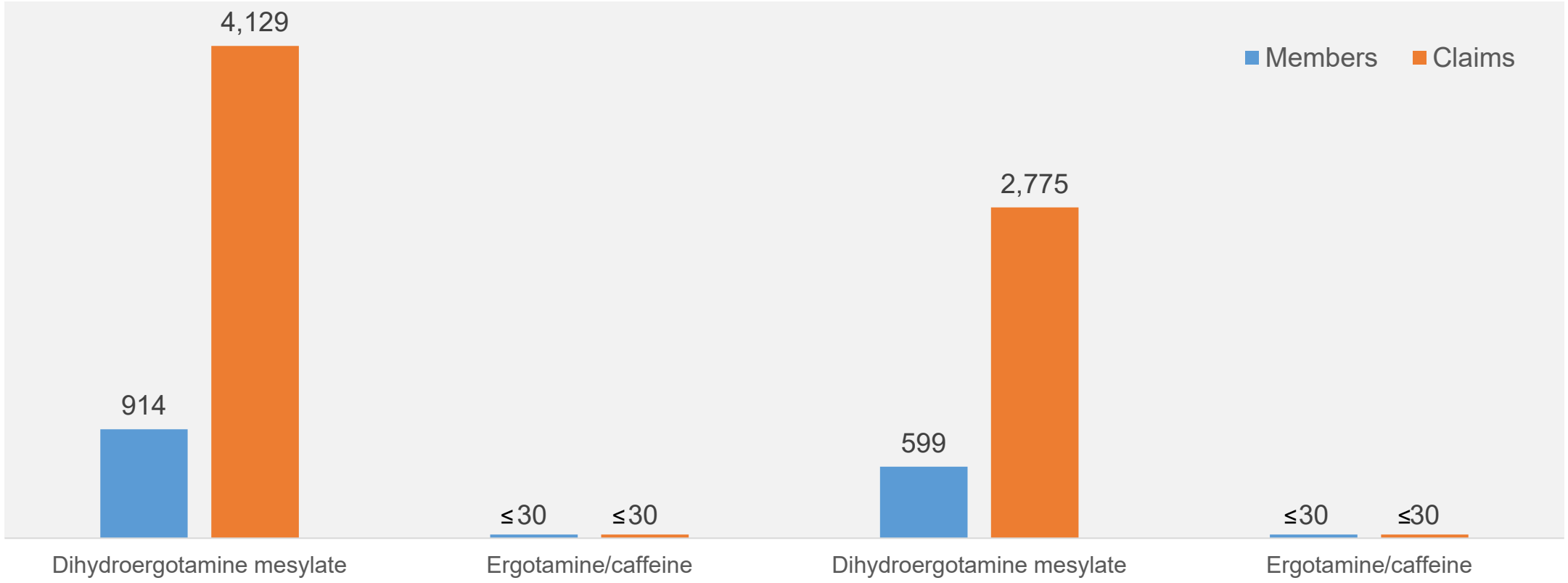
- Medicaid Confidential Data Cell Size Policy (OHIP-0001)
  - Requires that no cell containing a value of 1 to 30 be reported; such values must be reported as ≤30 in all public-facing documents
- The following limitations should also be considered:
  - While time periods analyzed take into account inherent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

Overall Utilization



Only includes pharmacy claims (does not include medical procedure claims); members are not additive
Data source: Medicaid Data Warehouse; date range: 04/01/2023 - 03/31/2025; extract date: 11/18/2025

Utilization by Generic Drug



Only includes pharmacy claims (does not include medical procedure claims); members are not additive
Data source: Medicaid Data Warehouse; date range: 04/01/2023 - 03/31/2025; extract date: 11/18/2025

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Diagnosis of Members – State Fiscal Year 2025

ICD-10	Description	Members
R519	HEADACHE, UNSPECIFIED	278
G43909	MIGRAINE, UNSPECIFIED, NOT INTRACTABLE, WITHOUT AURA	217
G43719	CHRONIC MIGRAINE WITHOUT AURA, INTRACTABLE	128

Includes pharmacy or medical procedure claims
ICD-10=International Classification of Disease codes, tenth revision;
Data source: Medicaid Data Warehouse; date range: 04/01/2023 - 03/31/2025; extract date: 11/18/2025
Members and percentages are not additive; only includes diagnoses with ≥100 members

Age and Gender in State Fiscal Year 2025

- 99.5% of members* were ≥18 years of age
- 73% were female

*Includes pharmacy or medical procedure claims
Data source: Medicaid Data Warehouse; date range: 04/01/2023 - 03/31/2025; extract date: 11/18/2025
Age is based on 04/01/2025

Step Therapy – Members and Claims by Drug Class in State Fiscal Year 2025

Class	Members	Claims
NSAID	444	3,355
ACETAMINOPHEN	207	807
TRIPTAN	183	1,641
TRIPTAN/NSAID	≤30	42
TOTAL, ANY CLASS	502	5,845

- Of the members who received a dihydroergotamine or ergotamine agent in State Fiscal Year 2025 (n=635), 79% (n=502) of members had evidence of using a nonsteroidal anti-inflammatory drug, acetaminophen, triptan, or triptan/nonsteroidal anti-inflammatory agent in the previous 2 years

*Includes pharmacy or medical procedure claims
NSAID=nonsteroidal anti-inflammatory drug
Data source: Medicaid Data Warehouse; date range: 04/01/2023 - 03/31/2025; extract date: 11/18/2025
Members are not additive

Step Therapy – Members and Claims by Drug Class in State Fiscal Year 2025

Class	Members	Claims
NSAID	444	3,355
CGRP/DITAN	211	2,047
ACETAMINOPHEN	207	807
TRIPTAN	183	1,641
TRIPTAN/NSAID	≤30	42
TOTAL, ANY CLASS	530	7,892

- Of the members who received a dihydroergotamine or ergotamine agent in State Fiscal Year 2025 (n=635), 84% (n=530) of members had evidence of using a nonsteroidal anti-inflammatory agent, calcitonin gene-related peptide agent inhibitor/ditan, acetaminophen, triptan, or triptan/nonsteroidal anti-inflammatory agent in the previous 2 years

*Includes pharmacy or medical procedure claims; also includes calcitonin gene-related peptide inhibitors and ditans (e.g., lasmiditan)
CGRP=calcitonin gene-related peptide inhibitor; NSAID=nonsteroidal anti-inflammatory drug
Data source: Medicaid Data Warehouse; date range: 04/01/2023 - 03/31/2025; extract date: 11/18/2025; members are not additive

Conclusions

- Per guideline and consensus statement recommendations, dihydroergotamine and ergotamine agents are not first-line for treatment of acute migraines and cluster headaches due to the risk for serious adverse events, drug interactions, and risk for overuse
  - Use should only be considered when other acute treatment options with better safety profiles are ineffective or contraindicated (e.g., triptans, nonsteroidal anti-inflammatory drugs, acetaminophen)
- Of the members who received a dihydroergotamine or ergotamine agent in State Fiscal Year 2025, 79% of members had evidence of using a guideline-recommended drug class (nonsteroidal anti-inflammatory drug, acetaminophen, triptan, or triptan/nonsteroidal anti-inflammatory agent) in the previous 2 years

See end of presentation for references

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Pharmacy Program Update: Crohn's Disease and Ulcerative Colitis

May 15, 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 the Pharmacy Program update is to review the Clinical Criteria for agents approved for treatment of Crohn's disease and ulcerative colitis and their utilization in the New York State Medicaid population
- Recommendations will be provided based on a review of the literature and results from utilization data analyses

Preferred Drug Program: Agents for Treatment of Crohn's Disease and Ulcerative Colitis*

Preferred	Non-Preferred	
Tumor necrosis factor inhibitor: Humira®	Interleukin inhibitors: Imuldosa® Omvoh™ pen Otulfi® Pyzchiva® Selarsdi™ Skyrizi® Skyrizi® On-Body Stelara® Steqeyma® Tremfya® Ustekinumab Yesintek™ Janus kinase inhibitors: Rinvoq® ER Rinvoq® LQ Xeljanz® Xeljanz® XR	Tumor necrosis factor inhibitors: Abrilada™ Adalimumab Amjevita® Cimzia® Hadlima® Hulio® Hyrimoz® Idacio® Simlandi® Simponi® Yuflyma® Yusimry® Zymfentra™ Miscellaneous: Entyvio® subcutaneous Velsipity™

*Only includes drugs approved for Crohn's disease or ulcerative colitis (excludes drugs in the Preferred Drug List category with indications for other diseases).

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See end of presentation for references

New York State Medicaid Clinical Criteria: Crohn's Disease and Ulcerative Colitis

- Systemic immunomodulators have the following Clinical Criteria and step therapy (for indications other than asthma, nasal polyps, atopic dermatitis, and chronic obstructive pulmonary disease):
  - Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a disease-modifying anti-rheumatic drug
  - Trial of a tumor necrosis factor inhibitor prior to treatment with a Janus kinase inhibitor

- Confirm diagnosis for Food and Drug Administration-approved or Compendia-supported uses

See end of presentation for references

Food and Drug Administration-Approved Indications

- All agents listed in the Preferred Drug Program are approved for both Crohn's disease and ulcerative colitis except:
  - Etrasimod (Velsipity™), golimumab (Simponi®), and tofacitinib (Xeljanz®, Xeljanz® XR) are only approved for ulcerative colitis
  - Certolizumab pegol (Cimzia®) is only approved for Crohn's disease

- Multiple products and formulations (agents administered orally and by injection/intravenous infusion) including biosimilars

See end of presentation for references

Guidelines – Crohn's Disease

- The American College of Gastroenterology (2025), American Gastroenterological Association (2025), and European Crohn's and Colitis Organization (2020) guidelines:
  - Recommend initiation of advanced treatments (e.g., anti-tumor necrosis factor agents, anti-integrin agents, interleukin inhibitors, Janus kinase inhibitors) instead of requiring a trial with conventional agents (e.g., corticosteroids, aminosalicylates)

See end of presentation for references

Guidelines – Ulcerative Colitis

- The American Gastroenterological Association (2024) guidelines:
  - Suggest early use of advanced treatments with or without an immunomodulator rather than gradually escalating treatment after failure of 5-aminosalicylates for the treatment of moderate to severe ulcerative colitis
  - Recommend infliximab, golimumab, vedolizumab, tofacitnib, upadacitinib, ustekinumab, ozanimod, etrasimod, risankizumab, and guselkumab over no treatment

- The American College of Gastroenterology (2025) guidelines:
  - Recommend more newly approved treatments (e.g., anti-tumor necrosis factor agents, Janus kinase inhibitors) and older agents (e.g., aminosalicylates, corticosteroids) for moderately to severely active ulcerative colitis
  - Also recommend older agents such as aminosalicylates as first-line for mildly to moderately active ulcerative proctitis

See end of presentation for references

Comparator State Medicaid Coverage

- Comparator states: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington
- Among the 9 programs, 8 require prior authorization (varies by drug) and 3 require step therapy

See end of presentation for references

Drug Utilization Data: Overview of Analyses

- A retrospective analysis of claims was conducted
- Members enrolled in the New York State Medicaid Program with a with a diagnosis of Crohn's disease or ulcerative colitis during State Fiscal Years 2024 and 2025 were included
  - 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

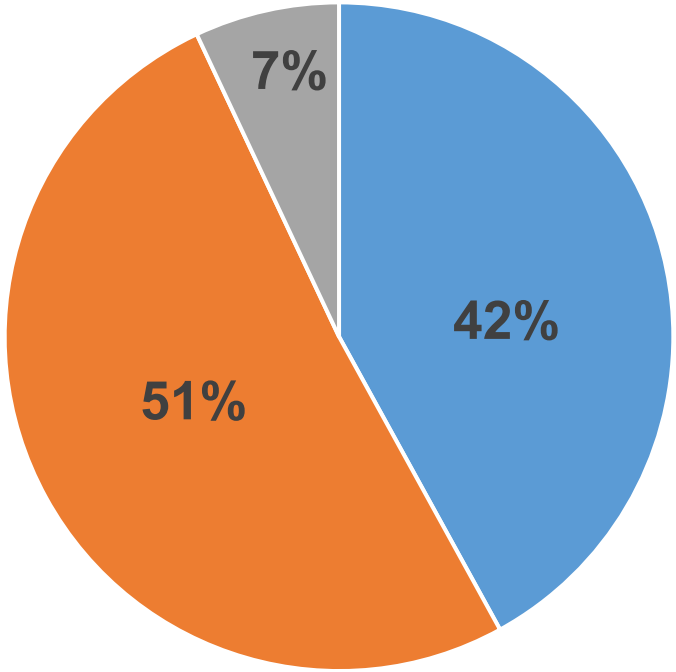
Drug Utilization Data: Disclaimers

- 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

Objectives

1. Determine the number of members with a diagnosis of Crohn's disease or ulcerative colitis during State Fiscal Years 2024 and 2025
2. Evaluate the utilization of agents approved by the Food and Drug Administration for treatment of Crohn's disease and/or ulcerative colitis in members who had a diagnosis of these conditions during State Fiscal Years 2024 and 2025
3. Determine the age and gender of members who had a diagnosis of Crohn's disease or ulcerative colitis during State Fiscal Years 2024 and 2025

Objective 1: Diagnosis of Members – State Fiscal Years 2024 and 2025

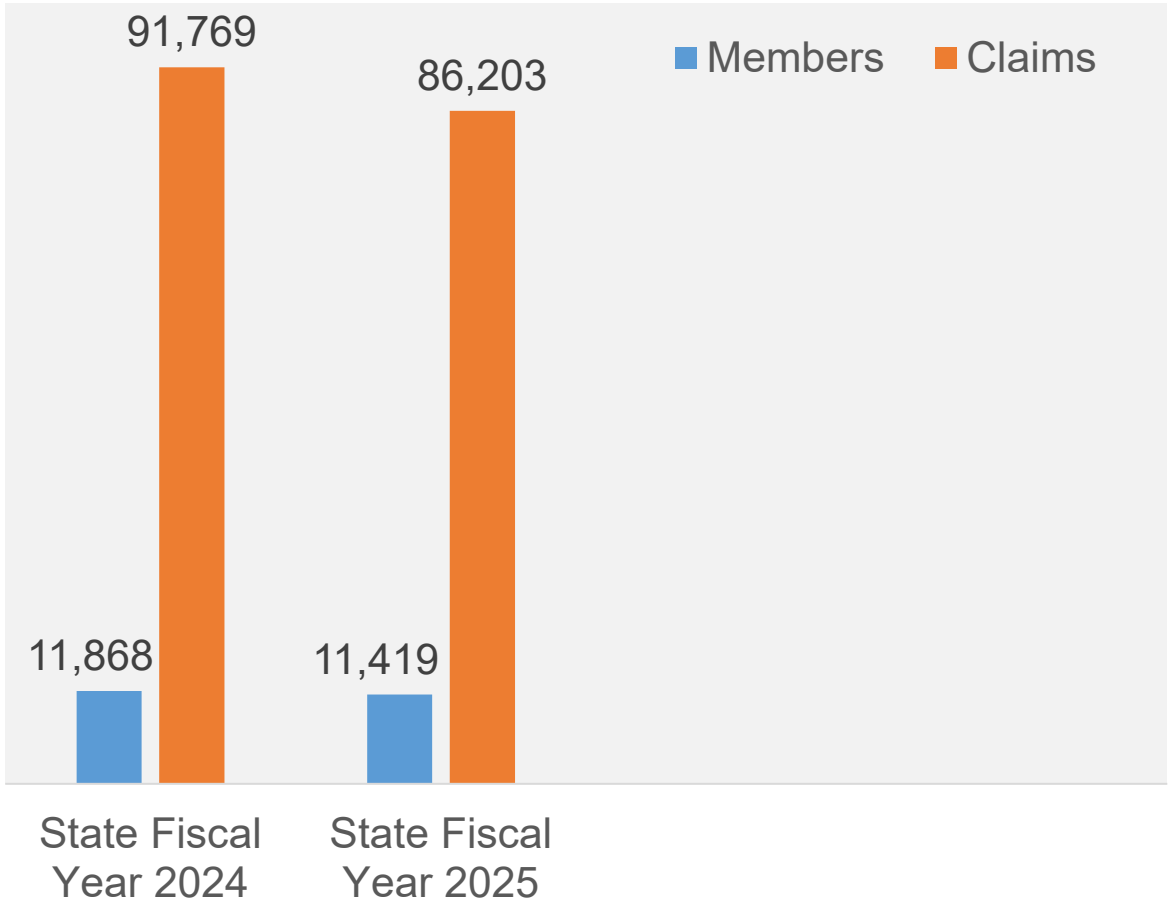


- There were a total of 41,439 unique members
- 63% (n=26,101) had ≥2 distinct dates of service for State Fiscal Years 2024 and 2025
- Of the 26,101 members, 55% (n=14,315) received treatment while 45% (n=11,786) did not receive treatment
- 7% were coded for both diagnoses

Crohn's disease Ulcerative colitis Both

Data source: Medicaid Data Warehouse; date range: 4/1/2023 - 3/31/2025; extract date: 12/16/2025

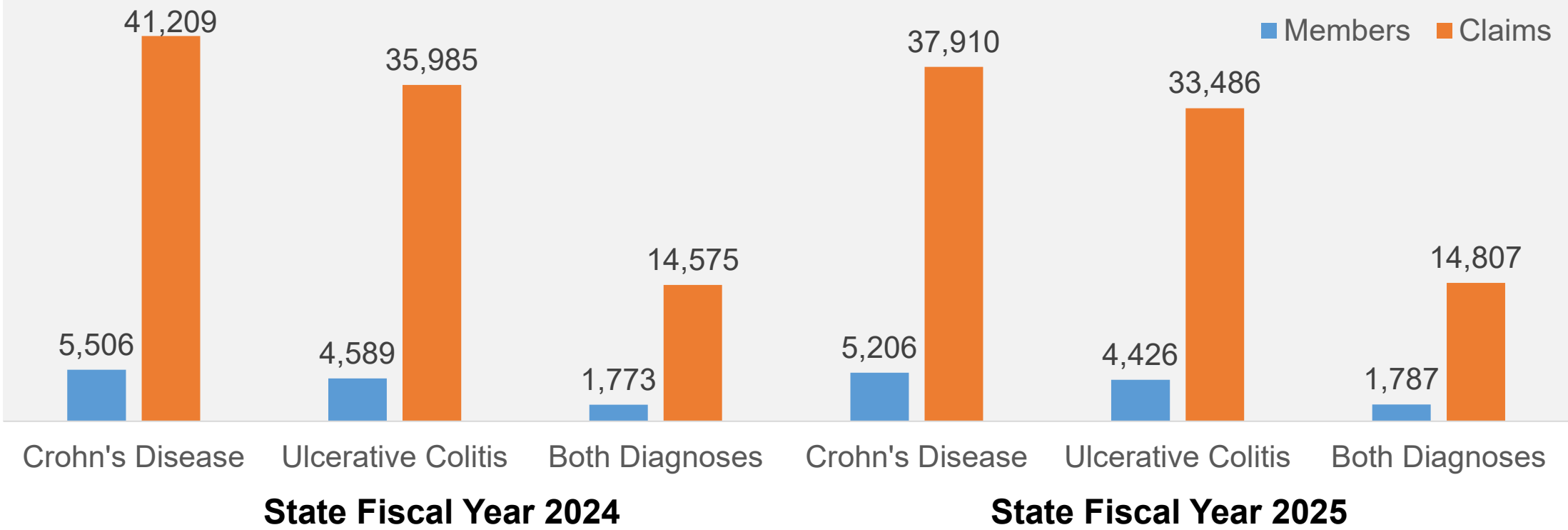
Objective 2: Overall Utilization – All Diagnoses



- Of the 26,101 members with ≥2 dates of service (includes pharmacy and medical claims), 11,868 had a claim in State Fiscal Year 2024 and 11,419 had a claim in State Fiscal Year 2025
- The number of claims decreased from 91,769 to 86,203 in State Fiscal Years 2024 and 2025, respectively

Data source: Medicaid Data Warehouse; date range: 4/1/2023 - 3/31/2025; extract date: 12/16/2025
Includes pharmacy and medical claims; members not additive; members must have >=2 dates of service

Utilization by Diagnosis and State Fiscal Year



- Members with only Crohn's disease accounted for 46% (5,506/11,868) and 46% (5,206/11,419) of the utilization in State Fiscal Years 2024 and 2025, respectively.

Data source: Medicaid Data Warehouse; date range: 4/1/2023 - 3/31/2025; extract date: 12/16/2025
Includes pharmacy and medical claims; members not additive; members must have >=2 dates of service

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Objective 3: Age and Gender in State Fiscal Years 2024 and 2025

- 92% of members were ≥18 years of age
- 50% were female

Data source: Medicaid Data Warehouse; date range: 4/1/2023 - 3/31/2025; extract date: 12/16/25; members must have >=2 dates of service; age based on 4/1/2024

Conclusions

- The American College of Gastroenterology (2025), American Gastroenterological Association (2025), and European Crohn's and Colitis Organization (2020) guidelines:
  - Recommend initiation of advanced treatments (e.g., anti-tumor necrosis factor agents, anti-integrin agents, interleukin inhibitors, Janus kinase inhibitors) instead of requiring a trial with conventional agents (e.g., corticosteroids, aminosalicylates)

See end of presentation for references

Conclusions – Cont.

- The American Gastroenterological Association (2024) guidelines:
  - Suggest early use of advanced treatments with or without an immunomodulator rather than gradually escalating treatment after failure of 5-aminosalicylates for the treatment of moderate to severe ulcerative colitis

- The American College of Gastroenterology (2025) guidelines:
  - Recommend more newly approved treatments (e.g., anti-tumor necrosis factor agents, Janus kinase inhibitors) and older agents (e.g., aminosalicylates, corticosteroids) for moderately to severely active ulcerative colitis

See end of presentation for references

Conclusions – Utilization Data

- 41,439 unique members had at least 1 diagnosis of Crohn's disease or ulcerative colitis in State Fiscal Years 2024 and 2025
- Of the total 41,439 unique members,
  - 42% (n=17,196) of members had a diagnosis of Crohn's disease only,
  - 51% (n=21,206) of members had a diagnosis of ulcerative colitis only, and
  - 7% (n=3,037) of members were coded for both diagnoses
- Of the 26,101 members who had ≥2 distinct dates of service with a Crohn's disease or ulcerative colitis diagnosis for State Fiscal Years 2024 and 2025,
  - 55% (n=14,315) received treatment,
  - while 45% (n=11,786) did not receive treatment

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