Prime THERAPEUTICS™

Immunomodulators & Related Agents – Topical

NYRx Drug Utilization Review Board meeting
October 3rd, 2025

Immunomodulators & Related Agents – Topical: Summary

New Products: Zoryve® (roflumilast) Cream, Zoryve® (roflumilast) Foam, Vtama® (tapinarof)

Practice Guideline Updates

Zoryve® (roflumilast) Cream

Clinical Information

Indications:

Roflumilast is a phosphodiesterase 4 inhibitor:

Roflumilast cream, 0.3%, is indicated for the topical treatment of plaque psoriasis in adult and pediatric patients 6 years of age and older.

Roflumilast cream, 0.15%, is indicated for the topical treatment of mild to moderate atopic dermatitis (AD) in adult and pediatric patients 6 years of age and older.

Administration and Usage:

Apply:

- 0.3% cream, once daily to affected areas of plaque psoriasis
- 0.15% cream, once daily to affected areas of mild to moderate atopic dermatitis

Contraindications:

Moderate to severe liver impairment (Child-Pugh B or C)

Adverse Reactions:

Plaque Psoriasis: diarrhea, headache, insomnia, nausea, application site pain, upper respiratory tract infections, and urinary tract infections

Atopic Dermatitis: headache, nausea, application site pain, diarrhea, and vomiting

Drug Interactions:

Cytochrome P450 (CYP) Inhibitor Interaction: Co-administration of roflumilast with strong CYP3A4 or dual CYP3A4/CYP1A2 inhibitors may increase systemic exposure and risk of adverse reactions.

Oral Contraceptive Interaction: Roflumilast exposure may be elevated when taken with gestodene/ethinyl estradiol-containing contraceptives, potentially increasing adverse effects.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215985s007lbl.pdf

Zoryve® (roflumilast) Cream

Clinical Information, continued

Specific Populations:

Pregnancy: Insufficient human data; animal studies show no structural abnormalities but increased risk of post-implantation loss, stillbirth, and impaired development at high doses.

Lactation: Unknown if roflumilast is present in human milk; detected in animal milk. Consider risks vs. benefits when prescribing to breastfeeding mothers.

Pediatric Use:

- Plaque Psoriasis: Approved for ages ≥6; supported by controlled and open-label studies. Not established in children <6 years.
- Atopic Dermatitis: Approved for ages ≥6; supported by large clinical trials. Not established in children <6 years.

Geriatric Use: No significant safety or efficacy differences observed in patients ≥65 years, but increased sensitivity in older adults cannot be ruled out.

Hepatic Impairment: Contraindicated in moderate to severe liver impairment (Child-Pugh B or C). No dose adjustment needed for mild impairment (Child-Pugh A).

Clinical Comparative Studies:

None

Zoryve® (roflumilast) Foam

Clinical Information

Indications:

Roflumilast is a phosphodiesterase 4 inhibitor:

Roflumilast foam, 0.3%, is indicated for the topical treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

Administration and Usage:

Apply:
- Apply once daily to affected areas.

Contraindications:

Moderate to severe liver impairment (Child-Pugh B or C)

Adverse Reactions:

Nasopharyngitis, nausea, and headache

Drug Interactions:

Cytochrome P450 (CYP) Inhibitor Interaction: Co-administration of roflumilast with strong CYP3A4 or dual CYP3A4/CYP1A2 inhibitors may increase systemic exposure and risk of adverse reactions.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217242s000lbl.pdf

Zoryve® (roflumilast) Foam

Clinical Information, continued

Specific Populations:

Pregnancy: Insufficient human data; animal studies show no structural abnormalities but increased risk of post-implantation loss, stillbirth, and impaired development at high doses.

Lactation: Unknown if roflumilast is present in human milk; detected in animal milk. Consider risks vs. benefits when prescribing to breastfeeding mothers.

Pediatric Use: Roflumilast foam for the treatment of seborrheic dermatitis is established in pediatric patients 9 years of age and older.

Geriatric Use: No significant safety or efficacy differences observed in patients ≥ 65 years, but increased sensitivity in older adults cannot be ruled out.

Hepatic Impairment: Contraindicated in moderate to severe liver impairment (Child-Pugh B or C). No dose adjustment needed for mild impairment (Child-Pugh A).

Clinical Comparative Studies:

None

Vtama® (tapinarof) Cream

Clinical Information

Indication:

Tapinarof cream, 1% is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults.

Administration and Usage:

Apply a thin layer of cream to affected areas once daily

Contraindications:

None

Adverse Reactions:

Folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza

Drug Interactions:

None

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215272s000lbl.pdf

Vtama® (tapinarof) Cream

Clinical Information, continued

Specific Populations:

Pregnancy: Insufficient human data; animal studies showed no significant adverse effects at high doses

Lactation: Unknown if tapinarof is present in human milk; detected in animal milk. Consider risks vs. benefits when prescribing to breastfeeding mothers.

Pediatric Use: Safety and efficacy not established in pediatric patients under 18 years with psoriasis.

Geriatric Use: No differences in safety or efficacy observed in patients ≥65 years compared to younger adults.

Clinical Comparative Studies:

None

Practice Guideline Updates

American Academy of Dermatology (AAD) published a focused update (June 2025)

Atopic Dermatitis (Adults)

New 2024 Food and Drug Administration Approvals included in updated recommendations.

For mild to moderate Atopic Dermatitis:

- Roflumilast 0.15% cream

For moderate to severe Atopic Dermatitis:

- Tapinarof 1% cream
- Injectable lebrikizumab
- Injectable nemolizumab

Guidelines remain current for 5 years post-publication or until updated.

Immunomodulators & Related Agents – Topical – Current Status

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

Prime THERAPEUTICS™

Immunomodulators Systemic

Therapeutic Class Review

Immunomodulators, Systemic: Summary

New Products: Steqeyma (ustekinumab-stab), Yesintek (ustekinumab-kfce), Imuldosa (ustekinumab-srlf), Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe), Selarsdi (ustekinumab-aekn), Nemluvio (nemolizumab-ilto), Ebglyss (lebrikizumab-lbkz), Tyenne (tocilizumab-aazg), Simlandi (adalimumab-ryvk)

New Formulations: Steqeyma (ustekinumab-stba), Spevigo (spesolimab-sbzo), Tyenne (tocilizumab-aazg), Otulfi (ustekinumab-aauz), Selarsdi (ustekinumab-aekn), Tremfya (guselkumab), Pyzchiva (ustekinumab-ttwe), Simlandi (ustekinumab-ryvk), Bimzelx (bimekizumab-bkzx), Idacio (adalimumab-aacf), Rinvoq (upadacinib), Zymfentra (infliximab-dyyb)

New Indications (many)

Key Label Revisions (many)

Practice Guideline Updates

Steqeyma® (ustekinumab-stba)

Clinical Information

Indications:

Ustekinumab-stba is a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis

Dosage and Administration:

- **Adult Psoriasis:**
  ≤100 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  >100 kg: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriasis (6–17 yrs):**
  60–100 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  >100 kg: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriatic Arthritis:**
  45 mg SC at week 0 & 4, then every 12 weeks
  If >100 kg with coexistent psoriasis: 90 mg subcutaneously same schedule
- **Pediatric Psoriatic Arthritis (6–17 yrs):**
  ≥60 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  >100 kg with psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Crohn's Disease & Ulcerative Colitis:**
  Intravenous Induction: ≤55 kg: 260 mg | 55–85 kg: 390 mg | >85 kg: 520 mg
  subcutaneously Maintenance: 90 mg 8 weeks post-IV, then every 8 weeks

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761338s000lbl.pdf

Steqeyma® (ustekinumab-stba)

Clinical Information, continued

Adverse Reactions:

- Psoriasis: nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- Crohn's Disease, induction: vomiting.
- Crohn's Disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis
- Ulcerative colitis, induction: nasopharyngitis
- Ulcerative colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea

Drug Interactions:

- No significant Cytochrome P450 interactions
- Avoid live vaccines
- Use caution when combining with other biologics or systemic immunosuppressants

Contraindications:

Clinically significant hypersensitivity to ustekinumab products or to any of the excipients in Steqeyma.

Warning and Precautions:

Infections: Do not initiate during active, clinically significant infections. Discontinue if serious infection develops.

Theoretical Infection risk: Consider risk for mycobacterial, salmonella, and Bacillus Calmette-Guérin-related infections in Interleukin-12/23-deficient patients; test as clinically indicated.

Tuberculosis: Screen for tuberculosis prior to initiation. Treat latent tuberculosis before starting therapy.

Malignancy Risk: Potential increased risk; safety in patients with current or prior malignancy is unknown.

Hypersensitivity: Discontinue immediately if anaphylaxis or other serious hypersensitivity occurs.

Posterior Reversible Encephalopathy Syndrome: Discontinue if Posterior Reversible Encephalopathy Syndrome is suspected.

Vaccinations: Avoid live vaccines during treatment.

Noninfectious Pneumonias: Discontinue if interstitial, eosinophilic, or cryptogenic organizing pneumonia is diagnosed.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761338s000lbl.pdf

Steqeyma® (ustekinumab-stba)

Clinical Information, continued

Special Populations:

- **Pregnancy**:
  - Limited human data; risk of fetal harm unknown.
  - Immunoglobulin G transfer increases in 3rd trimester—potential fetal exposure.
  - No adverse effects seen in animal studies at >100× maximum recommended human dose.
- **Lactation**:
  - Ustekinumab detected in breast milk; effects on infant and milk production unknown.
  - No reported adverse effects in breastfed infants.
  - Weigh benefits of breastfeeding vs. maternal need for therapy.
- **Pediatric Use**:
  - **Plaque Psoriasis**: Approved for ages 6–17; supported by clinical trials.
  - **Psoriatic Arthritis**: Approved for ages 6–17; extrapolated from adult data + pediatric pharmacokinetic/safety.
  - Not established for <6 years or for **Crohn's disease/Ulcerative colitis** in pediatric patients.
- **Geriatric Use**:
  - Limited data in patients ≥65 years; no clear differences in response vs. younger adults.

Clinical Comparative Studies:

One double blind study comparing Steqeyma to Stelara in moderate-to-severe plaque psoriasis

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761338s000lbl.pdf

Yesintek ® (ustekinumab-kfce)

Clinical Information

Indications:

Ustekinumab-kfce is a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis

Dosage and Administration:

- **Adult Psoriasis** (≤100 kg): 45 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriasis** (>100 kg): 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriasis** (6–17 yrs):
  - <60 kg: 0.75 mg/kg subcutaneously at week 0 & 4, then every 12 weeks
  - 60–100 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriatic Arthritis**: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - If >100 kg with coexistent psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriatic Arthritis** (6–17 yrs):
  - <60 kg: 0.75 mg/kg subcutaneously at week 0 & 4, then every 12 weeks
  - ≥60 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg with psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Crohn's Disease & Ulcerative Colitis** (Adult):
  - Intravenous Induction: up to 55 kg: 260 mg | 55–85 kg: 390 mg | >85 kg: 520 mg
  - subcutaneously Maintenance: 90 mg every 8 weeks starting 8 weeks after IV dose

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761406s000lbl.pdf

Yesintek ® (ustekinumab-kfce)

Clinical Information, continued

Adverse Reactions:

- Psoriasis: nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- Crohn's Disease, induction: vomiting.
- Crohn's Disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis
- Ulcerative colitis, induction: nasopharyngitis
- UlceCytochrome P450 ive colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea

Drug Interactions:

- No significant Cytochrome P450 interactions
- Avoid live vaccines
- Use caution when combining with other biologics or systemic immunosuppressants

Contraindications:

Clinically significant hypersensitivity to ustekinumab products or to any of the excipients in Yesintek.

Warning and Precautions:

Infections: Do not initiate during active, clinically significant infections. Discontinue if serious infection develops.

Theoretical Infection risk: Consider risk for mycobacterial, salmonella, and Bacillus Calmette-Guérin-related infections in Interleukin-12/23-deficient patients; test as clinically indicated.

Tuberculosis: Screen for tuberculosis prior to initiation. Treat latent tuberculosis before starting therapy.

Malignancy Risk: Potential increased risk; safety in patients with current or prior malignancy is unknown.

Hypersensitivity: Discontinue immediately if anaphylaxis or other serious hypersensitivity occurs.

Posterior Reversible Encephalopathy Syndrome: Discontinue if Posterior Reversible Encephalopathy Syndrome is suspected.

Vaccinations: Avoid live vaccines during treatment.

Noninfectious Pneumonias: Discontinue if interstitial, eosinophilic, or cryptogenic organizing pneumonia is diagnosed.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761406s000lbl.pdf

Yesintek ® (ustekinumab-kfce)

Clinical Information, continued

Special Populations:

- **Pregnancy**:
  - Limited human data; risk of fetal harm unknown.
  - Immunoglobulin G transfer increases in 3rd trimester—potential fetal exposure.
  - No adverse effects seen in animal studies at >100× maximum recommended human dose.
- **Lactation**:
  - Ustekinumab detected in breast milk; effects on infant and milk production unknown.
  - No reported adverse effects in breastfed infants.
  - Weigh benefits of breastfeeding vs. maternal need for therapy.
- **Pediatric Use**:
  - **Plaque Psoriasis**: Approved for ages 6–17; supported by clinical trials.
  - **Psoriatic Arthritis**: Approved for ages 6–17; extrapolated from adult data + pediatric pharmacokinetic/safety.
  - Not established for <6 years or for **Crohn's disease/ulcerative colitis** in pediatric patients.
- **Geriatric Use**:
  - Limited data in patients ≥65 years; no clear differences in response vs. younger adults.

Clinical Comparative Studies:

One double blind study comparing Yesintek to Stelara in moderate-to-severe plaque psoriasis

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761406s000lbl.pdf

Imuldosa® (ustekinumab-srlf)

Clinical Information

Indications:

Ustekinumab-srlf a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:
- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:
- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis

Dosage and Administration:

- **Adult Psoriasis** (≤100 kg): 45 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriasis** (>100 kg): 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriasis** (6–17 yrs):
  - 60–100 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriatic Arthritis**:
  - 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - If >100 kg with coexistent psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriatic Arthritis** (6–17 yrs):
  - ≥60 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg with psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Crohn's Disease & Ulcerative Colitis** (Adult):
  - Intravenous Induction: up to 55 kg: 260 mg | 55–85 kg: 390 mg | >85 kg: 520 mg
  - subcutaneously Maintenance: 90 mg every 8 weeks starting 8 weeks after IV dose

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761364s000lbl.pdf

Imuldosa® (ustekinumab-srlf)

Clinical Information, continued

Adverse Reactions:

- Psoriasis: nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- Crohn's Disease, induction: vomiting.
- Crohn's Disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis
- Ulcerative colitis, induction: nasopharyngitis
- Ulcerative colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea

Drug Interactions:

- No significant Cytochrome P450 interactions
- Avoid live vaccines
- Use caution when combining with other biologics or systemic immunosuppressants

Contraindications:

Clinically significant hypersensitivity to ustekinumab products or to any of the excipients in Imuldosa.

Warning and Precautions:

Infections: Do not initiate during active, clinically significant infections. Discontinue if serious infection develops.

Theoretical Infection risk: Consider risk for mycobacterial, salmonella, and Bacillus Calmette-Guérin-related infections in Interleukin-12/23-deficient patients; test as clinically indicated.

Tuberculosis: Screen for tuberculosis prior to initiation. Treat latent tuberculosis before starting therapy.

Malignancy Risk: Potential increased risk; safety in patients with current or prior malignancy is unknown.

Hypersensitivity: Discontinue immediately if anaphylaxis or other serious hypersensitivity occurs.

Posterior Reversible Encephalopathy Syndrome: Discontinue if Posterior Reversible Encephalopathy Syndrome is suspected.

Vaccinations: Avoid live vaccines during treatment.

Noninfectious Pneumonias: Discontinue if interstitial, eosinophilic, or cryptogenic organizing pneumonia is diagnosed.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761364s000lbl.pdf

Imuldosa® (ustekinumab-srlf)

Clinical Information, continued

Special Populations:

- **Pregnancy**:
  - Limited human data; risk of fetal harm unknown.
  - Immunoglobulin G transfer increases in 3rd trimester—potential fetal exposure.
  - No adverse effects seen in animal studies at >100× maximum recommended human dose.
- **Lactation**:
  - Ustekinumab detected in breast milk; effects on infant and milk production unknown.
  - No reported adverse effects in breastfed infants.
  - Weigh benefits of breastfeeding vs. maternal need for therapy.
- **Pediatric Use**:
  - **Plaque Psoriasis**: Approved for ages 6–17; supported by clinical trials.
  - **Psoriatic Arthritis**: Approved for ages 6–17; extrapolated from adult data + pediatric pharmacokinetic/safety.
  - Not established for <6 years or for **Crohn's disease/Ulcerative colitis** in pediatric patients.
- **Geriatric Use**:
  - Limited data in patients ≥65 years; no clear differences in response vs. younger adults.

Clinical Comparative Studies:

One double blind study comparing Imuldosa to Stelara in moderate-to-severe plaque psoriasis

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761364s000lbl.pdf

Otulfi ® (ustekinumab-aauz)

Clinical Information

Indications:

Ustekinumab-aauz is a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:
- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:
- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis

Dosage and Administration:

- **Adult Psoriasis** (≤100 kg): 45 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriasis** (>100 kg): 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriasis** (6–17 yrs):
  - 60–100 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriatic Arthritis**:
  - 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - If >100 kg with coexistent psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriatic Arthritis** (6–17 yrs):
  - ≥60 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg with psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Crohn's Disease & Ulcerative Colitis** (Adult):
  - Intravenous Induction: up to 55 kg: 260 mg | 55–85 kg: 390 mg | >85 kg: 520 mg
  - Subcutaneous Maintenance: 90 mg SC every 8 weeks starting 8 weeks after IV dose

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761379s001lbl.pdf

Otulfi ® (ustekinumab-aauz)

Clinical Information, continued

Adverse Reactions:

- Psoriasis: nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- Crohn's Disease, induction: vomiting.
- Crohn's Disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis
- Ulcerative colitis, induction: nasopharyngitis
- Ulcerative colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea

Drug Interactions:

- No significant Cytochrome P450 interactions
- Avoid live vaccines
- Use caution when combining with other biologics or systemic immunosuppressants

Contraindications:

Clinically significant hypersensitivity to ustekinumab products or to any of the excipients in Otulfi.

Warning and Precautions:

Infections: Do not initiate during active, clinically significant infections. Discontinue if serious infection develops.

Theoretical Infection risk: Consider risk for mycobacterial, salmonella, and Bacillus Calmette-Guérin-related infections in Interleukin-12/23-deficient patients; test as clinically indicated.

Tuberculosis: Screen for tuberculosis prior to initiation. Treat latent tuberculosis before starting therapy.

Malignancy Risk: Potential increased risk; safety in patients with current or prior malignancy is unknown.

Hypersensitivity: Discontinue immediately if anaphylaxis or other serious hypersensitivity occurs.

Posterior Reversible Encephalopathy Syndrome: Discontinue if Posterior Reversible Encephalopathy Syndrome is suspected.

Vaccinations: Avoid live vaccines during treatment.

Noninfectious Pneumonias: Discontinue if interstitial, eosinophilic, or cryptogenic organizing pneumonia is diagnosed.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761379s001lbl.pdf

Otulfi ® (ustekinumab-aauz)

Clinical Information, continued

Special Populations:

- **Pregnancy**:
  - Limited human data; risk of fetal harm unknown.
  - Immunoglobulin G transfer increases in 3rd trimester—potential fetal exposure.
  - No adverse effects seen in animal studies at >100× maximum recommended human dose.
- **Lactation**:
  - Ustekinumab detected in breast milk; effects on infant and milk production unknown.
  - No reported adverse effects in breastfed infants.
  - Weigh benefits of breastfeeding vs. maternal need for therapy.
- **Pediatric Use**:
  - **Plaque Psoriasis**: Approved for ages 6–17; supported by clinical trials.
  - **Psoriatic Arthritis**: Approved for ages 6–17; extrapolated from adult data + pediatric pharmacokinetic/safety.
  - Not established for <6 years or for **Crohn's disease/ulcerative colitis** in pediatric patients.
- **Geriatric Use**:
  - Limited data in patients ≥65 years; no clear differences in response vs. younger adults.

Clinical Comparative Studies:

One double blind study comparing Otulfi to Stelara in moderate-to-severe plaque psoriasis

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761379s001lbl.pdf

Pyzchiva ® (ustekinumab-ttwe)

Clinical Information

Indications:

Ustekinumab-ttwe is a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:
- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:
- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis

Dosage and Administration:

- **Adult Psoriasis** (≤100 kg): 45 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriasis** (>100 kg): 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriasis** (6–17 yrs):
  - 60–100 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriatic Arthritis**:
  - 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - If >100 kg with coexistent psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriatic Arthritis** (6–17 yrs):
  - ≥60 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg with psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Crohn's Disease & Ulcerative Colitis** (Adult):
  - Intravenous Induction: up to 55 kg: 260 mg | 55–85 kg: 390 mg | >85 kg: 520 mg
  - Subcutaneous Maintenance: 90 mg subcutaneously every 8 weeks starting 8 weeks after IV dose

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761373s000,761425s000lbl.pdf

Pyzchiva ® (ustekinumab-ttwe)

Clinical Information, continued

Adverse Reactions:

- Psoriasis: nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- Crohn's Disease, induction: vomiting.
- Crohn's Disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis
- Ulcerative colitis, induction: nasopharyngitis
- Ulcerative colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea

Drug Interactions:

- No significant Cytochrome P450 interactions
- Avoid live vaccines
- Use caution when combining with other biologics or systemic immunosuppressants

Contraindications:

Clinically significant hypersensitivity to ustekinumab products or to any of the excipients in Pyzchiva.

Warning and Precautions:

Infections: Do not initiate during active, clinically significant infections. Discontinue if serious infection develops.

Theoretical Infection risk: Consider risk for mycobacterial, salmonella, and Bacillus Calmette-Guérin-related infections in Interleukin-12/23-deficient patients; test as clinically indicated.

Tuberculosis: Screen for tuberculosis prior to initiation. Treat latent tuberculosis before starting therapy.

Malignancy Risk: Potential increased risk; safety in patients with current or prior malignancy is unknown.

Hypersensitivity: Discontinue immediately if anaphylaxis or other serious hypersensitivity occurs.

Posterior Reversible Encephalopathy Syndrome: Discontinue if Posterior Reversible Encephalopathy Syndrome is suspected.

Vaccinations: Avoid live vaccines during treatment.

Noninfectious Pneumonias: Discontinue if interstitial, eosinophilic, or cryptogenic organizing pneumonia is diagnosed.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761373s000,761425s000lbl.pdf

Pyzchiva ® (ustekinumab-ttwe)

Clinical Information, continued

Special Populations:

- **Pregnancy**:
  - Limited human data; risk of fetal harm unknown.
  - Immunoglobulin G transfer increases in 3rd trimester—potential fetal exposure.
  - No adverse effects seen in animal studies at >100× maximum recommended human dose.
- **Lactation**:
  - Ustekinumab detected in breast milk; effects on infant and milk production unknown.
  - No reported adverse effects in breastfed infants.
  - Weigh benefits of breastfeeding vs. maternal need for therapy.
- **Pediatric Use**:
  - **Plaque Psoriasis**: Approved for ages 6–17; supported by clinical trials.
  - **Psoriatic Arthritis**: Approved for ages 6–17; extrapolated from adult data + pediatric pharmacokinetic/safety.
  - Not established for <6 years or for **Crohn's disease/ulcerative colitis** in pediatric patients.
- **Geriatric Use**:
  - Limited data in patients ≥65 years; no clear differences in response vs. younger adults.

Clinical Comparative Studies:

One double blind study comparing Pyzchiva to Stelara in moderate-to-severe plaque psoriasis

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761373s000,761425s000lbl.pdf

Selarsdi® (ustekinumab-aekn)

Clinical Information

Indications:

Ustekinumab-aekn is a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:
- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:
- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis

Dosage and Administration:

- **Adult Psoriasis** (≤100 kg): 45 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriasis** (>100 kg): 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriasis** (6–17 yrs):
  - 60–100 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Adult Psoriatic Arthritis**:
  - 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - If >100 kg with coexistent psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Pediatric Psoriatic Arthritis** (6–17 yrs):
  - ≥60 kg: 45 mg subcutaneously at week 0 & 4, then every 12 weeks
  - >100 kg with psoriasis: 90 mg subcutaneously at week 0 & 4, then every 12 weeks
- **Crohn's Disease & Ulcerative Colitis** (Adult):
  - Intravenous Induction: up to 55 kg: 260 mg | 55–85 kg: 390 mg | >85 kg: 520 mg
  - Subcutaneous Maintenance: 90 mg subcutaneously every 8 weeks starting 8 weeks after IV dose

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761343s002lbl.pdf

Selarsdi® (ustekinumab-aekn)

Clinical Information, continued

Adverse Reactions:

- Psoriasis: nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- Crohn's Disease, induction: vomiting.
- Crohn's Disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis
- Ulcerative colitis, induction: nasopharyngitis
- Ulcerative colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea

Drug Interactions:

- No significant Cytochrome P450 interactions
- Avoid live vaccines
- Use caution when combining with other biologics or systemic immunosuppressants

Contraindications:

Clinically significant hypersensitivity to ustekinumab products or to any of the excipients in Selarsdi.

Warning and Precautions:

Infections: Do not initiate during active, clinically significant infections. Discontinue if serious infection develops.

Theoretical Infection risk: Consider risk for mycobacterial, salmonella, and Bacillus Calmette-Guérin-related infections in Interleukin-12/23-deficient patients; test as clinically indicated.

Tuberculosis: Screen for tuberculosis prior to initiation. Treat latent tuberculosis before starting therapy.

Malignancy Risk: Potential increased risk; safety in patients with current or prior malignancy is unknown.

Hypersensitivity: Discontinue immediately if anaphylaxis or other serious hypersensitivity occurs.

Posterior Reversible Encephalopathy Syndrome: Discontinue if Posterior Reversible Encephalopathy Syndrome is suspected.

Vaccinations: Avoid live vaccines during treatment.

Noninfectious Pneumonias: Discontinue if interstitial, eosinophilic, or cryptogenic organizing pneumonia is diagnosed.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761343s002lbl.pdf

Selarsdi® (ustekinumab-aekn)

Clinical Information, continued

Special Populations:

- **Pregnancy**:
  - Limited human data; risk of fetal harm unknown.
  - Immunoglobulin G transfer increases in 3rd trimester—potential fetal exposure.
  - No adverse effects seen in animal studies at >100× maximum recommended human dose.
- **Lactation**:
  - Ustekinumab detected in breast milk; effects on infant and milk production unknown.
  - No reported adverse effects in breastfed infants.
  - Weigh benefits of breastfeeding vs. maternal need for therapy.
- **Pediatric Use**:
  - **Plaque Psoriasis**: Approved for ages 6–17; supported by clinical trials.
  - **Psoriatic Arthritis**: Approved for ages 6–17; extrapolated from adult data + pediatric pharmacokinetic/safety.
  - Not established for <6 years or for **Crohn's disease/ulcerative colitis** in pediatric patients.
- **Geriatric Use**:
  - Limited data in patients ≥65 years; no clear differences in response vs. younger adults.

Clinical Comparative Studies:

One double blind study comparing Selarsdi to Stelara in moderate-to-severe plaque psoriasis

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761343s002lbl.pdf

Nemluvio® (nemolizumab-ilto)

Clinical Information

Indications:

Nemolizumab-ilto is an interleukin-31 receptor antagonist indicated for:

- **Moderate-to-severe atopic dermatitis** in patients **≥12 years**
  - Use in combination with topical corticosteroids and/or calcineurin inhibitors
  - For cases not adequately controlled by topical prescription therapies

Administration and Usage:

Initial Dose: 60 mg (two 30 mg injections)

Maintenance: 30 mg every 4 weeks

After 16 Weeks: If clear/almost clear skin → reduce to 30 mg every 8 weeks

Use with: Topical corticosteroids and/or calcineurin inhibitors

Discontinue topicals once disease sufficiently improves

Contraindications:

Known hypersensitivity to nemolizumab-ilto or to any of the excipients in Nemluvio.

Adverse Reactions:

Headache (including migraine), arthralgia, urticaria, and myalgia

Drug Interactions:

No clinically significant impact on Cytochrome P450 metabolism

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761391s000lbl.pdf

Nemluvio® (nemolizumab-ilto)

Clinical Information, continued

Specific Populations:

Pregnancy:
- Limited human data; fetal risk unknown
- May cross placenta, especially in 3rd trimester
- Animal studies showed increased early postnatal death at high doses (clinical relevance unclear)

Lactation:
- No human data; detected in animal milk
- Potential infant exposure unknown
- Consider breastfeeding benefits vs. maternal need

Pediatric Use:
- Approved for ages ≥12 with moderate-to-severe atopic dermatitis
- Supported by 2 placebo-controlled trials
- Not established in children <12 years

Geriatric Use:
- Limited data in patients ≥65 years
- No clear differences in safety or efficacy observed

Clinical Comparative Studies:

None

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761391s000lbl.pdf

Ebglyss® (lebrikizumab-lbkz)

Clinical Information

Indications:

Lebrikizumab-lbkz is a human interleukin-13 antagonist indicated for the treatment of:

Adult patients with:
- Moderate to severe atopic dermatitis
- Disease not adequately controlled with topical prescription therapies (or when those therapies are not advisable)

Pediatric patients >=12 years and >=40kg:
- Moderate to severe atopic dermatitis
- Disease not adequately controlled with topical prescription therapies (or when those therapies are not advisable)

Dosage and Administration:

- Initial dose: 500mg subcutaneously at weeks 0, 2;
  - Then 250mg subcutaneously every 2 weeks until week 16 or later, when adequate clinical response is achieved
- Maintenance dose: 250mg subcutaneously every 4 weeks

https://pi.lilly.com/us/ebglyss-uspi.pdf

Ebglyss® (lebrikizumab-lbkz)

Clinical Information, continued

Adverse Reactions (most common):
- Conjunctivitis, injection site reactions, and herpes zoster

Drug Interactions:
- The effect of lebrikizumab-lbkz on the pharmacokinetic of co-administered medications has not been studied

Contraindications:
Clinically significant hypersensitivity to lebrikizumab-lbkz or to any of the excipients in Ebglyss.

Warning and Precautions:

Hypersensitivity: Hypersensitivity reactions including angioedema and urticaria, have occurred after administration of lebrikizumab-lbkz. Discontinue lebrikizumab-lbkz in the event of a serious hypersensitivity reaction

Vaccinations: Avoid live vaccines during treatment.

Conjunctivitis and Keratitis: Report new onset or worsening eye symptoms to a healthcare provider.

Parasitic (Helminth) Infections: Treat patients with pre-existing helminth infections before initiating lebrikizumab-lbkz. If patients become infected while receiving lebrikizumab-lbkz and do not respond to antihelminth treatment, discontinue treatment with lebrikizumab-lbkz until the infection resolves.

Ebglyss® (lebrikizumab-lbkz)

Clinical Information, continued

Special Populations:

- **Pregnancy**:
  - Limited human data; risk of fetal harm unknown.
  - May cross placenta, especially in third trimester.
  - No adverse effects seen in animal studies.
- **Lactation**:
  - No human data; detected in animal milk
  - Infant exposure and risks unknown
  - Consider breastfeeding benefits vs. maternal need
- **Pediatric Use**:
  - Approved for >= 12 years and >= 40kg with moderate to severe atopic dermatitis
  - Not established for <12 or <40kg.
- **Geriatric Use**:
  - Limited data in patients ≥65 years; no clear differences in response vs. younger adults.

Clinical Comparative Studies:

None

Tyenne® (tocilizumab-aazg)

Clinical Information

Indications:

Tocilizumab-aazg is a human interleukin-6 antagonist indicated for the treatment of:

- Rheumatoid Arthritis (Adult)
- Giant Cell Arteritis (Adult)
- Polyarticular Juvenile Idiopathic Arthritis (>= 2 years)
- Systemic Juvenile Idiopathic Arthritis (>= 2 years)

Dosage and Administration:

Initiation Criteria: Avoid if absolute neutrophil count <2000/mm³, platelets <100,000/mm³, or Alanine aminotransferase/Aspartate Transferase >1.5× upper limits of normal

Max Intravenous Dose: Rheumatoid Arthritis ≤800 mg; Giant Cell Arteritis ≤600 mg

Rheumatoid Arthritis Dosing:

Intravenous: 4–8 mg/kg every 4 weeks

Subcutaneously: <100 kg – 162 mg every other week→ every week based on clinical response

≥100 kg – 162 mg every week

Giant Cell Arteritis Dosing:

Intravenous: 6 mg/kg every 4 weeks + glucocorticoids

subcutaneously: 162 mg every week or every other week + glucocorticoids

Polyarticular Juvenile Idiopathic Arthritis Dosing:

Intravenous every 4 weeks: <30 kg – 10 mg/kg; ≥30 kg – 8 mg/kg

subcutaneously: <30 kg – 162 mg every 3 weeks; ≥30 kg – 162 mg every other week

Systemic Juvenile Idiopathic Arthritis Dosing:

Intravenous every other week: <30 kg – 12 mg/kg; ≥30 kg – 8 mg/kg

subcutaneously: <30 kg – 162 mg every other week; ≥30 kg – 162 mg every week

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761275s000lbl.pdf

Tyenne® (tocilizumab-aazg)

Clinical Information, continued

Adverse Reactions (most common):
- Conjunctivitis, injection site reactions, and herpes zoster

Drug Interactions:
- **Rheumatoid Arthritis**: No impact on clearance with methotrexate, Non-steroidal anti-inflammatory drugs, or corticosteroids
- **Giant Cell Arteritis**: Corticosteroids do not affect tocilizumab exposure
- **Cytochrome P450 Effects**: Interleukin-6 inhibition may restore Cytochrome P450 activity → ↑ metabolism of Cytochrome P450 substrates ↓ exposure of Cytochrome 3A4 substrates (e.g., simvastatin ↓57%, omeprazole ↓28%)
- **Monitor & adjust** doses of narrow therapeutic index drugs (e.g., warfarin, cyclosporine, theophylline)
- **Use caution** with Cytochrome 3A4 substrates where reduced efficacy is critical (e.g., oral contraceptives, statins)
- Cytochrome P450 effects may persist **weeks after discontinuation**

Contraindications:
Clinically significant hypersensitivity to tocilizumab products.

Warning and Precautions:

Hypersensitivity: Hypersensitivity reactions including angioedema and urticaria, have occurred after administration of tocilizumab-aazg. Discontinue tocilizumab-aazg in the event of a serious hypersensitivity reaction

Vaccinations: Avoid live vaccines during treatment.

Serious Infections: do not administer tocilizumab-aazg during an active infection, including localized infections. If a serious infection develops, interrupt tocilizumab-aazg until the infection is controlled.

Gastrointestinal perforation: use with caution in patients who may be at increased risk.

Hepatotoxicity: monitor patients for signs and symptoms of hepatic injury. Modify or discontinue tocilizumab-aazg if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Laboratory monitoring: recommended due to potential consequences of treatment-related changes in neutrophils, platelets, lipids, and liver function tests.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761275s000lbl.pdf

Tyenne® (tocilizumab-aazg)

Clinical Information, continued

Special Populations:

- **Pregnancy**: Limited human data; may cross placenta in 3rd trimester. Animal studies show ↑ risk of fetal loss at high doses. Interleukin-6 inhibition may delay parturition.
- **Lactation**: Unknown if present in human milk; potential infant exposure unclear. Weigh benefits of breastfeeding vs. maternal need.
- **Pediatric Use**: Approved for Polyarticular Juvenile Idiopathic Arthritis & Systemic Juvenile Idiopathic Arthritis in patients ≥2 years (intravenous & subcutaneously). Not established for other conditions or <2 years. In <2 years Systemic Juvenile Idiopathic Arthritis study, hypersensitivity & immunogenicity observed.
- **Geriatric Use**: Higher rate of serious infections in patients ≥65 yrs; use caution.

Clinical Comparative Studies:

One study comparing Tyenne to Actemra

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761275s000lbl.pdf

Simlandi® (adalimumab-ryvk)

Clinical Information

Indications:

Adalimumab-ryvk is a human tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Rheumatoid Arthritis
- Psoriatic Arthritis
- Juvenile Idiopathic Arthritis (>= 2 years)
- Ankylosing Spondylitis
- Crohn's Disease
- Ulcerative Colitis
- Plaque Psoriasis
- Hidradenitis Suppurativa
- Uveitis

Black Boxed Warning:

Serious Infections: ↑ risk of tuberculosis, bacterial sepsis, invasive fungal infections, and opportunistic pathogens.

Malignancy: Lymphoma and other malignancies (some fatal) reported in pediatric patients. Rare cases of hepatosplenic T-cell lymphoma in adolescents/young adults with inflammatory bowel disease

Dosage and Administration:

- **Rheumatoid Arthritis , Psoriatic Arthritis , Ankylosing Spondylitis**: 40 mg subcutaneously every other week; may increase to 40 mg weekly or 80 mg every other week if not on methotrexate
- **Juvenile Idiopathic Arthritis (≥2 yrs, ≥30 kg)**: 40 mg subcutaneously every other week
- **Crohn's Disease & ulcerative colitis**:
  - Adults: 160 mg Day 1 → 80 mg Day 15 → 40 mg every other week from Day 29
  - Pediatrics (≥6 yrs, ≥40 kg): Same as adult dosing
- **Plaque Psoriasis / Uveitis**: 80 mg initial → 40 mg every other week starting 1 week later
- **Hidradenitis Suppurativa**:
  - Day 1: 160 mg → Day 15: 80 mg → Day 29+: 40 mg weekly or 80 mg every other week

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761299s000lbl.pdf

Simlandi® (adalimumab-ryvk)

Clinical Information, continued

Adverse Reactions (most common):
- Infections, injection site reactions, headache, and rash

Drug Interactions:
- Abatacept: Increased risk of serious infection.
- Anakinra: Increased risk of serious infection.
- Live vaccines: Avoid use with adalimumab-ryvk.

Contraindications:
None

Warning and Precautions:

Serious infections: Do not start adalimumab-ryvk during an active infection. If an infection develops, monitor carefully, and stop adalimumab-ryvk if infection becomes serious. (5.1)

Invasive fungal infections: For patients who develop a systemic illness on adalimumab-ryvk, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic.

Malignancies: Incidence of malignancies was greater in adalimumab treated patients than in controls.

Anaphylaxis or serious hypersensitivity reactions may occur.

Hepatitis B virus reactivation: Monitor Hepatitis B carriers during and several months after therapy. If reactivation occurs, stop adalimumab-ryvk and begin anti-viral therapy.

Demyelinating disease: Exacerbation or new onset, may occur.

Cytopenias, pancytopenia: Advise patients to seek immediate medical attention if symptoms develop, and consider stopping adalimumab-ryvk.

Heart failure: Worsening or new onset, may occur.

Lupus-like syndrome: Stop adalimumab-ryvk if syndrome develops.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761299s000lbl.pdf

Simlandi® (adalimumab-ryvk)

Clinical Information, continued

Special Populations:

- **Pregnancy**: No clear link to birth defects; crosses placenta in 3rd trimester. Registry data show similar defect rates vs. disease-matched controls. Animal studies show no fetal harm at high doses.
- **Lactation**: Present in breast milk at low levels; systemic exposure in infants expected to be minimal. No reported adverse effects.
- **Pediatric Use**: Approved for Juvenile Idiopathic Arthritis (≥2 yrs) and Crohn's disease (≥6 yrs). Not established for <2 yrs or <6 yrs respectively. Live vaccines in exposed infants require risk-benefit assessment.
- **Geriatric Use**: No difference in efficacy vs. younger adults. ↑ risk of serious infections and malignancy in patients ≥65 yrs; monitor closely.

Clinical Comparative Studies:

One study comparing Simlandi to Humira

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761299s000lbl.pdf

Immunomodulators, Systemic

New Formulations

- **Steqeyma, Otulfi, Selarsdi, Pyzchiva (Ustekinumab)** : New vial presentations (45 mg/0.5 mL) approved for pediatrics <60 kg; biosimilars to Stelara
- **Tyenne (tocilizumab-aazg)**: subcutaneous autoinjector & vial formats approved (162 mg/0.9 mL); intravenous formats also expanded
- **Spevigo (spesolimab-sbzo)**: New 300 mg/2 mL subcutaneous syringe added to existing options
- **Tremfya (guselkumab)**: 100 mg/mL autoinjector approved
- **Simlandi (adalimumab-ryvk)**: 80 mg/0.8 mL autoinjector added to existing prefilled syringe formats, biosimilar to Humira
- **Bimzelx (bimekizumab-bkzx)**: New 320 mg/2 mL autoinjector & prefilled syringe approved
- **Idacio (adalimumab-aacf)**: Expanded subcutaneous formats including starter kits and institutional vial
- **Rinvoq LQ (Upadacitinib)**: Pediatric oral solution (1 mg/mL) approved; weight-based dosing for Psoriatic Arthritis / Polyarticular Juvenile Idiopathic Arthritis
- **Zymfentra (infliximab-dyyb)**: First subcutaneous infliximab for ulcerative colitis/Crohn's disease maintenance; not biosimilar to Remicade

Immunomodulators, Systemic

New Indications

Actemra (tocilizumab): COVID-19 indication expanded to pediatrics ≥2 yrs; intravenous dosing based on weight
Otezla (apremilast): Psoriatic Arthritis indication expanded to pediatrics ≥6 yrs (≥20 kg); weight-based oral dosing
Dupixent (dupilumab): New approvals for bullous pemphigoid, chronic spontaneous urticaria (≥12 yrs), chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype, controlled chronic rhinosinusitis with nasal polyps (≥12 yrs); subcutaneous dosing varies by condition and weight
Nucala (mepolizumab): Approved for Chronic Obstructive Pulmonary Disease and an eosinophilic phenotype; 100 mg subcutaneously every 4 weeks
Rinvoq (Upadacitinib): Approved for Giant Cell Arteritis ; 15 mg daily with steroid taper
Tremfya (guselkumab): New approvals for Crohn's disease & ulcerative colitis; intravenous induction + subcutaneous maintenance; lowest effective dose recommended
Omvoh (mirikizumab-mrkz): Crohn's disease indication added; intravenous induction → subcutaneous maintenance
Nemluvio (nemolizumab-ilto): Atopic dermatitis indication expanded to ≥12 yrs; initial 60 mg → 30 mg every 4 weeks or every 8 weeks
Bimzelx (bimekizumab-bkzx): New approvals for hidradenitis suppurativa, Psoriatic Arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis; subcutaneous dosing varies by condition
Selarsdi (ustekinumab-aekn): Approved for Crohn's disease & ulcerative colitis; aligns with Stelara dosing
Cimzia (certolizumab pegol): Approved for Polyarticular Juvenile Idiopathic Arthritis in patients ≥2 yrs; weight-based subcutaneous dosing with healthcare provider-admin for <200 mg
Fasenra (benralizumab): Approved for eosinophilic granulomatosis with polyangiitis in adults; 30 mg subcutaneous every 4 weeks
Skyrizi (risankizumab-rzaa): Approved for ulcerative colitis in adults; intravenous induction → subcutaneous maintenance (180–360 mg every 8 weeks)
Kevzara (sarilumab): Approved for Polyarticular Juvenile Idiopathic Arthritis in patients ≥63 kg; 200 mg subcutaneous every other week; not approved for <63 kg

Immunomodulators, Systemic

Label Revisions

Cosentyx (secukinumab): Package Insert updated with new hypersensitivity warnings (e.g., angioedema, vasculitis), infection risks (Hepatitis B, tuberculosis), and storage instructions.
Humira & Biosimilars (Simlandi, Amjevita, Yuflyma, Abrilada, Hulio) (adalimumab): Multiple presentations approved as interchangeable; package insert updates include immunogenicity, unbranded labeling, and latex content.
Nemluvio (nemolizumab-ilto): Combined Biologic License Applications into one label; added drug-drug interaction study data.
Stelara/Otulfi (ustekinumab): Added pregnancy registry results; no Cytochrome P450 interactions in Crohn's disease.
Symponi (golimumab): Pregnancy data shows no increased risk.
Skyrizi (risankizumab-rzaa): New 180 mg/1.2 mL prefilled syringe with needlestick protection added for subcutaneous maintenance dosing in adult Crohn's disease and ulcerative colitis; package insert revised with updated administration and preparation instructions.
Taltz (ixekizumab): Infections section of Warnings and Precautions has been updated to include postmarket reports of serious bacterial, viral, and fungal opportunistic infections. New section of Warnings and Precautions has been added for eczematous eruptions.
Kineret (anakinra): package insert updated with addition of information that pertains to the risk of drug reaction with eosinophilia and systemic symptoms.
Actemra (tocilizumab): Added warnings for infections, drug reaction with eosinophilia and systemic symptoms, and change to use in pregnancy information with addition of information regarding disease-associated maternal risk (increased rheumatoid arthritis disease activity).
Xeljanz (tofacitinib): Pediatric use in Systemic Juvenile Idiopathic Arthritis and pregnancy registry info added.
Rinvoq (upadacitinib): Pyrexia added to ulcerative colitis adverse drug reactions.
Enbrel (etanercept) : Added glomerulonephritis; revised autoinjector instructions.
Tyenne (tocilizumab-aazg): Package insert aligned with Actemra; added Drug Reaction with Eosinophilia and Systemic Symptoms risk.

Immunomodulators, Systemic

Practice Guideline Updates

American College of Gastroenterology Guidelines: Eosinophilic Esophagitis Diagnosis & Management (Jan 2025)

Diagnosis:

- Symptoms of esophageal dysfunction **plus** ≥15 eosinophils/high-power field on biopsy.

Treatment Recommendations:

- **First-line:** Proton pump inhibitors
- **Topical steroids:** Swallowed fluticasone propionate or budesonide.
- **Dietary therapy:** Empiric food elimination diet.
  Note: Allergy testing to guide diet is **not recommended**.
- **Biologic Therapy:**
  - **Dupilumab:** Suggested for patients ≥12 years and pediatric patients unresponsive to PPIs.
  - **Omalizumab: Not recommended**.
- **Stricture Management:** Endoscopic dilation suggested for dysphagia due to esophageal stricture

https://journals.lww.com/ajg/pages/articleviewer.aspx?year=2025&issue=01000&article=00016&type=Fulltext

Immunomodulators, Systemic – Current Status

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic CC, ST		
Cosentyx® Dupixent® Enbrel® Fasenra® Humira® Nucala® Xolair®	Abrilada™ (adalimumab-AFZB) Actemra® subcutaneous adalimumab-AACF (gen Idacio®) adalimumab-AATY (gen Yuflyma®) adalimumab-ADAZ (gen Hyrimoz®) adalimumab-ADBM (gen Cyltezo®) adalimumab-FKJP (gen Hulio®) adalimumab-RYVK (gen Simlandi®) adalimumab-RYVK Adbry™ Amjevita™ Bimzelx® Cibinqo™ Cimzia® Cyltezo® (adalimumab-ADBM) Ebglyss™ Entyvio® SQ Hadlima™ Hulio® (adalimumab-FKJP) Hyrimoz® (adalimumab-ADAZ) Idacio® (adalimumab-AACF) Ilumya® Imuldosa® Kevzara® Kineret® Nemluvio® Olumiant® Omvoh™ SQ Orencia® SQ Otezla® Otulfi™ Pyzchiva®	**CLINICAL CRITERIA (CC)** • Confirm diagnosis for FDA- or compendia-supported uses **STEP THERAPY (ST)** For indications not specified below • Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a 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)

Immunomodulators, Systemic – Current Status

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IX. Immunologic Agents		
	Rinvoq™ ER Rinvoq® LQ Selarsdi™ Siliq™ Simlandi® (adalimumab-RYVK) Simponi® Skyrizi® Skyrizi® On-Body Sotyktu™ Spevigo® Stelara® Steqeyma® Taltz® Tezspire® pen Tremfya® Tyenne® ustekinumab (gen Stelara®) ustekinumab-AEKN Velsipity™ Xeljanz® Xeljanz® XR Yesintek™ Yuflyma® (adalimumab-AATY) Yusimry™ Zymfentra™	

Leukotriene Modifiers

NYRx Drug Utilization Review Board meeting
October 3rd, 2025

Prime THERAPEUTICS™

Drug to be added:

Zyflo®

Zyflo® (zileuton)

Clinical Information

Indication & Usage:

Zileuton is an orally active inhibitor of 5-lipoxygenase that is indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older.

Administration & Usage:

One 600mg tablet by mouth four times a day for a total daily dose of 2400mg.

Warnings & Precautions:

- Hepatotoxicity
- Neuropsychiatric events

Contraindications:

Zileuton is contraindicated in patients with:

- Active liver disease or transaminase elevations greater than or equal to three times the upper limit of normal
- Hypersensitivity to zileuton or any of its inactive ingredients

Adverse Reactions:

Sinusitis, nausea, and pharyngolaryngeal pain

Drug Interactions:

- Zileuton increases theophylline levels
- Zileuton increases warfarin levels
- Zileuton increases propranolol levels and beta blocker activity

https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020471s017lbl.pdf

Zyflo® (zileuton)

Clinical Information, continued

Specific Populations:

Pregnancy: No adequate human data available. Animal studies show risk of cleft palate, reduced fetal weight, and skeletal variations at high exposures

Lactation: Zileuton/metabolites found in rat milk; unknown if present in human milk

Pediatric Use: Not approved for children <12 years due to hepatotoxicity risk

Geriatric Use: Females ≥65 years may have increased risk of alanine aminotransferase elevations

Clinical Comparative Studies:

- One randomized controlled trial comparing zileuton with theophylline in moderate asthma

https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020471s017lbl.pdf

Leukotriene Modifiers – Current Status

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
XV. Respiratory		
Leukotriene Modifiers		
montelukast tablet, chew tab	Accolate® montelukast granules Singulair® zafirlukast zileuton ER Zyflo®	

Elevidys®
(delandistrogene moxeparvovec-rokl)

October 3, 2025
DURB Meeting

Purpose

- The aim of this review is to examine delandistrogene moxeparvovec-rokl (Elevidys®) and its potential utilization in the New York State Medicaid population
- Recommendations will be provided based on a review of the literature and results from utilization data analyses

Duchenne Muscular Dystrophy

- X-linked recessive orphan disease caused by mutations in the *dystrophin* (*DMD*) gene
  - Dystrophin protein is needed for maintenance of muscle fiber integrity and protection of skeletal and cardiac muscle cells
- Patients with Duchenne muscular dystrophy lack functional dystrophin protein
  - Leads to progressive muscle weakness, loss of ambulation, respiratory weakness, and cardiomyopathy
- Available therapies are not curative

Harrison's Principles of Internal Medicine, 21e. McGraw-Hill Education; 2022.
Mendell JR et al. *Front Cell Dev Biol*. 2023;11:1167762.
Cowen L, et al. *BMC Neurol*. 2019;19:84.

Approved Medications for Duchenne Muscular Dystrophy

Generic Name (Trade Name)	Indication	Approval Date	Manufacturer	Availability
Corticosteroids				
Deflazacort (Emflaza®)	Treatment of Duchenne muscular dystrophy in patients ≥ 2 years of age.	February 2017	PTC Therapeutics, Inc.	Oral tablets: 6 mg, 18 mg, 30 mg, 36 mg Oral suspension: 22.75 mg/mL (13 mL)
Vamorolone (Agamree®)	Treatment of Duchenne muscular dystrophy in patients ≥ 2 years of age.	October 2023	Catalyst Pharmaceuticals, Inc.	Oral suspension: 40 mg/mL (100 mL)
Exon-skipping therapies / antisense oligonucleotides				
Casimersen (Amondys® 45)	Treatment of Duchenne muscular dystrophy in patients with confirmed mutation in the *DMD* gene that is amenable to exon 45 skipping.	February 2021	Sarepta Therapeutics, Inc.	Injection solution in single-dose vial: 100 mg/2 mL
Eteplirsen (Exondys® 51)	Treatment of Duchenne muscular dystrophy in patients with confirmed mutation in the *DMD* gene that is amenable to exon 51 skipping.	September 2016	Sarepta Therapeutics, Inc.	Injection solution in single-dose vial: 100 mg/2 mL, 500 mg/10 mL
Golodirsen (Vyondys® 53)	Treatment of Duchenne muscular dystrophy in patients with confirmed mutation in the *DMD* gene that is amenable to exon 53 skipping.	December 2019	Sarepta Therapeutics, Inc.	Injection solution in single-dose vial: 100 mg/2 mL
Viltolarsen (Viltepso®)	Treatment of Duchenne muscular dystrophy in patients with confirmed mutation in the *DMD* gene that is amenable to exon 53 skipping.	August 2020	NS Pharma, Inc.	Injection solution in single-dose vial: 250 mg/5 mL
Histone deacetylase inhibitor				
Givinostat (Duvyzat®)	Treatment of Duchenne muscular dystrophy in patients ≥ 6 years of age.	March 2024	Italfarmaco SPA	Oral suspension: 8.86 mg/mL (140 mL)

Delandistrogene Moxeparvovec

- Adeno-associated virus vector-based therapy
  - Delivers micro-dystrophin to muscles involved in the pathology of Duchenne muscular dystrophy
- First gene therapy to be approved for the treatment of Duchenne muscular dystrophy

National Organization for Rare Diseases. https://rarediseases.org/rare-diseases/duchenne-muscular-dystrophy/
US Food and Drug Administration. Elevidys. BLA Clinical Review Memorandum. https://www.fda.gov/media/170231/download?attachment

Approval and Regulatory History

June 2023:
Elevidys® approved for treatment of ambulatory patients, 4 through 5 years of age, with Duchenne muscular dystrophy and a confirmed mutation in the *DMD* gene

June 2024:
Supplemental indication approved – includes ambulatory and non-ambulatory patients ≥ 4 years of age

June 2025:
Manufacturer advises against administration to non-ambulatory patients of any age based on 2 reports of death due to acute liver failure

July 18-21, 2025:
Food and Drug Administration requests that manufacturer suspend distribution and place hold on clinical trials following another report of death due to acute liver failure – manufacturer complies within 3 days

July 28, 2025:
Food and Drug Administration notifies manufacturer that shipment can be resumed for ambulatory patients with Duchenne muscular dystrophy

US Food and Drug Administration. Elevidys. Accelerated BLA Approval letter. https://www.fda.gov/media/170231/download?attachment
US Food and Drug Administration. Elevidys. Supplement Accelerated Approval letter. https://www.fda.gov/media/179484/download?attachment
Sarepta Therapeutics https://investorrelations.sarepta.com/news-releases/news-release-details/sarepta-provides-safety-update-elevidys-and-initiates-steps

Overview of Delandistrogene Moxeparvovec

Characteristics	Elevidys® (delandistrogene moxeparvovec-rokl)
Food and Drug Administration-approved indications	• Treatment of Duchenne muscular dystrophy in patients ≥ 4 years of age who are ambulatory and have a confirmed mutation in the *DMD* gene. • Treatment of Duchenne muscular dystrophy in patients ≥ 4 years of age who are **non-ambulatory** and have a confirmed mutation in the *DMD* gene. – **As of July 2025, the manufacturer advises against use of Elevidys® in non-ambulatory patients.** • Continued approval may be contingent on verification of clinical benefit in a confirmatory trial(s).
Compendia-supported uses	• No additional uses.
Manufacturer	• Sarepta Therapeutics, Inc.
Limitation(s) of use	• None reported by the manufacturer.
Dosing regimen	• Single-dose only. • Body weight-dependent dose: 10 to 70 kg: 1.33×10^{14} vector genomes per kg; ≥ 70 kg: 9.31×10^{15} vector genomes total. • Dose in mL: body weight in kg x 10.
Administration	• Administer by intravenous infusion through a peripheral venous catheter at a rate of < 10 mL/kg/hour. • Prior to administration: ○ Confirm anti-adeno-associated virus serotype rh74 total binding antibody titers < 1:400. ○ Confirm absence of infection. ○ Perform liver function tests, obtain platelet count and troponin-I levels. ○ Initiate a corticosteroid 1 day before administration of gene therapy; continue corticosteroid therapy for ≥ 60 days unless earlier tapering is indicated.
Availability and storage	• Customized kit containing ten to seventy 10 mL single-dose vials, each containing a suspension with concentration of 1.33×10^{13} vector genomes/mL. • Each kit is designed to meet the dosing requirement for each patient and is shipped frozen. • Once brought to room temperature, the product is stable for up to 24 hours.

Elevidys®. Prescribing information. Sarepta Therapeutics, Inc.; 2024.

Overview, Continued

Characteristics	Elevidys® (delandistrogene moxeparvovec-rokl)
Contraindications	• Any deletion in exon 8 and/or exon 9 in the *DMD* gene, due to increased risk for a severe, immune-mediated myositis reaction.
Warnings and precautions	• Infusion-related reactions – hypersensitivity reactions and anaphylaxis have occurred during administration and up to several hours following infusion. • Acute serious liver injury – elevations in liver enzymes and total bilirubin observed within 8 weeks in clinical studies. • Immune-mediated myositis – observed approximately 1 month following infusion in patients with deletion mutation in exon 8 and/or exon 9 in the *DMD* gene. • Myocarditis and elevations in troponin-I – observed following infusion. • Pre-existing anti-adeno-associated virus antibodies may interfere with transgene expression.
Adverse events	• Reactions occurring in ≥ 5% of patients receiving delandistrogene moxeparvovec: vomiting, nausea, liver injury, pyrexia, and thrombocytopenia.
Drug interactions	• Vaccinations should be completed ≥ 4 weeks before initiating the corticosteroid regimen.
Monitoring parameters	• Following infusion, assess: ○ Liver function, weekly for the first 3 months. ○ Platelet counts, weekly for the first 2 weeks. ○ Troponin-I levels, weekly for the first month. • Continue monitoring if clinically indicated.
Immunogenicity	• In clinical studies, following gene therapy, patients developed anti-adeno-associated virus serotype rh74 antibodies reaching at least 1:102,400. • Maximum titers observed were > 1:26,214,400 in certain patients. • An authorized test for detection of total binding antibodies is not available; available tests may vary in accuracy and design.
Wholesale acquisition cost	• $3,200,000 per kit.

Elevidys®. Prescribing information. Sarepta Therapeutics, Inc.; 2024.
Red Book. In: Merative Micromedex®. www.micromedexsolutions.com

Biologics License Application

- **September 2022**: Sarepta Therapeutics submitted data from 3 studies to the Food and Drug Administration
  - Study 101: phase 1/2a trial (open-label, single-arm)
  - Study 102: ongoing 3-part phase 2 trial (randomized, double-blind, crossover)
  - Study 103 (ENDEAVOR): ongoing 2-part phase 1b study with 4 cohorts
- Under Accelerated Approval, the manufacturer was permitted to investigate expression of Elevidys® micro-dystrophin as a surrogate endpoint and the North Star Ambulatory Assessment as a clinical outcome measure
  - Food and Drug Administration reviewers commented that **the only reliable ambulatory assessment data in this application were from part 1 of Study 102**

US Food and Drug Administration. Elevidys. BLA Clinical Review Memorandum. https://www.fda.gov/media/170231/download?attachment
Mendell JR et al. *Muscle Nerve*. 2024;69:93-98.
Mendell JR et al. *Front Cell Dev Biol*. 2023;11:1167762.
Zaidman CM et al. *Ann Neurol*. 2023;94:955-968.

Study Methods and Results

Study	Design	Population	Intervention / Exposure	Key Endpoints	Outcomes
101	Open-label, single-arm, phase 1/2a	n=4 ambulatory boys with Duchenne muscular dystrophy • Age 4-7 y	Gene therapy, 1.33×10^{14} vector genomes/kg	Primary: • Safety Secondary: • Change from baseline in micro-dystrophin at week 12 • Change from baseline in North Star Ambulatory Assessment total score	Primary: 72 adverse events reported, 25% were treatment-related. All were mild or moderate and resolved. Secondary: • Micro-dystrophin levels increased by 13.5% to 182.6% • Increases observed in total scores: mean at year 4 was +7.0 points
102	Double-blind, crossover, phase 2 • **Part 1: randomized, placebo-controlled, 48 weeks** • Part 2: crossover with blinding	**n=41 ambulatory boys with Duchenne muscular dystrophy** • **Age 4-7 y**	Gene therapy, 1.33×10^{14} vector genomes/kg (n=8), 12 subjects received a smaller dose than intended, placebo (n=21)	Primary: • **Change from baseline in micro-dystrophin at week 12** • **Change from baseline in North Star Ambulatory Assessment total score at week 48**	Primary: • Increases in mean micro-dystrophin levels observed; part 1: 23.82% (p< 0.0001); part 2: 39.64% (p< 0.0001) • **Total score, least-squares mean for treatment vs. placebo: +1.7 vs. +0.9, p=0.37** ○ **Age 4 to 5 years: +2.5 points (p=0.0172)** ○ Age 6 to 7 years: -0.7 points (p=0.5384)
103 ENDEAVOR	Open-label, single-arm, phase 1b	n=40 boys with Duchenne muscular dystrophy across 4 cohorts: • 1: ambulatory, age 4-7 y • 2: ambulatory, age 8-17 y • 3: non-ambulatory, any age • 4: ambulatory, age 3 y	Gene therapy, 1.33×10^{14} vector genomes/kg	Primary: • Change from baseline in micro-dystrophin at week 12	Primary: • Results only reported for cohort 1 • Increase observed: mean 54.2% (p< 0.0001)

Supplemental Biologics License Application

- **December 2023**: Sarepta Therapeutics submitted data from 2 studies to the Food and Drug Administration
  - Study 301 (EMBARK): phase 3 randomized, double-blind, placebo-controlled, crossover trial
  - Study 103 (ENDEAVOR): phase 1b study; data from a fifth cohort
- The primary endpoint of Study 301 was change from baseline to week 52 in the North Star Ambulatory Assessment total score; a difference was observed between treatment and placebo but was not statistically significant
  - **Reviewers at the Food and Drug Administration concluded that the study failed to verify the benefit of delandistrogene moxeparvovec**

US Food and Drug Administration. Integrated Clinical and Clinical Pharmacology Review Memo – Elevidys. https://www.fda.gov/media/179486/download?attachment
Zaidman CM et al. *Ann Neurol*. 2023;94:955-968.
Mendell JR et al. *Nat Med*. 2025;31:332-341.

Supplemental Biologics License Application, Continued

- **Multiple reviewers recommended a Complete Response**; however, the Director of the Center for Biologics Evaluation and Research asserted that the data were supportive of its clinical benefit and that the benefit-to-risk considerations were favorable
- **Ultimately, the manufacturer received approval but is required to complete a randomized controlled trial to verify and confirm the benefit of delandistrogene moxeparvovec in patients who are non-ambulatory**

US Food and Drug Administration. Integrated Clinical and Clinical Pharmacology Review Memo – Elevidys. https://www.fda.gov/media/179486/download?attachment
Zaidman CM et al. *Ann Neurol*. 2023;94:955-968.
Mendell JR et al. *Nat Med*. 2025;31:332-341.

Study Methods and Results

Study	Design	Population	Intervention / Exposure	Key Endpoints	Outcomes
301 EMBARK	Randomized, double-blind, placebo-controlled, phase 3 • **Part 1: randomized, placebo-controlled, 52 weeks** • Part 2: crossover with blinding • Part 3: open-label follow-up	**n=125 ambulatory boys with Duchenne muscular dystrophy** • **Age 4-7 years**	Gene therapy, 1.33 x 10^{14} vector genomes/kg (n=63) Placebo (n=62)	**Primary:** • **Change from baseline to week 52 in North Star Ambulatory Assessment total score** Secondary: • Change from baseline to week 52 in time to rise from floor • Change from baseline to week 52 in time to walk/run 10 meters	Results only reported for Part 1 **Primary:** • **Increases observed in total scores but difference between groups was not statistically significant** • Gene therapy: 2.57 • Placebo: 1.92 • Difference: 0.65 (-0.45 to 1.74) Secondary: • Significant reductions observed with gene therapy: difference -0.64 (-1.06 to -0.23) • Significant reductions observed with gene therapy: difference -0.42 (-0.71 to -0.13)
1 03 ENDEAVOR	Open-label, single-arm, phase 1b	n=48 boys with Duchenne muscular dystrophy across 5 cohorts: • 1: ambulatory, age 4-7 years • 2: ambulatory, age 8-17 years • 3: non-ambulatory, any age • 4: ambulatory, age 3 years • **5a: ambulatory, age 4 to <9 years (n=6)** • **5b: boys of any age, nonambulatory for ≥9 months (n=2)**	Gene therapy, 1.33 x 10^{14} vector genomes/kg	Primary: • Change from baseline in micro-dystrophin at week 12 • **Change from baseline in North Star Ambulatory Assessment total score**	Primary: • Increases observed in all cohorts; means not report ($p< 0.05$ for all) • Changes from baseline to Week 52 and Week 104 reported for cohorts 1, 2, and 4: ○ **Cohort 1 – improvement at Week 52 and Week 104** ○ **Cohort 2 – decline at Week 52 and further decline at Week 104** ○ **Cohort 4 – improvement at Week 52, insufficient data for Week 104**

American Academy of Neurology Review

- Focused review of delandistrogene moxeparvovec published in June 2025
- Purpose: to summarize the available evidence on the efficacy and safety of delandistrogene moxeparvovec for Duchenne muscular dystrophy
- Summary points:
  - Study data available on 134 boys, mostly ambulatory and ≥ 4 to < 8 years of age
  - Gene therapy has not been evaluated in patients with moderate-to-severe cardiomyopathy, severe pulmonary disease, or significant neurodevelopmental impairment
  - Efficacy compared to placebo is not well-established

Oskoui M et al. *Neurology.* 2025;104:e213604.

New York State Medicaid Coverage

- Coverage policy for antisense oligonucleotide (exon skipping drugs), effective April 1, 2022
  - Casimersen (Amondys® 45)
  - Eteplirsen (Exondys® 51)
  - Golodirsen (Vyondys® 53)
  - Viltolarsen (Viltepso®)

- New York State Medicaid will reimburse for a covered drug if all of the following criteria apply:
  - Diagnosis of Duchenne muscular dystrophy
  - Documentation of genetic testing that confirms the *DMD* gene mutation is amenable to exon 45, 51, or 53 skipping
  - Documentation confirming a stable dose of corticosteroids before initiating therapy or a reason not to be on corticosteroids
  - Documentation of renal function testing prior to initiation (except eteplirsen)
  - No concurrent use of another exon skipping therapy for Duchenne muscular dystrophy

New York State Department of Health. https://www.health.ny.gov/health_care/medicaid/program/update/2022/no01_2022-01.htm#guidance

Drug Utilization Data: Overview of Analyses

- A retrospective analysis of claims for Duchenne muscular dystrophy therapies was conducted
- **Data source**: Medicaid Data Warehouse
- **Sample**: members with pharmacy claims and claims with procedure codes indicating utilization of therapies for Duchenne muscular dystrophy
- **Analysis period**: April 1, 2021 – March 31, 2025
  - State Fiscal Year 2022: April 1, 2021 – March 31, 2022
  - State Fiscal Year 2023: April 1, 2022 – March 31, 2023
  - State Fiscal Year 2024: April 1, 2023 – March 31, 2024
  - State Fiscal Year 2025: April 1, 2024 – March 31, 2025

Drug Utilization Data: Disclaimers

- Medicaid Confidential Data Cell Size Policy (OHIP-0001)
  - Requires that no cell containing a value of 1 to 30 be reported; such values must be reported as ≤ 30 in all public-facing documents
- The following limitations should also be considered:
  - While time periods analyzed take into account inherent delays in claim/encounter submissions, data may not be fully complete
  - Per a memo issued September 23, 2022, by the MDW Customer Care Center, the MDW Encounters Intake System (EIS) is rejecting Pharmacy/National Council for Prescription Drug Programs (NCPDP)
    - Encounters for a subset of national drug codes (NDC) are missing from its reference data
    - Encounters containing NDCs added to the approved formulary since December 2021 are being rejected and this could potentially result in incorrect data analytics/reporting

Overall Utilization

Variable	State Fiscal Year				
	2022	2023	2024	2025	Total (2022 – 2025)
All included Duchenne muscular dystrophy therapies					
Members*	110	117	126	154	185
Claims	2,078	2,378	2,913	2,905	10,274
Estimated cost**	$31,034,744	$37,846,479	$48,629,781	$91,724,649	$209,235,652
Estimated cost per claim	$14,935	$15,915	$16,694	$31,575	$20,366
Delandistrogene moxeparvovec					
Members*	0	0	≤ 30	≤ 30	≤ 30
Claims	0	0	≤ 30	≤ 30	≤ 30
Estimated cost**	$0	$0	Unable to report	Unable to report	Unable to report

Data source: Medicaid Data Warehouse; April 1, 2021 – March 31, 2025
*Members not additive
**Estimated cost does not include rebates

Overall Utilization

- No utilization of gene therapy was observed in New York State Medicaid until State Fiscal Year 2024
  - Delandistrogene moxeparvovec was approved in June 2023
- In total, ≤ 30 members received delandistrogene moxeparvovec in State Fiscal Year 2024 or 2025

Data source: Medicaid Data Warehouse; April 1, 2021 – March 31, 2025

Utilization by Product in State Fiscal Year 2025

Product	Members*		Claims		Estimated Cost**	
	Number	Percentage	Number	Percentage	Number	Percentage
All included products	154	100%	2,905	100%	$91,724,649	100%
Corticosteroids	117	76.0%	1,323	45.5%	Unable to report	Unable to report
Exon skipping therapy	36	23.4%	1,548	53.3%	Unable to report	Unable to report
Histone deactylase inhibitor	≤ 30	Unable to report	≤ 30	Unable to report	Unable to report	Unable to report
Delandistrogene moxeparvovec	≤ 30	Unable to report	≤ 30	Unable to report	Unable to report	Unable to report

Corticosteroids (approved for treatment of Duchenne muscular dystrophy): deflazacort or vamorolone
Exon skipping therapy: casimersen, eteplirsen, golodirsen, viltolarsen
Histone deactylase inhibitor: givinostat

Data source: Medicaid Data Warehouse; April 1, 2024 – March 31, 2025
*Members not additive
**Estimated cost does not include rebates

Utilization by Product in State Fiscal Year 2025, Continued

- The most commonly utilized products among New York State Medicaid members were corticosteroids
- There were ≤ 30 members with claims for delandistrogene moxeparvovec
  - However, the cost of gene therapy accounted for nearly half of the estimated cost of Duchenne muscular dystrophy therapy overall that year

Data source: Medicaid Data Warehouse; April 1, 2024 – March 31, 2025

Medicaid Confidential Data Cell Size Policy

- Due to the limited number of utilizers, additional analyses pertaining to utilization of delandistrogene moxeparvovec cannot be presented at this time

Conclusions

- Duchenne muscular dystrophy is an X-linked recessive orphan disease caused by mutations in the *DMD* gene
- There are several treatment options, though none are curative
- The Food and Drug Administration approved delandistrogene moxeparvovec in June 2023 for the treatment of ambulatory pediatric patients, 4 to 5 years of age, with Duchenne muscular dystrophy and a confirmed mutation in the *DMD* gene
- In June 2024, the indication was expanded to include patients aged ≥ 4 years with a confirmed mutation in the *DMD* gene
- In June and July 2025, multiple safety announcements were issued following cases of death due to liver failure in patients who had received delandistrogene moxeparvovec and shipment was paused
- At this time, the manufacturer is continuing to distribute Elevidys® for ambulatory patients with Duchenne muscular dystrophy

Harrison's Principles of Internal Medicine, 21e. McGraw-Hill Education; 2022.
Mendell JR et al. *Front Cell Dev Biol*. 2023;11:1167762.
Cowen L, et al. *BMC Neurol*. 2019;19:84.

Conclusions, Continued

- In the Biologics License Application and Supplemental Biologics License Application, data from multiple studies were submitted
  - Only 2 studies were randomized controlled trials
    - Participants were ambulatory boys, age 4-7 years, with confirmed mutations in the *DMD* gene
    - Primary endpoints included change in micro-dystrophin levels from baseline to 12 weeks and change in North Star Ambulatory Assessment total scores from baseline to 48 or 52 weeks
    - Significant increases were observed in micro-dystrophin levels, but results were mixed for ambulatory scores
  - Multiple reviewers at the Food and Drug Administration recommended a Complete Response for the Supplemental Biologics License Application
    - Director of the Center for Biologics Evaluation and Research countered their recommendation

US Food and Drug Administration. Elevidys. BLA Clinical Review Memorandum. https://www.fda.gov/media/170231/download?attachment
US Food and Drug Administration. Integrated Clinical and Clinical Pharmacology Review Memo – Elevidys. https://www.fda.gov/media/179486/download?attachment

Conclusions, Continued

- A retrospective analysis of claims for Duchenne muscular dystrophy therapies was conducted using data from the Medicaid Data Warehouse, over State Fiscal Years 2022 through 2025
- Utilization of delandistrogene moxeparvovec was identified in State Fiscal Year 2024 and 2025
- In total, ≤ 30 members received the gene therapy

Data source: Medicaid Data Warehouse; April 1, 2024 – March 31, 2025

UB Recommendations

- Consider implementation of prior authorization for delandistrogene moxeparvovec (Elevidys®) with the following clinical criteria:
  - Male sex
  - Member age: 4-5 years
  - Confirmation of a diagnosis of Duchenne muscular dystrophy with documented mutation in *DMD* gene
  - Attestation of ambulatory status (patient should be ambulatory)
  - Assessment of ambulation with the North Star Ambulatory Assessment or 6-minute walk test

UB Recommendations, Continued

- Consider implementation of prior authorization for Elevidys® with the following clinical criteria:
  - Laboratory measurements of liver function, anti-adeno-associated virus serotype rh74 antibody titers, platelet count, and troponin-I levels prior to and following administration of gene therapy
  - Performance of echocardiogram to confirm absence of cardiomyopathy
  - Current use of a corticosteroid, or rationale for non-use
  - Completion of age-appropriate vaccinations as recommended in current immunization guidelines prior to administration of gene therapy
  - Attestation of awareness that continued Food and Drug Administration approval of delandistrogene moxeparvovec may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)

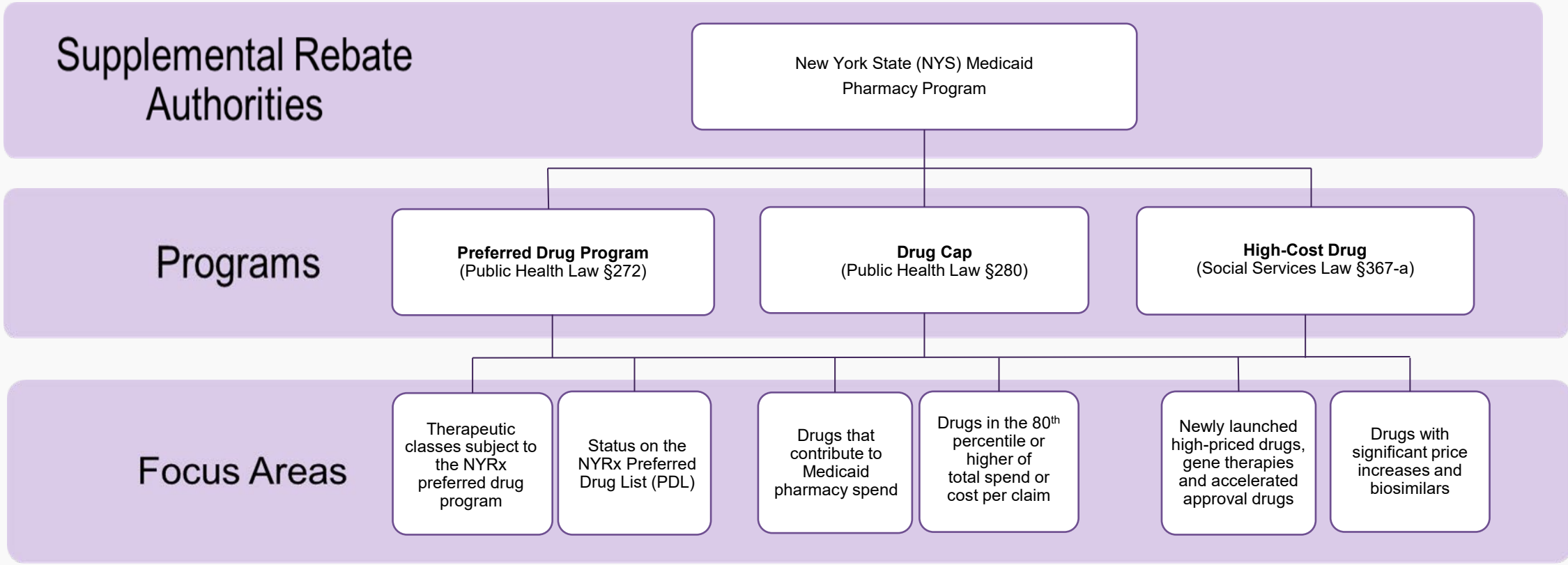
NEW YORK STATE | Department of Health

NYS Medicaid Supplemental Rebate Authorities

NYS MEDICAID DRUG UTILIZATION REVIEW BOARD

October 3, 2025

SUPPLEMENTAL REBATE PROGRAMS



NEW YORK STATE | Department of Health

DRUG CAP AND HIGH-COST DRUG COMPARISON

	Drug Cap	High-Cost Drug
Authorizing Statute	NYS Public Health Law §280	NYS Social Services Law §367-a
Applicable	All drug expenditures (reviewed at least annually)	Newly launched high-cost drugs (as of April 1, 2020)
Criteria for Identification of Drugs	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.	Meets one of the following conditions: • Brand name drug/biologic with launch wholesale acquisition cost (WAC) >$30,000/year or course of treatment. • Biosimilar drug with launch WAC that is not at least 15% lower than the referenced brand biologic at time of launch. • Generic drug with WAC >$100 for a 30-day supply or recommended dosage approved for labeling by FDA. • Brand name drug/biologic with a WAC increase of >$3,000 in any 12-month period, or course of treatment <12 months.
Overview of Process	Step 1: Voluntary Supplemental Rebate Step 2: Request for Confidential Financial Information Step 3: DUR Board Referral	

NEW YORK STATE | Department of Health

The supplemental rebate authorities under Social Services Law 367-a also include gene therapies, accelerated approved drugs, and antiretrovirals for HIV/AIDS

DRUG CAP AND THE HIGH-COST DRUG DUR BOARD REVIEWS

Year	Drug	Manufacturer	Supplemental Rebate Authority
2018	Orkambi	Vertex	Drug Cap
2019	Remicade	Janssen	Drug Cap
2020	Spinraza	Biogen	Drug Cap
2025	Elevidys	Sarepta	High-Cost Drug

NEW YORK STATE | Department of Health

Dipeptidyl Peptidase-4 Inhibitors and Glucagon-like Peptide-1 Receptor Agonists

October 3, 2025
Drug Utilization Review Board Meeting

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

Purpose

- The aim of this review is to examine the concurrent use of dipeptidyl peptidase-4 inhibitors and glucagon-like peptide-1 receptor agonists
- Recommendations will be provided based on a review of the literature and results from utilization data analyses

Approved Uses

- **Dipeptidyl peptidase-4 inhibitors AND glucagon-like peptide-1 receptor agonists**
  - Improvement of glycemic control in patients with type 2 diabetes mellitus

- Additional uses for **selected glucagon-like peptide-1 receptor agonists**:
  - Reduction in the risk of major adverse cardiovascular events in patients with type 2 diabetes mellitus and established cardiovascular disease
    - Trulicity® (dulaglutide), Victoza® (liraglutide), Ozempic® (semaglutide)
  - Reduction in the risk of major adverse cardiovascular events in patients with established cardiovascular disease and overweight or obese
    - Wegovy® (semaglutide)
  - Reduction in the risk of kidney disease progression and cardiovascular death in patients with type 2 diabetes mellitus and chronic kidney disease
    - Ozempic® (semaglutide)
  - Chronic weight management in patients who are obese or overweight with ≥ 1 weight-related comorbidity
    - Saxenda® (liraglutide), Wegovy® (semaglutide), Zepbound® (tirzepatide)
  - Treatment of moderate to severe obstructive sleep apnea in patients with obesity
    - Zepbound® (tirzepatide)

See end of presentation for product labeling references

Dipeptidyl Peptidase-4 Inhibitors

Generic Drug Name (Trade Name)	Manufacturer	Available Dosage Forms
Alogliptin (Nesina®)	Takeda Pharmaceuticals	Oral tablet: 6.25, 12.5, 25 mg
• Alogliptin/metformin (Kazano®)		Oral tablet: 12.5 mg/500 mg metformin
• Alogliptin/pioglitazone (Oseni®)		Oral tablet: 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg, 12.5 mg/30 mg
Linagliptin (Tradjenta®)	Boehringer Ingelheim Pharmaceuticals	Oral tablet: 5 mg
• Linagliptin/empagliflozin (Glyxambi®)		Oral tablet: 5 mg/10 mg, 5 mg/25 mg
• Linagliptin/empagliflozin/metformin (Trijardy® XR)		Oral tablet: 2.5 mg/5 mg/1000 mg, 2.5. mg/12.5 mg/1000 mg, 5 mg/10 mg/1000 mg, 5 mg/25 mg/1000 mg
• Linagliptin/metformin (Jentadueto®, Jentadueto® XR)		Oral tablet, IR and XR: 2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg
Saxagliptin (Onglyza®)	AstraZeneca Pharmaceuticals	Oral tablet: 2.5, 5 mg
• Saxagliptin/dapagliflozin (Qtern®)		Oral tablet: 5 mg/5 mg, 5 mg/10 mg
• Saxagliptin/metformin (Kombiglyze® XR)		Oral tablet: 5 mg/500 mg, 5 mg/1000 mg, 2.5 mg/1000 mg
Sitagliptin (Januvia®, Zituvio®)	Merck Sharp & Dohme (Januvia®); Zydus Pharmaceuticals (Zituvio®)	Oral tablet: 25, 50, 100 mg
• Sitagliptin/ertugliflozin (Steglujan®)	Merck Sharp & Dohme	Oral tablet: 100 mg/5 mg, 100 mg/15 mg
• Sitagliptin/metformin (Janumet®, Janumet® XR, Zituvimet®, Zituvimet® XR)	Merck Sharp & Dohme (Janumet®, Janumet® XR); Zydus Pharmaceuticals (Zituvimet®, Zituvimet® XR)	Oral tablet, IR: 50 mg/500 mg, 50 mg/1000 mg; XR: 50 mg/500 mg, 50 mg/1000 mg, 100 mg/1000 mg

Glucagon-like Peptide-1 Receptor Agonists

Generic Drug Name (Trade Name)	Manufacturer	Available Dosage Forms
Dulaglutide (Trulicity®)	Eli Lilly	Injection solution in single-dose pen: 0.75, 1.5, 3, 4.5 mg per dose
Exenatide (Byetta®)	AstraZeneca Pharmaceuticals	Injection solution in multi-dose pen: 5, 10 mcg per dose
Liraglutide (Victoza®, Saxenda®)	Novo Nordisk	Injection solution in multi-dose pen: • Victoza®: 0.6, 1.2, 1.8 mg per dose • Saxenda®: 0.6, 1.2, 1.8, 2.4, 3 mg per dose
• Liraglutide/insulin degludec (Xultophy® 100/3.6)		Injection solution in multi-dose pen: 3.6 mg/mL, 100 units/mL
Lixisenatide/insulin glargine (Soliqua® 100/33)	Sanofi-Aventis	Injection solution in multi-dose pen: 33 mcg/mL, 100 units/mL
Semaglutide (Ozempic®, Rybelsus®, Wegovy®)	Novo Nordisk	(Ozempic®) Injection solution in multi-dose pen: 0.25, 0.5, 1, 2 mg per dose (Wegovy®) Injection solution in single-dose pen: 0.25, 0.5, 1, 1.7, 2.4 mg (Rybelsus®) Oral tablets: 3, 7, 14 mg
Tirzepatide (Mounjaro®, Zepbound®)	Eli Lilly	Injection solution in single-dose pen and single-dose vial: 2.5, 5, 7.5, 10, 12.5, 15 mg per dose

Clinical Pharmacology

Dipeptidyl peptidase-4 inhibitors

- Dipeptidyl peptidase:
  - Enzyme located on capillary endothelial cells
  - Metabolizes the incretins glucagon-like peptide-1 and glucose-dependent insulinotropic polypeptide
- Inhibitors → increased plasma concentrations of incretins, prolonging action

Glucagon-like peptide-1 receptor agonists

- Glucagon-like peptide-1:
  - Incretin that stimulates release of insulin in response to glucose levels
  - Suppresses secretion of glucagon
  - Delays gastric emptying
  - Reduces feelings of hunger
- Receptor agonists → mimic the effect of incretins

Katzung's Basic and Clinical Pharmacology. 16th ed. McGraw-Hill; 2024.
Goodman and Gilman's: The Pharmacological Basis of Therapeutics. 14th ed. McGraw-Hill Education; 2023.

Guidelines

American Diabetes Association, Standards of Care in Diabetes - 2025

Recommend against concurrent use of a dipeptidyl peptidase-4 inhibitor and a glucagon-like peptide-1 receptor agonist

- Lack of additional glucose lowering

American Association of Clinical Endocrinology, Comprehensive Type 2 Diabetes Management Algorithm - 2023

Diabetes Care. 2025;48(Suppl 1): S181-S206.
Endocr Pract. 2023;29(9):746.

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Guidelines, Continued

- American Diabetes Association (2025) and American Association of Clinical Endocrinologists (2023)
  - Combination therapy may be necessary for glycemic control
    - Consider addition of a glucagon-like peptide-1 receptor agonist or dual glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 agonist to metformin
    - If more intensive control needed, initiate basal insulin
- American College of Physicians (2024)
  - Recommends against use of dipeptidyl peptidase-4 inhibitors as additive drugs for adults with type 2 diabetes and inadequate glycemic control

Diabetes Care. 2025;48(Suppl 1): S181-S206.
Endocr Pract. 2023;29(9):746.
Ann Intern Med. 2024;177(5):658-666.

New York State Medicaid Coverage

Preferred Drugs	Non-preferred Drugs	Coverage Parameters
Dipeptidyl Peptidase-4 Inhibitors		
Alogliptin Alogliptin/metformin Glyxambi® (empagliflozin/linagliptin) Janumet® (sitagliptin/metformin) Janumet® XR Januvia® (sitagliptin)* Jentadueto® (linagliptin/metformin) Jentadueto® XR Kazano® (alogliptin/metformin) Nesina® (alogliptin) Tradjenta® (linagliptin)	Alogliptin/pioglitazone Qtern® (dapagliflozin/saxagliptin) Saxagliptin Saxagliptin/metformin Sitagliptin Sitagliptin/metformin Steglujan® (ertugliflozin/sitagliptin) Zituvimet (sitagliptin/metformin) Zituvimet XR Zituvio™ (sitagliptin)	*Dose optimization, applicable to Januvia®
Glucagon-like Peptide-1 Receptor Agonists		
Exenatide Ozempic® (semaglutide) Trulicity® (dulaglutide) Victoza® (liraglutide)	Bydureon® BCise™ (exenatide) Byetta® Liraglutide Mounjaro® (tirzepatide) Rybelsus® (semaglutide) Soliqua® (insulin glargine/lixisenatide) Xultophy® (liraglutide/insulin degludec)	Clinical criteria: confirm diagnosis of FDA-approved, compendia-supported, and Medicaid covered indication

Prime Therapeutics. https://newyork.fhsc.com/downloads/providers/nyrx_pdp_pdl.pdf

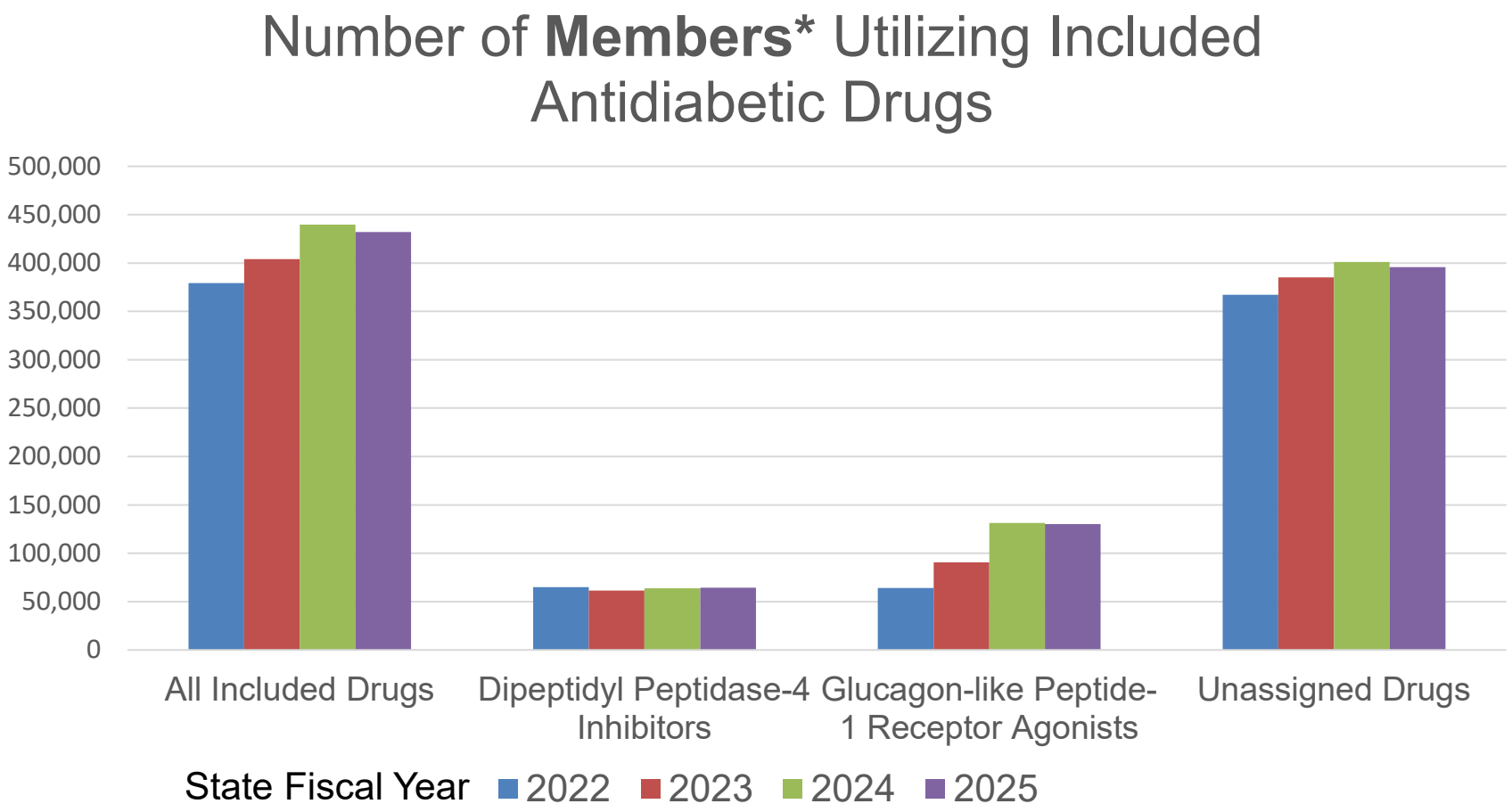
Drug Utilization Data: Overview of Analyses

- A retrospective analysis of claims was conducted
- **Data source**: Medicaid Data Warehouse
- **Sample**: members with pharmacy claims for antidiabetic drugs
  - Hierarchical Ingredient Codes Level 3 used to identify the drugs
  - Products classified as “dipeptidyl peptidase-4 inhibitors”, “glucagon-like peptide-1 receptor agonists”, or “unassigned”
    - “Unassigned”: sodium-glucose cotransporter type 2 inhibitors, amylin analogs, biguanides, alpha-glucosidase inhibitors, thiazolidinediones, insulin secretagogues, and insulins
- **Analysis period**: April 1, 2021 – March 31, 2025
  - State Fiscal Year 2022: April 1, 2021 – March 31, 2022
  - State Fiscal Year 2023: April 1, 2022 – March 31, 2023
  - State Fiscal Year 2024: April 1, 2023 – March 31, 2024
  - State Fiscal Year 2025: April 1, 2024 – March 31, 2025

Drug Utilization Data: Disclaimers

- Medicaid Confidential Data Cell Size Policy (OHIP-0001)
  - Requires that no cell containing a value of 1 to 30 be reported; such values must be reported as ≤30 in all public-facing documents
- The following 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



*Members not additive

Data source: Medicaid Data Warehouse; April 1, 2021 – March 31, 2025

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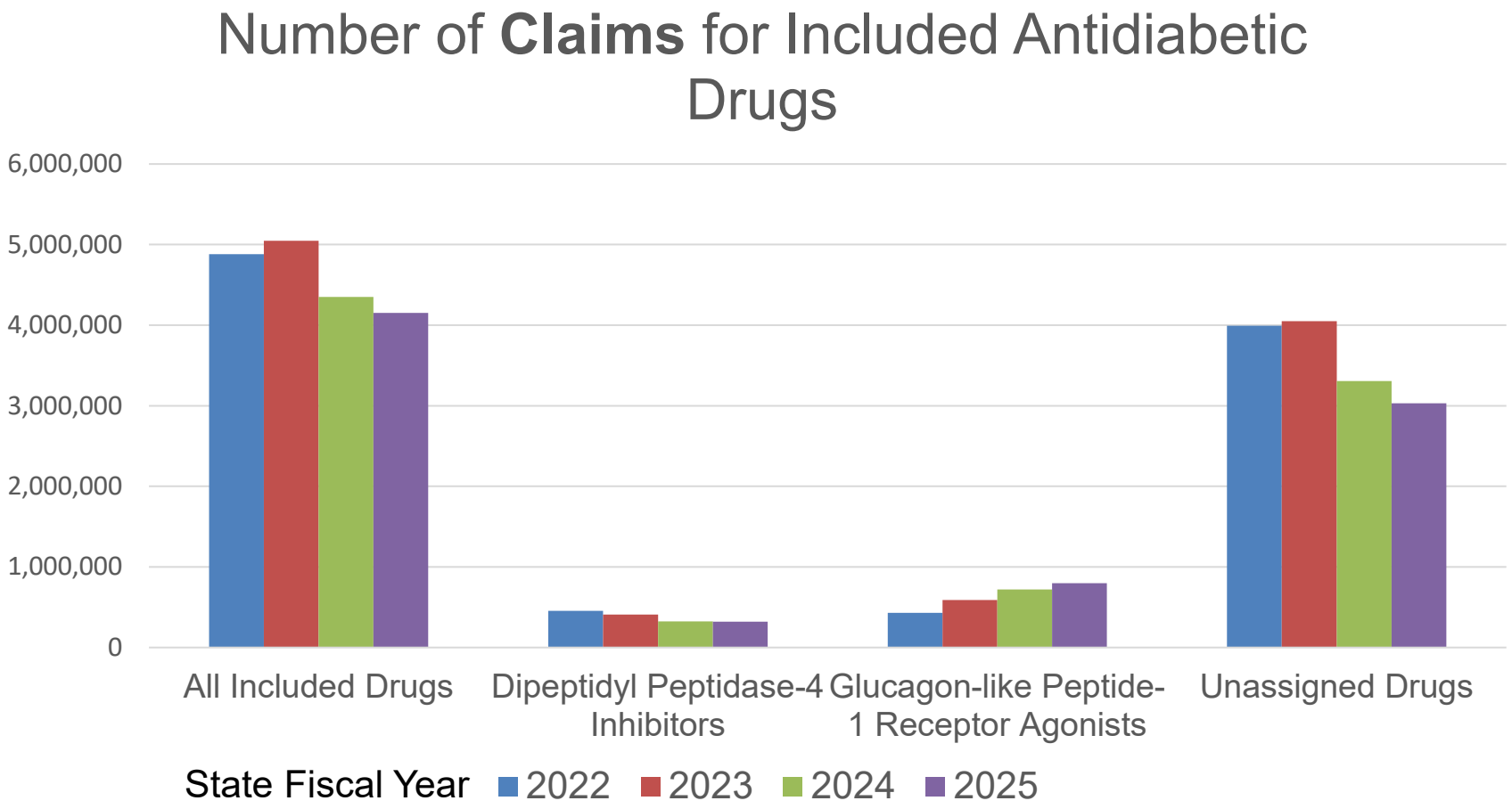
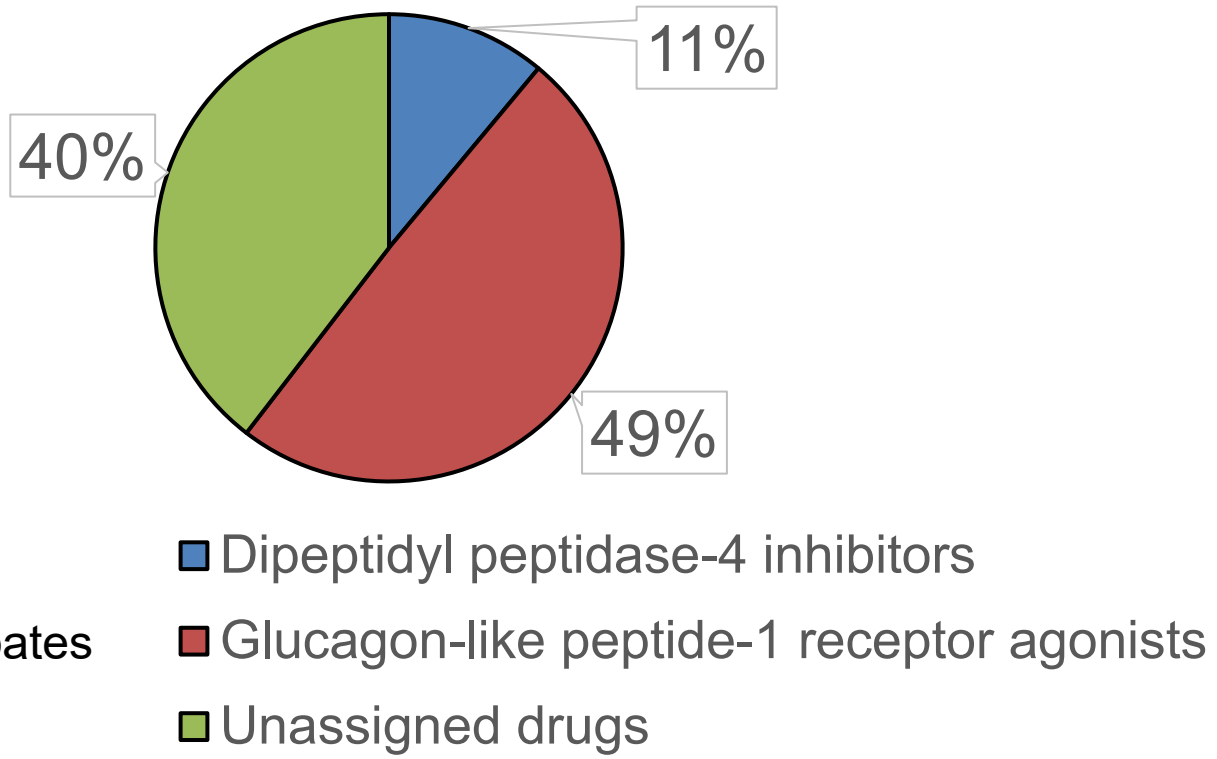
Overall Utilization, Continued



Data source: Medicaid Data Warehouse; April 1, 2021 – March 31, 2025

State Fiscal Year 2025

Estimated Costs of Claims*



*Does not include rebates

Data source: Medicaid Data Warehouse; April 1, 2024 – March 31, 2025

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Age and Gender Distribution of Members* Utilizing Included Drugs in State Fiscal Year 2025

Age or Gender	All Drugs		Dipeptidyl Peptidase-4 Inhibitors		Glucagon-like Peptide-1 Receptor Agonists		Unassigned Drugs	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Age Distribution								
All ages	432,163	100%	64,466	100%	130,257	100%	395,779	100%
<18	10,477	2%	≤30	0%	846	1%	10,298	3%
18-34	50,734	12%	1,603	2%	13,387	10%	45,661	12%
35-44	57,045	13%	4,729	7%	20,979	16%	50,064	13%
45-54	91,380	21%	12,395	19%	34,389	26%	82,330	21%
≥55	222,476	51%	45,725	71%	60,656	47%	207,375	52%
Gender Distribution								
Female	245,391	57%	33,968	53%	79,303	61%	220,765	56%
Male	186,759	43%	30,498	47%	50,954	39%	175,001	44%
Other	≤30	0%	0	0%	0	0%	≤30	0%

*Members not additive across drug groupings

Data source: Medicaid Data Warehouse; April 1, 2024 – March 31, 2025

Concurrent Utilization of Dipeptidyl Peptidase-4 Inhibitors and Glucagon-like Peptide-1 Receptor Agonists in State Fiscal Year 2025

Duration of Overlap (Days)	Members*	Estimated Costs		
		Total	Dipeptidyl Peptidase-4 Inhibitors	Glucagon-like Peptide-1 Receptor Agonists
Any (≥1 days)	12,410	$70,131,570	$21,788,319	$48,343,252
1-60	8,890	$18,492,834	$5,790,686	$12,702,148
61-90	3,080	$12,129,743	$3,741,384	$8,388,359
91-120	1,382	$7,227,991	$2,274,893	$4,953,098
121-180	1,629	$11,572,676	$3,628,831	$7,943,845
>180	1,658	$20,708,327	$6,352,526	$14,355,801
1-90	10,549	$30,622,577	$9,532,069	$21,090,508
>90	4,202	$39,508,993	$12,256,249	$27,252,744

*Members not additive across drug groupings or durations of overlap
Data source: Medicaid Data Warehouse; April 1, 2024 – March 31, 2025

Conclusions

- Dipeptidyl peptidase-4 inhibitors and glucagon-like peptide-1 receptor agonists are approved for improvement of glycemic control in patients with type 2 diabetes mellitus
  - Selected glucagon-like peptide-1 receptor agonists have additional uses
- There are several commercially available products
- There are multiple clinical practice guidelines with recommendations on the management of type 2 diabetes mellitus
  - Two organizations recommend against the use of a dipeptidyl peptidase-4 inhibitor and a glucagon-like peptide-1 receptor agonist together due to lack of additional glucose lowering beyond that of glucagon-like peptide-1 receptor agonists alone

Diabetes Care. 2025;48(Suppl 1): S181-S206.
Endocr Pract. 2023;29(9):746.

Conclusions, Continued

- A retrospective analysis of claims for antidiabetic drugs, including dipeptidyl peptidase-4 inhibitors and glucagon-like peptide-1 receptor agonists, was conducted using data from the MDW, for the period of SFY 2022 through SFY 2025
- Overall, there were 295,614 members with 4,049,030 claims for a dipeptidyl peptidase-4 inhibitor or glucagon-like peptide-1 receptor agonist
- In State Fiscal Year 2025:
  - 51% of members were ≥ 55 years of age
  - 57% of member were female
  - 12,410 members had any overlapping use of a dipeptidyl peptidase-4 inhibitor and a glucagon-like peptide-1 receptor agonist, with estimated cost of > $70 M
  - 4,202 members had concurrent claims > 90 days, with an associated cost of > $39.5 M
    - Cost associated with dipeptidyl peptidase-4 inhibitors: $12 M

Data source: Medicaid Data Warehouse; April 1, 2021 – March 31, 2025

UB Recommendation

- Based on the available literature and utilization data, the following is recommended:
  - Prior authorization be required for patients utilizing a dipeptidyl peptidase-4 inhibitor and a glucagon-like peptide-1 receptor agonist concurrently for more than 90 days

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Nonsteroidal Anti-Inflammatory Drugs Evaluation

October 3, 2025

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

Objectives

1. Review the historical nonsteroidal anti-inflammatory drug (NSAID) utilization trends between State Fiscal Year 2022 and State Fiscal Year 2025.

2. Evaluate the utilization trends of non-preferred NSAIDs for State Fiscal Year 2025.

3. Identify members utilizing ≥ 2 NSAIDs overlapping for a cumulative ≥ 30 days in 180 days and 365 days.

NYRx Preferred Drug Program
NSAIDs

Preferred	Non-Preferred	
Celebrex® celecoxib diclofenac 1% topical gel diclofenac sodium oral ibuprofen Rx tablet, suspension ibuprofen OTC suspension indomethacin capsule ketorolac meloxicam tablet nabumetone naproxen tablet piroxicam sulindac	Arthrotec® Daypro® diclofenac epolamine patch diclofenac capsule diclofenac/misoprostol diclofenac potassium diclofenac potassium (generic Cambia®) diclofenac sodium ER diclofenac topical solution diflunisal Dolobid Elyxyb™ F/Q/D etodolac etodolac ER Feldene® Fenoprofen Fenopron™ flurbiprofen ibuprofen/famotidine (generic Duexis®)	indomethacin ER indomethacin suspension ketoprofen ketoprofen ER ketorolac nasal spray (generic Sprix®) Kiprofen™ meclofenamate mefenamic acid meloxicam capsule (generic Vivlodex®) Nalfon® Naprelan® naproxen susp naproxen CR naproxen EC naproxen-esomeprazole naproxen sodium oxaprozin Relafen® DS tolmetin Vimovo®

Clinical criteria: Elyxyb™ (celecoxib) – 4.8 mL bottle (120 mg) maximum quantity: 9 bottles / 30 days

NYRx Preferred Drug Program. Revised August 21, 2025. Available at NYRx, the Medicaid Pharmacy Program | Preferred Drug Program. Accessed September 2025.

NSAIDs

- Food and Drug Administration (FDA)- approved for use as:
  - Antipyretics,
  - Anti-inflammatory, and
  - Analgesic agents.

- Used to treat conditions such as:
  - Acute Pain,
  - Chronic Pain,
  - Muscle Pain,
  - Osteoarthritis (OA),
  - Rheumatoid Arthritis (RA),
  - Ankylosing Spondylitis (AS),
  - Gout,
  - Dysmenorrhea, and
  - Migraines.

United States Food and Drug Administration. Drugs@FDA. Food and Drug Administration Approved Drug Products. Available at https://www.accessdata.fda.gov/. Accessed July 2025.

Product Information

- Both oral and topical NSAIDs have boxed warnings regarding:
  - The increased risk of cardiovascular thrombotic events, including myocardial infarction and stroke;
  - Contraindication in the setting of coronary artery bypass graft surgery; and
  - The increased risk of gastrointestinal bleeding, ulceration, and perforation, especially in elderly patients and patients with a history of peptic ulcer disease and/or a gastrointestinal bleed.

- For topical and oral NSAIDs, the concomitant use of ≥2 NSAIDs or NSAIDs with salicylates increases the risk of gastrointestinal toxicity with a minimal increase in efficacy and is not recommended.

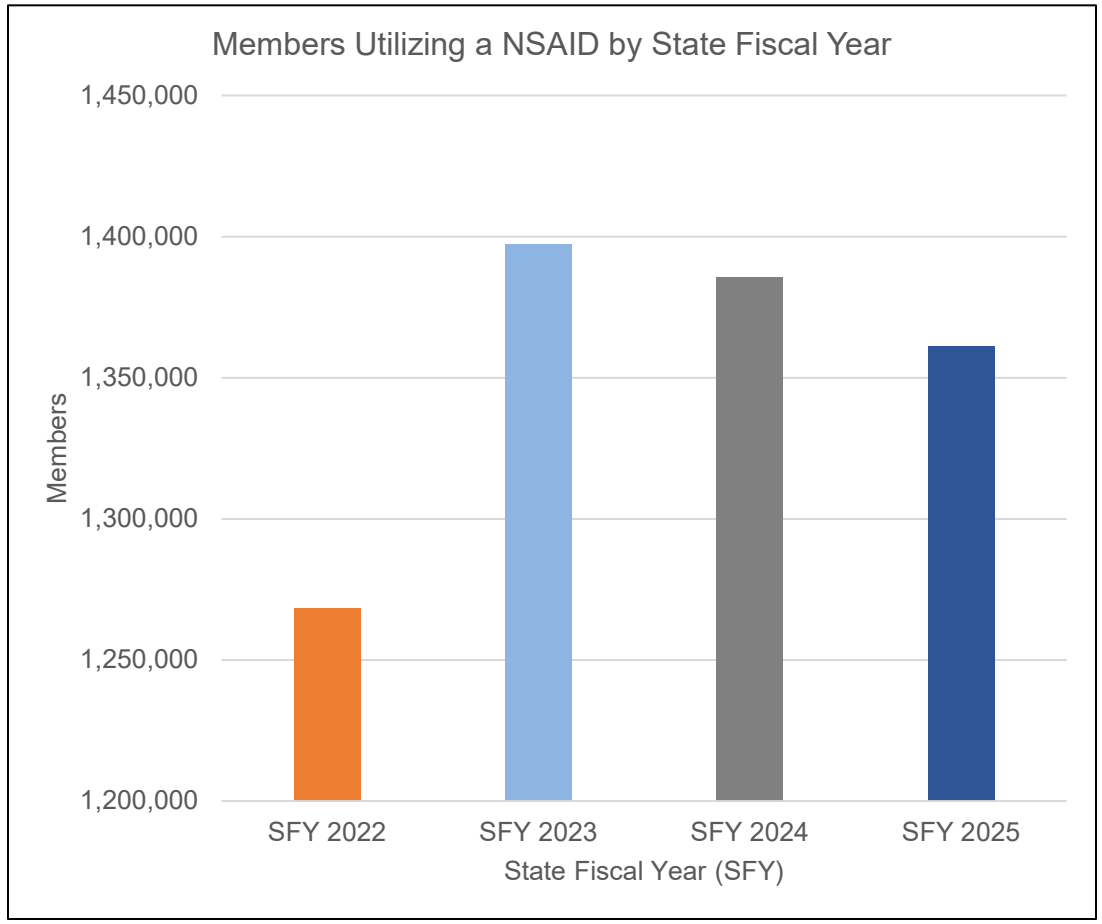
- The systemic absorption of topical NSAIDs is less when compared to oral NSAIDs and there is no benefit in the concomitant use of topical and oral NSAIDs.

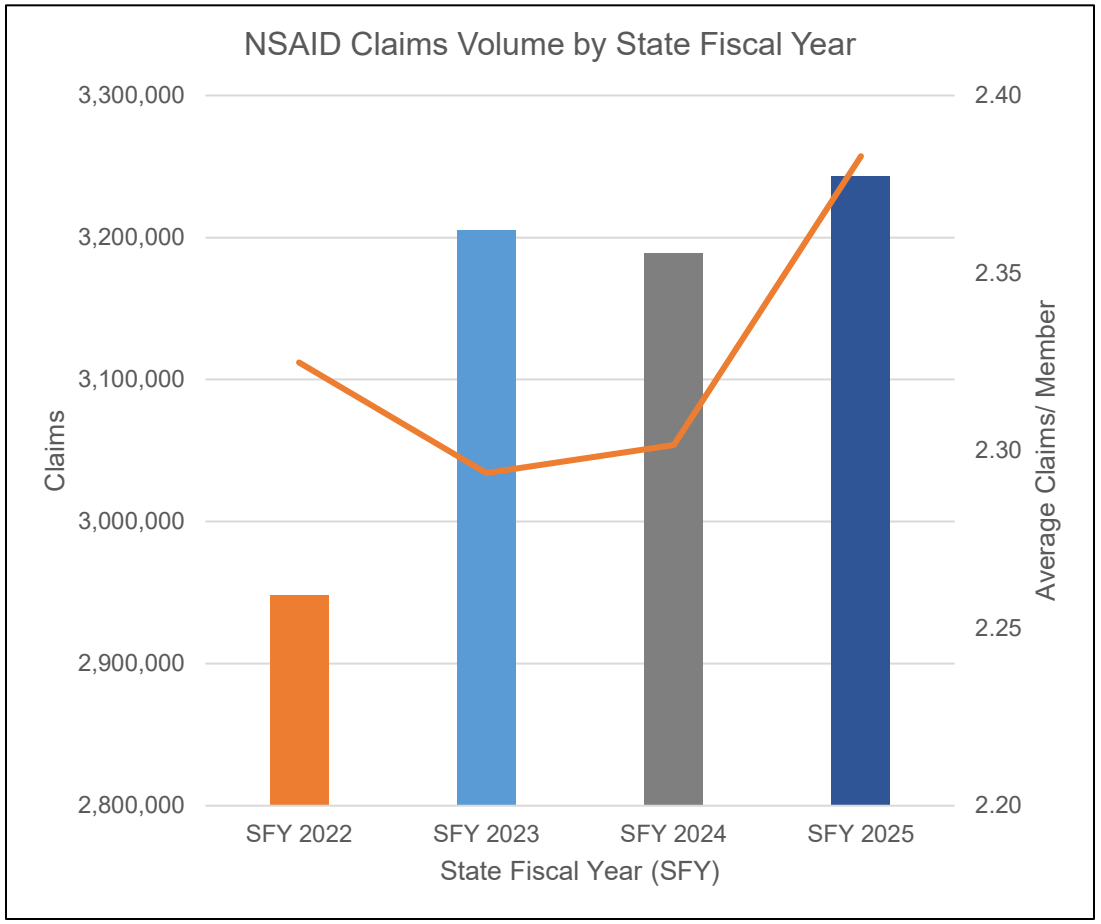
United States Food and Drug Administration. Drugs@FDA. Food and Drug Administration Approved Drug Products. Available at https://www.accessdata.fda.gov/. Accessed July 2025.

Methodology
Historical Trends Evaluation

- Retrospective analysis of claims was conducted.
- The data source was the Medicaid Data Warehouse (MDW).
- Timeframes:
  - State Fiscal Year 2022: April 1, 2021, through March 31, 2022
  - State Fiscal Year 2023: April 1, 2022, through March 31, 2023
  - State Fiscal Year 2024: April 1, 2023, through March 31, 2024 (NYRx pharmacy benefit transition)
  - State Fiscal Year 2025: April 1, 2024, through March 31, 2025
- Limitations:
  - Cell sizes ≤ 30 are not reported per the Medicaid Confidential Data Cell Size Policy,
  - Rebates are not included in the estimated total spend, and
  - Delays in claim/ encounter submission can occur, affecting the analysis.

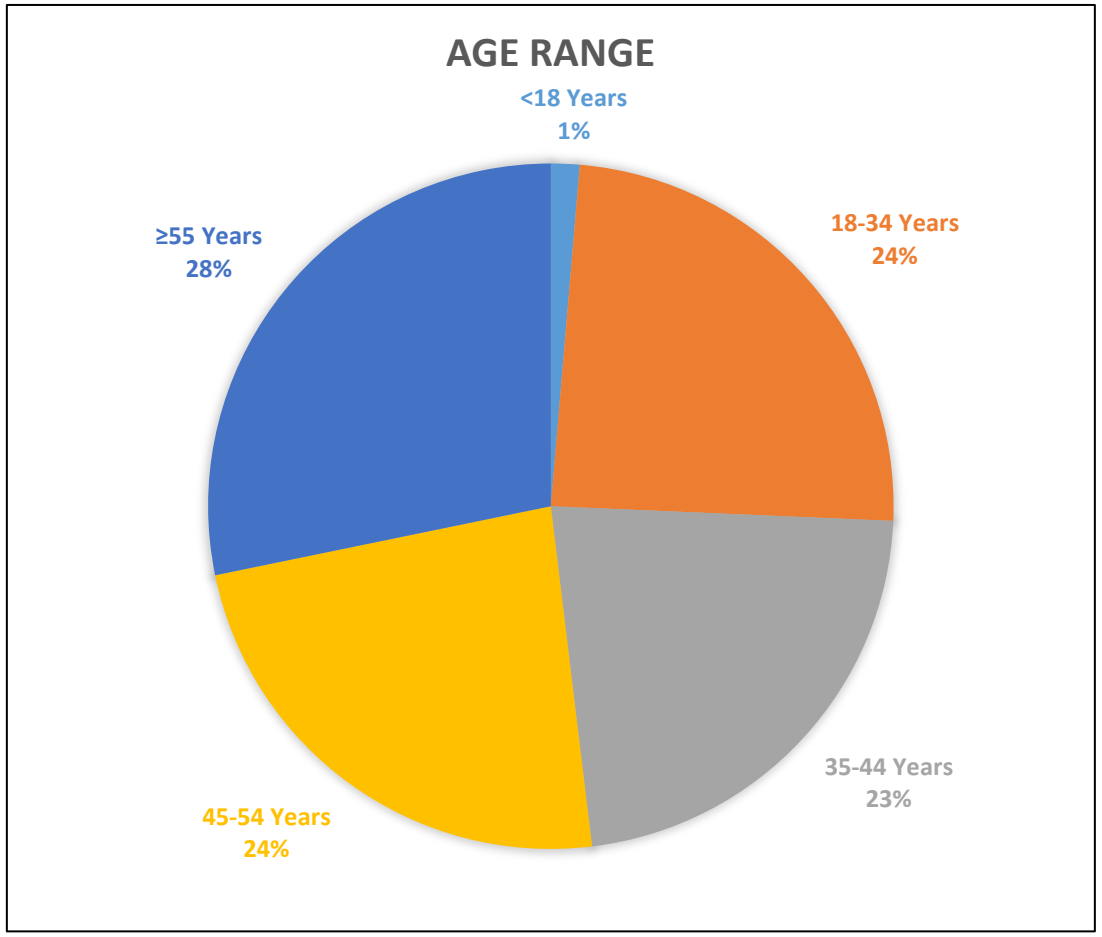
Results
NSAID Trends by State Fiscal Year

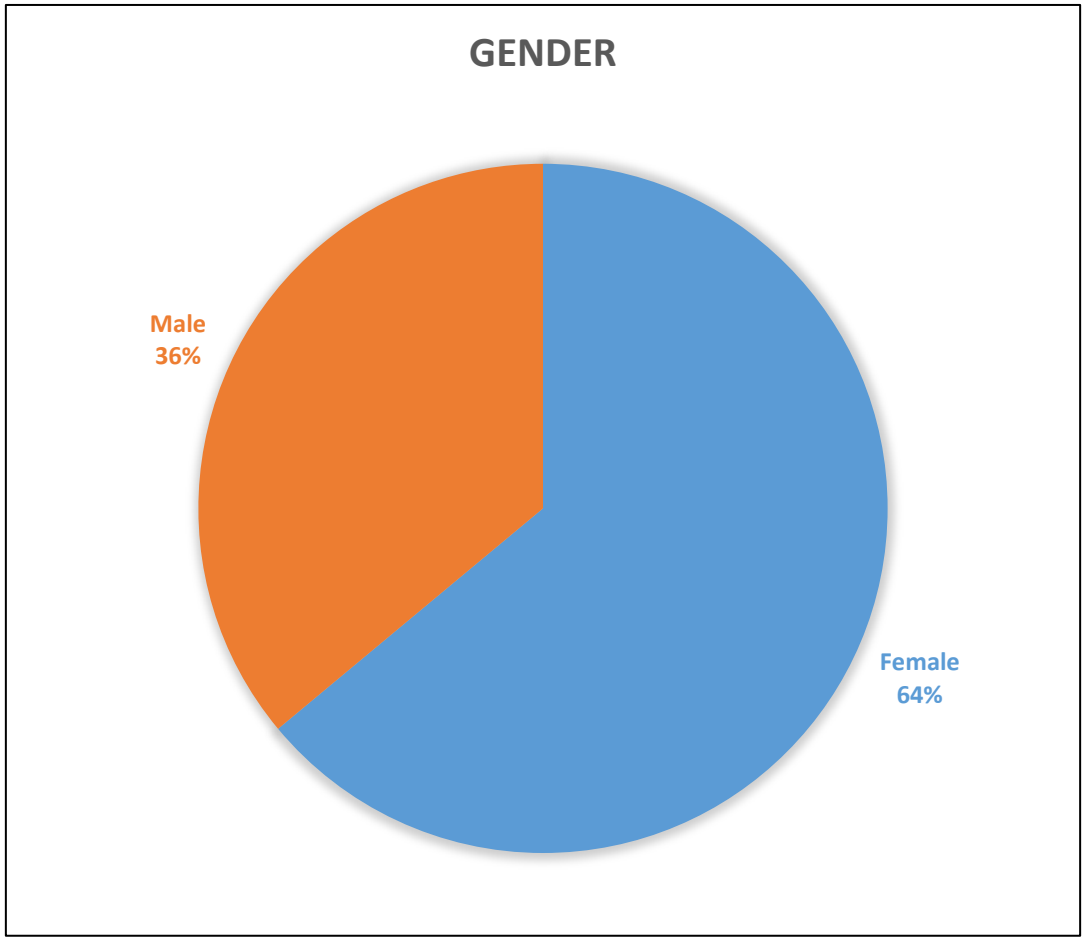




Source: Medicaid Data Warehouse Extract date= July 2025

Results
Demographics of Members Receiving an NSAID

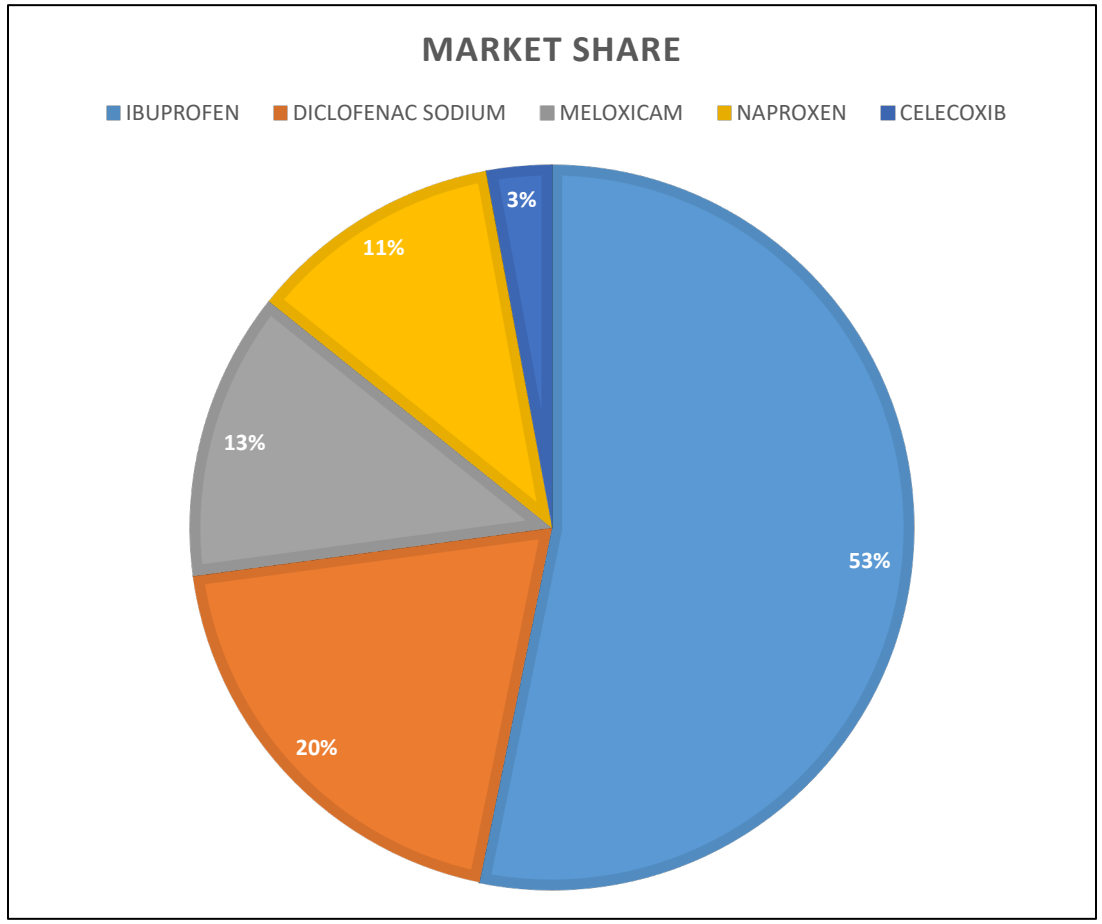




The demographic data represent the average of the entire analysis period.

Source: Medicaid Data Warehouse Extract date= July 2025

Results
Market Share



Source: Medicaid Data Warehouse Extract date= July 2025

- Between State Fiscal Year 2022 and State Fiscal Year 2025, the average total number of claims was 12.6M.
- The top 5 NSAIDs represented approximately 96% of the overall market share, accounting for 12.1M claims.
- The top 5 NSAIDs utilized were:
  1. Ibuprofen,
  2. Diclofenac sodium,
  3. Meloxicam,
  4. Naproxen, and
  5. Celecoxib.

Results
State Fiscal Year 2025 Trends

- Utilization of preferred NSAIDs represented:
  - 97.5% of members (n= 1.3M),
  - 92.9% of claims (3.0M), and
  - 33.2% of estimated cost ($42.1M).
  - The estimated average cost/ claim was $14.

- Utilization of non-preferred NSAIDs represented:
  - 6.1% of members (n= 82.2K)
    - Members are not additive, as a member could have received both a preferred and a non-preferred NSAID.
  - 7.1% (229K) of claims, and
  - 66.8% ($84.7M) of the estimated total spend.
  - The estimated average cost/ claim was $370.

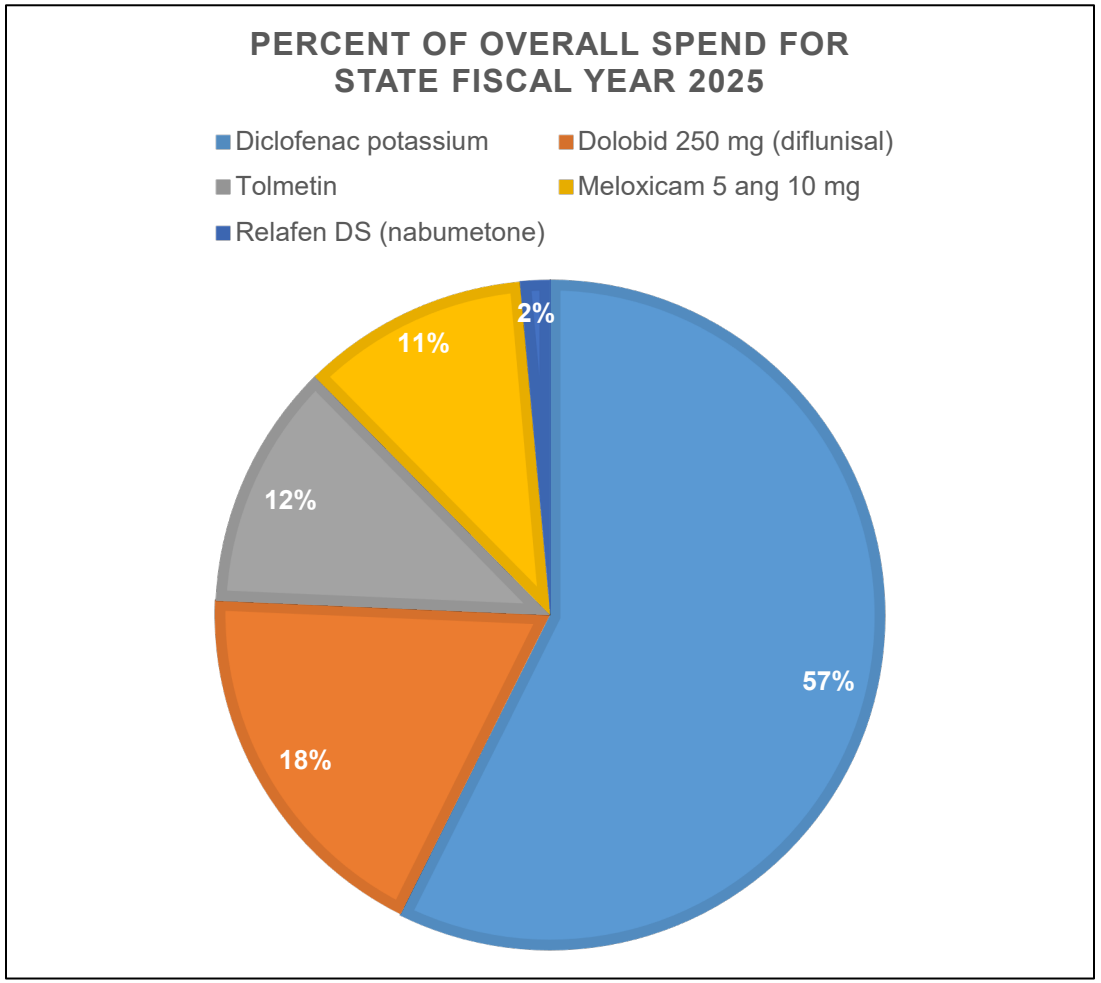
Premium Priced Non-Preferred NSAIDs State Fiscal Year 2025

For State Fiscal Year 2025, 5 non-preferred oral NSAIDs represented:

- 2.0% (65K) of the claims and
- 48.0% ($61M) of the estimated total spend.

The maximum reimbursable amount per unit for the non-preferred NSAIDs listed was:

- Diclofenac potassium 25 mg tablet: $14.25
- Dolobid (diflunisal) 250 mg tablet: $34.44
- Tolmetin sodium 400 mg capsule: $30.55
- Meloxicam 5 mg capsule: $11.17
- Meloxicam 10 mg capsule: $11.17
- Relafen DS (nabumetone) 1000 mg tablet: $56.37
  - Maximum Reimbursable Amount. EMedNY. Available at Information - Formulary File. Accessed July 2025.



Source: Medicaid Data Warehouse Extract date= July 2025

Therapeutic Duplication

- National Council for Prescription Drug Programs (NCPDP) has established a therapeutic duplication edit at the pharmacy point-of-sale.

- In the NYRx program, by entering an established code, the therapeutic duplication edit can be overridden at the pharmacy point-of-sale.

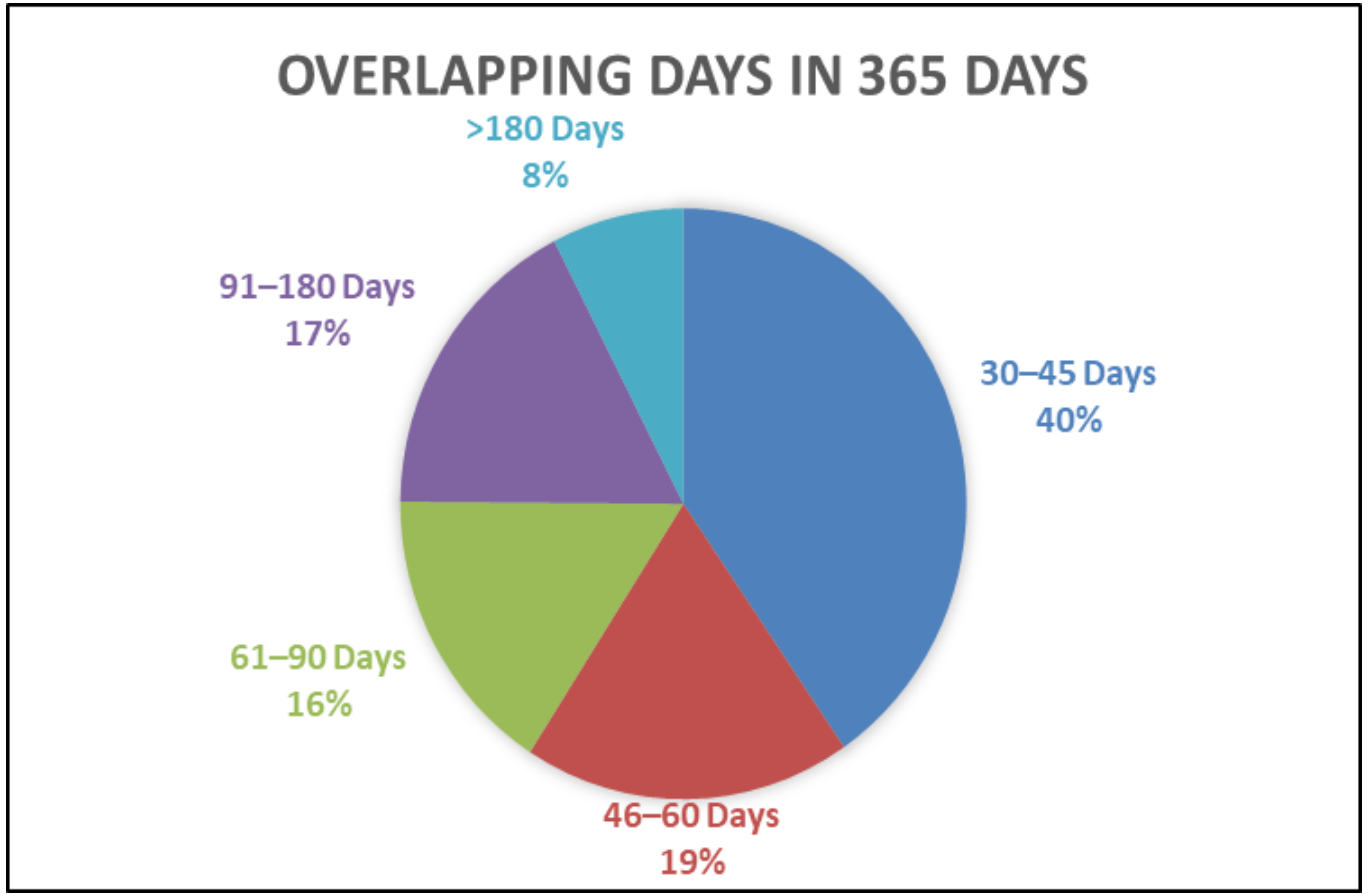
Methodology:

- Aim: To identify members who are utilizing ≥ 2 NSAIDs concurrently for a cumulative ≥ 30 days within 180 days and then 365 days.
- Time Frame: State Fiscal Year 2025 (April 1, 2024 through March 31, 2025)
- Sample: Members who received ≥ 2 different NSAIDs as identified by the generic code number.
- From the member's last NSAID claim in State Fiscal Year 2025, a look back of 180 and 365 days was used to determine if the member had received a cumulative of ≥ 30 days of ≥ 2 NSAIDs concurrently.

Results
Overlapping Days in 365 Days (State Fiscal Year 2025)

- 3.7% of members (n= 50K) had ≥ 2 NSAIDs overlapping for a cumulative total ≥ 30 days during the 365-day time frame, resulting in:
  - 15.2% (491K) of the total claims and
  - 40.5% ($127M) of the total estimated spend.
  - Average number of claims per member was 9.8 claims.

- Number of different NSAIDs:
  - 2 NSAIDs= 72.1% of members
  - 3 NSAIDs= 24.1% of members
  - ≥ 4 NSAIDs= 3.8% of members

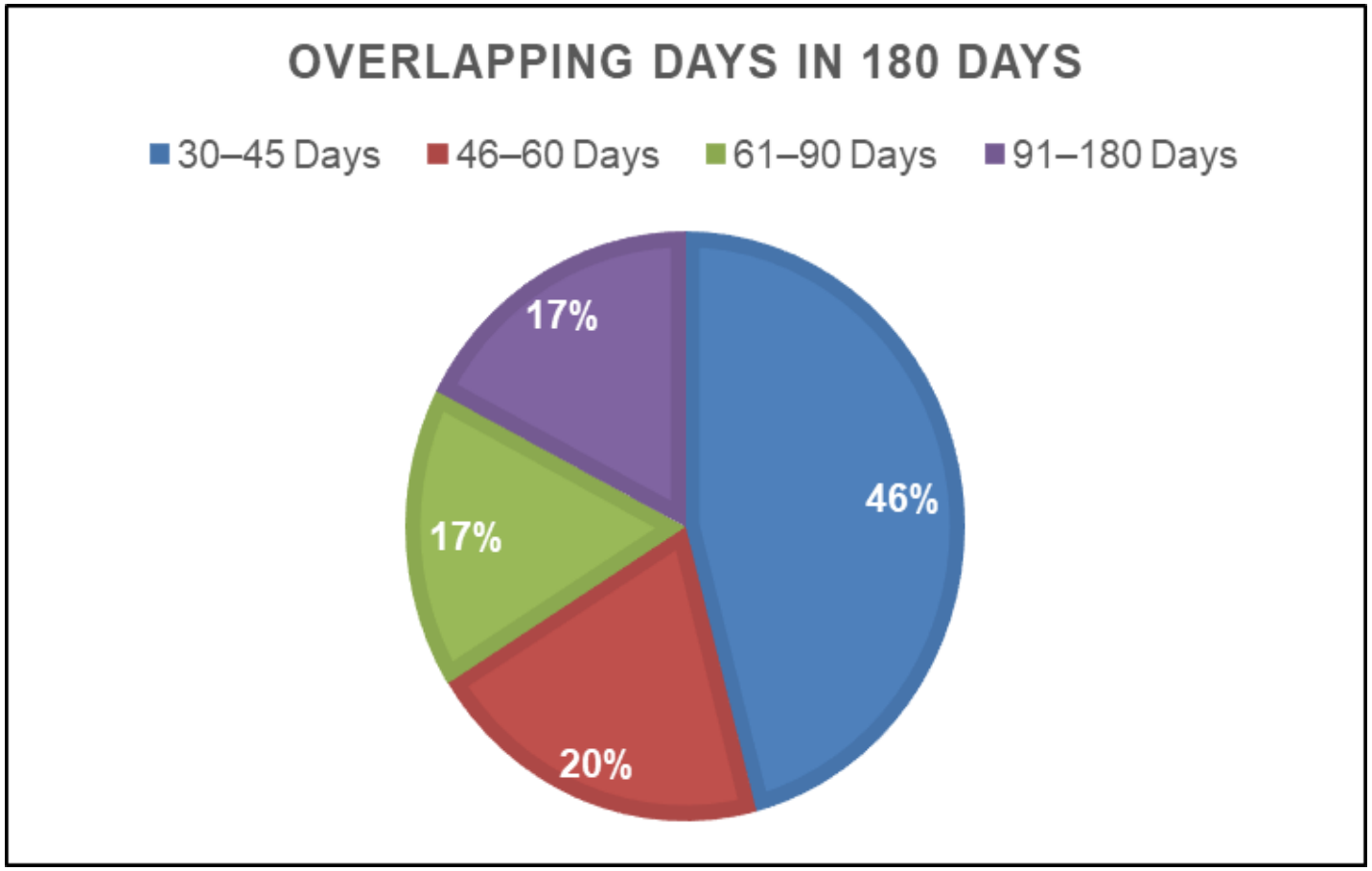


Source: MDW Extract Date= July 2025

Results
Overlapping Days in 180 Days (State Fiscal Year 2025)

- 2.9% (26K) of members had ≥ 2 NSAIDs overlapping for ≥ 30 days during a180-day period

- Number of different NSAIDs:
  - 2 NSAIDs= 74.3% of members
  - 3 NSAIDs= 22.1% of members
  - ≥ 4 NSAIDs= 3.5% of members



Source: Medicaid Data Warehouse Extract date= July 2025

Key Takeaways

- For both topical and oral drugs, the concomitant use of ≥ 2 NSAIDs or NSAIDs with salicylates increases the risk of gastrointestinal toxicity with a minimal increase in efficacy and is not recommended.

- The systemic absorption of topical NSAIDs is less when compared to oral NSAIDs and there is no benefit in the concurrent use of topical and oral NSAIDs.

- For State Fiscal Year 2025:
  - 97.5% of members received a preferred NSAID,
  - 92.9% of the claims were for a preferred NSAID, and
  - 33.2% of the estimated spend was for a preferred NSAID.

Key Takeaways (continued)

- For State Fiscal Year 2025, 3.7% of members had ≥ 2 NSAIDs overlapping for a cumulative total ≥ 30 days during the 365-day time frame, which resulted in:
  - 15.2% of total claims and
  - 40.5% of the overall estimated spend.

  - The average number of claims per member was 9.8 for State Fiscal Year 2025.

  - Number of overlapping NSAIDs used for State Fiscal Year 2025:
    - 2 NSAIDs= 72.1% of members
    - 3 NSAIDs= 24.1% of members
    - ≥ 4 NSAIDs= 3.8% of members

Key Takeaways (continued)

- For State Fiscal Year 2025:
  - Five non-preferred drugs accounted for 2.0% of claims and 48.0% of the total spend:
    1. Diclofenac potassium 25 mg tablet: $14.25/ unit
    2. Dolobid (diflunisal) 250 mg tablet: $34.44/ unit
    3. Tolmetin sodium 400 mg capsule: $30.55/ unit
    4. Meloxicam 5 mg and 10 mg capsule: $11.17/ unit
    5. Relafen DS (nabumetone) 1000 mg tablet: $56.37/ unit

Recommendations

1. Require a trial of ≥ 2 oral preferred NSAIDs before the use of an oral non-preferred NSAID.
   - The provider must attest that the member experienced a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction with ≥2 preferred NSAIDs at their maximally tolerated dose.

2. For members utilizing ≥ 2 NSAIDs overlapping for ≥ 30 days cumulatively, prior authorization is required.

Skeletal Muscle Relaxant Treatment Duration

October 3, 2025

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

Objectives

1. Review the historical skeletal muscle relaxant utilization trends between State Fiscal Year 2022 and State Fiscal Year 2025.

2. Evaluate the utilization trends of non-preferred agents for State Fiscal Year 2025.

3. Identify members initiating a skeletal muscle relaxant as an antispasmodic and evaluate the duration of therapy.

NYRx Preferred Drug Program
Skeletal Muscle Relaxant Therapeutic Category

Preferred	Non-Preferred
baclofen tablet chlorzoxazone 500 mg cyclobenzaprine 5 mg, 10 mg tablet dantrolene methocarbamol orphenadrine ER tizanidine tablet	Amrix® baclofen 15mg tablet baclofen solution baclofen suspension (generic Fleqsuvy™) carisoprodol[ST, F/Q/D] chlorzoxazone (generic Lorzone) 375 mg, 750 mg chlorzoxazone 250 mg tablet cyclobenzaprine 7.5 mg cyclobenzaprine ER capsule (generic Amrix) Dantrium® Fexmid® Fleqsuvy™ Lorzone® Lyvispah™ metaxalone methocarbamol 1000 mg Metaxalone orphenadrine-aspirin-caffeine Soma®[ST, F/Q/D] Tanlor® tizanidine capsule Zanaflex®

NYRx Preferred Drug Program. Revised August 21, 2025. Available at NYRx, the Medicaid Pharmacy Program | Preferred Drug Program. Accessed August 2025.

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

SUNY The State University of New York

ST= Step Therapy, F/Q/D= Frequency/ Quantity/ Duration

NYRx Preferred Drug Program
Clinical Criteria

Clinical Criteria:

1. For carisoprodol only, a trial with 1 analgesic and 2 skeletal muscle relaxants before the use of carisoprodol,
2. For carisoprodol only, the quantity limit is a maximum of 4 units per day,
3. For carisoprodol only, the duration limit is a 21-day supply, and
4. For skeletal muscle spasms, a trial of a skeletal muscle relaxant is required before a benzodiazepine.

- Note:
  - The carisoprodol clinical criteria recommendations were discussed at the December 22, 2011, Drug Utilization Review Board. The transcript is available at Drug Utilization Review (DUR) Board Meeting Summary December 20, 2011.
  - The step edit clinical criteria, a trial of skeletal muscle relaxant before the use of benzodiazepine, was discussed at the December 12, 2013, Drug Utilization Review Board. The transcript is available at Medicaid Drug Utilization Review (DUR) Board Meeting Summary for December 12, 2013.

NYRx Preferred Drug Program. Revised July 10, 2025. Available at NYRx, the Medicaid Pharmacy Program | Preferred Drug Program. Accessed August 2025.

Skeletal Muscle Relaxants

- Skeletal muscle relaxants are categorized as spasmolytic or antispasmodic drugs.

1. Spasmolytics are centrally acting muscle relaxants used to treat spasticity from upper motor neuron lesions.
   - Baclofen, dantrolene, and tizanidine

2. Antispasmodics are second-line agents for the short-term treatment of muscle spasms associated with painful musculoskeletal conditions, often resulting from injuries to muscles, tendons, or ligaments.
   - Carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, and orphenadrine
   - Tizanidine has compendia support for the management of muscle spasms and as adjunctive therapy for the management of musculoskeletal pain.

Basic & Clinical Pharmacology, 15e. McGraw-Hill; 2021. Accessed May 13, 2025. https://accesspharmacy-mhmedical-com.gate.lib.buffalo.edu/content.aspx?bookid=2988&sectionid=250598374.

Antispasmodics

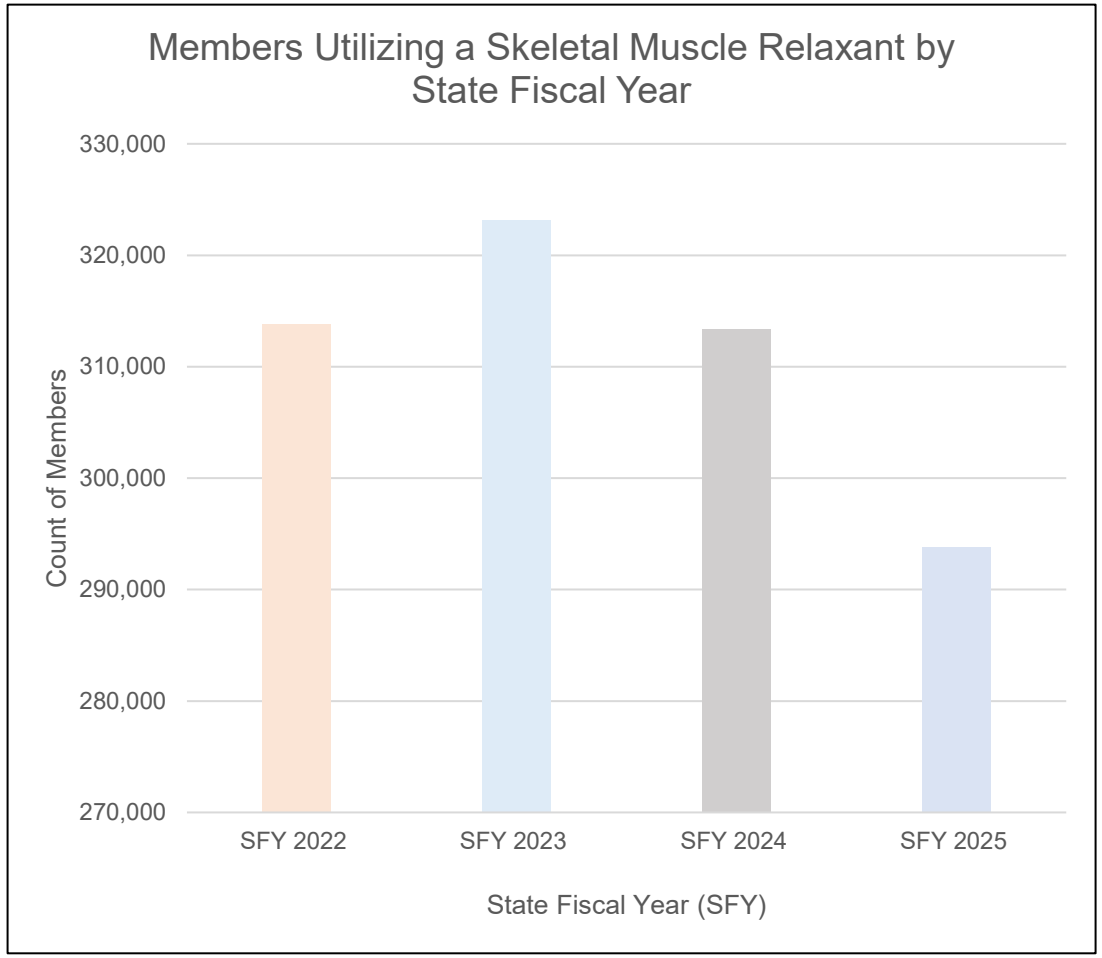
- Second-line therapy for the short-term treatment of acute lower back pain.
- Provide symptomatic relief and do not have any disease-modifying properties.
- Chronic use of these drugs is generally not recommended, as there is little information on their long-term safety and efficacy.
- A 2025 meta-analysis found that the agents increased the likelihood of short-term pain relief. However, there was a high incidence of adverse events such as dizziness and drowsiness when compared to the placebo group.

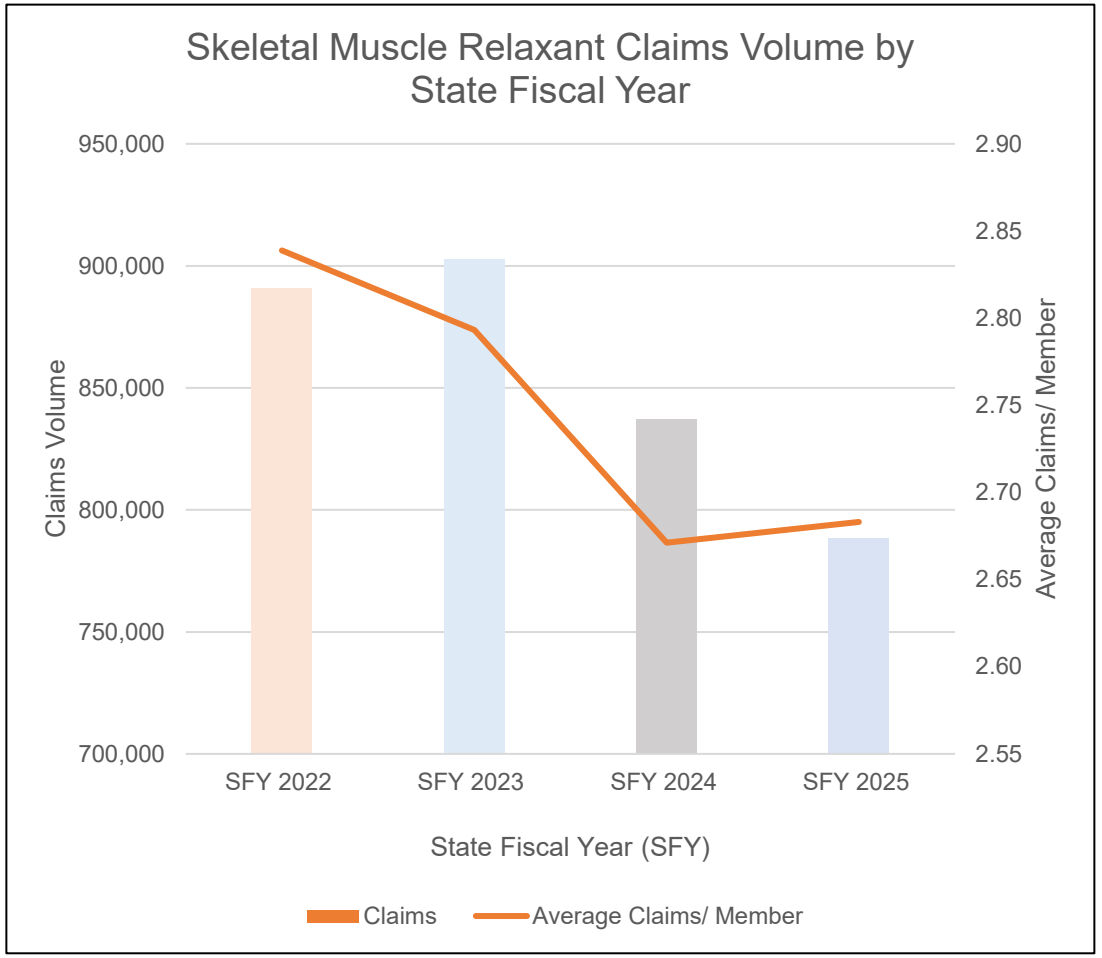
Ann Intern Med. 2017;166:514-530. doi:10.7326/M16-2367.
European Spine Journal. Apr 2025. doi.org/10.1007/s00586-025-08786-0.

Methodology
Historical Trends Evaluation

- Retrospective analysis of claims was conducted.
- Data source was the Medicaid Data Warehouse (MDW).
- Timeframes:
  - State Fiscal Year 2022: April 1, 2021, through March 31, 2022
  - State Fiscal Year 2023: April 1, 2022, through March 31, 2023
  - State Fiscal Year 2024: April 1, 2023, through March 31, 2024 (NYRx pharmacy benefit transition)
  - State Fiscal Year 2025: April 1, 2024, through March 31, 2025
- Limitations:
  - Cell sizes ≤ 30 are not reported per the Medicaid Confidential Data Cell Size Policy,
  - Rebates are not included in the estimated total spend, and
  - Delays in claim/ encounter submission can occur, affecting the analysis.

Results
Utilization Trends





Data source= Medicaid Data Warehouse Extract date= July 2025

Results
Utilization

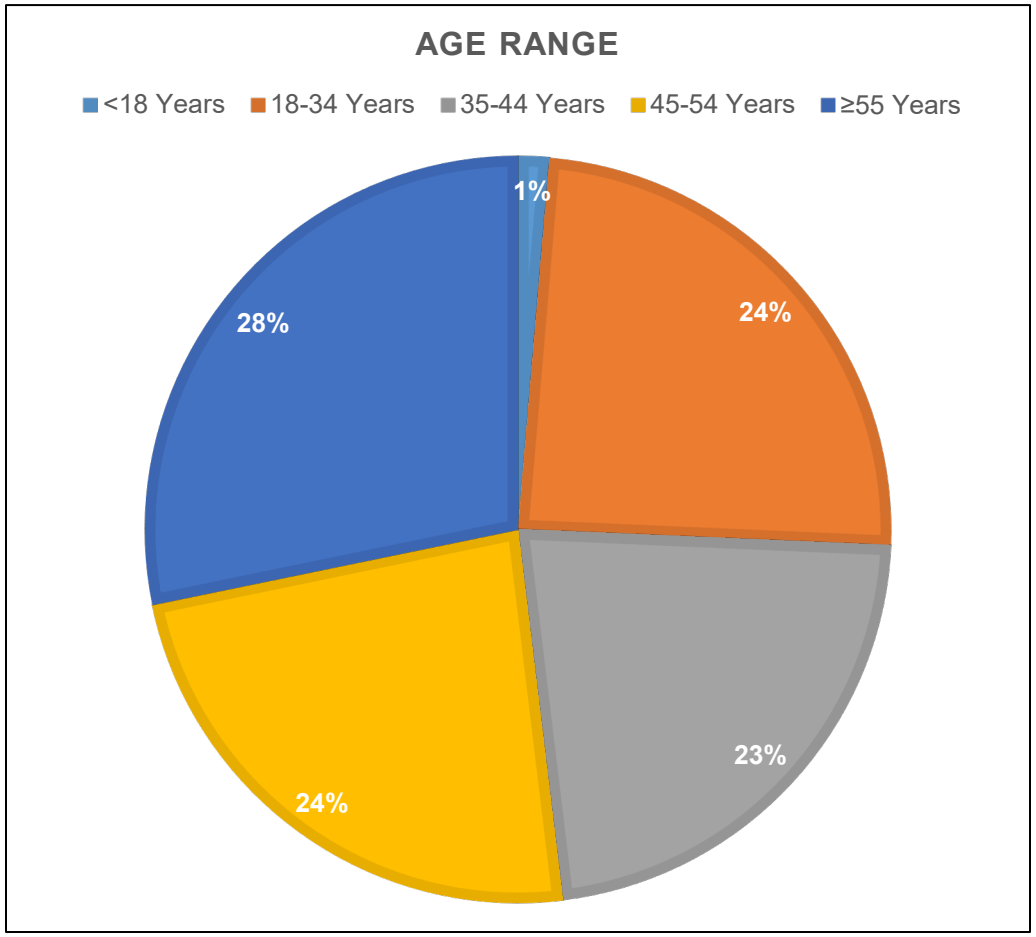
- The total number of members with a claim for a skeletal muscle relaxant between State Fiscal Year 2022 and State Fiscal Year 2025 was 833K (unique count of members), and the total number of claims was 3M.

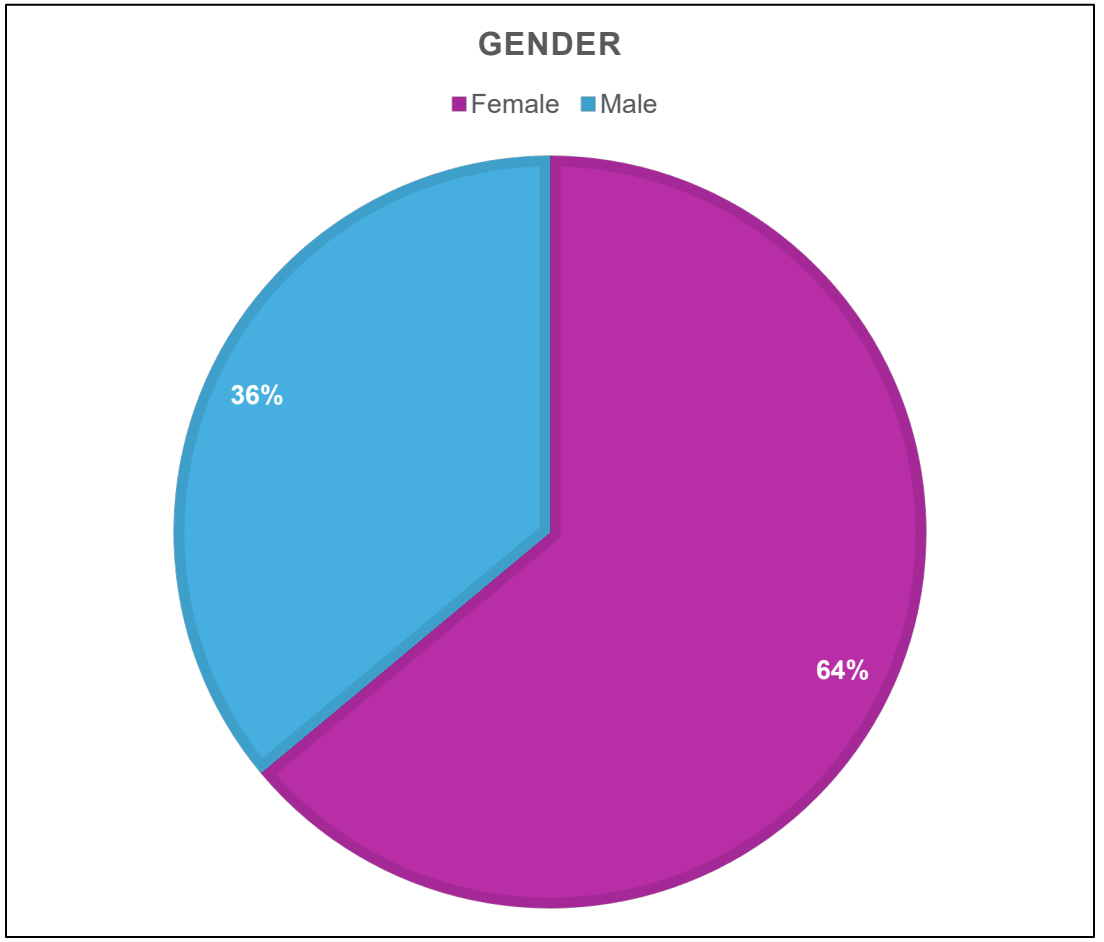
- The average number of members utilizing a skeletal muscle relaxant across the State Fiscal Years was 311K (standard deviation ±11K), and claims were 855K (standard deviation ±46K).

- Four products, cyclobenzaprine, baclofen, tizanidine, and methocarbamol, represented approximately 99% of the overall market share.

- Cyclobenzaprine products had the highest market share, ranging from 47.3% to 49.3% during the specified time frame.

Results
Demographics

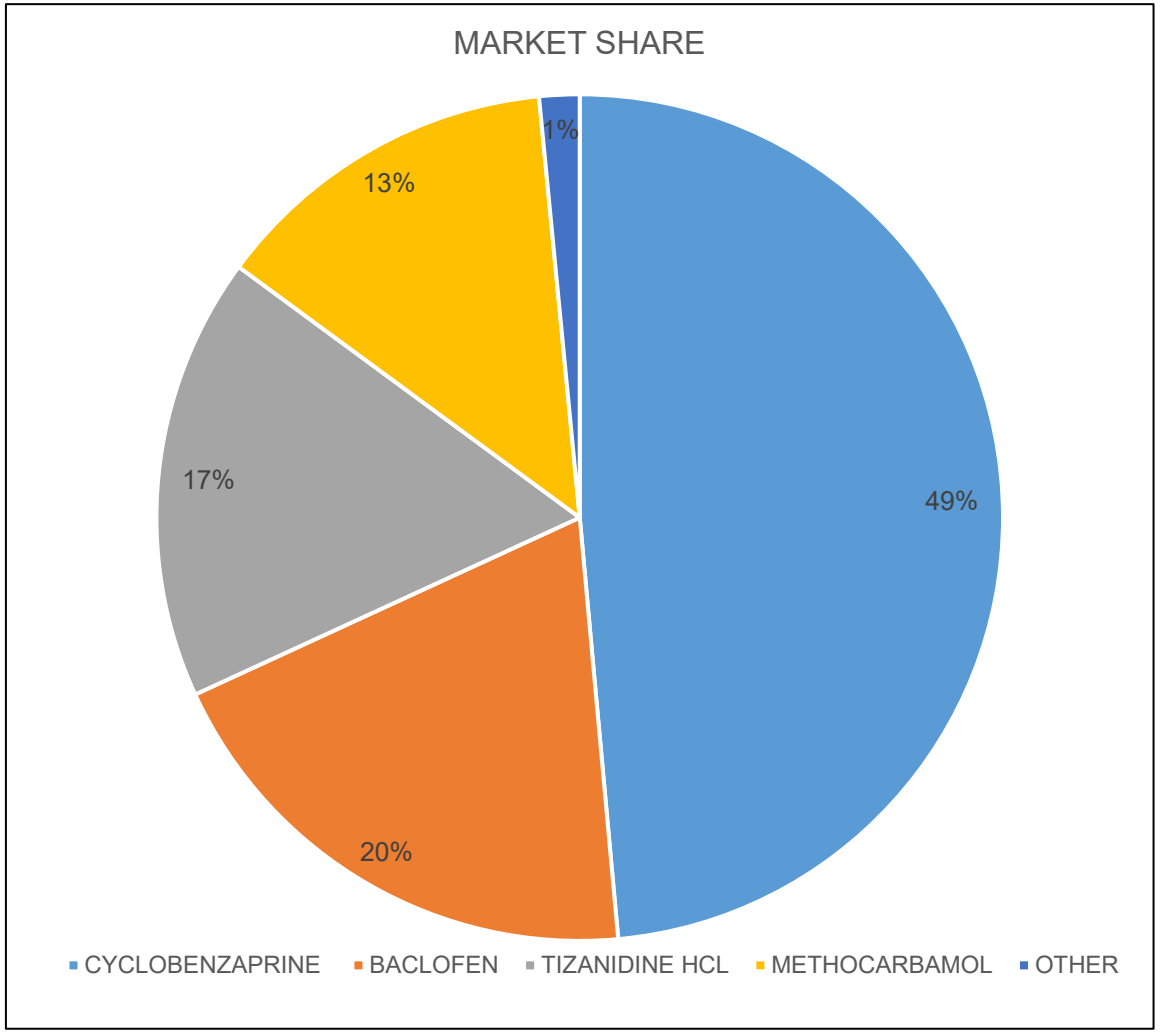




Data source= Medicaid Data Warehouse Extract date= July 2025

Results
Overall Market Share

- Between State Fiscal Year 2022 and State Fiscal Year 2025, 4 skeletal muscle relaxants accounted for approximately 99% of the market share. The products were:
    1. Cyclobenzaprine,
    2. Baclofen,
    3. Tizanidine, and
    4. Methocarbamol.



Data source= Medicaid Data Warehouse Extract date= July 2025

Results
State Fiscal Year 2025

- 293K members accounted for 788K claims at an estimated spend of $1.3M.

- 97.2% of the claims were for preferred agents, resulting in 63.4% of the total spend.

- Number of claims/ members:
    - 1 to 4 claims= 84.4% of members
    - 5 to 8 claims= 8.7% of members
    - 9 to 12 claims= 4.9% of members
    - ≥13 claims= 2.0% of members

- Preferred agents categorized as antispasmodics account for 62.0% of claims.

Results
State Fiscal Year 2025

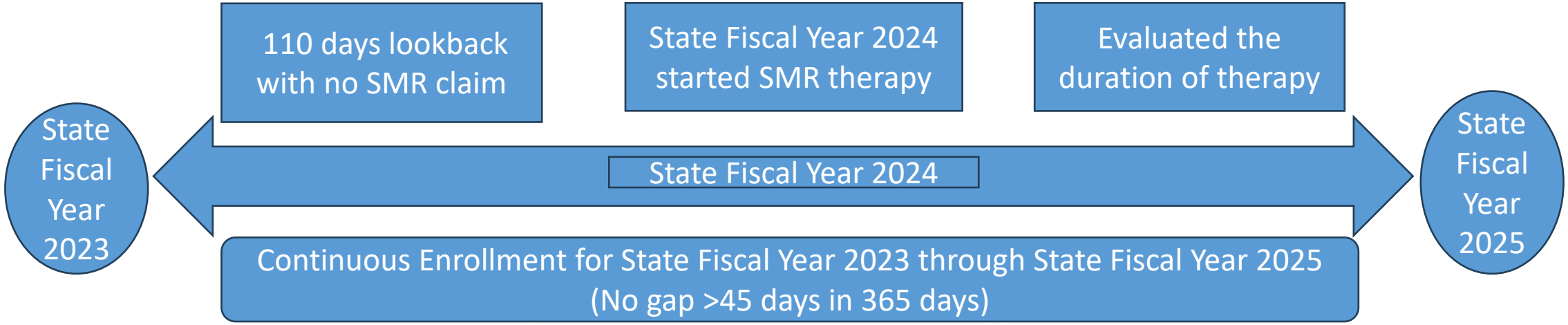
- Non-preferred agents categorized as antispasmodics represent 1.3% (11K) of claims and 22.5% ($3M) of the estimated total spend.

- The estimated average cost/ claim for a non-preferred agent was $288.

- Non-preferred agents with higher average cost/ claim:
  - Norgesic® Forte 50-770-60 tablet (orphenadrine 50 mg/ aspirin 770 mg/ caffeine 60 mg): $3,004/ claim
  - Orphengesic® Forte 50-770-60 MG (orphenadrine 50 mg/ aspirin 770 mg/ caffeine 60 mg): $2,344/ claim
  - Orphenadrine-aspirin-caffeine 25-385-30 mg: $1,934/ claim
  - Tanlor® (methocarbamol) 1,000 mg tablet: $1,899/ claim
  - Metaxalone 400 mg tablet: $258/ claim
  - Chlorzoxazone 375 and 750 mg tablet: $161 to $168/ claim

Methodology
Identifying Members Initiating Therapy

- Methods
  - Time frame: State Fiscal Year 2023 through State Fiscal Year 2025
  - Members continuously enrolled between State Fiscal Year 2023 and State Fiscal Year 2025
    - Continuous enrollment was defined as no gap >45 days in a 365-day period
  - The member initiated skeletal muscle relaxant claim in State Fiscal Year 2024
    - A new start was defined as no skeletal muscle relaxant claim in the previous 110 days from the index claim in State Fiscal Year 2024.
    - Drugs included were carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, and orphenadrine.



SMR= skeletal muscle relaxant

Results
Identifying the Members Initiating Therapy

Variable		Estimated Number of Members
Received any skeletal muscle relaxant in SFY 2024		247K
Naïve -- no fill 110 days before initial fill (T0) in 2024		209K
SAMPLE: Naïve and continuously enrolled in SFY 2023, 2024, 2025		124K

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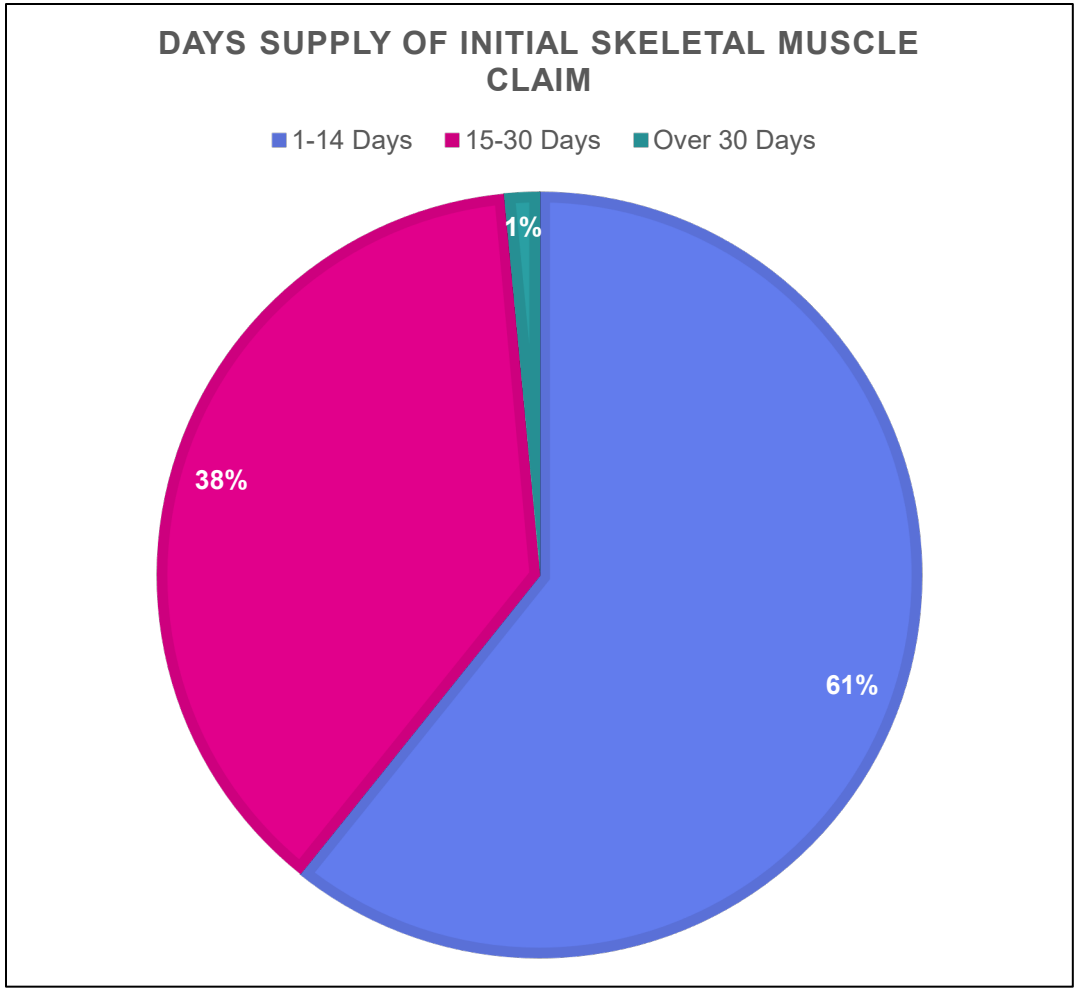
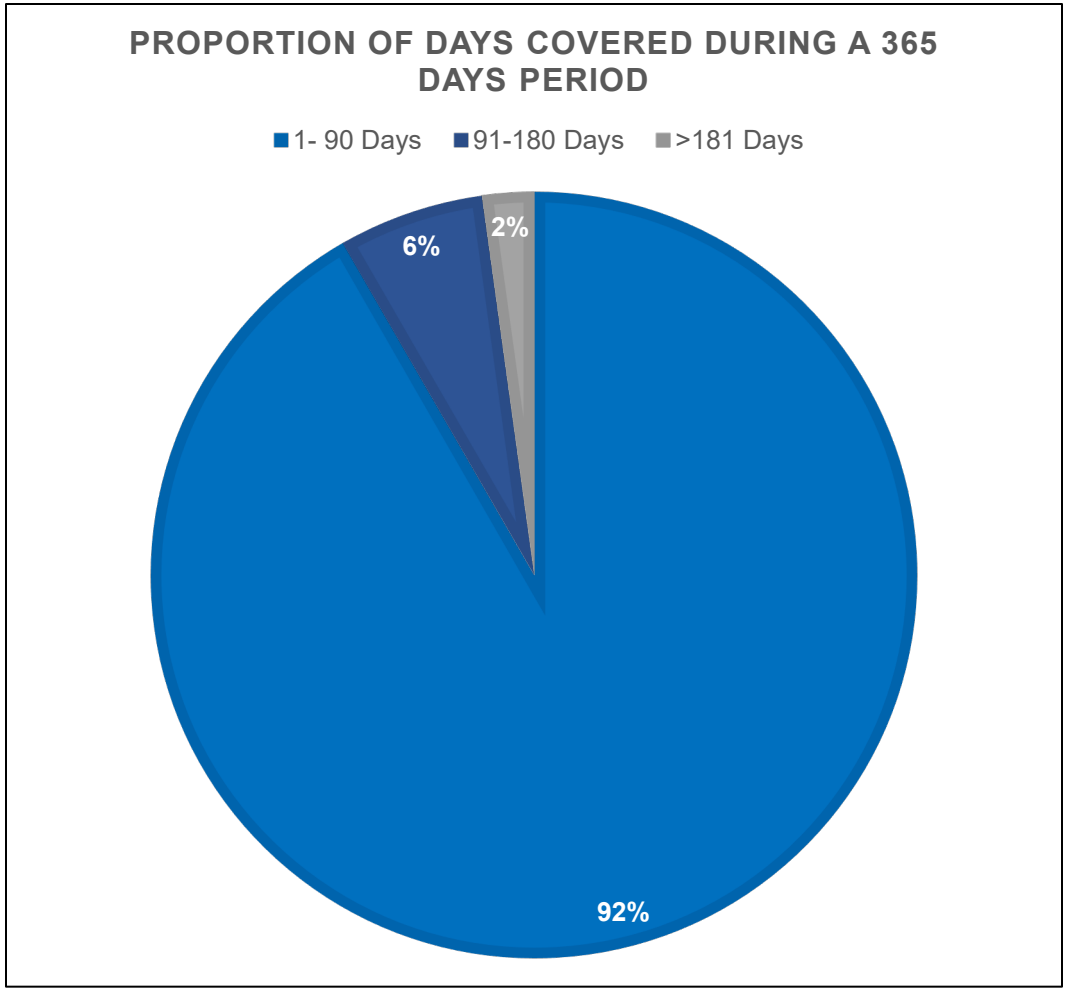
Results
Members Initiating Therapy
Days Supply and Duration





Data source= Medicaid Data Warehouse Extract date= July 2025

Key Takeaways

- The total number of members with a claim for a skeletal muscle relaxant between State Fiscal Year 2022 and State Fiscal Year 2025 was 833K (unique count of members), and the total number of claims was 3M.

- The average number of members utilizing a skeletal muscle relaxant across the State Fiscal Years was 311K (standard deviation ±11K), and claims were 855K (standard deviation ±46K).

- In State Fiscal Year 2025, non-preferred agents categorized as antispasmodics represented 1.3% of claims but resulted in 22.5% of the estimated total spend.

- The estimated average cost/claim was $288.

- The highest costs per claim were for Norgesic® Forte at $3,004, Orphenadrine Forte at $2,344, and orphenadrine/aspirin/caffeine at $1,934.

Key Takeaways (continued)

- An evaluation of members continuously enrolled between State Fiscal Year 2022 and State Fiscal Year 2025 who initiated skeletal muscle relaxant therapy was conducted.

- 60.8% of members received 1 to 14 days.

- 26.2% of members had a second claim for a skeletal muscle relaxant within 91 days of their first claim.

Recommendations

1. Require a trial of ≥2 preferred skeletal muscle relaxant agents for the treatment of musculoskeletal conditions before the use of a non-preferred agent.
    - The agents included are carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, and orphenadrine.
    - Additionally, tizanidine should also have clinical criteria requiring a trial of ≥2 preferred skeletal muscle relaxant agents when used to treat a musculoskeletal condition.
    - Members utilizing baclofen and dantrolene would be exempt from the clinical criteria. Additionally, cyclobenzaprine sublingual tablets would be excluded from the edit due to their indication.

2. Maintain the specific carisoprodol clinical criteria associated with the treatment of musculoskeletal conditions, as carisoprodol is a schedule-IV controlled substance. Currently, before the use of carisoprodol, the step criteria require a trial with 1 analgesic and 2 skeletal muscle relaxants.

Recommendations (continued)

3. Consider establishing a quantity limit for patients initiating therapy that allows for a 14-day supply with 1 refill for the treatment of musculoskeletal conditions.
    - The agents included would be carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, and orphenadrine.
    - Additionally, tizanidine should be included when used to treat a musculoskeletal condition.

4. Consider other projects that explore the long-term use of skeletal muscle relaxants.

Vonoprazan (Voquezna®)

October 3, 2025

Drug Utilization Review Board Meeting

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

Purpose

- The aim of this review is to examine vonoprazan (Voquezna®) and its utilization in the New York State Medicaid population
- Recommendations will be provided based on a review of the literature and results from utilization data analyses

Background

- Vonoprazan is a potassium-competitive acid blocker
- Binds reversibly to the gastric hydrogen potassium adenosine triphosphate enzymes to inhibit potassium ions from binding to proton pumps in gastric parietal cells
- Affects the final step in the acid secretory pathway thereby suppressing acid secretion
- Does not require acid for activation and is not a prodrug allowing for a more rapid onset of action unlike proton pump inhibitors
- Potentially provides more potent acid suppression than proton pump inhibitors due to its longer half-life (binds for a longer period of time)

Voquezna®. Prescribing information. Phathom Pharmaceuticals, Inc.; 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215151
Patel A, et al. *Gastroenterology*. 2024;167(6):1228-1238.

Characteristics	Voquezna®
Approved uses	• Healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults • To maintain healing of all grades of erosive esophagitis and relieve heartburn associated with erosive esophagitis in adults • In combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori (H. pylori)* infection in adults • In combination with amoxicillin for the treatment of *H. pylori* infection in adults
Compendia-supported uses	• None
Manufacturer	• Phathom Pharmaceuticals, Inc.

Dosing regimen	• Healing of erosive esophagitis: 20 mg once daily for 8 weeks
	• Maintenance of healed erosive esophagitis: 10 mg once daily for up to 6 months
	• Relief of heartburn associated with non-erosive gastroesophageal reflux disease: 10 mg once daily for 4 weeks
	• For *H. pylori* infections:
	  ○ Triple therapy: vonoprazan 20 mg, amoxicillin 1,000 mg, and clarithromycin 500 mg, each given twice daily for 14 days
	  ○ Dual therapy: vonoprazan 20 mg given twice daily and amoxicillin 1,000 mg three times daily for 14 days

Voquezna®. Prescribing information. Phathom Pharmaceuticals, Inc.; 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215151
Voquezna® Dual Pak®. Prescribing information. Phathom Pharmaceuticals, Inc.; 2025. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215153
Voquezna® Triple Pak®. Prescribing information. Phathom Pharmaceuticals, Inc.; 2025. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215152

Characteristics	Voquezna®
Contraindications	• Rilpirivine-containing products
Warnings and precautions	• Patients should be assessed for gastric malignancy if they have a suboptimal response or early symptomatic relapse • Treatment should be discontinued if acute tubulointerstitial nephritis is suspected • Increases the risk for *Clostridium* difficile-associated diarrhea especially in hospitalized patients; patients should receive shortest duration of treatment and if diarrhea does not improve, patients should be evaluated • Increases risk for osteoporosis-related fractures (hip, wrist, spine) in patients who received high doses and/or long-term treatment (≥1 year) • Vitamin B12 deficiency has been reported in patients who received long-term treatment • Severe cutaneous reactions have occurred (e.g., Stevens-Johnson syndrome) • Hypomagnesemia has been reported which may result in hypocalcemia and/or hypokalemia • Serum chromogranin levels may increase secondary to drug-induced decrease in gastric acidity; vonoprazan should be discontinued 4 weeks before assessing serum chromogranin levels • Increased risk of fundic gland polyps with long-term use
Special populations	• Pregnancy: no adequate, well-controlled studies are available • Lactation: no data are available regarding the presence of vonoprazan in human breastmilk • Pediatric: safety and effectiveness have not been established • Geriatric: no differences in effectiveness or safety were observed compared to patients <65 years of age; no clinically meaningful differences in pharmacokinetics were detected when compared to patients <65 years of age • Hepatic and renal impairment: dosage adjustments are required
Monitoring parameters	• Serum magnesium and calcium levels should be monitored when initiating treatment and periodically throughout

Voquezna®. Prescribing information. Phathom Pharmaceuticals, Inc.; 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215151

Characteristics	Voquezna®
Drug interactions	• Drugs dependent on gastric pH for absorption (e.g., rilpivirine-containing products [contraindicated]; atazanavir, nelfinavir [avoid use]); may decrease absorption of iron salts, erlotinib, dasatinib, nilotinib, mycophenolate mofetil, ketoconazole, itraconazole • Cytochrome 3A substrates: vonoprazan is a weak cytochrome 3A inhibitor; concentrations of cytochrome 3A substrates may be increased (may require monitoring) • Strong/moderate cytochrome 3A4 inducers: vonoprazan is a cytochrome 3A substrate and inducers may decrease its exposure (avoid concurrent use) • Cytochrome 2C19 substrates: vonoprazan is a cytochrome 2C19 inhibitor; concentrations of cytochrome 2C19 substrates may be decreased (e.g., the active metabolite of clopidogrel is reduced); may increase exposure of cytochrome 2C19 substrates (e.g., citalopram, cilostazol) (concurrent use should be monitored) • May interact with the chromogranin test for neuroendocrine tumors and the secretin stimulation test
How supplied	• Voquezna® 10 mg, 20 mg tablets • Voquezna® Triple Pak®: vonoprazan 20 mg tablets, amoxicillin 500 mg capsules, clarithromycin 500 mg tablets • Voquezna® Dual Pak®: vonoprazan 20 mg tablets, amoxicillin 500 mg capsules
Cost	• Wholesale acquisition cost for 10 mg and 20 mg tablets = $27.30

Voquezna®. Prescribing information. Phathom Pharmaceuticals, Inc.; 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215151
Voquezna® Dual Pak®. Prescribing information. Phathom Pharmaceuticals, Inc.; 2025. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215153
Voquezna® Triple Pak®. Prescribing information. Phathom Pharmaceuticals, Inc.; 2025. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215152

Place in Therapy

- American Gastroenterological Association practice update/expert review on integrating potassium-competitive acid blockers into clinical practice (2024):
  - Non-erosive reflux disease (heartburn symptoms and non-erosive gastroesophageal reflux disease): potassium-competitive acid blockers are not recommended as first-line therapy
    - Should be considered in selected patients with documented acid-related reflux who fail twice daily proton pump inhibitor therapy
  - Milder erosive esophagitis (Los Angeles grade A/B): potassium-competitive acid blockers are not recommended as first-line therapy
    - Should be considered in selected patients with documented acid-related reflux who fail twice daily proton pump inhibitor therapy
  - More severe erosive esophagitis (Los Angeles grade C/D): potassium-competitive acid blockers can be considered; clinicians may also consider a proton pump inhibitor due to the higher cost and the lack of randomized trials comparing double-dose proton pump inhibitors to potassium-competitive acid blocker therapy on endoscopic outcomes

Patel A, et al. *Gastroenterology*. 2024;167(6):1228-1238.

Place in Therapy – Cont.

- American Gastroenterological Association practice update/expert review on integrating potassium-competitive acid blockers into clinical practice (2024):
  - *H. pylori:* potassium-competitive acid blocker treatment is recommended in place of a proton pump inhibitor for the eradication of *H. pylori;* the duration of vonoprazan treatment should be 14 days
  - Peptic ulcer disease: potassium-competitive acid blocker therapy is not recommended as first-line for the treatment or prophylaxis of peptic ulcer disease
    - Insufficient evidence to use potassium-competitive acid blockers as first-line therapy in patients with bleeding gastroduodenal ulcers and high-risk stigmata

Patel A, et al. *Gastroenterology*. 2024;167(6):1228-1238.

New York State Medicaid Coverage

- Voquezna®, Voquezna® Dual Pak®, Voquezna® Triple Pak®: Non-preferred agents with quantity limits
  - Vonoprazan (Voquezna®): Quantity limit=30 tablets
  - Vonoprazan/amoxicillin (Voquezna® Dual Pak) and vonoprazan/amoxicillin/clarithromycin (Voquezna® Triple Pak): Quantity limit=112 tablets

Comparator State Medicaid Coverage

- Comparator states: California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington
- Among the 9 programs, 7 offer restricted coverage of Voquezna®
  - 7 of the 9 programs require prior authorization
  - 2 programs do not list the products in their preferred drug list

Drug Utilization Data: Overview of Analyses

- Members enrolled in the New York State Medicaid Program with a pharmacy claim for a proton pump inhibitor or vonoprazan during State Fiscal Year 2025 were included
  - The diagnosis lookback timeframe was State Fiscal Years 2024 and 2025
- Data source: Medicaid Data Warehouse
- Timeframe: April 1, 2021 – March 31, 2025

Drug Utilization Data: Disclaimers

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

Generic Name	SFY 2022	SFY 2023	SFY 2024	SFY 2025
Bismuth/Metronid/Tetracycline*	131	126	1,247	1,545
Dexlansoprazole	2,149	2,303	4,601	4,776
Esomeprazole Magnesium	14,086	14,037	21,744	22,084
Esomeprazole Sodium			≤30	≤30
Lansoprazole	11,288	10,593	11,322	9,912
Lansoprazole/Amoxicillin/Clarith	99	113	310	83
Naproxen/Esomeprazole Mag	713	503	2,224	1,592
Omeprazole	359,778	358,965	351,152	314,953
Omeprazole Magnesium	4,856	6,341	2,183	1,057
Omeprazole/Amoxicillin/Rifabutin	140	151	597	558
Omeprazole/Sodium Bicarbonate	1,485	1,621	5,189	5,845
Pantoprazole Sodium	138,885	146,963	163,621	163,402
Rabeprazole Sodium	786	893	1,130	1,335
Vonoprazan Fumarate			116	3,946
Vonoprazan/Amoxicillin				77
Vonoprazan/Amoxicillin/Clarith				94

SFY=State Fiscal Year. SFY 2022=April 1, 2021-March 31, 2022; SFY 2023=April 1, 2022-March 31, 2023; SFY 2024=April 1, 2023-March 31, 2024; SFY 2025=April 1, 2024-March 31, 2025. *Included since used for the treatment of *H. pylori.*

- There was almost a 3,300% increase in the utilization of vonoprazan fumarate by **members** between State Fiscal Years 2024 and 2025

Generic Name	SFY 2022	SFY 2023	SFY 2024	SFY 2025
Bismuth/Metronid/Tetracycline*	144	127	1,296	1,612
Dexlansoprazole	12,469	12,207	16,578	17,262
Esomeprazole Magnesium	59,817	62,367	73,515	74,813
Esomeprazole Sodium			128	103
Lansoprazole	51,229	47,704	40,692	34,666
Lansoprazole/Amoxicillin/Clarith	102	117	314	85
Naproxen/Esomeprazole Mag	2,869	1,912	6,277	5,484
Omeprazole	1,485,746	1,468,910	1,258,010	1,058,346
Omeprazole Magnesium	12,123	18,080	4,609	2,657
Omeprazole/Amoxicill/Rifabutin	146	153	608	572
Omeprazole/Sodium Bicarbonate	6,749	7,317	21,236	25,085
Pantoprazole Sodium	565,999	592,103	557,376	536,350
Rabeprazole Sodium	3,852	4,476	4,063	4,249
Vonoprazan Fumarate			123	9,804
Vonoprazan/Amoxicillin				79
Vonoprazan/Amoxicillin/Clarith				97

SFY=State Fiscal Year; SFY 2022=April 1, 2021-March 31, 2022; SFY 2023=April 1, 2022-March 31, 2023; SFY 2024=April 1, 2023-March 31, 2024; SFY 2025=April 1, 2024-March 31, 2025.*Included since used for the treatment of *H. pylori.*

- There was almost an 8,000% increase in the number of **claims** for vonoprazan between State Fiscal Years 2024 and 2025

Utilization in State Fiscal Year 2025

Generic Name	Members	Claims
Bismuth/Metronid/Tetracycline*	1,545	1,612
Dexlansoprazole	4,776	17,262
Esomeprazole Magnesium	22,084	74,813
Esomeprazole Sodium	≤30	103
Lansoprazole	9,912	34,666
Lansoprazole/Amoxicillin/Clarith	83	85
Naproxen/Esomeprazole Mag	1,592	5,484
Omeprazole	314,953	1,058,346
Omeprazole Magnesium	1,057	2,657
Omeprazole/Amoxicillin/Rifabutin	558	572
Omeprazole/Sodium Bicarbonate	5,845	25,085
Pantoprazole Sodium	163,402	536,350
Rabeprazole Sodium	1,335	4,249
Vonoprazan Fumarate	3,946	9,804
Vonoprazan/Amoxicillin	77	79
Vonoprazan/Amoxicillin/Clarith	94	97

State Fiscal Year 2025=April 1, 2024-March 31, 2025.*Included since used for the treatment of *H. pylori.*

Most Common Diagnoses – State Fiscal Year 2025

ICD10	Description	Members
K219	GASTRO-ESOPHAGEAL REFLUX DISEASE	295,058
R079	CHEST PAIN, UNSPECIFIED	127,629
R109	UNSPECIFIED ABDOMINAL PAIN	125,006
R1013	EPIGASTRIC PAIN	123,554
K2970	GASTRITIS, UNSPECIFIED, WITHOUT BLEEDING	88,836
R1084	GENERALIZED ABDOMINAL PAIN	65,372
R12	HEARTBURN	38,377
K2900	ACUTE GASTRITIS WITHOUT BLEEDING	31,200
B9681	HELICOBACTER PYLORI AS THE CAUSE OF DISEASE	28,278
K2090	ESOPHAGITIS, UNSPECIFIED WITHOUT BLEEDING	20,203

State Fiscal Year 2025=April 1, 2024-March 31, 2025

- In members using a proton pump inhibitor or vonoprazan in State Fiscal Year 2025, the most common diagnoses were gastroesophageal reflux diseases and pain related to the abdomen/gastric/chest areas

Step Therapy – State Fiscal Year 2025

	Members	%
Members on vonoprazan fumarate	3,946	
Proton pump inhibitor >= twice/day	928	23.5%
Proton pump inhibitor daily	2,178	55.2%
No proton pump inhibitor prior	840	21.3%
Proton pump inhibitor <= 30 days duration BEFORE	403	10.2%
Proton pump inhibitor > 30 days duration BEFORE	2,710	68.7%
Proton pump inhibitor < 30 days duration AFTER	433	11.0%
Proton pump inhibitor >= 30 days duration AFTER	1,076	27.3%

State Fiscal Year 2025=April 1, 2024-March 31, 2025

- Members with a claim in State Fiscal Year 2025 were included in the analysis; the lookback period for proton pump inhibitor use was State Fiscal Years 2024 and 2025
- 23.5% (n=928) of members had evidence of step therapy with twice daily dosing of a proton pump inhibitor prior to vonoprazan
- 21.3% (n=840) had no evidence of using a proton pump inhibitor prior to vonoprazan

Conclusions

- The American Gastroenterological Association asserts that potassium-competitive acid blockers are not first-line and are not cost-effective for heartburn symptoms, non-erosive gastroesophageal reflux disease, mild erosive esophagitis, and peptic ulcer disease when compared to proton pump inhibitors dosed twice daily
  - Potassium-competitive acid blockers should be considered in selected patients with documented acid-related reflux who fail twice daily proton pump inhibitor treatment
- The American Gastroenterological Association recommends that potassium-competitive acid blockers be considered in patients with more severe erosive esophagitis
- The American Gastroenterological Association recommends potassium-competitive acid blockers treatment in patients with *H. pylori*

UB Recommendations

- Consider requiring documentation of a contraindication, intolerance, or inadequate response to 2 or more proton pump inhibitors dosed twice daily prior to use of vonoprazan
  - Excludes patients with *H. pylori*

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