# Lab to Label: 2026 New Drug Update

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## Disclosures

Given the nature of this presentation, I will include brand names for reference

Except where noted, information is based upon FDA-approved product labeling

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## Objectives

- Identify medications that were approved and came to market in the last year
- Develop a general understanding of each medication's indication, dosing, potential adverse effects, place in therapy, and unique characteristics
- Implement new clinical treatment guidelines that were published in the last year

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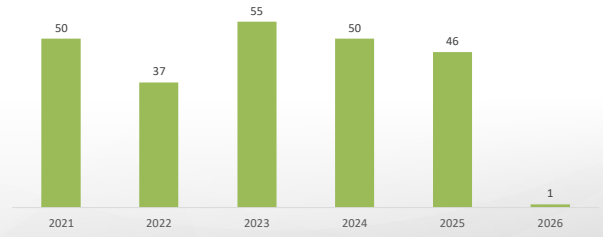
## FDA Novel Drug Approvals by Year

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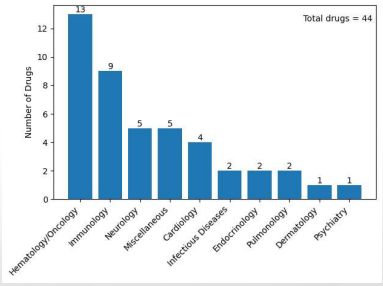
## Newly Approved FDA Medications (February 2025 – February 2026)

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## Methodology for Included Medications and Guidelines

Given time constraints, only covering medications and guidelines that are most likely to

- Affect a large patient population
- Involve multiple medical specialties

Excluded

- Hematology/Oncology
- Immunology
- Other Specialty Drugs/Orphan Drugs

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## Clinical Practice Guidelines Being Covered

| | |
|---|---|
| American Thoracic Society | • Diagnosis and Management of Community-acquired Pneumonia. An Official American Thoracic Society Clinical Practice Guideline |
| Infectious Diseases Society of America | • Clinical Practice Guideline by Infectious Diseases Society of America (IDSA): 2025 Guideline on Management and Treatment of Complicated Urinary Tract Infections |
| American College of Cardiology/American Heart Association | • 2025 AHA/ACC/AANP/AAPA/ABC/ACCP/ ACPM/AGS/AMA/ASPC/NMA/PCNA/ SGIM Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines<br>• 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines |
| Advisory Committee on Immunization Practices/Center for Disease Control and Prevention | • Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2025 |

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## Medications Being Covered

| | | | | |
|---|---|---|---|---|
| Etripamil | Aficamten | Lerodalcibep-liga | Nerandomilast | Brensocatib |
| Gepotidacin | Zoliflodacin | Tradipitant | Acoltremon | Delgocitinib |
| | Aceclidine | Atrasentan | Elinzanetant | |

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## "Systematic" Approach to Covered Medications

- **Overview**
  - Approval Date
  - Indication
  - Dosage
  - Mechanism of Action
- **Special Populations**
  - Pregnancy
  - Lactation
  - Pediatrics
  - Geriatrics
- **Accessibility**
  - Pharmacy
  - Patient Assistance
- Efficacy Data
- Warnings & Precautions
- Safety Data
- Contraindications

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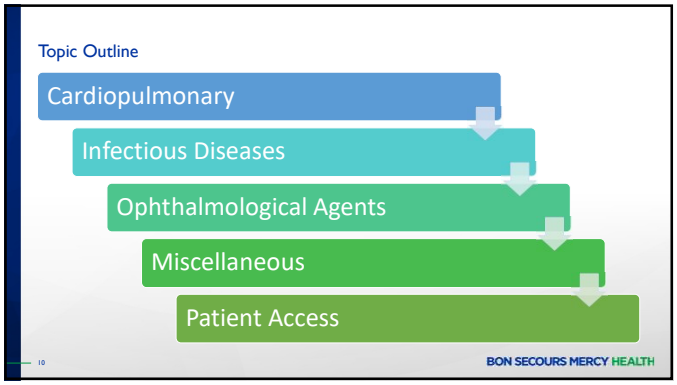
Topic Outline
Cardiopulmonary
Infectious Diseases
Ophthalmological Agents
Miscellaneous
Patient Access
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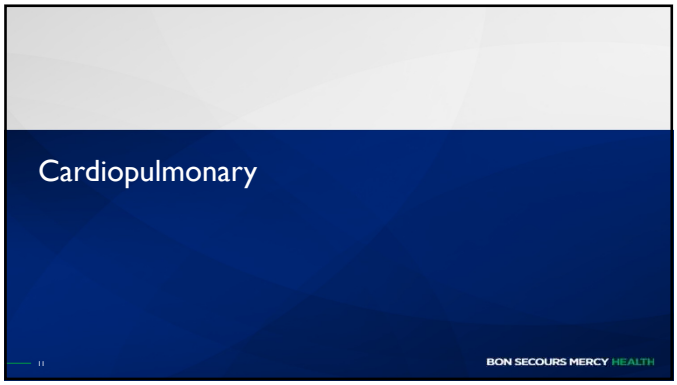
Cardiopulmonary
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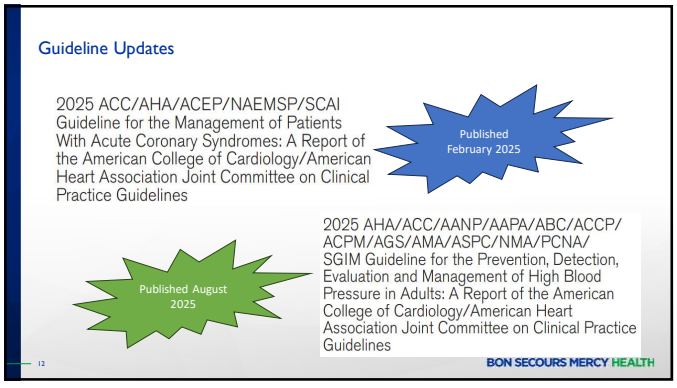
Guideline Updates
2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines
Published February 2025
Published August 2025
2025 AHA/ACC/AANP/AAPA/ABC/ACCP/ACPM/AGS/AMA/ASPC/NMA/PCNA/SGIM Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines
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## Acute Coronary Syndromes Guideline Highlights

**Dual antiplatelet therapy is recommended for patients with acute coronary syndromes (ACS)**

- Ticagrelor or prasugrel is recommended in preference to clopidogrel in patients with ACS who are undergoing percutaneous coronary intervention (PCI)
- In patients with non–ST-segment elevation ACS who are scheduled for an invasive strategy with timing of angiography to be > 24 hours, upstream treatment with clopidogrel or ticagrelor may be considered to reduce major adverse cardiovascular events



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Rao SV. Circulation. 2025;151(13):e771–e862.

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## Acute Coronary Syndromes Guideline Highlights

**Dual antiplatelet therapy with aspirin and an oral P2Y12 inhibitor is indicated for at least 12 months as the default strategy in patients with ACS who are not at high bleeding risk**

**Several strategies are available to reduce bleeding risk in patients with ACS who have undergone PCI and require antiplatelet therapy**

- In patients at risk for gastrointestinal bleeding, a proton pump inhibitor is recommended
- In patients who have tolerated dual antiplatelet therapy with ticagrelor, transition to ticagrelor monotherapy is recommended ≥1 month after PCI
- In patients who require long-term anticoagulation, aspirin discontinuation is recommended 1 to 4 weeks after PCI with continued use of a P2Y12 inhibitor (preferably clopidogrel)



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Rao SV. Circulation. 2025;151(13):e771–e862.

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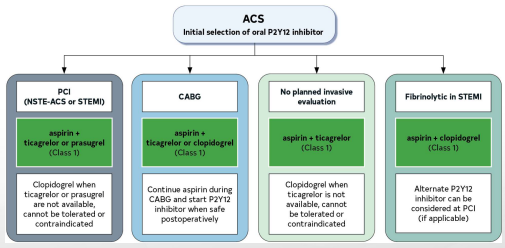
## Acute Coronary Syndromes Guideline Highlights



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Rao SV. Circulation. 2025;151(13):e771–e862.

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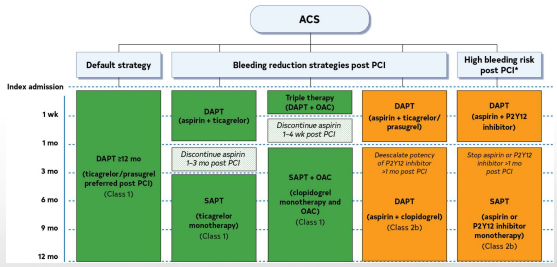
## Acute Coronary Syndromes Guideline Highlights



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Rao SV. Circulation. 2025;151(13):e771–e862.

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## Acute Coronary Syndromes Guideline Highlights

High-intensity statin therapy is recommended for all patients with ACS, and with the option to initiate concurrent ezetimibe

A nonstatin lipid-lowering agent (eg, ezetimibe, evolocumab, alirocumab, inclisiran, bempedoic acid) is recommended for patients already on maximally tolerated statin who have a low-density lipoprotein cholesterol level of ≥ 70 mg/dL (1.8 mmol/L)

- It is reasonable in this high-risk population to further intensify lipid-lowering therapy if the low-density lipoprotein cholesterol level is 55 to <70 mg/dL (1.4 to <1.8 mmol/L) and patient is already on a maximally tolerated statin



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## Acute Coronary Syndromes Guideline Highlights

**Table 12. Statin Classification**

| Statin Classification by Expected LDL-C Reduction | | |
|---|---|---|
| High-Intensity Therapy* | Moderate-Intensity Therapy† | Low-Intensity Therapy‡ |
| Atorvastatin 40-80 mg | Atorvastatin 10-20 mg | Simvastatin 10 mg |
| Rosuvastatin 20-40 mg | Rosuvastatin 5-10 mg | Pravastatin 10-20 mg |
| | Simvastatin 20-40 mg | Lovastatin 20 mg |
| | Pravastatin 40-80 mg | Fluvastatin 20-40 mg |
| | Lovastatin 40 mg | |
| | Fluvastatin XL 80 mg | |
| | Fluvastatin 40 mg BID | |
| | Pitavastatin 1-4 mg | |

Modified with permission from Grundy et al.[47] Copyright 2018 American Heart Association, Inc., and American College of Cardiology Foundation.
*Expected LDL-C reduction ≥50%.
†Expected LDL-C reduction ≥30% to 49%.
‡Expected LDL-C reduction <30%.
BID indicates twice daily; LDL-C, low-density lipoprotein cholesterol.



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Rao SV. Circulation. 2025;151(13):e771–e862.

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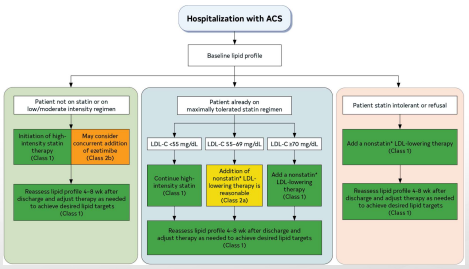
## Acute Coronary Syndromes Guideline Highlights



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Rao SV. Circulation. 2025;151(13):e771–e862.

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## Acute Coronary Syndromes Guideline Highlights

Red blood cell transfusion to maintain a hemoglobin of 10 g/dL may be reasonable in patients with ACS and acute or chronic anemia who are not actively bleeding



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Rao SV. Circulation. 2025;151(13):e771–e862.

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## Hypertension Guideline Highlights

The overarching blood pressure treatment goal is < 130/80 mmHg for all adults, with additional considerations for those who require institutional care, have a limited predicted lifespan, or are pregnant

**Table 4. Categories of Blood Pressure in Adults***

| | SBP | | DBP |
|---|---|---|---|
| **BP Category** | | | |
| **Normal** | <120 mm Hg | and | <80 mm Hg |
| **Elevated** | 120 to 129 mm Hg | and | <80 mm Hg |
| **Hypertension** | | | |
| **Stage 1** | 130 to 139 mm Hg | or | 80 to 89 mm Hg |
| **Stage 2** | ≥140 mm Hg | or | ≥90 mm Hg |

BP indicates blood pressure (based on an average of ≥2 careful readings obtained on ≥2 occasions, as detailed in Section 3 ("Evaluation and Diagnosis"); DBP, diastolic blood pressure; and SBP, systolic blood pressure.

*Adults with SBP and DBP in 2 categories should be designated to the higher BP category. This table excludes individuals who are pregnant (see Section 11.5, "Hypertension and Pregnancy"). Adapted with permission from Whelton et al.[5] Copyright 2018 American College of Cardiology Foundation and American Heart Association, Inc.



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Jones DW. Hypertension. 2025;82(6):e212–e316.

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## Hypertension Guideline Highlights

For all adults, lifestyle changes, including the following, are strongly recommended to prevent or treat elevated blood pressure and hypertension

- Maintaining or achieving a healthy weight
- Following a heart-healthy eating pattern
- Reducing sodium intake
- Increasing dietary potassium intake
- Adopting a moderate physical activity program
- Managing stress
- Reducing or eliminating alcohol intake

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Jones DW. Hypertension. 2025;82(03):e212-e316.

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## Hypertension Guideline Highlights

Initiation of medication therapy to lower blood pressure in addition to lifestyle interventions is recommended for the following

- All adults with average blood pressure ≥ 140/90 mm Hg
- Selected adults with average blood pressure ≥ 130/80 mm Hg who have clinical cardiovascular disease, previous stroke, diabetes, chronic kidney disease, or increased 10-year predicted cardiovascular risk of ≥ 7.5%

**First-Line Agents**

- Thiazide-type Diuretics
- ACE-inhibitors/ARBs
- Dihydropyridine CCBs

**Alternative Agents**

- Nondihydropyridine CCBs
- Loop Diuretics
- Potassium-sparing Diuretics
- Aldosterone Antagonists
- Alpha/Beta-Blockers
- Direct Renin Inhibitor
- Central Alpha-2-Agonists
- Direct Vasodilators
- Dial Endothelin Receptor Antagonist

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Jones DW. Hypertension. 2025;82(03):e212-e316.

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## Hypertension Guideline Highlights

In adults with average blood pressure ≥ 130/80 mm Hg and at lower 10-year cardiovascular disease risk of < 7.5%, initiation of medication therapy to lower blood pressure is recommended if average blood pressure remains ≥ 130/80 mm Hg after an initial 3 to 6-month trial of lifestyle modification

For all adults with stage 2 hypertension, the initiation of antihypertensive drug therapy with 2 first-line agents of different classes in a single-pill, fixed-dose combination is preferred over 2 separate pills to improve adherence and reduce time to achieve blood pressure control

Severe hypertension in nonpregnant individuals, defined as blood pressure > 180/120 mm Hg, without evidence of acute target organ damage, should be evaluated and treated in the outpatient setting with initiation, reinstitution, or intensification of oral antihypertensive medications in a timely manner

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Jones DW. Hypertension. 2025;82(03):e212-e316.

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## Novel Cardiopulmonary Drug Approvals Overview

**Brensocatib**
- Non-cystic fibrosis bronchiectasis

**Nerandomilast**
- Idiopathic and/or progressive pulmonary fibrosis

**Etripamil**
- Paroxysmal supraventricular tachycardia (PSVT) conversion

**Lerodalcibep-liga**
- Low-density lipoprotein cholesterol (LDL-C) reduction

**Aficamten**
- Symptomatic obstructive hypertrophic cardiomyopathy

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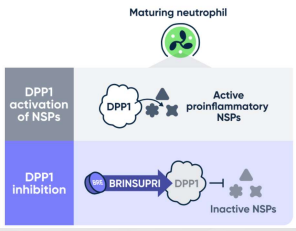
## (BREN soe KA tib) Brensocatib (Brinsupri) Overview

**Approval Date**
- 8/12/2025

**Indication**
- Treatment of non-cystic fibrosis bronchiectasis in adult and pediatric patients 12 years of age and older

**Dosage**
- 10 – 25 mg orally once daily

**Mechanism of Action**
- Dipeptidyl peptidase 1 (DPP1) inhibition

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Brinsupri [package insert]. Bridgewater, NJ: Insmed Incorporated; 2025.

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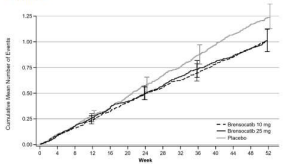
## Brensocatib (Brinsupri) Efficacy

**WILLOW Trial (N = 256 adults)**
- Time to first pulmonary exacerbation was significantly longer in the brensocatib groups than the placebo group

**ASPEN Trial (N = 1721 adult and pediatrics)**
- Annualized rate of pulmonary exacerbations were lower in the brensocatib groups
- Median time to first pulmonary exacerbation was longer in the brensocatib groups
- More patients were event free at 52 weeks in the brensocatib groups

**Figure 1 Cumulative Mean Number of Pulmonary Exacerbations through Week 52**

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Brinsupri [package insert]. Bridgewater, NJ: Insmed Incorporated; 2025.

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## Brensocatib (Brinsupri) Safety

**WILLOW Trial**

- Similar safety outcomes as ASPEN Trial, expect higher incidence of gingival and periodontal adverse reactions (~10% in brensocatib group vs 2.4% in placebo group)

**ASPEN Trial**

- More common (see table)
- LFT elevations
- Skin cancers
- Alopecia

**Table 1 Adverse Reactions with BRINSUPRI with an Incidence of ≥2% and More Common than Placebo in ASPEN**

| Adverse Reaction | Placebo (N=563) n (%) | BRINSUPRI 10 mg QD (N=582) n (%) | BRINSUPRI 25 mg QD (N=574) n (%) |
|---|---|---|---|
| Upper respiratory tract infection[1] | 141 (25) | 157 (27) | 169 (29) |
| Headache | 39 (7) | 39 (7) | 49 (9) |
| Rash[2] | 22 (4) | 25 (4) | 35 (6) |
| Dry skin[3] | 8 (1) | 17 (3) | 25 (4) |
| Hyperkeratosis[4] | 5 (1) | 8 (1) | 16 (3) |
| Hypertension | 17 (3) | 28 (5) | 13 (2) |

[1] Upper respiratory tract infection includes coronavirus infection, COVID-19, influenza, upper respiratory tract infection, viral infection, and viral upper respiratory tract infection.
[2] Rash includes rash, rash maculo-papular, rash pruritic, rash erythematous, dermatitis, and erythema.
[3] Dry skin includes dry skin, chapped lips, cheilitis, lip dry, skin exfoliation, skin fissures, xeroderma, and xerosis.
[4] Hyperkeratosis includes hyperkeratosis, palmoplantar keratoderma, and skin hypertrophy.

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Brinsupri [package insert]. Bridgewater, NJ: Insmed Incorporated; 2025.

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## Brensocatib (Brinsupri) Contraindications/Warnings/Precautions

**Contraindications**

- None per current labeling

**Warnings and Precautions**

- Dermatologic Adverse Reactions
  - Monitor for new conditions and refer to dermatologist if new findings noted
- Gingival and Periodontal Adverse Reactions
  - Routine dental hygiene and check-ups warranted
- Live Attenuated Vaccines
  - Avoid due to lack of data

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## Brensocatib (Brinsupri) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient data | Insufficient data | Safety/efficacy established in patients at least 12 years of age | No observed differences in safety/efficacy in geriatric patients compared to younger adults |

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Brinsupri [package insert]. Bridgewater, NJ: Insmed Incorporated; 2025.

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## Brensocatib (Brinsupri) Accessibility

**Pharmacy Availability**
- Amber Specialty Pharmacy
- Maxor Specialty Pharmacy
- PANTHERx Rare Pharmacy

**Patient Assistance**
- InLighten Patient Support Program

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Brinsupri [package insert]. Bridgewater, NJ: Insmed Incorporated; 2025.

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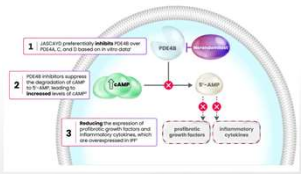
## (NER an DOE mi last)
## Nerandomilast (Jascayd) Overview

**Approval Date**
- 10/7/2025

**Indication**
- Treatment of idiopathic and/or progressive pulmonary fibrosis in adult patients

**Dosage**
- 9 – 18 mg orally twice daily with or without food

**Mechanism of Action**
- Inhibition of PDE4

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Jascayd [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; 2025.

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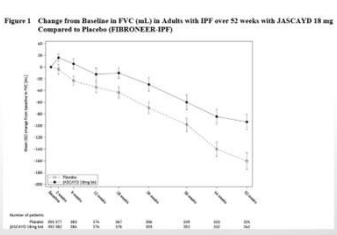
## Nerandomilast (Jascayd) Efficacy

**FIBRONEER-IPF (N = 1177 adults)**
- Absolute change from baseline in forced vital capacity at 52 weeks was less in both nerandomilast groups than placebo

**FIBRONEER-ILD (N = 1178 adults)**
- Absolute change from baseline in forced vital capacity at 52 weeks was less in both nerandomilast groups than placebo

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Jascayd [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; 2025.

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## Nerandomilast (Jascayd) Safety

**FIBRONEER-IPF**

- See table

**FIBRONEER-ILD**

- Most common adverse reactions in patients with PPF were consistent with those observed in patients with IPF

**Table 1 Adverse Reactions with JASCAYD with Incidence of ≥5% and More Common than Placebo in Patients[1] with IPF (FIBRONEER-IPF Trial)**

| | JASCAYD 18 mg BID n=392 | JASCAYD 9 mg BID n=392 | Placebo n=393 |
|---|---|---|---|
| Diarrhea | 42% | 31% | 17% |
| COVID-19 | 13% | 16% | 12% |
| Upper respiratory tract infection | 13% | 11% | 10% |
| Depression[2] | 12% | 11% | 10% |
| Weight decreased | 11% | 10% | 8% |
| Decreased appetite | 9% | 9% | 5% |
| Nausea | 8% | 9% | 7% |
| Fatigue | 7% | 8% | 6% |
| Headache | 7% | 6% | 5% |
| Vomiting | 6% | 5% | 5% |
| Back pain | 6% | 5% | 4% |
| Dizziness | 5% | 6% | 5% |

[1]Studied population including patients who received JASCAYD with or without background antifibrotic treatment (nintedanib or pirfenidone)
[2]Includes depression, depressed mood, depression rating scale score increased, suicidal ideation, adjustment disorder with depressed mood, depressive symptom
BID: twice daily; COVID-19: infection with SARS-CoV-2 virus

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Jascayd [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; 2025.

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## Nerandomilast (Jascayd) Contraindications/Warnings/Precautions

**Contraindications**

- None

**Warnings and Precautions**

- Nerandomilast must be swallowed whole or dispersed in water

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Jascayd [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; 2025.

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## Nerandomilast (Jascayd) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient data | Insufficient data | Insufficient data | No overall differences in safety or effectiveness of JASCAYD have been observed between patients 65 years of age and older and younger adult patients |

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Jascayd [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; 2025.

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## Nerandomilast (Jascayd) Accessibility

**Pharmacy Availability**

- Accredo Specialty Pharmacy
- Walgreens Specialty Pharmacy
- CenterWell Specialty Pharmacy
- CVS Specialty Pharmacy
- OPTUM Specialty Pharmacy
- Orsini Healthcare

**Patient Assistance**

- JASCAYD Bridge Program
- JASCAYD Copay Program



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Jascayd [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; 2025.

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## Etripamil (Cardamyst) Overview

**Approval Date**
- 12/12/2025

**Indication**
- Conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults

**Dosage**
- 35 mg of etripamil in each nostril – may repeat in 10 minutes if persistent symptoms

**Mechanism of Action**
- Inhibition of L-type calcium channels




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Cardamyst [package insert]. Charlotte, NC: Milestone Pharmaceuticals USA; 2025.

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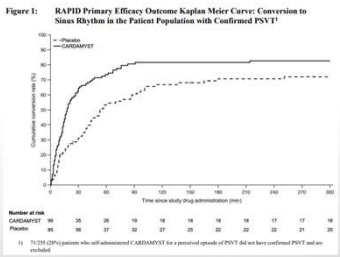
## Etripamil (Cardamyst) Efficacy

**RAPID Trial (N = 692 adults)**

- Conversion of confirmed PSVT within 30 minutes was 64% compared to 31% with placebo
- Median time to conversion was 17.2 minutes with etripamil (vs. 53.5 minutes with placebo)
- Findings consistent across major subgroups



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Cardamyst [package insert]. Charlotte, NC: Milestone Pharmaceuticals USA; 2025.

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## Etripamil (Cardamyst) Safety

**Pooled Data (4 total trials, 321 patients)**

- Hypotension w/ syncope (0.4%)
- Other adverse reactions related to local reactions

**Table 1: Most frequent (≥5.0%) Adverse Reactions[1] Observed in Randomized Controlled Studies**

| | Placebo N=223 % | CARDAMYST 70 mg N=235 % | CARDAMYST 2x70 mg[2] N=86 % |
|---|---|---|---|
| Nasal Discomfort | 6 | 28 | 23 |
| Nasal Congestion | 1 | 14 | 12 |
| Rhinorrhea | 2 | 12 | 10 |
| Throat Irritation | 1 | 7 | 6 |
| Epistaxis | 1 | 6 | 7 |

1) Adverse reactions that occurred within 24 hours of study drug administration (TEAE24h) for perceived PSVT in the double-blind, placebo-controlled studies, NODE-1, NODE-301 Part 1, RAPID and RAPID Extension that had an overall incidence of 5% or greater and where the incidence is at least 1% greater than the placebo group.
2) 2x70 mg: first administration of etripamil 70 mg followed by a second dose of etripamil 70 mg 10 minutes later if symptoms persisted.

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Cardamyst [package insert]. Charlotte, NC: Milestone Pharmaceuticals USA; 2025.

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## Etripamil (Cardamyst) Contraindications/Warnings/Precautions

**Contraindications**

- Hypersensitivity to Cardamyst or any of its components
- New York Heart Association Class II to IV Heart Failure
- Wolff-Parkinson-White (WPW), Lown-Ganong-Levine (LGL) syndromes, or manifest pre-excitation (delta wave) on a 12-lead electrocardiogram (ECG)
- Sick sinus syndrome without a permanent pacemaker
- Second degree atrioventricular (AV) Mobitz 2 block or higher degree of AV block

**Warnings and Precautions**

- Patients with a history of hypotensive episodes or those at increased risk for hemodynamic instability should be monitored appropriately when initiating
- If syncope occurs, patients should be placed in the recumbent position and treated supportively
- Administer in a sitting position in a location where the fall risk is minimal when possible

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BON SECOURS MERCY HEALTH

Cardamyst [package insert]. Charlotte, NC: Milestone Pharmaceuticals USA; 2025.

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## Etripamil (Cardamyst) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient data | Insufficient data (verapamil is present in breast milk and is structurally related) | Insufficient data | No meaningful differences in safety or effectiveness were observed between elderly patients and younger groups |

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Cardamyst [package insert]. Charlotte, NC: Milestone Pharmaceuticals USA; 2025.

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## Etripamil (Cardamyst) Accessibility

**Pharmacy Availability**
- Any pharmacy who can procure it

**Patient Assistance**
- CARDAMYST Copay Savings Program
- Nurse Educator Support Program for administration support


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Cardamyst [package insert]. Charlotte, NC: Milestone Pharmaceuticals USA; 2025.

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## (LER oh DAL si bep)
## Lerodalcibep-liga (Lerochol) Overview

**Approval Date**
- 12/12/2025

**Indication**
- To reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH)

**Dosage**
- 300 mg subcutaneously once monthly

**Mechanism of Action**
- Inhibition of proprotein convertase subtilisin kexin type 9 (PCSK9)

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BON SECOURS MERCY HEALTH

Lerochol [package insert]. Cincinnati, OH: Ide Therapeutics Inc; 2025.

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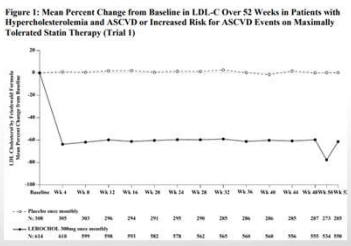
## Lerodalcibep-liga (Lerochol) Efficacy

**Trial 1(N = 922)**
- Percentage decrease in LDL-C at 52 weeks was 55% (compared to 0.1% in placebo group)

**Trial 3(N = 478)**
- Percentage decrease in LDL-C at 24 weeks was 51% (compared to an 8% increase in placebo group)

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Lerochol [package insert]. Cincinnati, OH: Ide Therapeutics Inc; 2025.

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## Lerodalcibep-liga (Lerochol) Safety

**Pooled Trials 1&2**

- Very minimal adverse events noted

**Trial 3**

- Similar as pooled Trials 1&2 with additional GI adverse effects

**Table 1: Adverse Reactions Occurring in ≥2% of LEROCHOL-treated Patients with Hypercholesterolemia and > 1% More Frequently than Placebo-treated Patients in Two Pooled 52-Week Trials (Trials 1 and 2)**

| Adverse Reaction* | LEROCHOL 300 mg (N=1,229) % | Placebo (N=612) % |
|---|---|---|
| Nasopharyngitis | 15 | 14 |
| Injection site reactions | 12 | 5 |
| Peripheral edema | 2 | <1 |

* Grouped terms composed of several similar terms

**Table 2: Adverse Reactions Occurring in ≥2% LEROCHOL-treated Patients with HeFH and >1% More Frequently than Placebo-treated Patients at 24 Weeks (Trial 3)**

| Adverse Reaction | LEROCHOL 300 mg (N=318) % | Placebo (N=159) % |
|---|---|---|
| Injection site reactions* | 18 | 3 |
| Nasopharyngitis* | 13 | 9 |
| Diarrhea | 3 | 1 |
| Nausea | 2 | 0 |
| Peripheral edema* | 2 | <1 |

* Grouped terms composed of several similar terms

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lerochol [package insert]. Cincinnati, OH: Lib Therapeutics Inc; 2025.

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## Lerodalcibep-liga (Lerochol) Contraindications/Warnings/Precautions

**Contraindications**

- None

**Warnings and Precautions**

- As with all therapeutic proteins, there is potential for immunogenicity

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lerochol [package insert]. Cincinnati, OH: Lib Therapeutics Inc; 2025.

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## Lerodalcibep-liga (Lerochol) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Discontinue when pregnancy is recognized | Insufficient data | Effectiveness was not demonstrated in 19 pediatric patients enrolled in an open label trial | No overall differences in safety or effectiveness were observed between patients 65 years of age and older and younger adult patients |

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lerochol [package insert]. Cincinnati, OH: Lib Therapeutics Inc; 2025.

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## Lerodalcibep-liga (Lerochol) Accessibility

| | |
|---|---|
| Pharmacy Availability | • Expected to be commercially available in Spring 2026 |
| Patient Assistance | • To be determined, nothing available as of yet |

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BON SECOURS MERCY HEALTH

lerochol [package insert]. Cincinnati, OH: Lib Therapeutics Inc; 2025.

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## (A fi KAM ten)
## Aficamten (Myqorzo) Overview

**Approval Date**
- 12/19/2025

**Indication**
- Treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms

**Dosage**
- Starting: 5 mg orally once daily

**Mechanism of Action**
- Allosterically and reversibly inhibits cardiac myosin motor activity reducing the force generated by myosin at the cardiac sarcomere, which contributes to hypertrophic cardiomyopathy (HCM) pathophysiology

**Table 1: Dose Adjustment of MYQORZO**

| LVEF | Valsalva LVOT-G | Dose Adjustment |
|---|---|---|
| ≥55% | ≥30 mmHg | Increase dose by 5 mg (up to the maximum dose of 20 mg once daily) |
| ≥55% | <30 mmHg | Maintain Dose |
| <55% and ≥50% | Any | Maintain Dose |
| <50% and ≥40% | Any | Decrease dose by 5 mg[1] If already on 5 mg, interrupt treatment for at least 7 days |
| <40% | Any | Interrupt treatment for at least 7 days |

1. Decrease dose as follows: 20 mg to 15 mg; 15 mg to 10 mg; 10 mg to 5 mg

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Myqorzo [package insert]. San Francisco, CA: Cytokinetics Incorporated; 2025.

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## Aficamten (Myqorzo) Efficacy

**SEQUOIA-HCM (N = 282)**
- Change in baseline peak VO2 was significantly higher in treatment arm (1.7) vs placebo (0) at 24 weeks
- See secondary outcomes

**FOREST-HCM (N = )**
- Ongoing, open-label, single-arm extension study available to patients who completed SEQUOIA-HCM

**Table 5. Results of Secondary Efficacy Endpoints in SEQUOIA-HCM**

| Endpoints | MYQORZO N=142 | Placebo N=140 | LS Mean Difference (95% CI) | p-Value |
|---|---|---|---|---|
| **Mean Change from Baseline in KCCQ-CSS[1,2]** | | | | |
| Week 12 | 11.1 (0.9) | 4.0 (0.9) | 7.0 (4.6, 9.5) | <0.0001 |
| Week 24 | 11.6 (1.0) | 4.3 (1.0) | 7.3 (4.6, 10.1) | <0.0001 |
| **Mean Change from Baseline in Valsalva LVOT-G (mmHg)[2]** | | | | |
| Week 12 | -45.0 (2.4) | 2.7 (2.4) | -47.7 (-54.5, -41.0) | <0.0001 |
| Week 24 | -46.7 (2.5) | 2.2 (2.5) | -48.8 (-55.7, -42.0) | <0.0001 |
| **Mean Duration of SRT Eligibility[1]** | | | | |
| Days spent SRT-eligible during 24 Weeks of Treatment | 35 (8) | 113 (8) | −78 (−100, −56) | <0.0001 |
| **Mean Change from Baseline in Total Workload (Watts) during CPET[1]** | | | | |
| Week 24 | 13.1 (2.1) | 0.9 (2.2) | 12.2 (6.3, 18.1) | <0.0001 |
| **Endpoints** | **MYQORZO N=142** | **Placebo N=140** | **Odds Ratio (95% CI)** | **p-Value** |
| **Proportion of Patients with ≥1 NYHA Class Improvement[2]** | | | | |
| Week 12 | 69 (48.6) | 25 (17.9) | OR: 4.6 (2.6, 8.4) | <0.0001 |
| Week 24 | 83 (58.5) | 34 (24.3) | OR: 4.4 (2.6, 7.6) | <0.0001 |
| **Proportion of Patients with Valsalva LVOT-G <30 (mmHg)[2]** | | | | |
| Week 12 | 73 (51.4) | 8 (5.7) | OR: 16.9 (7.7, 37.2) | <0.0001 |
| Week 24 | 70 (49.3) | 5 (3.6) | OR: 22.9 (8.8, 59.6) | <0.0001 |

CPET: Cardiac Pulmonary Exercise Test; KCCQ CSS: Kansas City Cardiomyopathy Questionnaire – Clinical Summary Score; NYHA: New York Heart Association; LVOT-G: left ventricular outflow tract gradient; SRT: septal reduction therapy.

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Myqorzo [package insert]. San Francisco, CA: Cytokinetics Incorporated; 2025.

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## Aficamten (Myqorzo) Safety

**SEQUOIA-HCM**

- Hypertension (8% vs. 2%) was the only adverse reaction occurring in > 5% of patients and more commonly on aficamten than on placebo
- Reduction in LVEF (reversible)

**WARNING: RISK OF HEART FAILURE**

MYQORZO reduces left ventricular ejection fraction (LVEF) and can cause heart failure due to systolic dysfunction *[see Warnings and Precautions (5.1)]*.

Echocardiogram assessments are required prior to and during treatment with MYQORZO to monitor for systolic dysfunction. Initiation of MYQORZO in patients with LVEF <55% is not recommended. Decrease the dose of MYQORZO if LVEF is <50% and ≥40% *[see Dosage and Administration (2.2) and Warnings and Precautions (5.1)]*. Interrupt the dose of MYQORZO if LVEF <40% or if the patient experiences heart failure symptoms or worsening clinical status due to systolic dysfunction *[see Dosage and Administration (2.2)]*.

Because of the risk of heart failure due to systolic dysfunction, MYQORZO is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MYQORZO REMS Program *[see Warnings and Precautions (5.2)]*.

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Myqorzo [package insert]. San Francisco, CA: Cytokinetics Incorporated; 2025.

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## Aficamten (Myqorzo) Contraindications/Warnings/Precautions

**Contraindications**

- Concurrent use of rifampin

**Warnings and Precautions**

- New-Onset Heart Failure/Avoid in LV dysfunction
- REMS Program
- CYP P450 Interactions leading to toxicity/loss of effectiveness

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Myqorzo [package insert]. San Francisco, CA: Cytokinetics Incorporated; 2025.

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## Aficamten (Myqorzo) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient data currently<br>Ongoing safety study | Insufficient data | Insufficient data | No overall differences in safety or effectiveness have been observed between patients 65 years of age and older and younger adult patients |

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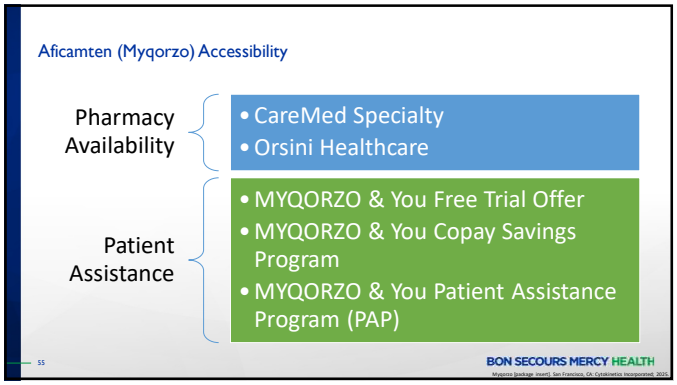
Aficamten (Myqorzo) Accessibility
Pharmacy Availability
• CareMed Specialty
• Orsini Healthcare
Patient Assistance
• MYQORZO & You Free Trial Offer
• MYQORZO & You Copay Savings Program
• MYQORZO & You Patient Assistance Program (PAP)
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Infectious Diseases
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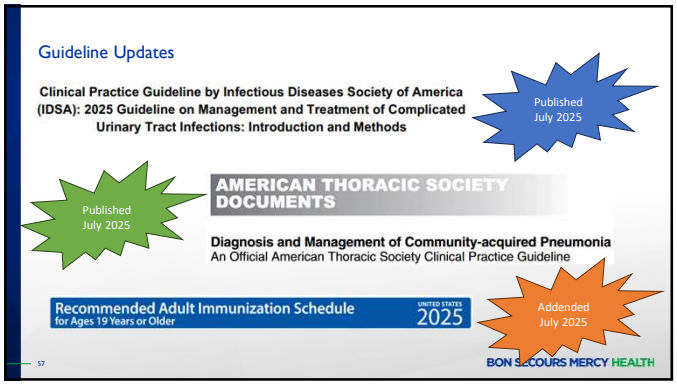
Guideline Updates
Clinical Practice Guideline by Infectious Diseases Society of America (IDSA): 2025 Guideline on Management and Treatment of Complicated Urinary Tract Infections: Introduction and Methods
Published July 2025
Published July 2025
AMERICAN THORACIC SOCIETY DOCUMENTS
Diagnosis and Management of Community-acquired Pneumonia
An Official American Thoracic Society Clinical Practice Guideline
Recommended Adult Immunization Schedule for Ages 19 Years or Older
UNITED STATES 2025
Addended July 2025
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## Complicated Urinary Tract Infections Guideline Highlights

### New classifications of uUTI and cUTI

**Old Classifications**

**Uncomplicated UTI:** Acute cystitis in afebrile nonpregnant premenopausal women with no diabetes and no urologic abnormalities

**Acute Pyelonephritis:** Acute kidney infection in women otherwise meeting the definition of uncomplicated UTI above

**Complicated UTI:** All other UTIs

**New Classifications**

**Uncomplicated UTI: Infection confined to the bladder** in afebrile women or men

**Complicated UTI: infection beyond the bladder** in women or men
- Pyelonephritis
- Febrile or bacteremic UTI
- Catheter-associated (CAUTI)
- Prostatitis* (*not covered by these guidelines)



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Trautner BW. Clin Infect Dis. Published online December 20, 2025.

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## Complicated Urinary Tract Infections Guideline Highlights

**Table 1.1: Potential Empiric Antibiotics for cUTI^ prior to using the four-step approach to choose among these options**

**Four-Step Approach** to choose among these antibiotics: Assess (1) severity of illness, (2) risk factors for resistance, (3) patient-specific considerations, and (4) if septic, consider the antibiogram. See discussion below for details of the four steps.

| Condition of the Patient | Preferred | Alternative |
|---|---|---|
| Sepsis with or without shock** | Third or fourth generation cephalosporins,* carbapenems,# piperacillin-tazobactam, fluoroquinolones[&] | Novel beta lactam-beta lactamase inhibitors,* cefiderocol, plazomicin, or older aminoglycosides[%] |
| Without sepsis, IV route of therapy | Third or fourth generation cephalosporins,* piperacillin-tazobactam, or fluoroquinolones[&] | Carbapenems,# newer agents (novel beta lactams-beta lactamase inhibitors,* cefiderocol, plazomicin), or older aminoglycosides[%] |
| Without sepsis, oral route of therapy | Fluoroquinolones[&] or trimethoprim-sulfamethoxazole | Amoxicillin-clavulanate or oral cephalosporins (see **Table 3.1**) |



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Trautner BW. Clin Infect Dis. Published online December 20, 2025.

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## Complicated Urinary Tract Infections Guideline Highlights

**Table 1.2: Dosing of oral antibiotics for complicated UTI (in alphabetical order)**

| Drugs | Oral absorption (%) | Urinary excretion (%) | Dose for patients with normal renal function |
|---|---|---|---|
| Amoxicillin-clavulanate | 80 (amoxicillin)[47] variable (clavulanate)[47] | 50-70 (amoxicillin)[47] 25-40% (clavulanate)[47] | 875mg-125mg every 8 to 12 hours[13,19,24,41,42] Other regimens may be more effective* |
| Cefixime | 50[48] | 50[48] | 400mg once daily* |
| Cefpodoxime | 50[48] | 80[48] | 200mg to 400mg every 12 hours[39,44,47] |
| Ceftibuten | 75-90[48] | 73[48] | 9mg/kg daily (children) [%] 400mg daily or 200mg every 12 hours (adults)[48,49] |
| Cefuroxime | 52[48,50] | 90[48,50] | 500mg every 12 hours[48,51] |
| Cephalexin | 90[48] | 90[48] | 500mg to 1000mg every 6 hours[13,19,23,24,41,42] Other regimens may be more effective* |

| | | | |
|---|---|---|---|
| Ciprofloxacin | 70[51] | 40-50[51] | 500mg to 750mg every 12 hours[20,28,34,38,54] |
| Levofloxacin | 99[51] | 64-100[51] | 500mg to 750mg daily[20,47,54,56] |
| Other oral beta-lactams (e.g. amoxicillin, cefadroxil, cefaclor, cefdinir) | Comparative clinical outcomes data vs highly bioavailable oral alternatives are more limited and/or discouraging; consider use with infectious disease pharmacist consultation if alternatives are not available. | | |
| Trimethoprim-sulfamethoxazole | 70-90[51] | 84 (sulfamethoxazole), 66 (trimethoprim)[47] | 800mg-160mg every 12 hours[34,38] |

*Despite routine use of optimized dosing, the majority of studies comparing switch to oral beta-lactams versus fluoroquinolones or trimethoprim-sulfamethoxazole for cUTI have found inferior outcomes with oral beta-lactams when amoxicillin-clavulanate or cephalexin were the predominant oral beta-lactams being used.

%Ceftibuten is the sole oral beta-lactam in this table with modern randomized, controlled trial data for cUTI in both children in adults; however, while it produced comparable clinical outcomes versus trimethoprim-sulfamethoxazole in children, in adults relapses were higher with ceftibuten versus norfloxacin.



BON SECOURS MERCY HEALTH

Trautner BW. Clin Infect Dis. Published online December 20, 2025.

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## ATS CAP Guideline Highlights

**Contents**





BON SECOURS MERCY HEALTH

Jones BE. Am J Respir Crit Care Med. Published online July 18, 2019.

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## ATS CAP Guideline Highlights

| | |
|---|---|
| Empiric antibiotics for CAP patients with positive viral infection | Outpatient + no comorbidities = no antibiotics |
| | Outpatient + comorbidities = antibiotics |
| | Inpatient + non-severe CAP = antibiotics |
| | Inpatient + severe CAP = antibiotics |



BON SECOURS MERCY HEALTH

Jones BE. Am J Respir Crit Care Med. Published online July 18, 2019.

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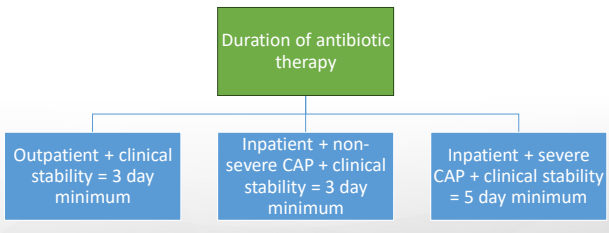
## ATS CAP Guideline Highlights



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Jones BE. Am J Respir Crit Care Med. Published online July 18, 2019.

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## ATS CAP Guideline Highlights

Use of corticosteroids in inpatient CAP management

- Non-severe CAP = not recommended
- Severe CAP = recommended

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Jones BE. Am J Respir Crit Care Med. Published online July 18, 2025.

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## CDC Vaccine Schedule Addendums

| Vaccines | Recommendations | Effective Date of Recommendation* |
|---|---|---|
| Meningococcal (MenACWY-CRM/MenB-4C, Penmenvy) | MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit in:<br>1. healthy persons aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccine and<br>2. persons aged > 10 years who are at increased risk for meningococcal disease (e.g., because of persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia). | June 25, 2025 |
| RSV (Abrysvo, Arexvy, mResvia) | Adults 50–59 years of age who are at increased risk of severe RSV disease[a] may receive a single dose of RSV vaccine[a][c].<br>a. CDC will publish Clinical Considerations that describe chronic medical conditions and other risk factors for severe RSV disease for use in this risk-based recommendation.<br>b. At this time, RSV vaccination is recommended as a single dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.<br>c. RSV vaccine can be administered with any product licensed in this age group. As of March 27, 2025, that includes GSK's Arexvy and Pfizer's Abrysvo. There is no preferential recommendation for any licensed product over another. | June 25, 2025 |
| Influenza | ACIP reaffirms the recommendations for routine annual influenza vaccination of all persons aged > 6 months who do not have contraindications for the 2025–2026 season | July 22, 2025 |
| Influenza | ACIP recommends only single-dose formulations of annual influenza vaccines that are free of thimerosal as a preservative for three populations:<br>- Children 18 years or younger<br>- Pregnant women<br>- All adults | July 22, 2025 |

**Note:** As of May 29, 2025, the schedule incorporates the HHS directive regarding COVID-19 vaccine recommendations. (Changes were made to tables and notes for COVID-19 vaccines in pregnant women).

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www.cdc.gov/vaccines/hcp/imz-schedules/app.html. Accessed 2/9/2026.

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## Novel Infectious Diseases Drug Approvals Overview

**Gepotidacin**

- uUTI and uncomplicated urogenital gonorrhea

**Zoliflodacin**

- Uncomplicated urogenital gonorrhea

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BON SECOURS MERCY HEALTH

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(JEP oh ti DAY sin)

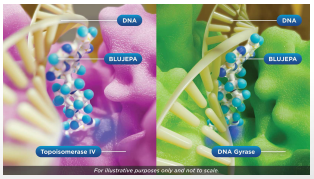
## Gepotidacin (Blujepa) Overview

**Approval Date**
- 3/25/2025

**Indications**
- Uncomplicated UTIs in females at least 12 years of age weighing at least 40 kg
- Uncomplicated urogenital gonorrhea in patients at least 12 years of age weighing at least 45 kg

**Dosage**
- uUTI: 1500 mg orally twice daily for 5 days
- Gonorrhea: 3000 mg orally every 12 hours x 2 doses

**Mechanism of Action**
- Bacterial type II & IV topoisomerase inhibition

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Blujepa [package insert]. Durham, NC: GlaxoSmithKline; 2025.

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## Gepotidacin (Blujepa) Efficacy

**uUTI Trials 1&2 (N = 3136)**
- When compared to nitrofurantoin, gepotidacin was non-inferior regarding both clinical and microbiological cure

**Gonorrhea Trial (N = 628)**
- When compared to IM ceftriaxone 500 mg + PO azithromycin 1000 mg, gepotidacin was non-inferior regarding microbiological cure

**Table 6. Composite Response Rates at the Test-of-Cure Visit by Baseline Uropathogen (Trial 1 and Trial 2 Pooled; Micro-ITTS Population)[a]**

| Pathogen[b] | BLUJEPA[a] n/N (%) | Nitrofurantoin[a] n/N (%) |
|---|---|---|
| *Escherichia coli* | 312/566 (55.1) | 234/520 (45.0) |
| *Klebsiella pneumoniae* | 6/14 (42.9) | 6/16 (37.5) |
| *Staphylococcus saprophyticus* | 9/15 (60.0) | 11/14 (78.6) |
| *Enterococcus faecalis* | 8/14 (57.1) | 2/7 (28.6) |
| *Citrobacter freundii* complex | 8/12 (66.7) | 2/5 (40.0) |

micro-ITTS = microbiological Intent to Treat nitrofurantoin-susceptible

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Blujepa [package insert]. Durham, NC: GlaxoSmithKline; 2025.

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## Gepotidacin (Blujepa) Safety

**uUTI Trials 1&2**
- See table

**Gonorrhea Trial**
- Similar to uUTI trials, although the higher dosing seemed to contributed to higher frequency of adverse events

**Table 1. Adverse Reactions Occurring in ≥1% of Uncomplicated Urinary Tract Infection Patients Treated with BLUJEPA (Trials 1 and 2 Pooled Data; Safety Population)**

| Adverse Reaction | BLUJEPA N = 1,570 n (%) | Nitrofurantoin N = 1,558 n (%) |
|---|---|---|
| Diarrhea | 258 (16) | 51 (3) |
| Nausea | 146 (9) | 64 (4) |
| Abdominal pain[a] | 60 (4) | 34 (2) |
| Flatulence | 43 (3) | 8 (<1) |
| Headache | 38 (2) | 40 (3) |
| Soft feces | 37 (2) | 8 (<1) |
| Dizziness | 29 (2) | 19 (1) |
| Vomiting | 28 (2) | 10 (<1) |
| Vulvovaginal candidiasis | 20 (1) | 18 (1) |

[a] Abdominal pain includes abdominal pain, abdominal pain upper, abdominal pain lower, abdominal tenderness, abdominal discomfort, and gastrointestinal pain.

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BON SECOURS MERCY HEALTH

Blujepa [package insert]. Durham, NC: GlaxoSmithKline; 2025.

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## Gepotidacin (Blujepa) Contraindications/Warnings/Precautions

**Contraindications**

- A history of hypersensitivity to gepotidacin

**Warnings and Precautions**

- QTc prolongation
- Concomitant CYP3A4 inhibitors
- Severe renal impairment
- Acetylcholinesterase inhibition
- Hypersensitivity reactions
- *Clostridioides difficile* infection

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Blujepa [package insert]. Durham, NC: GlaxoSmithKline; 2025.

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## Gepotidacin (Blujepa) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient data<br>Pregnancy exposure registry established | Insufficient data | Safety established for both indications in patients ages 12 and up | No overall differences in safety or effectiveness were observed between patients 65 years of age and older and younger adult patients |

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BON SECOURS MERCY HEALTH

Blujepa [package insert]. Durham, NC: GlaxoSmithKline; 2025.

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## Gepotidacin (Blujepa) Accessibility

**Pharmacy Availability**

- No pharmacy restrictions noted

**Patient Assistance**

- BLUJEPA Coverage Finder Tool
- BLUJEPA Copay Assistance

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BON SECOURS MERCY HEALTH

Blujepa [package insert]. Durham, NC: GlaxoSmithKline; 2025.

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(ZOE li floe DAY sin)

## Zoliflodacin (Nuzolvence) Overview

**Approval Date**
- 12/12/2025

**Indication**
- Treatment of uncomplicated urogenital gonorrhea in patients 12 years of age or older weighing at least 35 kg

**Dosage**
- 3 g mixed with 60 mL water and taken orally once

**Mechanism of Action**
- Bacterial type II topoisomerase inhibiton

**ADMINISTRATION OF NUZOLVENCE (WITH OR WITHOUT FOOD BASED ON WEIGHT)**

| Dose of NUZOLVENCE | Body weight | Administration of NUZOLVENCE relative to the ingestion of food |
|---|---|---|
| 3 g administered as a single, oral dose | ≥35 kg to <50 kg | Take on empty stomach, 1 hour before or 2 hours after food |
| | ≥50 kg | Take with food |

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BON SECOURS MERCY HEALTH

Nuzolvence [package insert]. Waltham, MA: Entasis Therapeutics; 2025.

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## Zoliflodacin (Nuzolvence) Efficacy

### Trial 1(N = 930)

- Zoliflodacin was non-inferior to ceftriaxone + azithromycin regarding primary endpoint of microbiological cure rates at urogenital site

**Table 6: Microbiological Cure Rates at the Urogenital Site at TOC, Micro-ITT Urogenital Population**

| | NUZOLVENCE n/N (%) | Ceftriaxone and Azithromycin n/N (%) | Difference (95% CI)[c] |
|---|---|---|---|
| Microbiological Cure[b] | 460/506 (90.9) | 229/238 (96.2) | -5.3 (-8.7, -1.4) |
| Failure | 46/506 (9.1) | 9/238 (3.8) | |
| Bacterial Persistence by Culture | 15/506 (3.0) | 0 | |
| Nonassessable[d] | 31/506 (6.1) | 9/238 (3.8) | |

TOC = Test of Cure; micro-ITT = microbiological Intent to Treat; CI=confidence interval; n = number of patients in a subcategory; N = number of patients in the specified population.
[c] Calculated with the Newcombe score method for the NUZOLVENCE – (ceftriaxone and azithromycin) treatment difference
[b] Microbiological cure is defined as negative or indeterminate *Neisseria gonorrhoeae* (NG) culture at the urogenital site at the TOC visit. There were no indeterminate NG cultures at the urogenital site at TOC.
[d] Nonassessable outcomes were due to missed TOC visits, unobtainable specimens, or TOC visits out of window.

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BON SECOURS MERCY HEALTH

Nuzolvence [package insert]. Waltham, MA: Entasis Therapeutics; 2025.

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## Zoliflodacin (Nuzolvence) Safety

### Trial 1

- Mostly non-specific adverse effects that were comparable to control group

**Table 2: Adverse Reactions in ≥2% of Patients with Suspected Uncomplicated Gonorrhea Infection Treated with NUZOLVENCE in Trial 1[a] (Safety Population)**

| Adverse Reaction | NUZOLVENCE N = 619 n (%) | Ceftriaxone and Azithromycin N = 308 n (%) |
|---|---|---|
| Headache[b] | 61 (10) | 15 (5) |
| Dizziness | 21 (3) | 5 (2) |
| Nausea | 16 (3) | 12 (4) |
| Diarrhea | 15 (2) | 22 (7) |

N, total number of patients in treatment arm; n, number of patients meeting criteria.
[a] Trial 1 was not designed to evaluate meaningful comparisons of the incidence of adverse reactions in the NUZOLVENCE and the ceftriaxone and azithromycin treatment groups. The safety population includes patients with urogenital gonorrhea as well as those with uncomplicated gonorrhea infections at other body sites not covered under the approved indication.
[b] Headache includes tension headache and headache.

**Table 3: Laboratory Abnormalities in ≥2% of Patients with Suspected Uncomplicated Gonorrhea Infection Treated with NUZOLVENCE, with Normal Baseline Values in Trial 1[a] (Safety Population)**

| Laboratory Parameters | NUZOLVENCE N = 609 n (%) | Ceftriaxone and Azithromycin N = 304 n (%) |
|---|---|---|
| Neutropenia[b] | 71 (12) | 43 (14) |
| <1500 to 1000 cells/μL | 56 (9) | 31 (10) |
| <1000 to 500 cells/μL | 14 (2) | 12 (4) |
| <500 cells/μL | 1 (0.2) | 0 |

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BON SECOURS MERCY HEALTH

Nuzolvence [package insert]. Waltham, MA: Entasis Therapeutics; 2025.

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## Zoliflodacin (Nuzolvence) Contraindications/Warnings/Precautions

**Contraindications**

- Known history of hypersensitivity
- Moderate/strong CYP3A4 inducers

**Warnings and Precautions**

- Potential risk for pregnant females (based on rat studies)
  - Even if male partner treated and female partner is not (needs protection for 3 months following treatment)
- Hypersensitivity reactions
- *Clostridioides difficile* infection
- Development of drug-resistant bacteria

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BON SECOURS MERCY HEALTH

Nuzolvence [package insert]. Waltham, MA: Entasis Therapeutics; 2025.

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## Zoliflodacin (Nuzolvence) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient human data<br>Postmarketing study ongoing | Insufficient data | Safe and effective in patients 12 years of age and older | Clinical studies did not include enough patients aged 65 years and older to determine whether they respond differently than younger patients |

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BON SECOURS MERCY HEALTH

Nuzolvence [package insert]. Waltham, MA: Entasis Therapeutics; 2025.

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## Zoliflodacin (Nuzolvence) Accessibility

| | |
|---|---|
| Pharmacy Availability | • Anticipated in the second half of 2026 |
| Patient Assistance | • None currently on website |

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Nuzolvence [package insert]. Waltham, MA: Entasis Therapeutics; 2025.

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# Ophthalmological Agents

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BON SECOURS MERCY HEALTH

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## Novel Ophthalmological Agent Drug Approvals Overview

**Acoltremon**
- Dry eyes

**Aceclidine**
- Presbyopia

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BON SECOURS MERCY HEALTH

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## Acoltremon (Tryptyr) Overview

**Approval Date**
- 5/28/2025

**Indication**
- Treatment of dry eye disease

**Dosage**
- Apply one drop in each eye twice

**Mechanism of Action**
- Agonism of transient receptor potential melastatin 8 (TRPM8) thermoreceptors, stimulating natural tear production

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BON SECOURS MERCY HEALTH

Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories; 2025.

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## Acoltremon (Tryptyr) Efficacy

**COMET-2 (N = 465)**

- Primary outcome was ≥ 10 mm increase in tear production at Day 14

**COMET-3 (N = 466)**

- Primary outcome was ≥ 10 mm increase in tear production at Day 14

Table 1: Percent of Patients Achieving ≥ 10 mm Improvement from Baseline in Schirmer Score at Day 14 in Patients with Dry Eye Disease

| | Tear Production | | | |
|---|---|---|---|---|
| | COMET-2 | | COMET-3 | |
| | TRYPTYR N = 230 | Vehicle N = 235 | TRYPTYR N = 232 | Vehicle N = 234 |
| ≥ 10 mm increase in tear production at Day 14 | 42.6% | 8.2% | 53.2% | 14.4% |
| Difference (95% CI) | 34.4% (26.9, 42.0) | | 38.8% (30.8, 46.8) | |
| P-value versus vehicle | < 0.01 | | < 0.01 | |

Consistent results were observed at all timepoints through Day 90.

COMET-2 also met significance for symptomatic improvement at day 28, while COMET-3 did not



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Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories; 2025.

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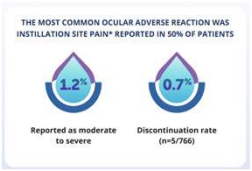
## Acoltremon (Tryptyr) Safety

**COMET-2 and COMET-3 Trials**

- Instillation site pain occurred in 50% of patients
- < 1% of patients discontinued therapy due to burning or stinging in the eyes







BON SECOURS MERCY HEALTH

Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories; 2025.

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## Acoltremon (Tryptyr) Contraindications/Warnings/Precautions

**Contraindications**

- None

**Warnings and Precautions**

- Potential for eye injury and contamination
  - Do not touch the vial tip to the eye or other surfaces
- Use with contact lenses
  - Lenses should be removed prior to the administration and remain out at least 15 minutes after application



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Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories; 2025.

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## Acoltremon (Tryptyr) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient data, but likely safe | Insufficient data, but likely safe | Insufficient data | No clinically relevant differences in safety have been observed between elderly and younger patients |

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BON SECOURS MERCY HEALTH

Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories; 2025.

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## Acoltremon (Tryptyr) Accessibility

**Pharmacy Availability**
- Available at retail pharmacies

**Patient Assistance**
- First fill free through BlinkRx
  - Also will determine Copay and streamline prior authorizations
- TRYPTYR Copay Assistance

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BON SECOURS MERCY HEALTH

Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories; 2025.

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(a SEK li deen)

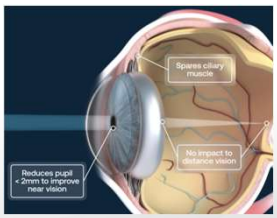
## Aceclidine (Vizz) Overview

**Approval Date**
- 7/31/2025

**Indication**
- Treatment of presbyopia in adults

**Dosage**
- Instill one drop in each eye, wait 2 minutes and instill a second drop in each eye once daily

**Mechanism of Action**
- Stimulating muscarinic receptors located on smooth muscles, causing contraction of the iris sphincter muscle, resulting in a pinhole effect that extends depth of focus to improve vision

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BON SECOURS MERCY HEALTH

Vizz [package insert]. Solana Beach, CA: LENZ Therapeutics Inc; 2025.

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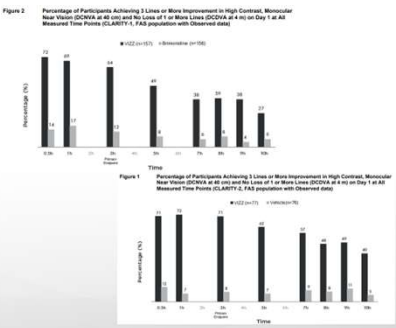
## Aceclidine (Vizz) Efficacy

**CLARITY-1 (N = 313)**

- Active comparator (brimonidine)

**CLARITY-2 (N = 153)**

- Placebo comparator





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BON SECOURS MERCY HEALTH

Vizz [package insert]. Solana Beach, CA: LENZ Therapeutics Inc; 2025.

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## Aceclidine (Vizz) Safety

**CLARITY 1-2**

- Short-term safety (42 days)

**CLARITY 3**

- Long-term safety (6 months)

| Adverse Reaction | Frequency |
|---|---|
| Instillation site irritation | 20% |
| Dim vision | 16% |
| Headache | 13% |
| Conjunctival hyperemia | 8% |
| Ocular hyperemia | 7% |

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BON SECOURS MERCY HEALTH

Vizz [package insert]. Solana Beach, CA: LENZ Therapeutics Inc; 2025.

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## Aceclidine (Vizz) Contraindications/Warnings/Precautions

**Contraindications**

- None

**Warnings and Precautions**

- Blurred vision (transient)
- Risk of retinal tear/detachment
- Iritis
- Hypersensitivity
- Contact lenses
  - Remove and replace 10 minutes after instillation
- Potential for eye injury or contamination

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BON SECOURS MERCY HEALTH

Vizz [package insert]. Solana Beach, CA: LENZ Therapeutics Inc; 2025.

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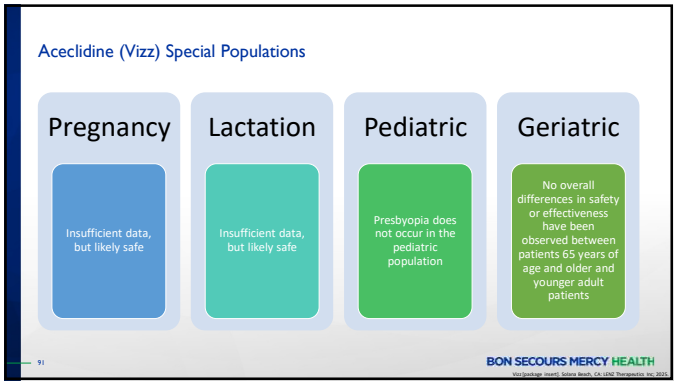
Aceclidine (Vizz) Special Populations
Pregnancy
Insufficient data, but likely safe
Lactation
Insufficient data, but likely safe
Pediatric
Presbyopia does not occur in the pediatric population
Geriatric
No overall differences in safety or effectiveness have been observed between patients 65 years of age and older and younger adult patients
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BON SECOURS MERCY HEALTH

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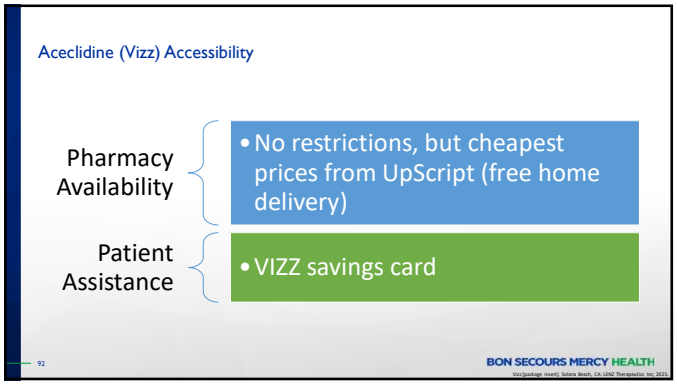
Aceclidine (Vizz) Accessibility
Pharmacy Availability
• No restrictions, but cheapest prices from UpScript (free home delivery)
Patient Assistance
• VIZZ savings card
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BON SECOURS MERCY HEALTH

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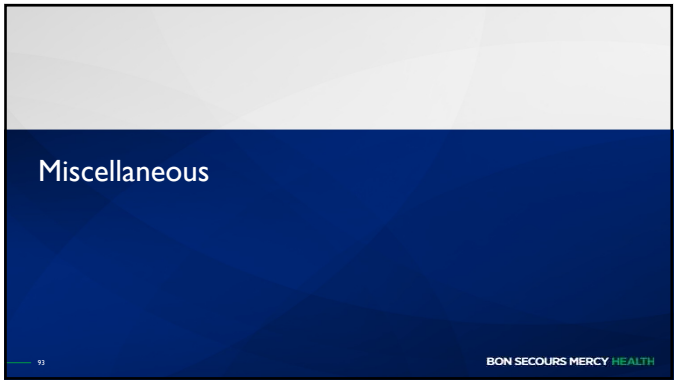
Miscellaneous
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BON SECOURS MERCY HEALTH

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## Novel Miscellaneous Drug Approvals Overview

**Atrasentan**
- IgA nephropathy proteinuria

**Delgocitinib**
- Chronic hand eczema

**Elinzanetant**
- Vasomotor symptoms associated with menopause

**Tradipitant**
- Vomiting associated with motion

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BON SECOURS MERCY HEALTH

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## (a TREH iss uhn tuhn) Atrasentan (Vanrafia) Overview

**Approval Date**
- 4/2/2025

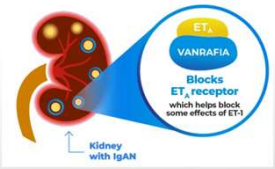
**Indication**
- Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression

**Dosage**
- 0.75 mg orally once daily with or without food

**Mechanism of Action**
- Blocks the activation of endothelin-A receptors (ETAR) by endothelin (ET)-1

**VANRAFIA in action**

By blocking the $ET_A$ receptor, VANRAFIA is thought to block some effects of ET-1 in IgAN.

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BON SECOURS MERCY HEALTH

Vanrafia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2025.

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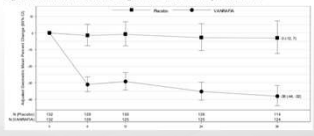
## Atrasentan (Vanrafia) Efficacy

**ALIGN Trial (N = 404)**
- Primary Endpoint was % reduction in urine protein-to-creatinine ratio (UPCR) at 36 weeks

**Table 2: Percent Reduction in UPCR at Week 36 Relative to Baseline in ALIGN**

| | VANRAFIA on top of supportive care[a] (N = 135) | Placebo on top of supportive care[a] (N = 125) |
|---|---|---|
| % Reduction in UPCR (95% CI) at Week 36 relative to baseline[b,c] | 38% (32%, 44%) | 3 % (-7%, 12%) |
| VANRAFIA versus placebo: % reduction in UPCR (95% CI) at Week 36 relative to baseline compared on a relative scale[c,d] | 36% (26%, 45%) | |
| p-value[e] | | < 0.0001 |

**Figure 1: Geometric Mean Percent Change from Baseline in UPCR by Visit in ALIGN**

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BON SECOURS MERCY HEALTH

Vanrafia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2025.

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## Atrasentan (Vanrafia) Safety

### ALIGN Trial

- Median duration of treatment was 47 weeks (range 0 – 128 weeks)
- Adverse Reactions
  - Peripheral Edema
  - Anemia
  - LFT Elevation
  - Hgb Decrease
  - Blood Pressure Decrease

**WARNING: EMBRYO-FETAL TOXICITY**

***See full prescribing information for complete boxed warning.***

- **VANRAFIA may cause major birth defects if used during pregnancy (4.1, 5.1, 8.1)**
- **Exclude pregnancy before start of treatment. (2.1, 4.1, 5.1, 8.3)**
- **Use effective contraception before start of treatment, during treatment and two weeks after treatment. (4.1, 5.1, 8.3)**
- **Discontinue VANRAFIA if pregnancy occurs. (4.1, 5.1)**

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BON SECOURS MERCY HEALTH

Vanrafia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2025.

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## Atrasentan (Vanrafia) Contraindications/Warnings/Precautions

### Contraindications

- Pregnancy
- Hypersensitivity

### Warnings and Precautions

- Embryo-Fetal Toxicity
  - Contraception prior to, during, and 2 weeks following the discontinuation of atrasentan
- Hepatotoxicity
- Fluid Retention
- Decreased sperm counts
  - Return to normal within 3 months following discontinuation

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BON SECOURS MERCY HEALTH

Vanrafia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2025.

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## Atrasentan (Vanrafia) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Contraindicated (based on animal data) | Contraindicated | Insufficient data | No overall differences in safety and effectiveness were observed between these patients and younger patients |

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BON SECOURS MERCY HEALTH

Vanrafia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2025.

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## Atrasentan (Vanrafia) Accessibility

**Pharmacy Availability**
- CareMed Specialty
- Biologics (by McKesson)

**Patient Assistance**
- VANRAFIA Co-Pay Plus
- VANRAFIA Medicare Extra Help

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BON SECOURS MERCY HEALTH

Vanrafia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2025.

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## Delgocitinib (Anzupgo) Overview

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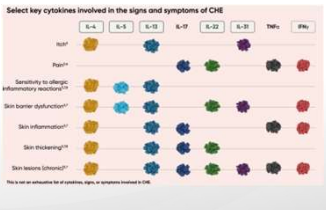
**Approval Date**
- 7/23/2025

**Indication**
- Topical treatment of moderate to severe chronic hand eczema in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable

**Dosage**
- Apply twice daily to the affected skin on the hands and wrist

**Mechanism of Action**
- Janus kinase (JAK) inhibitor, inhibits the activity of JAK1, JAK2, JAK3, and tyrosine kinase 2 (TYK2)

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BON SECOURS MERCY HEALTH

Anzupgo [package insert]. Madison, NJ: Madison, NJ; 2025.

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## Delgocitinib (Anzupgo) Efficacy

**Trial 1 (N = 487)**
- Vehicle controlled
- Primary outcome centered around visual response
- Secondary outcomes regarding itch and pain

**Trial 2 (N = 472)**
- Same as Trial 1

**Table 1: Efficacy Results of ANZUPGO in Adults with Moderate to Severe CHE at Week 16 in TRIAL 1 and TRIAL 2**

| | TRIAL 1 | | TRIAL 2 | |
|---|---|---|---|---|
| | ANZUPGO (N=325) | Vehicle (N=162) | ANZUPGO (N=313) | Vehicle (N=159) |
| IGA-CHE TS, % responders[a, b] | 20% (64/325) | 10% (16/162) | 29% (91/313) | 7% (11/159) |
| Difference from Vehicle (95% CI) | 10% (4%, 16%) | | 22% (16%, 29%) | |
| HESD itch ≥ 4-point improvement, % responders[a, c] | 47% (152/323) | 23% (37/161) | 47% (146/309) | 20% (31/156) |
| Difference from Vehicle (95% CI) | 24% (16%, 33%) | | 27% (19%, 36%) | |
| HESD pain ≥ 4-point improvement, % responders[a, c] | 49% (143/291) | 28% (41/149) | 49% (143/294) | 23% (32/141) |
| Difference from Vehicle (95% CI) | 22% (12%, 31%) | | 26% (17%, 35%) | |

Abbreviations: N=number of subjects in the full analysis set (all subjects randomized and dosed);
a. Data after initiation of rescue treatment, permanent discontinuation of treatment, or missing data were considered non-response.
b. IGA-CHE treatment success (IGA-CHE TS) was defined as a score of 0 (clear) or 1 (almost clear) with at least a 2-point improvement from baseline.
c. Based on the number of subjects whose weekly average baseline value was ≥ 4 (scale from 0-10).

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BON SECOURS MERCY HEALTH

Anzupgo [package insert]. Madison, NJ: Madison, NJ; 2025.

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## Delgocitinib (Anzupgo) Safety

**Trials 1 & 2**

- Rare adverse reactions (< 1% of the time)
- Application site pain
- Paresthesia
- Pruritus
- Erythema
- Bacterial skin infections

**LOW RATES OF DISCONTINUATION DUE TO AEs[4]**

ANZUPGO vs cream vehicle
- 0.5% vs 3.4%

**LOW RATES OF APPLICATION SITE PARESTHESIA (EG, STINGING AND BURNING) AND PAIN[4]**

ANZUPGO vs cream vehicle
- Paresthesia: 0.5% vs 0.6%
- Pain: 0.6% vs 0.6%

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BON SECOURS MERCY HEALTH

Anzupgo [package insert]. Madison, NJ: Madison, NJ; 2025.

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## Delgocitinib (Anzupgo) Contraindications/Warnings/Precautions

**Contraindications**

- None

**Warnings and Precautions**

- Serious infections
- Viral reactivation
- Non-melanoma skin cancers
- Live immunizations
- Potential risks related to JAK inhibition
  - Increased lipid profiles (not HDL)

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BON SECOURS MERCY HEALTH

Anzupgo [package insert]. Madison, NJ: Madison, NJ; 2025.

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## Delgocitinib (Anzupgo) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient data | Insufficient data | Insufficient data | No overall differences in safety or effectiveness were observed between subjects 65 years of age and older and younger adult subjects |

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BON SECOURS MERCY HEALTH

Anzupgo [package insert]. Madison, NJ: Madison, NJ; 2025.

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## Delgocitinib (Anzupgo) Accessibility

**Pharmacy Availability**

- Accredo Specialty
- Apotheco Pharmacy
- Carepoint Pharmacy
- CVS Specialty
- DFW Wellness Pharmacy
- Lumicera Specialty
- Optum Specialty
- Walgreens Specialty

**Patient Assistance**

- ANZUPGO Bridge Program
- ANZUPGO Copay Program

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BON SECOURS MERCY HEALTH

Anzupgo [package insert]. Madison, NJ: Madison, NJ; 2025.

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(E lin ZA ne tant)

## Elinzanetant (Lynkuet) Overview

**Approval Date**

- 10/24/2025

**Indication**

- Moderate to severe vasomotor symptoms due to menopause

**Dosage**

- 120 mg orally once daily at bedtime
  - With or without food
  - Swallow capsules whole

**Mechanism of Action**

- Inhibition of NK1 (neurokinin) and NK3 receptors


**Kisspeptin/neurokinin B/dynorphin (KNDy) neurons located in the hypothalamus are thought to play a key role in thermoregulation.**[1,2]

Thermoregulation is the maintenance of physiologic core body temperature by balancing heat generation with heat loss.[3]

During menopause, KNDy neurons can become hyperactive. This increased neuronal activity is associated with overexpression of Substance P (SP) and Neurokinin B (NKB).[1,4,5]

- NKB is known to be involved in the initiation of hot flashes via **NK3 receptors** on thermoregulatory KNDy neuronal pathways.[6,7]
- SP, via **NK1 receptors**, is thought to amplify KNDy neuronal activity.[6,8]

KNDy neuron hyperactivity is associated with overexpression of SP and NKB during menopause.[1,4]

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BON SECOURS MERCY HEALTH

Lynkuet [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2025.

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## Elinzanetant (Lynkuet) Efficacy

**OASIS 1&2 (N = 796)**

- Primary outcome = clinically meaningful reduction in hot flash severity
- Statistically significant in both studies
- Co-primary endpoint per table

**OASIS 3 (N = 627)**

- Assessed long-term safety (52 weeks)
- Relative safety established

**Table 4: Mean Baseline and Mean Change in Frequency of Moderate to Severe VMS over 24 hours from Baseline to Weeks 4 and 12 (OASIS 1 and 2)**

| | OASIS 1 | | OASIS 2 | |
|---|---|---|---|---|
| **Parameter** | **LYNKUET 120 mg (N= 199)** | **Placebo (N= 197)** | **LYNKUET 120 mg (N= 200)** | **Placebo (N= 200)** |
| **Baseline** Mean (SD) | 13.38 (6.57) | 14.26 (13.94) | 14.66 (11.08) | 16.16 (11.15) |
| **Change from Baseline to Week 4** | | | | |
| LS-Means (SE) | -7.60 (0.43) | -4.31 (0.43) | -8.58 (0.49) | -5.54 (0.49) |
| Difference vs. Placebo | -3.29 | | -3.04 | |
| (95% CI) | (-4.47, -2.10) | | (-4.40, -1.68) | |
| P-value* | <0.0001 | | <0.0001 | |
| **Change from Baseline to Week 12** | | | | |
| LS-Means (SE) | -8.66 (0.58) | -5.44 (0.59) | -9.72 (0.50) | -6.48 (0.49) |
| Difference vs. Placebo | -3.22 | | -3.24 | |
| (95% CI) | (-4.81, -1.63) | | (-4.60, -1.88) | |
| P-value* | <0.0001 | | <0.0001 | |

CI = Confidence Interval, LS-Means = Least Squares Means estimated from a mixed model for repeated measures analysis of covariance, SD = standard deviation, SE = Standard Error
* - one-sided p-value.

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BON SECOURS MERCY HEALTH

Lynkuet [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2025.

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## Elinzanetant (Lynkuet) Safety

### OASIS 1-3

- Similar safety outcomes
- Including OASIS 3 results given longer duration of trial

**Table 2. Common Adverse Reactions Reported in ≥ 2% in LYNKUET and Greater than Placebo, Weeks 1-52 (OASIS 3)**

| Adverse Reaction | LYNKUET N=313 n (%) | Placebo N=314 n (%) |
|---|---|---|
| Headache | 30 (9.6) | 22 (7.0) |
| Fatigue[a] | 23 (7.3) | 9 (2.9) |
| Dizziness[b] | 19 (6.1) | 6 (1.9) |
| Somnolence[c] | 16 (5.1) | 4 (1.3) |
| Abdominal pain[d] | 14 (4.5) | 8 (2.5) |
| Rash[e] | 13 (4.2) | 5 (1.6) |
| Diarrhea | 12 (3.8) | 3 (1.0) |
| Muscle spasms[f] | 10 (3.2) | 2 (0.6) |

[a]Includes asthenia.
[b]Includes balance disorder, presyncope, vertigo, vertigo CNS origin, vertigo positional, and vestibular neuronitis.
[c]Includes lethargy.
[d]Includes abdominal discomfort, abdominal pain lower/upper.
[e]Includes dermatitis, urticaria.
[f]Includes muscle tightness.


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Lynkuet (package insert). Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2025.

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## Elinzanetant (Lynkuet) Contraindications/Warnings/Precautions

### Contraindications

- Pregnancy

### Warnings and Precautions

- CNS depression and daytime impairment
- LFT elevation
- Risk of pregnancy loss
- Risk of seizure in patients with seizure history


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Lynkuet (package insert). Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2025.

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## Elinzanetant (Lynkuet) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Contraindicated based on animal data | Insufficient data | Insufficient data | Insufficient data |


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Lynkuet (package insert). Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2025.

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## Elinzanetant (Lynkuet) Accessibility

**Pharmacy Availability**

- BlinkRX for lowest price and access to access Savings & Support Program
- No information on availability at other pharmacies

**Patient Assistance**

- LYNKUET Copay Savings Program



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Lynkuet [package insert]. Whippany, NJ. Bayer HealthCare Pharmaceuticals; 2025.

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(tra DI pi tant)

## Tradipitant (Nereus) Overview

**Approval Date**
- 12/30/2025

**Indication**
- Prevention of vomiting induced by motion in adults

**Dosage**
- 85 – 170 mg orally as once dose
  - Administered 60 minutes prior to an anticipated inciting event

**Mechanism of Action**
- Substance P/neurokinin-1 (NK-1) receptor antagonism



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Nereus [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc; 2025.

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## Tradipitant (Nereus) Efficacy

**Trials 1&2 (N = 365)**

- Primary endpoint was subjects with vomiting during a boat trip (see table)
- Statistical significance not reached for prevention of nausea in either study

**Table 2: Percentage of Subjects with Vomiting During a Boat Trip**

| | NEREUS 85 mg[a] | NEREUS 170 mg[a] | Placebo |
|---|---|---|---|
| **Study 1** | N = 123 | N = 120 | N = 122 |
| Incidence of Vomiting (%) | 20% | 18% | 44% |
| Treatment Difference (95% CI)[b] | -25% (-36%, -14%) | -26% (-37%, -15%) | |
| **Study 2** | N = 104 | N = 106 | N = 106 |
| Incidence of Vomiting (%) | 18% | 10% | 38% |
| Treatment Difference (95% CI)[b] | -19% (-31%, -8%) | -27% (-38%, -16%) | |

CI = confidence interval
[a] NEREUS was administered as a single 85 mg or 170 mg dose approximately 60 minutes prior to a boat trip and without food.
[b] The difference (%) for NEREUS minus placebo is based on the unadjusted risk difference. The 95% CI is calculated using the Wald method.



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Nereus [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc; 2025.

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## Tradipitant (Nereus) Safety

**Trials 1-3**

- Single-dose trials

**Randomized Trial with Multiple Exposures**

- Median exposure = 18 doses
- Safety data consistent with presented table

**Table 1: Adverse Reactions[a] in Adult Subjects with a History of Motion Sickness in Single-Dose, Placebo-Controlled Studies Among Subjects Receiving NEREUS**

| | Studies 1 and 2 | | Studies 1, 2, and 3 | |
|---|---|---|---|---|
| Adverse Reaction | NEREUS 85 mg[b] N = 227 n (%) | Placebo N = 228 n (%) | NEREUS 170 mg[c] N=289 n (%) | Placebo N = 291 n (%) |
| Somnolence | 14 (6) | 9 (4) | 36 (12) | 17 (6) |
| Headache | 16 (7) | 12 (5) | 28 (10) | 17 (6) |
| Fatigue | 14 (6) | 6 (3) | 24 (8) | 6 (2) |

[a] Reported in at least 5% of subjects and at a higher frequency than placebo.
[b] NEREUS was administered as a single 85 mg dose approximately 60 minutes prior to a boat trip and without food.
[c] NEREUS was administered as a single 170 mg dose approximately 60 minutes prior to a boat trip and without food.

Nereus [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc; 2020.



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## Tradipitant (Nereus) Contraindications/Warnings/Precautions

**Contraindications**

- None

**Warnings and Precautions**

- Effects on the ability to drive or operate machinery



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## Tradipitant (Nereus) Special Populations

| Pregnancy | Lactation | Pediatric | Geriatric |
|---|---|---|---|
| Insufficient data | Insufficient data | Insufficient data | No overall differences in safety or effectiveness were observed between subjects 65 years of age and older and younger adult subjects |



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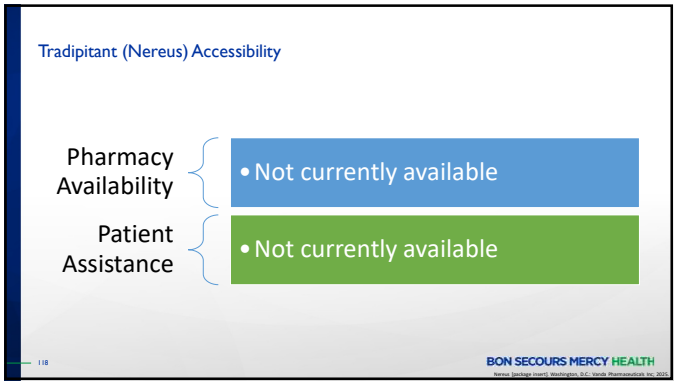
Tradipitant (Nereus) Accessibility
Pharmacy Availability
• Not currently available
Patient Assistance
• Not currently available
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BON SECOURS MERCY HEALTH
Nereus [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc; 2023.

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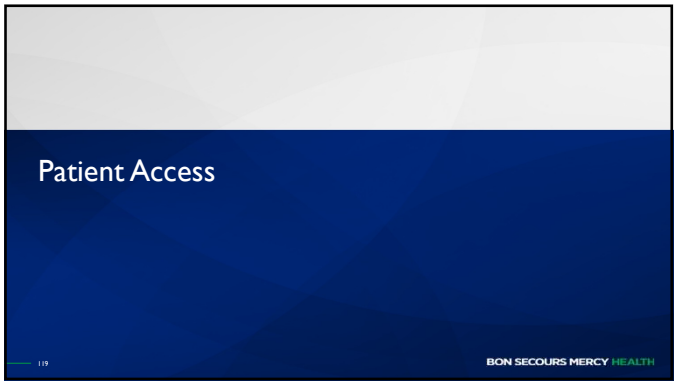
Patient Access
119
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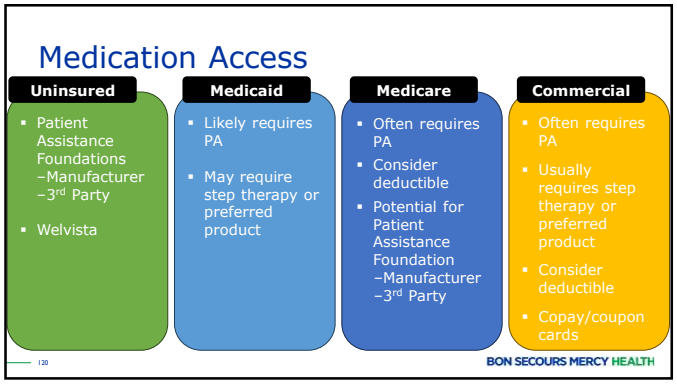
Medication Access
Uninsured
▪ Patient Assistance Foundations –Manufacturer –3rd Party
▪ Welvista
Medicaid
▪ Likely requires PA
▪ May require step therapy or preferred product
Medicare
▪ Often requires PA
▪ Consider deductible
▪ Potential for Patient Assistance Foundation –Manufacturer –3rd Party
Commercial
▪ Often requires PA
▪ Usually requires step therapy or preferred product
▪ Consider deductible
▪ Copay/coupon cards
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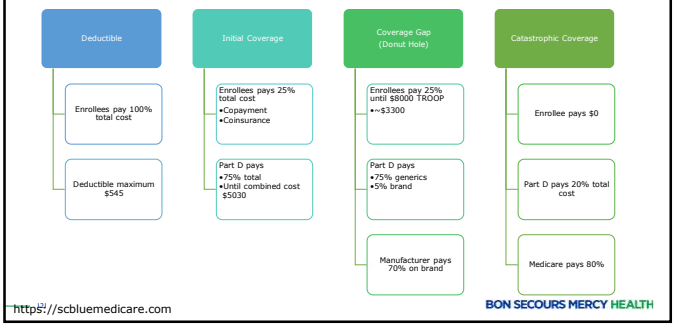
## 2024 Part D Benefits




https://scbluemedicare.com

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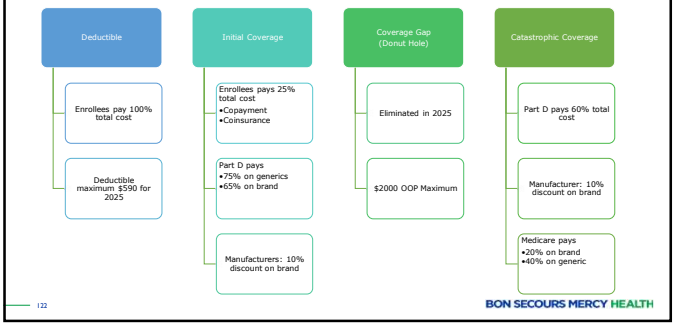
## 2025 Part D Benefits

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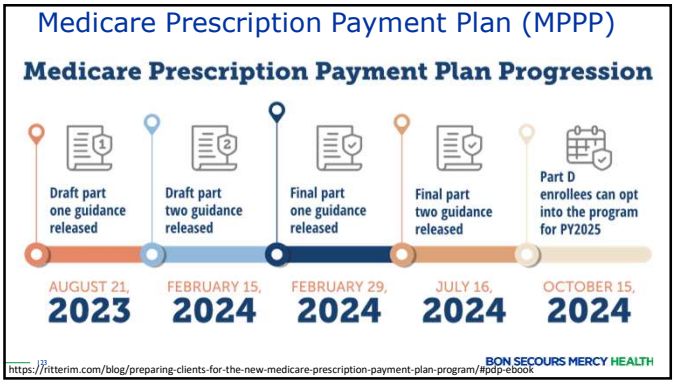
## Medicare Prescription Payment Plan (MPPP)




https://ritterim.com/blog/preparing-clients-for-the-new-medicare-prescription-payment-plan-program/#pdp-ebook

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## Medicare Prescription Payment Plan (MPPP)

| | Jan | Feb | Mar | Apr | May | Jun |
|---|---|---|---|---|---|---|
| Drug Cost | $410.00 | $305.00 | $210.00 | $210.00 | $210.00 | $210.00 |
| MPPP Cost | $34.17 | $61.89 | $82.89 | $106.23 | $132.48 | $162.48 |

| | Jul | Aug | Sep | Oct | Nov | Dec |
|---|---|---|---|---|---|---|
| Drug Cost | $210.00 | $210.00 | $25.00 | $0 | $0 | $0 |
| MPPP Cost | $197.48 | $239.48 | $245.73 | $245.73 | $245.73 | $245.73 |

**Total Drug Cost: $2000 = Total MPPP Cost: $2000**

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## Medicare Prescription Payment Plan (MPPP)

Key Updates with Medicare Part D and MPPP:

- No coverage gap (donut hole) in 2025
  - Prices will not suddenly increase after deductible has been met
- MPPP must be opted into by contacting Medicare via
  - phone (1-800-633-4227)
  - website (www.medicare.gov)
- If opted into MPPP, then cost will be added to monthly premiums
  - Copay should not be paid at the pharmacy
- All Part D plans have a maximum out of pocket of $2000

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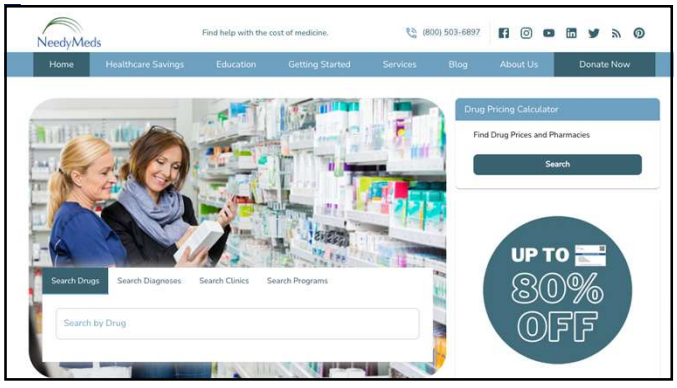


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## Welvista Pharmacy (welvista.org)

Income criteria: ≤200% Federal Poverty Level

Completely Free

90-day supplies shipped directly to patient

Brand & Generic Products

**Do You Qualify?**

To find out if you qualify and to apply, you must be able to provide several pieces of information. Here's a quick overview:

- You must be uninsured – no Medicaid, Medicare, VA Health Benefits, etc.
- You must live in South Carolina
- You must provide proof of income for each person in your home

Learn More About Eligibility

**View The Medications Available**

We regularly have over 180 available medications and get new shipments every month. You may view the entire list online!

View The Medications List

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## Copay Cards & Patient Assistance

**Copay Cards**

- Restricted to commercially insured patients
- Reduce copay with annual or monthly maximum
- If prior authorization required by insurance, will need approved

**Patient Assistance**

- May be available through manufacturer or third-party
- Available on basis of uninsured or under-insured status
- Income cut-offs for eligibility

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## Lab to Label: 2026 New Drug Update

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