Acentra HEALTH

West Virginia Retrospective Drug Utilization Review

NEWSLETTER

Quarter 3 2026

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FDA APPROVAL SPOTLIGHT

Urinary tract infections (UTIs) are among the most common infections treated in both outpatient and inpatient settings. UTIs are most common in females 16 -35 years of age and are at least 4-times more frequent in females than males. While many patients present with classic lower urinary symptoms, those with structural or functional abnormalities may have more severe infections requiring broader-spectrum therapy. The 2025 Infectious Diseases Society of America (IDSA) UTI guideline update redefined the clinical classifications of complicated UTI (cUTI) and uncomplicated UTI (uUTI). The differentiation between uncomplicated and complicated UTIs is vital because this distinction directly impacts antibiotic selection, route of administration, and treatment duration. Additionally, cUTIs account for ~2% of all hospitalizations.

Utebzi (tebipenem pivoxil) tablets 300 mg

- **Utebzi (tebipenem pivoxil)** was FDA approved on June 17, 2026 for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae species complex, Klebsiella oxytoca, and Enterococcus faecalis* in adult patients who have limited or no alternative oral treatment options.

First FDA approved oral carbapenem antibiotic

- Approval was based on the PIVOT-PO trial, which demonstrated non-inferiority of tebipenem pivoxil compared to intravenous imipenem-cilastatin in ohspitalized patients with cUTI.

Utebzi (tebipenem pivoxil) Prescribing Information	
Dosing	600mg (two 300mg tablets) taken orally with or without food, every 6 hours for 7 to 10 days in adults with an estimated glomerular filtration rate (eGFR) between 60 -150 mL/min. • *Reduced dosing necessary in patients with renal impairment*
Contraindications	1. Hypersensitivity to beta-lactam antibacterials 2. Primary or secondary carnitine deficiency or inborn errors of metabolism may result in clinically significant carnitine deficiency.
Drug Interactions	Organic Anion Transporter 1 (OAT1) and 3 (OAT3) inhibitors: OAT1 and OAT3 inhibitors (e.g., probenecid) increase the plasma concentration of tebipenem
Adverse Drug Reactions	Diarrhea Headache Nausea Abdominal pain Hepatic enzyme elevation *Clostridioides difficile*

ZAYNICH™
cefepime and zidebactam
For Injection (3g)

- **Zaynich (cefepime and zidebactam)**, an intravenous combination antibiotic, FDA approved on May 29, 2026, for the treatment of adult patients with cUTI, including pyelonephritis, caused by susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabillis, Enterobacter cloacae complex, and Pseudomonas aeruginosa*.
- Approval supported by results from the Phase 3 ENHANCE-1 trial, which compared the efficacy, safety, and tolerability to meropenom.

- Zaynich is a novel drug, shown to have broad-spectrum activity against gram-negative bacteria, including multidrug-resistant strains. Combining a cephalosporin (cefepime) with the novel component, zidebactam, Zaynich offers a dual-target approach to cUTI treatment. Zidebactam inhibits certain β-lactamases and directly binds to penicillin-binding protein 2 (PBP2), offering its own antibacterial activity that complements the cefepime component of Zaynich.

Zaynich (cefepime and zidebactam) Prescribing Information	
Dosing	3 grams every 8 hours by IV infusion over 1 hour for 7-10 days in adult patients with an eGFR ≥ 60mL/min • *Reduced dosing necessary in patients with renal impairment*
Contraindications	1. Hypersensitivity to beta-lactam antibacterials
Warnings and Precautions	1. Hypersensitivity reactions: serious hypersensitivity reactions 2. Neurotoxicity: reported with cefepime component, most occurred in those with renal impairment without the necessary renal dosage adjustments 3. *Clostridioides difficile* infection: *Clostridioides difficile* reported with many antibacterial agents
Adverse Drug Reactions	Diarrhea Headache Hypertension Hypokalemia *Clostridioides difficile*

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Legislative Update

West Virginia House Bill 5004

West Virginia's (WV) House Bill 5004 (HB5004), signed into law in March 2026 and effective June 2026, is a public health awareness law. HB5004 directs the WV Bureau for Public Health to incorporate education and awareness of Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) into existing public health programs and education initiatives.

The intent of HB5004 is not to mandate any changes in prescribing authority, coverage requirements, or treatment standards, but to increase provider awareness and education around identification and management of PANS/PANDAS. The department will continue to stay informed and engage in providing appropriate resources for providers.

PANS and PANDAS are clinical diagnoses.	
Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)	**Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)**

• Abrupt onset of obsessive-compulsive symptoms (OCD) and/or severe food restriction
• Additional neuropsychiatric symptoms such as
  ○ Anxiety
  ○ Emotional dysregulation
  ○ Irritability, aggression, and/or oppositional behaviors
  ○ Behavioral regression
  ○ Academic deterioration
  ○ Motor/sensory abnormalities
  ○ Somatic abnormalities
• Triggered by infection, inflammation, or immune dysregulation
	• Subtype of PANS
	• Associated with streptococcal infection
	• Abrupt onset OCD and/or tics
	• Immune-mediated neuropsychiatric disorder

References

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