

# FDA approves new antibiotic for three indications

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The U.S. Food and Drug Administration has approved the antibiotic Zevtera (ceftobiprole medocartil sodium for injection) for three different indications, including treatment of adults with *Staphylococcus aureus* bloodstream infections, adults with acute bacterial skin and skin structure infections, and adult and pediatric patients (age 3 months and

older) with community-acquired bacterial pneumonia.

The priority review approval was based on four randomized controlled trials.

For *S. aureus* bloodstream infections, a trial with 390 participants showed 69.8% of those receiving Zevtera achieved overall success (survival, symptom improvement, *S. aureus* bacteremia bloodstream clearance, no new *S. aureus* bacteremia complications, and no use of other potentially effective antibiotics) versus 68.7% of those receiving the comparator.

For acute bacterial skin and skin structure infections, among 679 participants, 91.3% of those receiving Zevtera achieved an early clinical response (48 to 72 hours after start of treatment) versus 88.1% of those receiving the comparator.

For community-acquired [bacterial pneumonia](#), efficacy (clinical cure rates at test-of-cure visit at seven to 14 days after end of treatment) occurred in 76.4% with Zevtera versus 79.3% of those receiving the comparator.

Patients should not use Zevtera if they have a history of severe hypersensitivity to ceftobiprole or other members of the cephalosporin antibacterial class. Additionally, Zevtera comes with warnings and precautions regarding increased mortality in ventilator-associated bacterial pneumonia patients (an unapproved use), [hypersensitivity reactions](#), seizures and other central nervous system reactions, and *Clostridioides difficile*-associated diarrhea.

"The FDA is committed to fostering new antibiotic availability when they prove to be safe and effective, and Zevtera will provide an additional treatment option for a number of serious bacterial infections,"

Peter Kim, M.D., from the FDA Center for Drug Evaluation and Research, said in a statement.

Approval of Zevtera was granted to Basilea Pharmaceutica International.

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