

FDA approves new antibiotic against UTIs

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As many patients already know, urinary tract infections (UTIs) can recur despite the use of antibiotics.

So, it's welcome news that the U.S. Food and Drug Administration on Wednesday approved Pivya (pivmecillinam) to fight bacterial [UTIs](#).

"UTIs are a very common condition impacting [women](#) and one of the most frequent reasons for antibiotic use," [Dr. Peter Kim](#), who directs the Division of Anti-Infectives in the FDA's Center for Drug Evaluation and Research, said in an [agency statement](#).

"The FDA is committed to fostering new antibiotic availability when they prove to be safe and effective, and Pivya will provide an additional treatment option for uncomplicated UTIs," he added.

Pivmecillinam has been [used in Europe](#) for more than 40 years, where it is typically a first-line therapy for women with uncomplicated UTIs.

Every woman will experience at least one UTI in her lifetime, the FDA noted. Uncomplicated UTIs occur in the bladders of females with no structural abnormalities of their urinary tract.

Pivya's approval was based on three [clinical trials](#) involving women 18 years of age or older with uncomplicated UTIs. Effectiveness of the new drug over 8 to 14 days of use was compared to that of another antibacterial pill, ibuprofen and a placebo.

Researchers looked at a combination of results: Whether bacteria counts in women's urine declined, and whether UTI symptoms resolved.

The trials found that Pivya achieved both those results 62% of the time, compared to placebo, and it fared about equally well when compared to the other antibacterial drug (72% and 76% success rates, respectively). Pivya bested ibuprofen by a wide margin -- 66% versus 22%, the FDA said.

According to the *New York Times*, this is the first time in two decades that the FDA has approved a new antibiotic against UTIs.

The emergence of drug-resistant strains of UTIs (and other infections) has long worried infectious disease experts, and UTI cases comprise a big percentage of [antibiotic use](#) in the United States.

"This is an exciting new possibility for treatment of lower [urinary tract infections](#)," [Dr. Shruti Gohil](#), a professor of infectious diseases at the University of California, Irvine School of Medicine, told the *Times*. "But I would also say that it is going to be important that we use the drug responsibly in this country so that we don't breed resistance against it."

Nausea and diarrhea were the most common side effects of Privya, which is made by UTILITY therapeutics Ltd.

The company told the *Times* that the drug should be available beginning in 2025, and they are working on an intravenous form of Pivya to be used in the [hospital setting](#) for more stubborn cases.

Pivya shouldn't be used by patients with a known sensitivity to this class of meds, called beta-lactam antibacterials, the FDA noted.

More information: Find out more about the treatment of UTIs at the [Mayo Clinic](#).

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