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Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Anti-infective Agents	**Original Policy Date:**	May 8, 2026
Subject:	Pivya	**Page:**	1 of 4

Last Review Date: June 11, 2026

Pivya

Description

Pivya (pivmecillinam)

Background
Pivya (pivmecillinam) is a penicillin antibacterial drug that is mainly active against gram-negative bacteria. Pivya works by interfering with the biosynthesis of the bacterial cell wall. Pivya has a high specificity against penicillin-binding protein-2 (PBP-2) in the gram-negative cell, unlike other beta-lactam agents, which preferentially bind gram-negative PBP-1A, -1B, or -3 (1).

Regulatory Status
FDA-approved indications: Pivya is a penicillin class antibacterial indicated for the treatment of female patients 18 years of age and older with uncomplicated urinary tract infections (uUTI) caused by susceptible isolates of *Escherichia coli, Proteus mirabilis*, and *Staphylococcus saprophyticus* (1).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Pivya and other antibacterial drugs, Pivya should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy (1).

Pivya is contraindicated in patients with primary or secondary carnitine deficiency resulting from inherited disorders of mitochondrial fatty acid oxidation and carnitine metabolism, and other

inborn errors of metabolism. Pivya is also contraindicated in patients with acute porphyria (1).

Severe Cutaneous Adverse Reactions (SCAR) including Acute Generalized Exanthematous Pustulosis (AGEP), Drug Reactions with Eosinophilia and Systemic Symptoms (DRESS), Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) have been reported with Pivya. Monitor patients closely and discontinue Pivya at the first signs or symptoms of SCAR or other signs of hypersensitivity.

Additional precautions and warnings regarding the use of Pivya include the development of *Clostridioides difficile*-associated diarrhea (CDAD), carnitine depletion, interference with isovaleric acidemia testing in newborns, and the development of drug-resistant bacteria.

The safety and effectiveness of Pivya in pediatric patients less than 18 years of age have not been established (1).

Related policies
Baxdela, Blujepa, Nuzyra, Orlynvah, Xenleta, Sivextro, Zyvox

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Pivya may be considered **medically necessary** if the conditions indicated below are met.

Pivya may be considered **investigational** for all other indications.

Prior-Approval Requirements

Patients who have filled a course of nitrofurantoin, sulfamethoxazole/trimethoprim, or fosfomycin in the last 30 days are exempt from these Prior Authorization (PA) requirements.

Age 18 years of age or older

Gender Female

Diagnoses

Patient must have the following:

1. Uncomplicated urinary tract infection (uUTI)
    a. Caused by *Escherichia coli*, *Proteus mirabilis*, or *Staphylococcus saprophyticus*
    b. Caused by or strongly suspected to be caused by susceptible bacteria based on culture and susceptibility, local epidemiology, or susceptibility patterns

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 21 tablets

Duration 30 days

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Pivya is a penicillin antibacterial drug that is mainly active against gram-negative and indicated for the treatment of uncomplicated urinary tract infection (uUTI) in female patients 18 years and older. The safety and effectiveness of Pivya in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Pivya while maintaining optimal therapeutic outcomes.

References

1. Pivya [package insert]. Florham Park, NJ: UTILITY therapeutics Ltd, UK; April 2024.

Policy History

Date	Action
May 2026	Addition to PA
June 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.