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Section:	Prescription Drugs	**Effective Date:**	April 10, 2026
Subsection:	Anti-infective Agents	**Original Policy Date:**	January 30, 2026
Subject:	Blujepa	**Page:**	1 of 4

Last Review Date: March 6, 2026

Blujepa

Description

Blujepa (gepotidacin)

Background
Blujepa is a triazaacenaphthylene bacterial type II topoisomerase inhibitor that exerts antimicrobial effect through inhibition of DNA replication. Blujepa has activity against both gram-negative and gram-positive bacteria (1).

Regulatory Status
FDA-approved indications: Blujepa is a triazaacenaphthylene bacterial type II topoisomerase inhibitor indicated for the treatment of the following infections caused by susceptible microorganisms (1):

- Uncomplicated urinary tract infections (uUTI) in female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg).
- Uncomplicated urogenital gonorrhea in adult and pediatric patients 12 years of age and older weighing at least 45 kilograms (kg) who have limited or no alternative treatment options.

Susceptible organisms for uUTI may include *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii* complex, *Staphylococcus saprophyticus,* and *Enterococcus faecalia*. Blujepa may be used to treat susceptible strains of *Neisseria gonorrheae* in uncomplicated urogenital gonorrhea (1).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Blujepa and other antibacterial drugs, Blujepa 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).

Blujepa contains warnings regarding hypersensitivity reactions, *Clostridioides difficile*-associated diarrhea, QTc prolongation, acetylcholinesterase inhibition, and development of drug-resistant bacteria (1).

The safety and effectiveness of Blujepa in pediatric patients less than 12 years of age have not been established (1).

Related policies
Baxdela, 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.

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

Blujepa 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 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Uncomplicated urinary tract infection (uUTI)
    a. Female gender assigned at birth
    b. Patient weight ≥ 40 kg
    c. Caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii* complex, *Staphylococcus saprophyticus*, or *Enterococcus faecalis*
    d. Caused by or strongly suspected to be caused by susceptible bacteria based on culture and susceptibility, local epidemiology, or susceptibility patterns
2. Uncomplicated urogenital gonorrhea
    a. Patient weight ≥ 45 kg
    b. Patient has limited or no alternative treatment options
    c. Caused by *Neisseria gonorrheae*
    d. 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

Diagnosis	Quantity
Uncomplicated urinary tract infection (uUTI)	20 tablets **OR**
Uncomplicated urogenital gonorrhea	8 tablets

Duration 30 days

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Blujepa is a triazaacenaphthylene bacterial type II topoisomerase inhibitor indicated for the treatment of uncomplicated urinary tract infection (uUTI) and uncomplicated urogenital gonorrhea in patients 12 years and older. The safety and effectiveness of Blujepa in pediatric patients less than 12 years of age have not been established (1).

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

References

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

Policy History

Date	Action
January 2026	Addition to PA
March 2026	Annual review
April 2026	Per FEP, removed ceftriaxone from step out language

Keywords

This policy was effective with interim approval on April 10, 2026 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026.