

Gepotidacin (BLUJEP) in Gonorrhea

Criteria for Use

May 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for gepotidacin.

- History of QTc prolongation or relevant pre-existing cardiac disease or taking drugs that prolong the QTc interval
- Concomitant use of **strong** CYP3A4 inhibitors
- Severe renal impairment (eGFR <30 mL/min)
- Severe hepatic impairment (Child-Pugh Class C)
- Concomitant use of **moderate** CYP3A4 inhibitors or ≥2 of the following risk factors: weight between 45 and 60 kg, moderate renal impairment (eGFR 30 to 59 mL/min), or moderate hepatic impairment (Child-Pugh Class B)

Abbreviations: eGFR, estimated glomerular filtration rate

Inclusion Criteria

ALL of the following must be selected to meet criteria.

- Prescribed by a VA/VA Community Care infectious diseases specialist or locally designated expert
- Uncomplicated urogenital **gonorrhea**

Additional Inclusion Criteria

ONE of the following must be selected to meet criteria.

- Isolate is susceptible to gepotidacin and non-susceptible to all other appropriate oral antibiotics²
- Isolate's susceptibility to gepotidacin is not available and patient had an inadequate clinical and/or microbiological response to all other appropriate oral antibiotics²
- Patient has severe hypersensitivity, contraindication, inadequate response, or intolerance to all other appropriate oral antibiotics²

Additional Inclusion Criteria – Select If Applicable

- For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and use of effective contraception during therapy
- For females who are lactating/providing breastmilk to an infant or planning to do so: Counseling provided on the risks vs benefits of treatment

Other Justification

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Footnotes

- 1 Patients unable to receive gentamicin injection (in combination with azithromycin) — including but not limited to those for whom gentamicin is medically inadvisable or traveling to a clinic for gentamicin injection is infeasible — may use gepotidacin as second-line therapy.

- 2 Examples of other appropriate oral agents for gonorrhea: (1) ceftriaxone (or if ceftriaxone injection is infeasible, oral cefixime unless contraindicated) and (2) gentamicin + azithromycin

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