

Clinical Policy: Tebipenem Pivoxil (Utebzi)

Reference Number: CP.PMN.313

Effective Date: 12.01.26

Last Review Date: 11.26

Line of Business: Commercial, HIM/ICHRA, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Tebipenem pivoxil (Utebzi®) is a carbapenem antibacterial.

FDA Approved Indication(s)

Utebzi is indicated for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae* species complex, *Klebsiella oxytoca*, and *Enterococcus faecalis* in adult patients who have limited or no alternative oral treatment options.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Utebzi and other antibacterial drugs, Utebzi should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Utebzi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Complicated Urinary Tract Infection (must meet all):**

1. Diagnosis of cUTI (including pyelonephritis);
2. Prescribed by or in consultation with an infectious disease specialist;
3. Age $\geq$ 18 years;
4. Documentation of urine culture with one of the following causative pathogens that shows susceptibility to Utebzi (a, b, c, d, or e):
 - a. *Escherichia coli*;
 - b. *Klebsiella pneumoniae*;
 - c. *Enterobacter cloacae* species complex;
 - d. *Klebsiella oxytoca*;
 - e. *Enterococcus faecalis*;
5. Both of the following (a and b):
 - a. Documentation of estimated glomerular filtration rate (eGFR);
 - b. $\text{eGFR} \geq 15 \text{ mL/min}$;
6. Member meets one of the following (a or b; *see Appendix B*):

- a. Failure of ≥ 2 IDSA-recommended antibiotics to which the isolated pathogen is susceptible per culture and susceptibility test, unless clinically significant adverse effects are experienced or all are contraindicated;
- b. Culture and susceptibility test shows resistance or lack of susceptibility of the isolated pathogen to ≥ 1 agent from each of the following IDSA-recommended antibiotics/classes (i, ii, and iii), unless clinically significant adverse effects are experienced or all are contraindicated:
 - i. Trimethoprim-sulfamethoxazole;
 - ii. A fluoroquinolone (i.e., ciprofloxacin, levofloxacin);
 - iii. A beta lactam (e.g., cefpodoxime, cefuroxime);
7. Total treatment period does not exceed 10 days;
8. Dose does not exceed 2,400 mg (8 tablets) per day.

Approval duration: up to 10 days per treatment course

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Complicated Urinary Tract Infection (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Both of the following (a and b):
 - a. Total treatment period does not exceed 10 days;
 - b. Member has received < 10 days of treatment;
4. If request is for a dose increase, new dose does not exceed 2,400 mg (8 tablets) per day.

Approval duration: up to 10 days per treatment course

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

cUTI: complicated urinary tract infection
eGFR: estimated glomerular filtration rate
FDA: Food and Drug Administration

IDSA: Infectious Diseases Society of America

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name*	Dosing Regimen*	Dose Limit/ Maximum Dose
trimethoprim-sulfamethoxazole	800 mg-160 mg Q 12 hours	See Prescribing Information
Fluoroquinolones		
ciprofloxacin	500 mg to 750 mg Q 12 hours	See Prescribing Information
levofloxacin	500 mg to 750 mg QD	See Prescribing Information
Beta Lactams		
amoxicillin-clavulanate	875 mg-125 mg Q 8-12 hours	See Prescribing Information
cefixime	400 mg QD	See Prescribing Information

Drug Name*	Dosing Regimen*	Dose Limit/ Maximum Dose
cefepodoxime	200 mg to 400 mg Q 12 hours	See Prescribing Information
ceftibuten	400 mg QD or 200 mg Q 12 hours	See Prescribing Information
cefuroxime	500 mg Q 12 hours	See Prescribing Information
cephalexin	500 mg to 1000 mg Q 6 hours	See Prescribing Information

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

**Oral agents and dosing regimens are recommended from the IDSA 2025 Guideline update on cUTI.*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to Utebzi or other beta-lactam antibacterials; primary or secondary carnitine deficiency or inborn errors of metabolism that may result in clinically significant carnitine deficiency
- Boxed warning(s): none

Appendix D: General Information

- Per IDSA guidelines, a cUTI is classified as an infection beyond the bladder in women or men. Clinical presentation consists of pyelonephritis, febrile or bacteremic UTI, catheter-associated UTI, or prostatitis. This contrasts with an uncomplicated UTI which is an infection confined to the bladder in afebrile women or men.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose												
cUTI	600 mg (two 300 mg tablets) PO Q 6 hours for 7 to 10 days in adults with an eGFR between 60 and 150 mL/min Recommended dose for renal impairment as follows: <table border="1"> <thead> <tr> <th>eGFR (mL/min)</th><th>Dose</th><th>Frequency</th></tr> </thead> <tbody> <tr> <td>60 to < 90</td><td>600 mg</td><td>Q 6 hours</td></tr> <tr> <td>30-59</td><td>300 mg</td><td>Q 6 hours</td></tr> <tr> <td>15-29</td><td>300 mg</td><td>Q 12 hours</td></tr> </tbody> </table>	eGFR (mL/min)	Dose	Frequency	60 to < 90	600 mg	Q 6 hours	30-59	300 mg	Q 6 hours	15-29	300 mg	Q 12 hours	See Dosing Regimen
eGFR (mL/min)	Dose	Frequency												
60 to < 90	600 mg	Q 6 hours												
30-59	300 mg	Q 6 hours												
15-29	300 mg	Q 12 hours												

VI. Product Availability

Oral tablet: 300 mg

VII. References

1. Utebzi Prescribing Information. Durham, NC: GlaxoSmithKline; June 2026. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Utebzi/pdf/UTEBZI-PI-PIL.PDF. Accessed July 2, 2026.
2. ClinicalTrials.gov. A study of oral tebipenem pivoxil hydrobromide (TBP-PI-HBr) compared to intravenous imipenem-cilastatin in participants with complicated urinary tract infection (cUTI) or acute pyelonephritis (AP) (PIVOT-PO). Available at: <https://clinicaltrials.gov/study/NCT06059846>. Accessed July 7, 2026.

3. IDSA 2025 Guideline update on complicated urinary tract infections. July 17, 2025.
Available at: <https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/>. Accessed July 7, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.07.26	11.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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