

A patient's health insurance plan or payer may require prior authorization (PA) or supporting documentation to process and cover a claim for treatment with UTEBZI® (tebipenem pivoxil). A PA allows the health plan to review the reason for the requested therapy and to determine medical appropriateness. A patient-specific Letter of Medical Necessity will help explain the physician's rationale and clinical decision-making in choosing UTEBZI. Please note that some health plans have specific forms that must be completed in order to request PA or to document medical necessity.

The following Letter of Medical Necessity template for UTEBZI can be customized based on your patient's medical history and demographic information.

SAMPLE LETTER OF MEDICAL NECESSITY

[Date]

[Plan/Payer Name]

[Payer street address]

[Payer city, state, ZIP code]

Re: Letter of Medical Necessity – **REQUEST FOR EXPEDITED REVIEW** [NDC] [Drug Name, Billing Unit]

Patient: [Patient Full Name]

Group/Policy Number: [Patient group & policy number]

Date(s) of Service: [Date(s)]

Diagnosis: [Code & Description]

Determination Requested: Expedited (within 24 to 48 hours of receipt)

Dear [Insert payer contact name and/or department]:

I am writing on behalf of my patient, [patient name], to document the medical necessity of UTEBZI® (tebipenem pivoxil) for the treatment of [diagnosis]. On behalf of [him/her], I request coverage approval for the prescribed treatment and an expedited determination within 24 to 48 hours of receipt.

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].

[Patient name] is a/an [age]-year-old [male/female] diagnosed with [diagnosis]. [Patient name] has been in my care since [date]. As a result of [diagnosis], my patient [enter a brief description of patient history]. Additionally, [patient name] has tried [previous therapies] and [outcomes]. The patient is currently on [current therapy] for the treatment of [diagnosis]. The attached medical records document [patient name]'s clinical condition and medical necessity for treatments with UTEBZI.

Based on the above facts, I am confident that you will agree that UTEBZI is indicated and medically necessary for this patient. The treatment plan is to initiate UTEBZI [dose] orally on [start date], administered every [frequency] for a total course duration of [number] days, with an anticipated final dose on [end date]. Please approve coverage and payment on behalf of [patient name] for the full course of therapy described above.

Please refer to the enclosed Prescribing Information for UTEBZI. If you have any further questions regarding this matter, please do not hesitate to call me at [physician phone number].

Thank you for your prompt attention to this matter.

Sincerely,

[Physician's name], [degree initials], [physician's practice name]

Suggested Enclosures

- Medical records and clinical notes and labs
- FDA approval letter available at:
<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=browseByLetter.page&productLetter=u>
- Prescribing Information (PI) - please also visit:
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Utebzi/pdf/UTEBZI-PI-PIL.PDF
- Important Safety Information