

taurolidine and heparin catheter lock solution (Defencath[®])

Policy # 00892

Original Effective Date: 10/14/2024

Current Effective Date: 10/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider taurolidine and heparin catheter lock solution (Defencath[®])[‡] to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC) to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility for taurolidine and heparin catheter lock solution (Defencath) will be considered when the following patient selection criteria are met:

- Patient is ≥ 18 years of age; AND
- Patient has a diagnosis of kidney failure requiring chronic hemodialysis (HD); AND
- Patient is receiving HD via a central venous catheter (CVC); AND
- Patient will likely require the use of a CVC for HD for 90 days or more; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has a history of multiple prior catheter-related bloodstream infections (CRBSI) OR *Staphylococcus aureus* nasal carriage; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has no known heparin-induced thrombocytopenia (HIT); AND
- Patient has NOT received any thrombolytic treatment [i.e. tissue plasminogen activator (tPA)] in the current CVC within the past 30 days; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient does NOT have a history of an atrial thrombus or known hypercoagulable state; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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- Patient does NOT have chronic bleeding diathesis or active or recurrent bleeding within the past month.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of taurolidine and heparin catheter lock solution (Defencath) when use of the CVC for HD is NOT likely for ≥ 90 days to be **not medically necessary.****

Based on review of available data, the Company considers the use of taurolidine and heparin catheter lock solution (Defencath) when the patient does NOT have a history of multiple prior catheter-related bloodstream infections (CRBSI) OR *Staphylococcus aureus* nasal carriage to be **not medically necessary.****

Based on review of available data, the Company considers the use of taurolidine and heparin catheter lock solution (Defencath) when the patient has received any thrombolytic treatment [i.e. tissue plasminogen activator (tPA)] in the current CVC within the past 30 days to be **not medically necessary.****

Based on review of available data, the Company considers the use of taurolidine and heparin catheter lock solution (Defencath) when the patient has a history of an atrial thrombus or known hypercoagulable state to be **not medically necessary.****

Based on review of available data, the Company considers the use of taurolidine and heparin catheter lock solution (Defencath) when the patient has a chronic bleeding diathesis or active or recurrent bleeding within the past month to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of taurolidine and heparin catheter lock solution (Defencath) when the patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

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Background/Overview

Defencath is a combination of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant, indicated to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis through a CVC. Approximately 80% of patients with end-stage renal disease (ESRD) in the United States initiate HD therapy through a CVC despite the increased risk of developing a catheter-related infection. In patients with a HD-CVC, CRBSIs are estimated to occur at a rate of 0.6 to 6.5 episodes per 1000 catheter days. Both the Centers for Disease Control and Prevention (CDC) and the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) Guidelines recommend reducing usage of CVCs for HD and establishing permanent vascular access placement, such as an arteriovenous (AV) fistula or graft, due to their lower rates of complications, such as infection. However, both AV fistulas and grafts require surgical placement and healing time prior to their use. Efforts to prevent CRBSIs include implementation of the CDC's core interventions for HD catheter care, proper personnel training, and infection control monitoring. Clinical guidelines from KDOQI (2019) currently do not recommend the routine use of antibiotic lock solutions for CRBSI prevention. However, guidelines do recommend the use of prophylactic antibiotic/antimicrobial locks to patients in need of long-term CVC placement who are at high risk for a CRBSI (e.g., multiple prior CRBSI or persistent *S. aureus* nasal carriers) or in facilities with high rates of CRBSIs (e.g., more than 3.5 infections/1,000 days). KDOQI guidelines cite cefotaxime, gentamicin, trimethoprim-sulfamethoxazole, methylene blue, and weekly TPA as locking solutions with low or moderate evidence for selective use of CRBSI prophylaxis. These products are not commercially available but must be compounded. Of note, at the time of the last guideline update, Defencath was not FDA-approved. Defencath is available in 3mL and 5mL single dose vials, each containing 13.5 mg/mL taurolidine and 1000 units/mL heparin. The recommended dose of Defencath depends upon the volume and number of catheter lumens of the CVC. At the end of each HD session, a sufficient volume to fill each CVC lumen should be withdrawn from a 3 mL or 5 mL vial and instilled into each catheter lumen. Prior to the next session of HD, Defencath must be aspirated from the catheter and discarded. Defencath is for instillation into a CVC only and is not intended for systemic administration. Defencath is contraindicated in patients with known HIT. If HIT occurs, the product should be discontinued immediately and supportive measures initiated.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Defencath[®] was approved in November of 2023 to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC). This drug is indicated for use in a limited and specific population of patients.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy and safety of Defencath for reducing the incidence of CRBSI in patients with kidney failure receiving chronic HD was evaluated in a randomized, double-blind, active-controlled, multicenter phase 3 trial (LOCK-IT-100). A total of 806 patients were randomized in a 1:1 ratio to receive either Defencath or heparin as a CLS. Enrollment was not limited to patients with specific types of HD catheters. Defencath or heparin was instilled into central venous HD catheters at the end of all dialysis sessions and was withdrawn prior to the initiation of the next dialysis session. The majority of patients (98%) had HD treatment three times per week, and 48% had their catheter implanted within three months prior to randomization. The primary endpoint was time to CRBSI occurrence as assessed by a blinded clinical adjudication committee (CAC). The CAC definition for CRBSI included one positive blood culture (other than for coagulase-negative staphylococci, which required a confirmatory culture) from a peripheral site or either the arterial or venous catheter hub or the arterial or venous dialysis blood line and the patient had to have signs and symptoms of infection and no other apparent source of bloodstream infection. Secondary endpoints included catheter removal (any reason) and loss of catheter potency (required use of recombinant t-pa or removal of catheter due to malfunction). In the full analysis population (N=795), 9 participants in the Defencath arm and 32 in the heparin arm had a CRBSI. Among those in the Defencath arm with a CAC-adjudicated CRBSI, 1 had a gram-negative organism isolated and 8 had a gram-positive organism isolated; among those in the heparin arm with a CAC-adjudicated CRBSI, 14 had a gram-negative organism isolated and 18 had a gram-positive organism isolated. Event rates per 1000 catheter-days were 0.13 and 0.46, respectively, with the difference in time to CRBSI being highly statistically significant for taurolidine/heparin ($P < 0.001$). The hazard ratio was 0.29 (95% confidence interval: 0.14, 0.62), corresponding to a 71% reduction in risk of CRBSI with taurolidine/heparin versus heparin. There were no significant differences between study arms in time to catheter removal for any reason or loss of catheter patency. The safety of taurolidine/heparin was comparable to that of heparin, and most treatment-emergent adverse events were mild or moderate.

References

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9. Defencath New Drug Review. IPD Analytics. December 2023.

Policy History

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09/05/2024 Medical Policy Committee review

09/11/2024 Medical Policy Implementation Committee approval. New policy

09/04/2025 Medical Policy Committee review

09/10/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No Codes
HCPCS	J0911
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.