

Medical Policy

DefenCath

Policy Number: 099

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required		X	
No Prior Authorization			X
Not covered	X		

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical appropriateness of DefenCath.

DefenCath is considered experimental and investigational for Commercial and Qualified Health Plan members.

MassHealth Variation

Mass General Brigham Health Plan uses the [MassHealth Drug List](#) for coverage determinations for members of the Mass General Brigham ACO. Criteria for DefenCath are found in [Table 66: Antibiotics and Anti-Infectives - Injectable](#).

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has no NCD or LCDs for DefenCath.**

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Authorized Code	Code Description
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)

Summary of Evidence

Several studies have evaluated the efficacy of taurolidine-containing catheter lock solutions, often combined with heparin or citrate, in reducing catheter-related bloodstream infections (CRBSIs) among hemodialysis patients.

In 2014, Murray et al. reported that taurolidine-citrate-heparin solutions reduce staphylococcal bacteremia in patient undergoing chronic hemodialysis. Nearly a decade later in 2023, Agarwal et al reported on the phase 3 randomized, double-blind, active-control, multicenter LOCK IT-100 trial, which demonstrated that a taurolidine/heparin lock solution significantly lowered infection rates in this population.

That same year, Ezzat et al. (2023) highlighted the additional benefit of taurolidine, citrate, and heparin in improving inflammatory status and dialysis adequacy. A year later, Nguyen et al. (2024) also reporting on the LOCK IT-100 trial, reviewed the use of taurolidine and heparin as catheter lock solutions, underscoring their role in infection prevention.

However, criticism of the LOCK IT-100 trial notes that there was no active control for those patients with previous bloodstream infections with the use of alternate antibiotics or other approaches or preventative strategies. Also, the rate of infection in the LOCK IT-100 trial was threefold higher than the common rate in the United States. Therefore, the protocols in use likely already account for any potential added value of DefenCath. Among those protocols are chlorhexidine-coated catheter caps. There are no available studies on the safety/efficacy of DefenCath when used in combination with chlorhexidine-coated catheter caps.

Taken together, while DefenCath is very effective for protection from CRBSIs, evidence supports it being one of several tools in the toolbox of preventive care for hemodialysis patients. Evidence of added benefit in addition to chlorhexidine-coated catheter caps is lacking, and the evidence does not show that DefenCath is a cost-effective alternative to chlorhexidine-coated caps.

Effective Dates

September 2025: Effective date.

References

Agarwal AK, Roy-Chaudhury P, Mounts P, et al. Taurolidine/Heparin Lock Solution and Catheter-Related Bloodstream Infection in Hemodialysis: A Randomized, Double-Blind, Active-Control, Phase 3 Study. *Clin J Am Soc Nephrol*. 2023 Nov 1;18(11):1446-1455. doi: 10.2215/CJN.000000000000278. Epub 2023 Sep 6. PMID: 37678222; PMCID: PMC10637459.

Allon M, Sexton DJ. Tunneled hemodialysis catheter-related bloodstream infection (CRBSI): management and prevention. In: *UpToDate*, Connor RF (Ed), Wolters Kluwer. Accessed 6/6/2025.

DefenCath [package insert]. Berkeley Heights, NJ: CorMedix Inc.; 2024.

Ezzat H, Elsharkawy M, Rezk K, Mohsen R, Mansour A, Emara A. Effect of taurolidine citrate and unfractionated heparin on inflammatory state and dialysis adequacy in hemodialysis patients. *J Vasc Access*. 2023 Jan;24(1):45-51. doi: 10.1177/11297298211023295. Epub 2021 Jun 11. PMID: 34112001.

IPD Analytics. New drug review: DefenCath (taurolidine and heparin). Dec 18, 2023. Accessed on 6/6/2025.

Murray EC, Deighan C, Geddes C, et al. Taurolidine-citrate-heparin catheter lock solution reduces staphylococcal bacteraemia rates in haemodialysis patients. *QJM*. 2014 Dec;107(12):995-1000. doi: 10.1093/qjmed/hcu128. Epub 2014 Jun 16. PMID: 24939191.



Nguyen T, Camins BC, Butler DA. Taurolidine and Heparin as Catheter Lock Solution for Central Venous Catheters in Hemodialysis. *Am J Ther.* 2024 Jul-Aug 01;31(4):e398-e409. doi: 10.1097/MJT.0000000000001736. Epub 2024 May 7. PMID: 38710029.

