

## Medical Necessity Guidelines DefenCath

**Policy Number: 099**

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### 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.

### Medicare Advantage

Prior Authorization Required	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity 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 medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan’s most recent policy review, Medicare had:**

- [Medicare Benefit Policy Manual Chapter 15: Covered Medical and Other Health Services](#)

### Mass General Brigham ACO

Prior Authorization Required	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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Mass General Brigham Health Plan uses the [MassHealth Drug List](#) for medical necessity determinations for members of the Mass General Brigham ACO. Criteria for DefenCath are found in [Table 66: Antibiotics and Anti-Infectives - Injectable](#).

### One Care and Senior Care Options (SCO)



Prior Authorization Required	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its One Care and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, or the member does not meet all of the medical necessity criteria for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. **See Medicare Advantage criteria and exclusions above. If Medicare Advantage criteria are not met, then MassHealth criteria are applied.**

## Commercial and Qualified Health Plans

This is not a covered service for commercial and qualified health plan members.

## 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

May 2026: Ad hoc update. Reformatted policy. Updated PA requirement for One Care and SCO members.



January 2026: Ad hoc update. Updated prior authorization table and added variation for One Care and SCO members.

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.

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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.

