



## Hospital Beds with Added Safety Enclosure Clinical Coverage Criteria

### Description

Under the Food and Drug Administration (FDA) Medical Specialty of General Hospital, an Enclosed Bed Canopy System (Product Code OYS: Patient Bed with Canopy/Restraints), is a passive bed enclosure that provides a solid framework and a soft canopy structure, which securely attaches to the bed and shelters and restrains the patient without touching the patient. The canopy provides access to the patient through secured openings, allowing the healthcare worker the ability to provide routine care to the patient, while providing a more controlled environment when the patient is unattended ([Food and Drug Administration Subchapter H, Part 880, Subpart G, Sec. 880.6760 Protective Restraint](#)). A protective restraint is defined in Sec. 880.6760 as a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.

Enclosed Bed Canopy Systems registered under Product Code OYS include but are not limited to, The Safety Sleeper (Abrams Nation, LLC), Cubby Bed (Sensory Medical, Inc.), and InSIGHT (SleepSafe Beds, LLC), and can be partially or fully enclosed with zippered mesh panels or can be fabricated with other materials, with or without interior padding, and can be stationary or portable, depending on the manufacturer or type of bed. Enclosed Bed Canopy Systems are exempted class I devices. A premarket notification application and FDA clearance is not required before marketing the device in the U.S. however, the manufacturers are required to register their establishment (Establishment Registration & Device Listing: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/rl.cfm>).

Manual Adjustable Hospital Beds (Product Code FNJ: Manual Adjustable Hospital Bed), under the FDA Medical Specialty of General Hospital are exempted class I devices. Manual Adjustable Hospital Beds do not require a premarket notification application and FDA clearance before marketing the device in the U.S., however, the manufacturer is required to register their establishment. A manual adjustable hospital bed is a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latchable side rails ([Food and Drug Administration, Subchapter H, Subpart F, Sec. 880.5120 Manual Adjustable Hospital Bed](#)).

At this time, The Safety Sleeper (Abrams Nation, LLC), Cubby Bed (Sensory Medical, Inc.), and InSIGHT (SleepSafe Beds, LLC) are registered as both Enclosed Bed Canopy Systems and Manual Adjustable Hospital Beds.

Some Enclosed Bed Canopy Systems have additional features, such as Bed-Patient Monitors that are used to indicate by an alarm or other signal when a patient attempts to leave the bed. Bed-Patient Monitors (Product Code KMI) are exempted class I devices, and as such, require registration prior to marketing. Cubby Bed Technology Hub (Sensory Medical, Inc.) is available for use with Cubby Bed (Sensory Medical, Inc.).

### Policy

This Policy applies to the following Fallon Health products:

- ☑ Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- ☑ MassHealth ACO
- ☑ NaviCare HMO SNP, NaviCare SCO
- ☑ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- ☑ Community Care

Hospital beds with added safety enclosure require prior authorization by a Fallon Health Medical Director.

All hospital beds, including hospital beds with added safety enclosure require a written prescription from the treating physician (or qualified non-physician practitioner, i.e., nurse practitioner, clinical nurse specialist or physician assistant).

Clinical documentation, from the treating physician's medical records, that clearly supports the medical necessity for the hospital bed with added safety enclosure, must be submitted with the prior authorization request.

Please note: When authorizing unlisted codes, such as E1399, and codes without established Medicare or MassHealth fee schedule rates, such as E0328, a single case agreement must be in place with an out-of-network provider, prior to issuing the authorization.

### **Fallon Health Clinical Coverage Criteria**

Fallon Health Clinical Coverage Criteria apply to Community Care members.

Consistent with Noridian Healthcare Solutions, LLC LCD L33820, fixed height hospital beds are covered only if one or more of the following criteria (1-4) are met:

1. The member has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed. or
2. The member requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain, or
3. The member requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration, or
4. The member requires traction equipment, which can only be attached to a hospital bed.

Side rails or safety enclosures are covered when they are required by the member's condition and they are an integral part of, or an accessory to, a covered hospital bed.

### **Medicare Variation**

Medicare statutes and regulations do not have coverage criteria for hospital beds with added safety enclosure. Medicare has an NCD for Hospital Beds (280.7). Noridian Healthcare Solutions, LLC, the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) with jurisdiction in the Plan's service area has an LCD for Hospital Beds and Accessories L33820 (MCD search 01/15/2025). Coverage criteria for hospital beds are fully established by Medicare, therefore, the Plan's clinical coverage criteria are not applicable.

Link: [NCD Hospital Beds \(280.7\)](#)

Link: [LCD Hospital Beds and Accessories L33820](#)

### **MassHealth Variation**

MassHealth has Guidelines for Medical Necessity Determination for Hospital Beds (MassHealth website search 01/15/2025), and these Guidelines include criteria for pediatric hospital beds with added safety enclosure. However, effective June 1, 2025, the following clinical coverage criteria will be used to determine medical necessity for pediatric hospital beds with added safety enclosures for MassHealth members. Criteria in the MassHealth Guidelines will be used to determine medical necessity for requests for other types of hospital beds.

Pediatric hospital beds with added safety enclosure are covered when criteria 1-3 are met:

1. The member has a medical diagnosis that supports use of an enclosed bed (one of the following):
  - a. Autism spectrum
  - b. Cerebral palsy
  - c. Epilepsy
  - d. Sensory processing disorder
  - e. Down syndrome
2. The member has displayed unsafe behavior which puts the member at risk of severe injury and is documented in the medical record (one of the following):
  - a. Falling out of bed
  - b. Self injury
  - c. Eating inedible items
  - d. Bolting or fleeing
3. The member has failed a trial or a trial is inappropriate as an alternative to the enclosed hospital bed (all must have been tried or are inappropriate):
  - a. Helmet
  - b. Mattress of the floor
  - c. Door and/or window locks
  - d. Removal of dangerous items from the member's room
  - e. Medications
  - f. Behavioral treatment

## Exclusions

- Technology Hub and Sensory System do not meet the definition of Durable Medical Equipment (or any other covered benefit), and are therefore excluded from coverage.

## Summary of Evidence

N/A

## Analysis of Evidence (Rationale for Determination)

N/A

## References

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD). Hospital Beds (280.7). Version Number 1. Effective Date of this Version: This is a longstanding national coverage determination. The effective date of this version has not been posted. Available at: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=227>. Accessed 01/15/2025.
2. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD). Hospital Beds and Accessories L33820. Original Effective Date: For services performed on or after 10/01/2015. Revision Effective Date: For services performed on or after 01/01/2020. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33820>. Accessed 01/15/2025.
3. MassHealth. MassHealth Guidelines for Medical Necessity Determination for Hospital Beds. Revised Policy Effective July 1, 2019. Available at: <https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-hospital-beds>. Accessed 02/24/2025.

## Coding

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

Please note: When authorizing unlisted codes, such as E1399, and codes without established Medicare or MassHealth fee schedule rates, such as E0328, a single case agreement must be in place with an out-of-network provider, prior to issuing the authorization.

Code	Description
E0316	Safety enclosure frame/canopy for use with hospital bed, any type
E0328	Hospital bed, pediatric, manual, 360 degree side enclosures, top of headboard, footboard and side rails up to 24 in above the spring, includes mattress
E1399	Durable medical equipment, miscellaneous

## Policy history

Origination date: 06/01/2025  
Review/Approval date(s): Technology Assessment Committee: 02/25/2025 (policy origination).  
Utilization Management Committee: 03/18/2025 (review and approval).

## Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.

