MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Specialty Enclosure Bed Systems**
Policy Number	**01.01.56**
Category	**Technology Assessment**
Original Effective Date	**05/15/25**
Committee Approval Date	**01/23/25**
Current Effective Date	**05/15/25**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. In general, nonstandard specialty enclosure bed systems (e.g., Cubby Bed, SleepSafe Bed, Abrams Safety Sleeper, Courtney Bed, and Hanna Bed) for in home use are considered **medically appropriate** when standard hospital beds with or without enclosure cannot achieve therapeutic benefit. Specialty enclosure beds are for children and adults with a disease or a medical condition that increases their risk of injury and making them susceptible to harm from injury by exiting the bed unsafely when **ALL** the following criteria are met:

A. **ONE** of the following diagnosis-related cognitive or communication impairment.
1. Autism Spectrum Disorder (ASD);
2. Cerebral Palsy (moderate to severe);
3. Psychiatric, neurological or metabolic diagnosis with documented risk of self-injury;
4. Neurological disorders causing disorientation or vertigo;
5. Seizure disorders with daily seizure activity, characterized by loss of consciousness or lack of awareness to surroundings;
6. Severe behavior disorders;
7. Traumatic Brain injuries (TBI); **or**
8. Uncontrolled perpetual movements related to a diagnosis;

AND

B. There is evidence of a safety risk that includes **ALL** of the following:
1. Evidence of mobility that puts the patient at risk for injury while in bed (more than standing at the side of the bed); **and**
2. The individual has history of injury related to bed mobility that has occurred prior to this request;

AND

C. **ALL** of the following documentation:
   1. Current prescription (written order) including the specific HCPCS code for item and each accessory with the make, model, and price quotation;
   2. A written monitoring plan which describes how and when the bed will be used;
   3. How the member will be monitored at specified time intervals by an adult or appropriate caregiver;
   4. Documentation the provider has ruled out physical and environmental factors as reasons for patient behavior (e.g., hunger, thirst, restlessness, pain, need to toilet, fatigue due to sleep deprivation, acute physical illness, temperature, noise levels, lighting, over- or under-stimulation, or a change in caregivers or routine);
   5. Assessment of the member's physical status including their age, weight, length, or height;
   6. Assessment of gross motor function and assessment of cognitive function including developmental age equivalent for motor function, cognitive function, and habilitation potential;
   7. How all of the member's needs will be met while using the enclosed bed (including eating, hydration, skin care, toileting, and general safety);
   8. Identification by relationship of all caregivers providing care to the member;
   9. An explanation of how any medical conditions (e.g., seizures) will be managed while the member is in the enclosed bed;
   10. Current sleep environment including less intensive alternatives to improve the individual safety have been tried and ruled out (include documentation of why they could not meet medical needs). Considerations include, but are not limited to:
      a. Bed rails, Bed tent or canopy, plastic shields
      b. Helmet
      c. Mattress placed on the floor;
      d. Removal of all safety hazards;
      e. Bed alarms;
      f. Video/audio monitors;
      g. Child protection devices such as locks on doors, windows, cabinets, furniture anchors, gates at steps and doors;
   11. Physician-directed medication to address seizures, behaviors and sleep and how they have failed;
   12. Environmental modification (e.g., white noise, headphones, night or daytime indicators) to encourage calming behaviors and sleep and how they have failed;
   13. Established routines addressing sensory needs and/or behavior modification to assist with improved naptime or nighttime behaviors and sleep and how they have failed;
   14. A home evaluation from a qualified occupational or physical therapist (or other clinician) that is comprehensive and specific to the individual; **and**
   15. A successful trial in the home or facility.

II. Specialty Enclosure Bed Systems are considered **not medically appropriate** for the following indications including but not limited to:

   A. Children who are under the age of three (3);
   B. For adults with confusion or dementia;
   C. For Entrapment;
   D. For caregiver need or convenience.

III. The following items are considered nonhospital beds or accessories items and are considered **not medically appropriate.**

   A. Beds sold as traditional furniture including adjustable beds (e.g., Craftmatic Adjustable Bed, Simmons Beautyrest adjustable, Electrometric adjustable bed, and Sealy Posturepedic Beds);

B. Accessory Items or services (e.g., technology hubs, vibrating pads, travel cases, memory foam mattresses, other bed accessories such as bed linens, tables, pillows) that do not contribute meaningfully to the treatment of an illness or injury or the functioning of a malformed body member.

IV. Repair and/or replacement of a medically necessary enclosed bed systems or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:
1. date of device initiation,
2. manufacturer warranty information, and
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;
4. all criteria are met as stated in Policy Statement I **AND ONE OF THE FOLLOWING STATEMENTS (B or C) APPLY**:

B. Repair of the currently used device when **ALL** of the following are met:
1. it is no longer functioning adequately,
2. inadequate function interferes with activities of daily living, and
3. repair is expected to make the equipment fully functional (as defined by manufacturer); **OR**

C. Replacement of the currently used device when the following are met:
1. it is no longer functioning adequately, and improvement is expected with a replacement unit, **AND EITHER**
2. has been determined to be non-repairable, **OR**
3. the cost of the repair is in excess of the replacement cost.

V. The replacement of properly functioning enclosed bed systems or external components is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

VI. Repair or replacement of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage.**

Refer to Corporate Medical Policy #1.01.00 Durable Medical Equipment - Standard and Non-Standard

Refer to Corporate Medical Policy #11.01.11 Comfort, Convenience, Custodial or Cosmetic Services

POLICY GUIDELINES

I. Requests for bed systems that have been determined by the U.S. Food and Drug Administration (FDA) to pose significant safety risk (e.g., Vail enclosed bed system), will not be covered. Please refer to the following site for more information: [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM] accessed 10/31/24.

II. Please reference the most current InterQual CP: Durable Medical Equipment Hospital Beds, Cribs and Accessories for all other non E1399 hospital bed requests (except managed Medicaid).

DESCRIPTION

Specialty Enclosure Bed Systems

A specialty enclosure bed system is a specialized bed that are sometimes referred to as adaptive beds, enclosed canopy beds, special needs beds, or child safe beds. They have been manufactured or customized with enclosure components for adults or children that allow it to function as a restraint. These beds can be fully or partially be enclosed with zippered mesh panels or fabricated with wooden or metal side panels, or side rails with interior padding that may only be opened from the outside and include other safety components. The beds are designed primarily for providing an enclosed sleeping area and preventing the individual from leaving their beds without supervision. Enclosure bed systems can vary widely in design and price. Bed features typically pertain to safety (e.g., high side or barriers) but can include additional features such as lighting, music, and other electronic features.

Safety enclosure canopies or posey enclosure systems are a frame or canopy used to prevent a patient from leaving the bed. This item encloses the standard hospital bed with a netting attached to a frame and is designed for patients or individuals who would need to be restrained when leg or wrist restraints are not used.

Pediatric specialty enclosure beds are distinguished by 360° enclosure of the perimeter. The enclosure bed can be for adults or pediatrics.

SleepSafe Beds is a safety bed with built-in safety rails and are available in many sizes, colors, and features. SleepSafe bed address concerns of safety (e.g., entrapment issues and prevention of falls with increased safety rail height). These beds are available with a variety of functions and features (e.g., either electric or non-electric foundations, with or without padding etc.).

Cubby bed is a safety bed for special needs children. It is a full-size canopy covered bed with mesh and fabric doors and safety sheets. Additional optional features include HD camera with night vision, two-way audio, motion and sound detection with alerts, smoke and carbon monoxide detection with alerts and circadian light. Cubby Bed is a class 1 medical device: patient bed with canopy/restraints - Product Code OYS. On March 14, 2022, Sensory Medical Inc issued a device recall (FDA recall Z-0918-2022) for its Cub 2 Enclosed Bed Canopy System product distributed before December 16, 2021, in order to update its warnings and precautions booklet with information on potential for the risk of misuse and possible entrapment.

Abrams Safety Sleeper was designed for children and adults with special needs. It features a soft, padded, and fully enclosed design that prevents climbing out of bed in the middle of the night.

Courtney bed has a solid hardwood frame, high sided fabric enclosure with zipper mesh sheath. The product can be manufactured to be used for adults or pediatrics.

Hannah bed has tall safety rails for child at risk for injuries, elopements or falls. The bed allows air flow, independent entering and exiting and the ability to see through the bed. The bed has many customized options for diverse needs.

RATIONALE

Specialty enclosure beds for in home are used to prevent falls, injuries, and entrapment for individuals who are at risk from injuring themselves while in bed. Neurological, developmental or mental health disorders can increase those risk factors. Enclosed bed systems are considered a restraint and the use of the system with protective components should be considered only after all available and less restrictive alternatives have been unsuccessful in maintaining the safety of the individual. The ideal approach is to address the underlying medical and/or behavioral issues that increase the risk of harm. Currently there is no evidence-based research to suggest that enclosure bed improves clinical outcomes and net benefits.

On March 22, 2005, the U.S. Food and Drug Administration (FDA) and the U.S. Department of Justice initiated seizures of all finished Vail 500, 1000, and 2000 Enclosed Bed Systems on the ground that use of these systems poses a public health risk because patients can become entrapped and suffocate, resulting in severe neurological damage or death. The FDA believed the Vail products seized do not meet the quality system regulations of the FDA and Cosmetic Act and pose significant health risk for consumers. Vail Products failed or refused to furnish material or information to the FDA as required by Medical Device Reporting regulation and the Reports of Corrections and Removals.

Anderson et al. (2012) published a Cochrane systematic review to assess the effectiveness of interventions designed to prevent patient injuries and falls from bed. Inclusion criteria were randomized controlled trials of interventions designed to prevent patient injuries from their beds which were conducted in hospitals, nursing care facilities or rehabilitation units. Two studies involving a total of 22,106 participants met inclusion criteria. One study evaluated low height beds. The second study evaluated bed exit alarms. Both studies used standard care for their control group and were conducted in hospitals. No study investigating bed rails met the inclusion criteria. The researchers concluded that the effectiveness of interventions designed to prevent patient injuries from their beds (including bed rails, low height beds and bed exit alarms) remains uncertain. The available evidence shows no significant increase or decrease in the rate of injuries with the use of low height beds and bed exit alarms. Limitations of the two included studies include lack of blinding and insufficient power. No randomized controlled trials of bed rails were identified. Researchers suggest future reports should

fully describe the standard care received by the control group. There have been no comparative studies or randomized controlled trials identified that compare the use of safety beds to standard bed rails, bed wedges, or enclosed hospital beds.

An enclosure bed could be considered a less restrictive alternative option for individuals with altered self-awareness or neurological impairments as part of an individualized care plan to prevent falls and injuries. According to Ogundele and Yemula 2022, there is a complex relationship between sleep disorders and children who have recognizable neurodevelopmental, emotional, behavioral and intellectual disorders (NDEBID). NDEBID include several conditions such as attention deficit/hyperactivity disorder, autism spectrum disorder, cerebral palsy, epilepsy and learning (intellectual) disorders. Sleep difficulties and disorders can be a common comorbidity for the NDEBID population. Chronic sleep deprivation is associated with significant risks of behavioral problems, impaired cognitive development and learning abilities, poor memory, mood disorders and school problems (Ogundele and Yemula, 2022). Most professional guidelines have consistently emphasized the role of effective sleep hygiene strategies behavioral interventions, parent and care giver education and training, as a first line treatment approach for improving sleep of children and adolescents either alone or in combination with pharmacologic treatment. Behavioral interventions, along with tracking devices, physical barriers (e.g., window, door locks, fencing), and other resources have shown to be successful in reducing elopement (Buckley et al., 2020).

Enclosed beds should not be used as a discipline measure or as a restraint during times of high agitation or aggression or to limit sensory deprivation. Enclosed beds should be used at night for sleeping and only for short rests or naps during the day due to the restrictive nature, extreme confinement, and functional use as a restraint, specialty beds or enclosure beds (e.g., Sleep Safe, Courtney Bed, Hanna Bed, Abrams Safety Sleeper, Cubby bed) can result in issues of sensory deprivation and potential for overuse.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN)*

CPT Codes

Code	Description
	No Codes

HCPCS Codes

Code	Description
E1399	Durable medical equipment, miscellaneous [when specified as a canopy bed or part of an enclosed bed]

ICD10 Codes

Code	Description
	Numerous

REFERENCES

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Enclosure bed: A protective and calming restraint. American Nurse Association website. [https://www.myamericannurse.com/use-enclosure-beds/] accessed 10/25/24.

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KEY WORDS

Enclosure beds, Safety Bed, Entrapment, Adjustable Bed, Electric Bed, Hospital Bed, Restraints

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD#280.7) Hospital Bed for hospital beds. Please refer to the following NCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=227&ncdver=1&bc=0] accessed 10/07/24.

There is currently a Local Coverage Determination (LCD# L33820) Hospital Beds and Accessories for Enclosure Bed Systems. Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33820&ver=21&bc=0] accessed 10/07/24.