National Coalition For Assistive & Rehab Technology

# Position on Adaptive/Protective Beds

## Adaptive/Protective Beds

### Problem

The use and potential misuse of adaptive/protective beds is an area of concern that has been identified by consumers, clinicians, manufacturers, suppliers, policymakers, and third-party payors. The benefits of an adaptive/protective bed, as a medical device, is often mischaracterized as furniture or a convenience item, considered experimental or investigational in nature, or inaccurately viewed as a non-medical restraint. This creates inequitable access to this medically necessary equipment and a disparity in healthcare funding for individuals with disabilities and complex medical conditions across their lifespan.

### Purpose

The purpose of this paper is to educate and advocate for the appropriate use of adaptive/protective beds, minimize the risk of preventable adverse occurrences and health outcomes, and improve the health, safety, and wellbeing of people with a medical need for this equipment by providing a safe sleeping environment. This document fills a gap in knowledge by providing appropriate definitions, outlining the need for intervention, and offering recommendations for documentation, prior authorization, and coding in support of an adaptive/protective bed. Utilization of this information is not intended to replace clinical judgement that must be applied to individual cases. This position paper is intended to assist consumers, clinicians, manufacturers, suppliers, policymakers, and third-party payors in making informed decisions regarding the provision of an adaptive/protective bed.

### Position

For the rights of individuals with disabilities and complex medical conditions, as outlined in this position paper, protective/adaptive beds are a medical necessity. These specialized beds play a critical role in minimizing the risk for preventable accidents, injuries[8,23,25] and adverse occurrences during sleep.[22,24.29] They are essential to support the overall health and therapeutic outcomes for individuals with complex needs such as congenital, genetic, neurological, and/or neurodivergent conditions. Denying access to such equipment compromises patient safety, dignity, and rightful access to necessary healthcare.

### (A) Definitions and Explanations

1. “Adaptive/Protective Bed” – A medical device, registered with the FDA, prescribed specifically for an individual of any age with a medically established diagnosis, disability, or complex medical condition, and/or has ‘special healthcare needs’ when in bed.
    a. Designed to protect the user from falls, injury, a preventable medical complication, an adverse outcome during sleep time, and/or to treat or mitigate their medical condition(s) while in use.[13,17,20,23,25]
    b. Intended for use in the home, in a child care facility, in a family care home, or places of public accommodation affecting commerce.
    c. Design and performance testing, and/or device history, shall demonstrate the mechanical and structural stability of the adaptive/protective bed under expected conditions of use, including the security of latches and other securement mechanisms when engaged.[4]

d. All products must be registered with the Food & Drug Administration (FDA) as a medical device, manufactured and distributed in compliance with FDA Quality System Regulation 21 CFR § 820[3], meet any applicable requirements set forth by the Centers for Medicare and Medicaid Services (CMS), and comply with all applicable Federal, State and Local laws.
e. Each device must be accompanied by information related to the use, care, maintenance, and safety guidelines established for the designed and intended use of the product.

2. "Enclosed Bed" – An adaptive/protective bed with the following characteristics:
   a. Meet or exceed the standards for Zone 3 (between the rail and the mattress) and Zone 7 (between the head or footboard and the end of the mattress) set forth in the Food & Drug Administration's (FDA) seven (7) zones of entrapment.[19]
   b. 360-degree unbroken perimeter around the mattress. The perimeter may be constructed of rigid (i.e., wood, composite board, laminate, aluminum, metal, etc.) and/or soft-sided (i.e., canvas, mesh, etc.) materials.
   c. Interior side height, as measured from the top of the panels to the top of the mattress in its sleep position, shall be at least 9" (22 cm)[10] but can be higher to accommodate the individual's height, strength, mobility risk(s) and/or their protective needs as required. Note: this does not pertain to changes in the position of components for medical care or transfer positions of the mattress.
   d. Perimeter gaps shall be no greater than 1" (2.5 cm) when the bed is in the closed position.
   e. Openings for medical equipment shall be no greater than 2 3/8" (6 cm)[4,11] wide and located away from all fasteners.
   f. Includes and/or accommodates a standard size mattress that must:
      i. Be larger than a standard crib measurement of 28" x 52 3/8" (71 cm x 132 cm).[9]
      ii. Fit tightly around the interior of all four (4) sides (no more than a 1" perimeter gap when uncompressed and a 2 3/8" perimeter gap when compressed)[19] to optimize the prevention of entrapment, entanglement, or impingement.[4]
      iii. Meet minimum flammability standards set forth in, or comparable to those outlined in 16 CFR 1632[1] and 16 CFR 1633.[2]
   g. All textiles used in the construction of the bed must:
      i. Be appropriate for the conditions of use, allow for proper sanitation, and be free from surface defects that could result in injuries.[4]
      ii. Meet minimum requirements for:
         a. Biocompatibility of materials used in the device that come in direct or indirect contact with the human body, and as outlined in the FDA guidance document ISO 10993-1.[16]
         b. Tensile strength sufficient to accommodate the individual's needs (i.e., fall protection, injury prevention).
         c. Tear strength sufficient to accommodate the individual's needs (i.e., fall protection, injury prevention).
   h. Hardware and fasteners shall be designed and constructed to minimize mechanical hazards and risk for injury.[4]
   i. Weight capacity of the bed and mattress must be at least two hundred fifty (250) pounds.
   j. Requires caregiver assistance to exit when closed and secured.
   k. May accommodate, but is not a defining component or feature of an enclosed bed:

i. Padding;
ii. Locking or retractable type casters to move the bed;
iii. One or more ports to accommodate supplemental medical equipment/tubing;
iv. A mechanism to raise, lower, or position the head and/or foot of the bed;
v. A mechanism to raise and lower the height of the mattress and/or bed frame;
vi. Monitoring and/or sensory technologies;
vii. A pressure relieving or positioning mattress and/or positioning components; or,
viii. Other additional medically necessary components for individual use.

3. "Enclosure" – A protective canopy used with an enclosed bed that:
    a. May be comprised of a soft mesh/fabric interfacing that includes a structural frame and base for support that is stretched over the top of an enclosed bed and attached directly to the protective sides or panels to create a completely closed space.
    b. May be an integrated protective canopy as part of an enclosed bed as long as it complies with the definition of an enclosed bed set forth herein.
4. "Extension" – A component used with an enclosed bed to increase the height of the headboard, footboard, and side.
5. "Restraint" – Any mechanical or personal restriction that immobilizes or reduces the ability of an individual to move his or her arms, legs, or head freely, not including devices to protect the beneficiary from falling out of bed or to permit the beneficiary to participate in activities without the risk of physical harm.[6,7]
6. "Safety Bed" – A commonly accepted term used in the medical community to describe an adaptive, protective, or enclosed bed with or without an add-on or integrated enclosure.
7. "Semi-Electric" – Allows for motorized control of the head, and/or foot of the bed.
8. "Technology - Monitoring" – Non-intrusive devices and/or systems (i.e., cameras, sensors) embedded in the environment that provide real-time information for early detection, intervention, prevention and/or warning for ongoing care and support.
9. "Technology - Sensory" – Non-invasive devices and/or systems designed to enhance, augment, or replace natural senses.
10. "Variable-Height" – A mechanism for height adjustment of the bed. May be manual or powered. May also be known as high – low bed or transfer height.

**(B) Coverage**

The beneficiary has a congenital, genetic, neurological, or neurodivergent condition and:

- Presents with impaired motor development, balance, safety awareness, pain perception, a sleep disorder,[22,28] and/or sensory regulation challenges[13,21] leading to impaired function; or
- Is at risk of falls,[13] has impaired motor skills,[13] poor executive function,[22] sensory outbursts,[18] wandering, and/or elopement;[8,25] or
- A motor and/or behavioral disorder that leads to a heightened risk of injury to themself, others, and/or property and is at an increased risk of morbidity or mortality;[8,13,17,23,25] and,
- Alternative solutions are NOT adequate.

The following criteria may be considered when making a medical necessity determination for an enclosed bed with or without an add-on or integrated enclosure.

1. The bed is:
    a. Prescribed by a medical professional within their scope of practice;

   b. Recommended following an in-person or telehealth assessment of the beneficiary by their treating healthcare professional(s) within their scope of practice;
   c. Consistent with symptoms or confirmed diagnosis of the illness or injury under treatment and is not in excess of the beneficiary's needs;
   d. Necessary to protect life; prevent illness or injury; ameliorate disability; mitigate pain; or minimize the risk for an adverse occurrence;
   e. Consistent with generally accepted medical and clinical standards of care; and,
   f. Reflective of the level of service that can be safely furnished, and for which no equally effective, less costly alternative is available. Note: less costly alternatives may be tried and failed, considered and ruled out, or contraindicated, alone or in combination, and may require justification as to why they are insufficient and/or not appropriate for use.
2. The beneficiary:
   a. Has a documented congenital, genetic, neurological, or neurodivergent condition; mental illness; and/or other medical condition(s), which have or will likely result in injury to self, others, and/or property due to wandering, elopement,[8] or a flight factor;[15] and,
   b. The use of a crib, toddler bed, standard bed, hospital bed, or other less costly alternatives are incapable of protecting the beneficiary from injury or do not permit them to participate in the activity of sleep without risk of physical harm.
3. A semi-electric adaptive/protective bed is covered when 1 and 2 above are met, and additional documentation shows that one or more of the following conditions (a – c) and (d) are met:
   a. There is a medical condition that necessitates the semi-electric feature; or,
   b. An immediate change in position is necessary to avert a life threatening situation; or,
   c. The change in position cannot be accomplished by using the side rails, a trapeze, or the long-term assistance of a caregiver; and,
   d. It is not for the convenience of the caregiver.
4. A variable-height feature is covered if, in addition to meeting the criteria for an enclosed bed, the physician or licensed practitioner orders a bed height different from a fixed-height bed to:
   a. Accommodate safe transfers to a chair, wheelchair or standing position; or,
   b. Allow for care to minimize the risk of beneficiary injury, illness, or to ameliorate disability.
   c. A variable-height feature is not covered when used for the convenience of the caregiver.
5. Additional options, accessories, or features may be deemed medically necessary on a case-by-case basis to meet the beneficiary's healthcare needs. These may include, but are not limited to:
   a. A size greater than a standard twin;
   b. Padding;
   c. Heavy-duty materials for increased weight capacity and/or beneficiary safety;
   d. A pressure relieving mattress and/or bed positioning components;
   e. Locking or retractable casters;
   f. Port(s) to accommodate medical equipment and/or tubing;
   g. Monitoring and/or sensory technologies; and,
   h. Other additional medically necessary components for individual use.
6. An enclosed bed, with or without an add-on or integrated enclosure, shall be considered not medically necessary if:[12,14]
   a. It is primarily intended for the convenience of the beneficiary or their caregiver(s); or
   b. The beneficiary is not at risk for injury or harm to themselves or others.

**(C) Documentation**

1. The enclosed bed, an enclosure, and any additional medically necessary options, accessories or features are prescribed by a medical professional within the scope of their practice.
2. A description of the medical/clinical problem(s) or functional need(s) to be addressed, including an explanation of why there is a significant probability of falls, injury, or danger to the beneficiary and/or others; or the impact of beneficiary sleep deprivation as a result their inability to participate in the activity of sleep without risk of physical harm.
3. Identification of the enclosed bed, with or without an add-on or integrated enclosure recommended, and an explanation of how the bed and any additional options/accessories address the beneficiary's healthcare and/or functional need(s).
4. An explanation of alternatives tried and failed, considered and ruled out, or contraindicated.
5. If no alternative means were tried, a rationale is given by the prescriber and/or treating healthcare practitioner(s) to explain why alternatives are contraindicated and/or no attempt was made.
6. Verification that the family or caregiver(s) are willing and able to appropriately manage and maintain the enclosed bed, with or without an add-on or integrated enclosure.[14,18]
7. A detailed monitoring plan[14,25] approved by the prescriber and/or the treating healthcare practitioner(s) and includes, at minimum:
    a. The times or situations in which the adaptive/protective bed will be used.
    b. How the beneficiary will be monitored.
    c. An explanation of how the beneficiary's needs will be met while in the adaptive/protective bed such as, but not limited to:
        i. General safety.
        ii. Management of medical conditions.
        iii. Nutrition.
        iv. Hydration.
        v. Skin care.
        vi. Toileting.
    d. Identification of all persons, including relationship to the beneficiary, who will be providing care and monitoring.
8. A diagnosis alone does not establish medical necessity.
9. The treating healthcare practitioner(s) evaluating, documenting the medical necessity for, and/or prescribing the adaptive/protective bed, with or without an integrated or add-on enclosure, cannot be employed by or have a financial relationship with the manufacturer or medical equipment supplier of the bed.

**(D) Prior Authorization**

1. Purchase of an enclosed bed, with or without an add-on or integrated enclosure, shall be subject to prior authorization, when applicable.
2. The addition of an enclosure, or an enclosed bed with an integrated enclosure, shall only be considered for approval when the medical/clinical benefit is shown to outweigh any inherent risk to use. Such risks should be addressed.
3. Additional items like those referenced in section A(2)(j) hereinabove shall not be considered as part of the standard components of an enclosed bed, with or without an add-on or integrated enclosure, and shall be reviewed and reimbursed individually.

**(E) Considerations**

1. An enclosed bed, with or without an add-on or integrated enclosure:
    a. Is contraindicated for individuals with a diagnosis of claustrophobia.[26]
    b. Should be carefully considered for individuals who:
        i. Are violent, combative, self-destructive, or suicidal.[26]
        ii. Are experiencing delusions, delirium, hallucinations, psychosis, in a confused state or going through drug or alcohol withdrawal.[26]
        iii. Become increasingly distressed, agitated, terrified or distraught while in the bed.
        iv. Require multiple medical IV lines, tubes, and catheters.
    c. Should not be considered a restraint unless:[30]
        i. It immobilizes the individual in the bed and/or presents undue physiological or psychological harm;[5]
        ii. It is used for any purposes other than to treat or mitigate a medical condition; prevent falls; protect the beneficiary from injury; allow the beneficiary to participate in the activity of sleep without risk of harm; or,
        iii. A less restrictive, medically appropriate alternative will meet the beneficiary's needs.
    d. Shall be deemed not medically necessary under any of the following circumstances:
        i. A regular bed, with or without adaptation, can meet the beneficiary's medical/clinical needs.
        ii. Interfacing with a non-medical, non-FDA regulated item is necessary to make the bed useful to accomplish its primary purpose, as designed by the manufacturer.
        iii. The bed is used for the sole purpose of:
            a. Behavior therapy or behavioral confinement.
            b. Calming or soothing, but not prevention of falls or physical injury.
            c. Caregiver convenience.
2. Even if they include side rails, panels or a perimeter, items that do not meet the definition of an adaptive/protective bed and are not considered an enclosed bed, with or without an add-on or integrated enclosure, include, but are not limited to:
    a. A pediatric medical crib or medical bassinet.
    b. A standard hospital bed, with or without a safety enclosure/frame.
    c. A crib, toddler bed, youth bed, or other bed manufactured and offered for sale commercially as household furniture.
    d. An institutional bed intended for use in a congregate setting (e.g., bunkhouse, prison).
    e. A lounge bed.
    f. A bed that can be transformed into the shape of a chair, rotated, or both for ease of ingress and egress.
    g. A playpen, "pack and play," or floor bed.
    h. A bed for which protective rails, sides, or panels are add-on accessories. This does not include an extension used with an enclosed bed.
    i. A commercially available tent or tent-like structure constructed primarily of fabric or mesh, typically used for camping or play.
    j. A product that is not deemed durable medical equipment.

## (F) Coding Guidelines[27]

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 inches above the spring, includes mattress.

E0329 – Hospital bed, pediatric electric or semi-electric, 360 degree side enclosures, top of headboard, footboard, and side rails up to 24 inches above the spring, includes mattress.

E1399 – Hospital bed, pediatric manual, electric, or semi-electric, 360 degree side enclosures, top of headboard, footboard, and side rails **greater than 24 inches** above the spring.

E1399 – Extension used with a fixed height enclosed bed to increase the height of the headboard, footboard, and side rails.

E1399 – Enclosed bed with an integrated enclosure.

E1399 – Adjustable-height feature.

E1399 – Medically necessary options and accessories used in conjunction with an enclosed bed that are not part of the required components.

## (G) References

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4. 21 CFR § 880.5140 – Pediatric Medical Crib. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-880/subpart-F/section-880.5140
5. 42 CFR § 482.13(e)(1)(i)(a) – Condition of Participation: Patient's Rights. Retrieved from https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-B/section-482.13
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