Clinical Policy Title: Air fluidized beds

Clinical Policy Number: 16.02.10

Effective Date: May 1, 2018
Initial Review Date: March 6, 2018
Most Recent Review Date: April 10, 2018
Next Review Date: April 2019

Related policies:

CP# 16.03.03  Negative pressure wound therapy for chronic ulcers

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of air fluidized beds for pressure ulcers presenting as full-thickness tissue loss or deep tissue destruction (excluding those of the foot) to be clinically proven and, therefore, medically necessary as durable medical equipment (DME) when the following criteria are met (Hayes, 2016; Tricco, 2015; Saha, 2013; Smith, 2013; Colin, 2012; McInnes, 2011; Hayes, 2010a; Hayes, 2010b):

- The member is bedridden or chair bound as a result of severely limited mobility.
- In the absence of an air-fluidized bed, the beneficiary would require institutionalization.
- A physician attests to a failure of the wound to progress in healing after member has completed a one-month course of conservative treatment designed to optimize conditions that promote wound healing. This includes:
  - Frequent repositioning with particular attention to relieving pressure over bony prominences (usually every two hours).
Use of a support surface to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation.

Necessary treatment to resolve any wound infection.

Optimization of nutrition status to promote wound healing.

Debridement by any means, including wet-to-dry gauze dressings, to remove devitalized tissue from the wound bed.

Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.

Education of the beneficiary and caregiver on the prevention and management of pressure ulcers.

Assessment by a physician, nurse, or other licensed health care provider at least weekly.

Appropriate management of moisture from incontinence.

- A physician directs the home treatment regimen, and re-evaluates and recertifies the need for the air-fluidized bed on a monthly basis.
- All other alternative equipment has been considered and ruled out.

Limitations:

An air-fluidized bed is not considered medically necessary under any of the following circumstances:

- There is coexisting pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions).
- Structural support is inadequate to support the weight of the air-fluidized bed system (it generally weighs at least 1,600 pounds).
- Electrical system is insufficient for the anticipated increase in energy consumption.
- Other known contraindications exist.

Coverage of an air-fluidized bed is limited to the DME itself. Architectural adjustments such as electrical or structural improvements for the air-fluidized bed are excluded from coverage.

Alternative covered services:

Routine patient evaluation and management by a network health care provider

Background

Pressure ulcers are moderate to severe areas of localized tissue damage to the skin and underlying structures secondary to chronic immobility. The use of support surfaces (e.g., specialized beds, pads, and cushions) designed to redistribute pressure in the prevention and treatment of pressure ulcers is an important part of care for a patient at risk and/or suffering from bedsores.

Pressure ulcers affect as many as 3 million Americans (Smith, 2013; Saha, 2013) and are major sources of morbidity, mortality, and health care costs. Pressure-relieving support surfaces are useful to abate
and/or reduce the pressure that promotes the development and prolongs the healing of decubiti. As such, these devices function as both a preventive measure and a key part of treatment where deformation already exists, and their use should constitute part of an overall preventive or curative strategy.

An “air-fluidized” bed is a bed with body support provided by thousands of tiny soda-lime glass beads suspended by pressurized, temperature-controlled air. Durable medical equipment (DME) is any equipment that provides therapeutic benefits to a patient in need because of certain medical conditions and/or illnesses. An item of DME must withstand repeated use and be appropriate for use in the hospital or home. Medicare maintains a list of approved DME. Among the items listed are hospital beds, including air-fluidized beds, and accessory items to hospital beds.

There are 3 manufacturers of air fluidized beds currently: Arjo-Huntleigh (FluidAir Elite), Hill-Rom (Clinitron RiteHite), and Aurora (HydroAir). There are vendors/distributors for these companies all over the country.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on February 8, 2018. Search terms were: “air fluidized beds,” “pressure-relieving support surface,” and “wound healing.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

A systematic review (Tricco, 2015) including over 54,000 patients evaluated multi-faceted wound-healing regimens to identify the best therapies for complex wounds. The most effective treatments
were bandages or stockings (multi-layer, high compression) and wound cleansing for venous leg ulcers; four-layer bandages for mixed arterial/venous leg ulcers; biologics, ultrasound, and hydrogel dressings for diabetic leg/foot ulcers; hydrocolloid dressings, electrotherapy, air-fluidized beds, and alternate foam mattresses for pressure ulcers; and silver dressings and ultrasound for unspecified mixed complex wounds. For surgical wound infections, topical negative pressure and vacuum-assisted closure were promising interventions, but this was based on moderate- to low-quality evidence.

A systematic review (Saha, 2013) addressed the effectiveness and/or harms of different treatments for pressure ulcers. These studies examined a wide range of interventions, but sample sizes often were small. There was moderate-strength evidence that some interventions were associated with wound improvement, including the use of air-fluidized beds (compared with other support surfaces), protein-containing nutritional supplements (compared with placebos or other routine measures of nutritional support), radiant heat dressings (compared with other dressings), and electrical stimulation (compared with a sham treatment). Only a minority of studies examined complete wound healing as an outcome. The authors concluded that in general, the evidence about the harms of any of these treatments was limited, and future research with larger sample sizes, more rigorous adherence to methodological standards for clinical trials, longer follow-up periods, and more standardized and clinically meaningful outcome measures is needed to better inform clinical practice and policy.

A systematic review (Smith, 2013) summarized the medical evidence on the effectiveness and safety of treatment strategies for adults with pressure ulcers. Moderate-strength evidence showed that air-fluidized beds (n = 908), protein-containing nutritional supplements (n = 562), radiant heat dressings (n = 160), and electrical stimulation (n = 397) may improve healing of pressure ulcers. In comparison with standard care, placebo, or sham interventions, there was low-strength evidence that alternating-pressure surfaces, hydrocolloid dressings, platelet-derived growth factor, and light therapy improved healing of pressure ulcers. However, the authors cautioned that the applicability of the results is limited by study quality, heterogeneity in methods and outcomes, and inadequate duration to assess complete wound healing.

A systematic review (Colin, 2012) reported that, in preventing pressure ulcers, a structured foam mattress is more efficient than a standard hospital mattress. An alternating pressure mattress is more effective than a visco-elastic mattress at limiting the occurrence of heel pressure ulcers, but those that do occur are more serious. A low-air-loss bed is more efficient than a mixed pulsating air mattress in preventing heel pressure ulcers. Some types of sheepskin can reduce sacral pressure ulcer incidence in orthopedic patients. Use of an overlay on an operating table limits the occurrence of perioperative and postoperative pressure ulcers. An air-fluidized bed improves pressure ulcer healing. However, the authors were compelled to criticize the methodological limitations of many studies, the lack of corporate interest in conducting such studies, and the relatively small number of available trials.

A systematic review (McInnes, 2011) assessed the effects of various support surfaces for prevention of pressure ulcers (n = 1309) and found the relative merits of higher-specification constant low-pressure and alternating-pressure support surfaces for preventing pressure ulcers are unclear, but alternating-
pressure mattresses may be more cost effective than alternating-pressure overlays. Pressure-relieving overlays on the operating table reduce postoperative pressure ulcer incidence, and providers would do well to consider the use of some forms of pressure relief for high-risk patients in the operating room. Foam alternatives to standard hospital foam mattresses reduce the incidence of pressure ulcers in people at risk (RR 0.40 95 percent confidence interval [CI] 0.21 to 0.74). Meta-analysis indicated that Australian standard medical sheepskins are also efficacious in preventing pressure ulcers (RR 0.56 95 percent CI 0.32 to 0.97).

Hayes (2010a) has evaluated beds and mattresses designed to prevent pressure ulcers and made the following determinations with regard to treatment safety and efficacy:

- C — This rating reflects inconsistent evidence of low quality supporting the use of specialized mattresses for pressure ulcer prevention. Despite certain weaknesses of the evidence, hospitals and other providers should consider acquiring some specialized pressure-relieving mattresses for use by patients who appear to have the greatest risk for ulcer development. In addition, providers should implement pressure ulcer prevention programs that involve frequent repositioning of patients and other aspects of conscientious nursing care, to minimize the likelihood of pressure ulcer formation. Specialized mattress technology intended to prevent pressure sores has been slow in adoption since specialized mattresses have been available for many years and are only one of several options for pressure relief.

Hayes (2010b) has evaluated pressure-reducing support surfaces for pressure ulcers and made the following determinations with regard to treatment safety and efficacy:

- C — For a viscoelastic polyurethane foam mattress instead of a standard foam mattress, for individuals at risk for pressure ulcer development. This rating reflects moderate-quality but conflicting evidence regarding the effect on pressure ulcer incidence in patients at risk for pressure ulcer development, and a lack of reported adverse events.
- C — For alternating pressure support surfaces instead of static support surfaces, for individuals at risk for pressure ulcer development. This rating reflects inconsistent evidence with respect to pressure ulcer incidence in patients at risk for pressure ulcer development, and incidental reports of adverse events.
- C — For all other pressure ulcer support surfaces presented in this report, for individuals at risk for pressure ulcer development and for individuals with existing pressure ulcers. This rating reflects a lack of evidence.
- D — For pressure ulcer support surfaces for individuals not at risk for pressure ulcer development. This rating reflects the absence of evidence in this patient population.

Hayes (2016) has evaluated waffle bariatric mattress overlay and made the following determinations with regard to treatment safety and efficacy:

- Based on a review of the abstracts of the very limited amount of available published literature, there is no evidence to support the use of any particular pressure-relieving support surface in bariatric populations.
The Centers for Medicaid and Medicare Services (CMS) national coverage determination (NCD) 280.7 stipulates that medical records and physicians' reports must establish the medical necessity for a DME hospital bed due to one of the following reasons:

- The patient's condition requires positioning of the body (e.g., to alleviate pain, promote good body alignment, prevent contractures, or avoid respiratory infections) in ways not feasible in an ordinary bed.
- The patient's condition requires special attachments that cannot be fixed and used on an ordinary bed.

InterQual (2017) criteria follow the lead of CMS (i.e., NCD 280.8) and mandate:

- A decision that use of an air-fluidized bed is reasonable and necessary requires that:
  - The patient has a stage 3 (full thickness tissue loss) or stage 4 (deep tissue destruction) pressure sore;
  - The patient is bedridden or chair bound as a result of severely limited mobility;
  - In the absence of an air-fluidized bed, the patient would require institutionalization;
  - The air-fluidized bed is ordered in writing by the patient’s attending physician based upon a comprehensive assessment and evaluation of the patient after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. This course of treatment must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment has been rendered.
  - Use of wet-to-dry dressings for wound debridement, begun during the period of conservative treatment and which continue beyond 30 days, will not preclude coverage of air-fluidized bed. Should additional debridement again become necessary, while a patient is using an air-fluidized bed (after the first 30-day course of conservative treatment) that will not cause the air-fluidized bed to become noncovered. In all instances documentation verifying the continued need for the bed must be available.
  - A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage;
  - A physician directs the home treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis; and
  - All other alternative equipment has been considered and ruled out.

Conservative treatment must include:

- Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every 2 hours);
• Use of a specialized support surface (Group II) designed to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation;
• Necessary treatment to resolve any wound infection;
• Optimization of nutrition status to promote wound healing;
• Debridement by any means (including wet to dry dressings—which does not require an occlusive covering) to remove devitalized tissue from the wound bed;
• Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.

Home use of the air-fluidized bed is not covered under any of the following circumstances:
• The patient has coexisting pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);
• The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material;
• The caregiver is unwilling or unable to provide the type of care required by the patient on an air-fluidized bed;
• Structural support is inadequate to support the weight of the air-fluidized bed system (it generally weighs 1600 pounds or more);
• Electrical system is insufficient for the anticipated increase in energy consumption; or
• Other known contraindications exist.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Hayes (2016)</td>
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| Waffle bariatric mattress overlay | • Hayes rating of waffle bariatric mattress overlay with regard to treatment safety and efficacy;  
|                         | • Based on a review of the abstracts of the very limited amount of available published literature, there is no evidence to support the use of any particular pressure-relieving support surface in bariatric populations. |
| Tricco (2015)          | Key points:                       |
| Seeking effective interventions to treat complex wounds: an overview of systematic reviews | • A systematic review including over 54,000 patients evaluated multi-faceted wound-healing regimens to identify the best therapies for complex wounds.  
|                         | • The most effective treatments were bandages or stockings (multi-layer, high compression) and wound cleansing for venous leg ulcers; four-layer bandages for mixed arterial/venous leg ulcers; biologics, ultrasound, and hydrogel dressings for diabetic leg/foot ulcers; hydrocolloid dressings, electrotherapy, air-fluidized beds, and alternate foam mattresses for pressure ulcers; and silver dressings and ultrasound for unspecified mixed complex wounds.  
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| Pressure ulcer treatment strategies: comparative effectiveness [internet] | - A systematic review addressed the effectiveness and/or harms of different treatments for pressure ulcers. These studies examined a wide range of interventions, but sample sizes often were small.  
- There was moderate-strength evidence that some interventions were associated with wound improvement, including the use of air-fluidized beds (compared with other support surfaces), protein-containing nutritional supplements (compared with placebos or other routine measures of nutritional support), radiant heat dressings (compared with other dressings), and electrical stimulation (compared with a sham treatment).  
- Only a minority of studies examined complete wound healing as an outcome.  
- The authors concluded that in general, the evidence about the harms of any of these treatments was limited, and future research with larger sample sizes, more rigorous adherence to methodological standards for clinical trials, longer follow-up periods, and more standardized and clinically meaningful outcome measures is needed to better inform clinical practice and policy. |

| **Smith (2013)**         | **Key points:**                                                                                   |
| Pressure ulcer treatment strategies: a systematic comparative effectiveness review | - A systematic review summarized the medical evidence on the effectiveness and safety of treatment strategies for adults with pressure ulcers.  
- Moderate-strength evidence showed that air-fluidized beds (n = 908), protein-containing nutritional supplements (n = 562), radiant heat dressings (n = 160), and electrical stimulation (n = 397) may affect improved healing of pressure ulcers.  
- In comparison with standard care, placebo, or sham interventions, there was low-strength evidence that alternating-pressure surfaces, hydrocolloid dressings, platelet-derived growth factor, and light therapy improved healing of pressure ulcers.  
- However, the authors cautioned that the applicability of the results is limited by study quality, heterogeneity in methods and outcomes, and inadequate duration to assess complete wound healing. |

| **Colin (2012)**         | **Key points:**                                                                                   |
| What is the best support surface in prevention and treatment, as of 2012, for a patient at risk and/or suffering from pressure ulcer sore? Developing French guidelines for clinical practice | - A systematic review reported that, in preventing pressure ulcers, a structured foam mattress is more efficient than a standard hospital mattress.  
- An alternating pressure mattress is more effective than a visco-elastic mattress at limiting the occurrence of heel pressure ulcers, but those that do occur are more serious.  
- A low-air-loss bed is more efficient than a mixed pulsating air mattress in preventing heel pressure ulcers.  
- Some types of sheepskin can reduce sacral pressure ulcer incidence in orthopedic patients.  
- Use of an overlay on an operating table limits the occurrence of perioperative and postoperative pressure ulcers. An air-fluidized bed improves pressure ulcer healing.  
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**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**
280.7 Hospital Beds. CMS Medicare Coverage Database website. [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=227&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=bed&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAACAAAAAAA A%3d%3d&]. Accessed February 8, 2018.

280.8 Air-Fluidized Bed. CMS Medicare Coverage Database website. [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=228&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=bed&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAACAAAAAAA A%3d%3d&]. Accessed February 8, 2018.

Local Coverage Determinations (LCDs):

L33820 Hospital Beds and Accessories. CMS Medicare Coverage Database website. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33820&ver=10&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=bed&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAACAAAAAAA A%3d%3d&]. Accessed February 8, 2018.

L33692 Pressure Reducing Support Surfaces. CMS Medicare Coverage Database website. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33692&ver=10&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=bed&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAACAAAAAAA A%3d%3d&]. Accessed February 8, 2018.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
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<td>Pressure ulcer of back</td>
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<tr>
<td>L89.200 - L89.229</td>
<td>Pressure ulcer of hip</td>
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<td>L89.301</td>
<td>Pressure ulcer of buttock</td>
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<td>L89.329</td>
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