Decision Memo for Air-Fluidized Beds for Pressure Ulcers (CAG-00017N)

Decision Summary

We will be issuing a Coverage Issues Manual revision that will include the following (new material in bold):

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 of at least one month's duration without successful progression toward healing. Conservative treatment includes:

1. Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every 2 hour);
2. Use of a specialized support surface (Group II) designed to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation;
3. Necessary treatment to resolve any wound infection;
4. Optimization of nutrition status to promote wound healing;
5. Debridement by any means (including wet to dry dressings) to remove devitalized tissue from the wound bed;
6. Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.

We recently met with the major manufacturer of Group III support surfaces to discuss our desire to obtain evidence to support the effectiveness of their use in the home setting. It is our understanding, that one or more studies are currently being planned that are expected to produce that evidence. When those study results become available we will again review national coverage policy. In the interim no changes other that the clarification described above are planned.

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Decision Memo

To: File: Pressure Reducing Therapy (Air-Fluidized Bed Therapy) CAG-00017N

From:

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Re: National Coverage Decision

Date: June 12, 2000

On November 5, 1999 the Health Care Financing Administration posted an Issues Tracking Sheet indicating the intent to review the coverage of Pressure Reducing Therapy (support surfaces). This notice was prompted, in part, by requests from various manufacturers of support surfaces for coverage of their products. The notice also referenced the July, 1997 Blue Cross and Blue Shield Association technology assessment of various types of support surfaces, which had concluded that there was insufficient evidence to show that one Group of support surfaces was more effective than another in terms of wound healing. Subsequent to the original posting, we issued a renotice, specifically seeking medical and scientific evidence to support current coverage of air-fluidized bed therapy (AFB), (Group III support surface) in the home setting as being more effective in the treatment of non-healing wounds than was a Group II support surface.

We requested four types of information:

1. Medical and other scientific evidence showing that the use of air-fluidized bed therapy is more effective in promoting wound healing than is air flotation bed therapy and powered pressure reducing air mattresses (alternating pressure low air loss or powered flotation without low air loss - GroupII support surface) in the home setting.
2. Evidence showing that the use of air-fluidized bed therapy prevents subsequent hospital stays for patients with pressure ulcers.
3. Information on the type of training and necessary skills required by caregivers (including the number of hours per day of care) when using air-fluidized bed therapy for patients in the home setting.
4. Evidence of clinical benefit or change in outcome from use of various types of support surfaces with specific emphasis on those types of support surfaces mentioned above.

History of coverage of support surface

Air-fluidized beds were covered in the home setting in accordance with Guidelines promulgated in 1989 by the National Center for Health Services Research and Health Care Technology Assessment. At that time and to date, no studies specifically dealing with improved health outcomes in the home setting as a result of AFB use have been presented to HCFA. It was felt, however, that successful experience with use of the bed in the institutional setting would likely carry over to the home setting with proper support from both the patient's physician and a trained caregiver. The bed was approved only for patients with severely limited mobility, with stage III or stage IV pressure wounds, and whose homes were constructed to support the use of the 1600 pound bed. The purpose of the bed was to promote healing in otherwise non-healing wounds and to prevent subsequent hospitalization for wound care. The bed was to be an adjunct to a regimen of adequate wound care directed by the attending physician.

Results of the posting

We received two responses to our request for information. One contained several items, including as evidence the results of a retrospective mail survey of nursing home use of air-fluidized beds, which did not deal with results in the home setting, as had been requested. The second response was a letter from a manufacturer of Group II support surfaces, which contained no evidence or scientific data.

The following is a summary of the information received:

1. A critique of the Blue Cross and Blue Shield Technology Assessment;
2. Testimonial letters from registered nurses, physicians and patients regarding their personal experiences with use of air-fluidized beds;
3. A video tape of user testimonials;
4. An article- "Measurement of Support Surface Efficacy: Pressure", by Richard I. Barnett, PhD and Frederick E. Shelton IV, MS. *Advances in Wound Care* 1997;10(7):21-29.
5. An Executive Summary- "National Pressure Ulcer Long Term Care Study Results Pressure Relieving Devices", April 20, 2000. (This is the retrospective mail survey mentioned above.)

The article that was submitted dealt with use of thermography and laser Doppler flowmetry in measuring the body's vascular response to extrinsic factors acting on the skin. This article did not deal with the use of an AFB in the home or any other setting.

None of the information that was submitted was responsive to our questions. However, as a result of reviewing current coverage policy, we have determined that a portion of that policy requires clarification. We intend to define the "conservative treatment", which must be employed before concluding that a wound is not healing and that, therefore, the patient is a candidate for air-fluidized bed therapy.

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