



BlueCross BlueShield
of Alabama

Name of Policy:

Noncontact Radiant Heat Bandage for the Treatment of Wounds

Policy #: 034

Category: Durable Medical Equipment

Latest Review Date: March 2010

Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

The ideal environment for wound healing is thought to include a moist normothermic environment that functions partially to enhance the subcutaneous oxygen tension and to elevate the blood flow to the wound. Warm-Up Active Wound Therapy is a device approved by the FDA that seeks to create this needed environment. The device includes a noncontact bandage and a warming unit designed to maintain 100% relative humidity and to produce normothermia in the wound and around the tissues. The bandage is made of a sterile foam collar that adheres to the periwound skin and a sterile, clear film that covers the top of the wound but does not touch it. An infrared warming card is inserted into the pocket in the film covering. Typically, treatments are given three times per day in one-hour sessions.

Policy:

Noncontact radiant heat bandage does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Standard wound care includes sharp debridement of devitalized tissue, infection control, non-weight bearing, and treatment of underlying co-morbidities, such as adequate nutrition or glycemic control in diabetics. Subsequently, validating any adjunct to standard wound care requires a random controlled trial to establish the contribution of the intervention compared to other wound management. A literature review identified one small, randomized crossover trial of Warm-Up Active Wound Therapy involving 13 patients who were followed for two weeks. More patients in the treatment group improved (62.5% vs. 37.5%) compared to the control group. The "improvement" was not fully defined and there was not any statistical analysis. Santaili and colleagues reported a two-week trial Warm-Up Active Wound Therapy where 17 patients with 31 wounds were their own control. Almost half who were refractory to prior therapy reported complete healing within 12 weeks after treatment. By using patients as their own control, the contribution of the intervention cannot be isolated. The wound healing may be in part to the increased attention given to the underlying wound rather than the Warm-Up Active Wound Therapy itself. Cherry and Wilson reported on a case series of five patients who received a two-week trial of Warm-Up Active Wound Therapy. Four of the five patients reported complete healing at six to fourteen weeks after treatment, but again a case series does not permit isolation of the addition of the Warm-Up Therapy. It should be noted that wound healing occurred several weeks after stopping the Warm-Up Therapy in this trial and the previous trial; thus, confounding any further evaluation of the therapy.

In an article published in the Federal Register, July 25, 2003, the Centers for Medicare and Medicaid Services (CMS) published the following information regarding Noncontact Normothermic Wound Therapy (NNWT): “The medical literature does not support a finding that NNWT heals any wound type better than conventional treatment”.

March 2008 Update

One small (49 patients) open-label randomized trial was identified with standard therapy controls. The study found an improvement in wound healing with NNWT; at 12 weeks, 18% of NNWT wounds had complete healing compared to 9% in the control group. However, as the authors noted, the three hours per day of off-loading (application for one hour three times per day), may have improved patient compliance to off-loading instructions. Study in larger patient population with the appropriate control groups, as described is needed.

March 2010 Update

A literature search did not identify any recent studies. Improved health outcomes have not been demonstrated with the use of a noncontact radiant heat bandage. Therefore, the policy statement is unchanged.

Key Words:

Warm-Up Active Wound Therapy, wound therapy, noncontact radiant heat bandage, normothermia, subcutaneous oxygen tension, Noncontact Normothermic Wound Therapy (NNWT)

Approved by Governing Bodies:

FDA approved March 28, 1997

Benefit Application:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

ITS: Home Policy provisions apply

Pre-certification/Pre-determination requirements: Not applicable

Coding:

HCPCS codes: **A6000**-Non-contact wound warming wound cover for use with the non-contact wound warming device and warming card
 E0231-Non-contact wound warming device (temperature control unit, AC adapter and power cord) for use with warming card and wound cover

**E0232-Warming card for use with the non-contact wound warming device
and non-contact wound warming wound cover**

References:

1. Alvarez O, Patel M, Rogers R, et al. Effect of non-contact normothermic wound therapy on the healing of diabetic neuropathic foot ulcers. J Tissue Viability 2006; 16(1): 8-11.
2. Bolton Laura L. Evidence corner: Radiant heat therapy and chronic wound healing, Wounds 2005; 17(10).
3. Cherry, G.W., Wilson, J. The treatment of ambulatory venous ulcer patients with warming therapy. Osteomy/Wound Management, 1999; 45: 65-70.
4. Federal Register. Noncontact normothermic wound therapy (NNWT), July 2003, Vol. 68, No. 143.
5. Robinson, C., Santilli, S.M. Warm-Up Active Wound Therapy : A novel approach to the management of chronic venous ulcers. J Vasc Nurs 1998;16:38-42.
6. Santilli, S.M., Valusek, P.A., Robinson, C. Use of a noncontact radiant heat bandage for the treatment of chronic venous stasis ulcers. Adv Wound Care, 1999;12:89-93.

Policy History:

Medical Policy Administration Committee, February 2002

Available for Comment April 9-May 23, 2002

Medical Policy Group, March 2004 (1)

Key Points updated, reference list updated, March 2008 (1)

Medical Policy Group, March 2010 (1)

Medical Policy Group, April 1, 2010: Active Policy but no longer scheduled for regular literature reviews and updates.

Medical Policy Group, October 2013 (1): Removed ICD-9 Diagnosis codes; no change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.