Name of Policy: Heating and Cooling Devices Used in the Home Setting

Policy #: 364       Latest Review Date: April 2014
Category: DME       Policy Grade: C

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:
Cold and/or compression therapy following surgery or musculoskeletal and soft tissue injury has long been accepted in the medical field as an effective tool for reducing inflammation, pain, and swelling. Ice packs and various bandages and wraps are commonly used. In addition, a variety of continuous cooling devices are commercially available and can be broadly subdivided into those providing manually operated passive cold therapy and those providing active cold therapy using a mechanical device. The CryoCuff® and the Polar Care Cub devices are examples of passive cooling devices. The CryoCuff device consists of an insulated container filled with iced water that is attached to a compressive cuff. When the container is raised, the water fills and pressurizes the cuff. The amount of pressure is proportional to the height of the container. When body heat warms the water, the cooler is lowered and the water drains out. The cooler is then raised above the affected limb and cold water refills the compressive cuff. The Polar Care Cub unit consists of pads held in place with elastic straps, which may also provide compression. The pads are attached to a built-in hand pump that circulates the water through the pads at the same time as increasing the compression around the joint.

In active cooling devices, a motorized pump circulates chilled water and may also provide pneumatic compression. For example, the AutoChill® device, which may be used in conjunction with a CryoCuff, consists of a pump that automatically exchanges water from the cuff to the cooler, eliminating the need for manual water recycling. The Hot/Ice Thermal Blanket is another example of an active cooling device. It consists of two rubber pads connected by a rubber hose to the main cooling unit. Fluid is then circulated via the hose through the thermal blankets. The temperature of the fluid is controlled by the main unit and can be either hot or cold. The Game Ready™ Accelerated Recovery System is an example of an active cooling device combined with a pneumatic component. The system consists of various soft wraps and a computer-controlled control unit to circulate the water through the wraps and provide intermittent pneumatic compression. The Hilotherm® Clinic circulates cooled water through preshaped thermoplastic polyurethane facial masks for use after different types of facial surgery. ThermaZone® provides thermal therapy with pads specific to various joints as well as different areas of the head (front, sides, back, eyes).

Heating devices used in the outpatient setting may include but may not be limited to the following types: standard electric heating pad, moist electric heating pad, water circulating heat pad with pump, and hot plus cold therapy. A passive heating device is a device that provides heating without the benefit of mechanical circulation of the thermal medium. A standard electric heating pad is a flexible device covered by fabric and contains electric resistive elements producing heat. A moist electric heating pad is the same as a standard electric heating pad but must have a component that will absorb and retain water. The water containing element must be protected from contact with the electrical components and the water must be in direct contact with the skin. An active heating device provides heating with the use of mechanical circulation of the thermal medium from a reservoir that will heat the medium before returning it to the site of injury. A water circulating heat pad with pump consists of a flexible pad containing a series of channels through which water is circulated by means of an electrical pumping mechanism.
There are devices that combine heating and cooling and some may have compression features. Examples are VitalWrap, Hot/Ice Machine and ThermoTek, and Vascutherm Compression Therapy. Some of these devices are also marketed for lymphedema. (Please see Blue Cross Blue Shield of Alabama policy #123- Lymphedema Pumps/Pneumatic Compression Devices).

**Policy:**
**Effective for dates of service on or after October 20, 2009:**
Active and passive cooling devices used in the home setting do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered not medically necessary.

Active and passive heating devices (including but not limited to: heating pads, moist electric heating pad or water circulating heat pad with pump,) do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered a convenience item.

Active or passive devices that combine cooling and heating do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

For combination active cooling and compression (cryopneumatic) devices (e.g.,The Game Ready) see policy #123

*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:**
The standard postoperative treatment for musculoskeletal surgeries consists of cryotherapy (cold therapy) and various types of compressive wraps. Both ice packs (with or without additives to maintain temperature) and cooling devices can provide cryotherapy. Active cooling devices are designed to provide a constant low temperature, which might provide additional benefit compared to the more variable temperature achieved with the intermittent replacement of ice packs. Passive cooling devices might also allow less variable cooling due to the larger volume of ice stored in the insulated tank and the use of circulated ice water.

Therefore, the evidence review focused on the following questions to evaluate whether cooling devices provide a benefit (e.g., decreased pain, swelling, or analgesic use) beyond convenience.

- Is there a health benefit from intermittent passive or active cooling devices when the number of exchanges of ice bags and episodes of water recirculation are the same?
- Do continuous cooling regimens provide more health benefits than intermittent cooling?
• Does the use of cooling devices in the outpatient setting provide health benefits when compared with icing regimens typically used in a home/outpatient environment?

Manually Operated Passive Cooling Devices

Intermittent Cooling Regimens
Konrath et al reported on the results of a trial that randomized 103 patients undergoing reconstruction of the anterior cruciate ligament (ACL) to one of four different postoperative cold therapy strategies: 1) active cooling with a Polar Care pad set at a temperature of 40 to 50 degrees or 2) 70 to 80 degrees centigrade, respectively; 3) ice packs; or 4) no cold therapy. Both the water in the Polar Care pad and the ice packs were changed every four hours. The length of hospital stay, range of motion at discharge, use of oral and intramuscular pain medicine, and drain output were not significantly different among groups. These results suggest that the Polar Care device provides no incremental benefit in comparison with ice packs when used with the same intermittent treatment regimen.

Continuous versus Intermittent Cooling Regimens
A systematic review of cryotherapy concluded that continuous cold therapy was associated with a significantly greater decrease in pain and wrist circumference after surgery than intermittent cold therapy. The one study reviewed compared continuous cryotherapy to intermittent 20-minute ice applications over the first three days after carpal tunnel release. Continuous cooling resulted in a decrease in pain and wrist circumference in comparison to intermittent ice packs. The systematic review concluded that for cryotherapy in general, there was a lack of high quality studies and recommended that future studies focus on modes, durations, and frequencies of ice application to optimize outcomes after injury. Another study compared the CryoCuff device to ice therapy in 44 patients who had undergone repair of the anterior cruciate ligament (ACL). Patients receiving ice therapy received an ice bag three times per day postoperatively. While those randomized to the CryoCuff group reported significant decreases in pain, swelling, and analgesic use, it is not clear whether icing three times per day is a typical icing regimen.

Unknown Cooling Regimens
Whitelaw et al reported results of a trial that randomized 102 patients undergoing knee arthroscopy in the outpatient setting to receive either a CryoCuff device or traditional ice therapy. Those in the CryoCuff group reported decreased pain medication compared to the control group, but there was no significant difference in average pain assessment. Interpretation of these results is limited, since the number of exchanges of ice packs and water recirculation was not reported. Healy et al reported that the CryoCuff device provided no benefit to pain control or swelling compared to ice packs in a randomized trial of 76 patients (105 knees) undergoing total knee arthroplasty. No data were provided on the number of ice pack exchanges, although the water was recirculated in the CryoCuff device every one to four hours.

No Icing Control
Edwards et al studied the outcomes of 71 patients undergoing ACL reconstruction who were randomized to receive either CryoCuff therapy with ice water, CryoCuff therapy with room temperature water, or no cold therapy. Therefore, this trial did not include the relevant control group of patients treated with conventional ice packs. Another randomized trial by Brandsson suffers from the same limitation; in this study of 50 patients undergoing ACL repair, no group
received standard therapy with ice packs. Levy and Marmar compared the outcomes in a trial randomizing 80 patients (100 knees) undergoing total knee arthroplasty to receive either passive cold therapy with a CryoCuff device or no cold therapy. Although the CryoCuff group reported a significant decrease in blood loss and mild decrease in analgesic requirements, this trial also did not include the relevant control group.

**Active Cooling Devices**
Several randomized studies compared active cooling devices to no cold therapy, and therefore are not relevant to the documentation of benefit compared to standard therapy with ice packs.

One study compared a consecutive series of patients who were instructed to use ice packs with results from a prior group who had used active cooling devices following ACL repair. For the first three days, patients were instructed to change the ice packs when the crushed ice had melted, then to apply ice as needed over days four through seven. Although pain scores and use of pain medication were lower in the cohort that used a cooling device in comparison with the group that was instructed to continuously apply ice packs, the study is limited by the non-concurrent design. One randomized controlled trial (n=60) compared a temperature-controlled cryotherapy device to a standard icing regimen following outpatient knee arthroscopy. Seven patients (12%) were excluded from analysis or lost to follow-up. Both groups were instructed to apply the treatment for 20 minutes every two hours during waking hours for the first four days after surgery. For the night time, the cooling device group was instructed to use the device throughout the first four nights, whereas the control group was advised to use ice packs at their own discretion. No differences in daytime pain were observed between the two groups. There was a tendency for more patients in the cryotherapy group to report that they did not awaken from pain during the night; this difference reached significance only for postoperative day two (36% vs. 6%, p = 0.04). Additional study with a larger number of patients is needed to determine whether use of continuous cooling at night improves health outcomes.

**Devices and Indications**
A literature search did not identify any published articles focusing on the use of active cooling devices equipped with pneumatic compression. Similarly, there were no published articles focusing on the role of cooling devices in nonsurgical settings, i.e., for the treatment of sprains or strains or chiropractic treatments.

In summary, the majority of the published randomized studies of cooling devices failed to adequately describe the cooling regimens or include the relevant control group of standard ice pack treatment. When cooling devices and ice packs were used with the same regimen, no differences in health outcomes were observed. Currently available evidence is insufficient to determine whether continuous cooling with these devices results in improved health outcomes when compared to usual ice pack exchange in the home environment. Thus, the available scientific literature is insufficient to document that the use of passive cooling systems is associated with a benefit beyond convenience; these devices are considered not medically necessary.

**2012 Update**
No new published articles were identified for heating and cooling devices in the home.
Additional Information
While there is no national coverage decision for Medicare, cooling devices are addressed in Durable Medical Equipment Resource Center (DMERC) policy. Last reviewed in July 2004, the DMERC policy reads as follows:

“A device in which ice water is put in a reservoir and then circulated through a pad by means of gravity is not considered durable medical equipment (DME). Other devices (not all-inclusive which are also not considered to be DME are: single use packs which generate cold temperature by a chemical reaction; packs which contain gel or other material which can be repeatedly frozen; simple containers into which ice water can be placed. All of these types of devices must be coded A9270 if claims are submitted to the DMERC.”

“Code E0218 describes a device which has an electric pump that circulates cold water through a pad…A water circulating cold pad with pump (E0218) will be denied as not medically necessary.”

General indications for therapeutic heat include pain, muscle spasm, contracture, tension, myalgia, hematoma resolution, bursitis, tenosynovitis, fibrositis, fibromyalgia, superficial thrombophlebitis, and collagen vascular diseases. Application of heat produces hyperemia, induction of reflex vasodilation, and acceleration of metabolic processes. Contraindications and precautions for the therapeutic heat include acute inflammation, trauma, or hemorrhage; bleeding disorders; temperature insensitivity; inability to communicate or respond to pain; poor thermal regulation; malignancy; edema; ischemia; atrophic skin; and scar tissue.

There are no studies or evidence that supports the use of circulating-water heating pads or moist electric heating pads or moist electric heating pads provide superior outcomes, in terms of enhancing recovery of function, compared to hot packs or electric heating pads. In uncomplicated cases, heat treatments of this type, as well as paraffin baths, may not require the skills of a physical therapist.

The available literature regarding either active or passive devices that combine the ability to provide cold and heat therapy is currently insufficient to allow conclusions regarding their effectiveness. The VitalWrap™ system is one such system. There is no available data in the published peer-reviewed literature regarding this active cooling/warming device in comparison to other methods of cooling or heating. Data addressing any incremental benefit over standard therapy modalities from the use of these types of devices is required to assess their efficacy in treating any type of condition.

2013 update
No new literature found that would alter the policy statement at the time of this review.

2014 Update
Several studies have been reported by one research group comparing the Hilotherm® device vs cooling compresses. In one randomized observer-blinded study, 42 patients were treated with open reduction and internal fixation for zygomatic bone fractures and then randomly assigned to a Hilotherm® cooling face mask or a standard cooling compress. Both cooling methods were
intended to be used continuously for 12 hours daily for three days after surgery; however no data was provided on whether patients in the control group used the cold compresses for a similar amount of time as patients used the face mask. Blinded evaluation with a 3-dimensional optical scanner showed a significant reduction in swelling on day one, two, three, and seven for the Hilotherm® group. The visual analog scale (VAS) for pain was lower in the Hilotherm® group on day one (2.38 vs. 4.10 on a 10 point scale) and day two (2.34 vs. 4.38), but not on day seven (1.43 vs. 1.90). There were also significant differences between the groups for postoperative neurological score and eye motility and diplopia on postoperative day one. Another randomized study with 32 patients assessed postoperative swelling of bilateral mandibular fractures using a cooling mask around the head and jaw. The study design was similar to that reported above by Modabber et al. Swelling was reduced for the cooling mask group on day one, two, and three after surgery. VAS for pain was also reduced for the cooling mask group on day one (3.87 vs. 5.53) and day two (3.63 vs. 6.31). There was no significant difference between groups in postoperative neurological score, trismus, or mandibular dysfunction.

Several small studies report that a cooling mask used after facial surgery provides greater pain relief and reduction of swelling compared to cool compresses, but these studies have limitations and results need to be replicated in larger, higher quality studies.

**Key Words:**
AutoChill, Cooling Devices, CryoCuff, Game Ready, Hot/Ice Thermal Blanket, Polar Care Cub, VitalWrap™, heating pads, circulating water heating pads, moist electric pad, Vascutherm Compression Therapy, Hilotherm® cooling face mask, ThermaZone®

**Approved by Governing Bodies:**
Not applicable

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

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

**Current Coding:**

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0210</td>
<td>Electric heat pad, standard</td>
</tr>
<tr>
<td>E0215</td>
<td>Electric heat pad, moist</td>
</tr>
<tr>
<td>E0217</td>
<td>Water circulating heat pad with pump</td>
</tr>
<tr>
<td>E0218</td>
<td>Water circulating cold pad with pump</td>
</tr>
<tr>
<td>E0236</td>
<td>Pump for water circulating pad</td>
</tr>
<tr>
<td>E0249</td>
<td>Pad for water circulating heat unit</td>
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</tbody>
</table>
Previous Coding

HCPCs    E0238    Non-electric heat pad, moist (deleted 01/01/2011)

References:

Policy History:
Medical Policy Group, July 2009 (3)
Medical Policy Administration Committee, August 2009
Available for comment August 10-September 3, 2009
Medical Policy Group, September 2009 (1)
Medical Policy Administration Committee, September 2009
Available for comment September 4-October 19, 2009
Medical Policy Group, December 2010
Medical Policy Group, March 2011
Medical Policy Group, February 2012
Medical Policy Group. April 2013 (4): 2013 updates to Key Points and References. Reference to policy 123 was added for cyropneumatic devices, no policy changes made.
Medical Policy Panel April 2104
Medical Policy Group April 2014 (4): Update to Description, Key Points, Key Words, Approved Governing Bodies, and References. No changes were made to the policy statement at this time.

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.