



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Cooling Devices Used in the Outpatient Setting

**Policy #** 00139

Original Effective Date: 06/28/2004

Current Effective Date: 01/15/2014

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### **Services Are Not Covered**

The use of active and passive cooling devices in the outpatient setting mainly for the comfort or convenience of the member is **not a covered benefit**.

### **Background/Overview**

Cooling devices use chilled water to decrease the local temperature of tissue. There are a variety of cooling devices available, ranging from gravity-fed devices that are manually filled with iced water, to motorized units that both cool and circulate the chilled water. These devices are typically used when ice packs would normally be applied, e.g., after orthopedic surgical procedures.

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®<sup>‡</sup> 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®<sup>‡</sup> 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™<sup>‡</sup> 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.



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### **FDA or Other Governmental Regulatory Approval**

Centers for Medicare and Medicaid Services (CMS)

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."

### **Rationale/Source**

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?

### **Literature Review**

#### Manually Operated Passive Cooling Devices

##### *Intermittent Cooling Regimens*

Konrath and colleagues reported on the results of a trial that randomized 103 patients undergoing reconstruction of the anterior cruciate ligament (ACL) to 1 of 4 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.



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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 1 study reviewed compared continuous cryotherapy to intermittent 20-minute ice applications over the first 3 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 ACL. Those 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 and colleagues 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 and colleagues 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 1 to 4 hours.

### *No Icing Control*

Edwards and colleagues 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 Marmor 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 3 days, patients were instructed to



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change the ice packs when the crushed ice had melted, then to apply ice as needed over days 4 through 7. 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 2 hours during waking hours for the first 4 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 2 (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.

### Other Devices and Indications

Use of cooling devices after total knee arthroplasty in the inpatient setting was examined in a 2009 systematic review and meta-analysis. The 11 randomized controlled trials included were heterogeneous for the type of cooling device and the exact control condition (ranging from no ice to frequent icing). Overall, cryotherapy was found to result in small benefits in blood loss and discharge knee range of motion. There were no benefits in transfusion and analgesia requirements, pain, swelling, length of stay, and gains in knee range of motion after discharge. These results are limited by the heterogeneity of the studies.

Literature searches 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.

A search of the literature did not identify any new relevant evidence on the use of cooling devices.

### 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 covered.

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## Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPSC	E0218, E0236, A9270

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ICD-9 Diagnosis	All Diagnoses
ICD-9 Procedure	No codes

### Policy History

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06/01/2004 Medical Director review  
06/15/2004 Medical Policy Committee review  
06/28/2004 Managed Care Advisory Council approval  
12/07/2004 Medical Director review  
12/14/2004 Medical Policy Committee review. Format revision. Name changed from Cryo Therapy to Cooling Devices Used in the Outpatient Setting. Policy/Guideline section revised to reflect member contract non-coverage of convenience items.  
01/31/2005 Managed Care Advisory Council approval  
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.  
01/10/2007 Medical Director review  
01/17/2007 Medical Policy Committee approval  
01/09/2008 Medical Director review  
01/23/2008 Medical Policy Committee approval  
01/07/2009 Medical Director review  
01/14/2009 Medical Policy Committee approval. No change to coverage.  
01/07/2010 Medical Director approval  
01/20/2010 Medical Policy Implementation Committee approval. No change to coverage. Coding review.  
01/06/2011 Medical Director approval  
01/19/2011 Medical Policy Implementation Committee approval. No change to coverage  
02/02/2012 Medical Policy Committee review  
02/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
01/03/2013 Medical Policy Committee review  
01/09/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
01/09/2014 Medical Policy Committee review  
01/15/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2015

\*\*Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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