



Kansas City

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## Cooling Devices Used in the Outpatient Setting

**Policy Number:** 1.01.26

**Last Review:** 10/2014

**Origination:** 10/2007

**Next Review:** 10/2015

### **Policy**

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Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for cooling devices used in the outpatient setting. This is considered not medically necessary.

*Heating pads and cooling pads (circulating or non-circulating) are benefit exclusions on most policies.*

### **When Policy Topic is covered**

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Not Applicable

### **When Policy Topic is not covered**

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Active and passive cooling devices are considered **not medically necessary**.

Combination active cooling and compression (cryopneumatic) devices are considered **investigational**.

### **Considerations**

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According to Medicare's durable medical equipment regional carrier (DMERC) policy, passive cooling devices are not considered durable medical equipment and thus should be coded as:

- A9270: Noncovered device or service

### **Description of Procedure or Service**

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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® 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 2 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).

## **Rationale**

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This policy was created in November 2004 and periodically updated with a literature review using the MEDLINE database. The most recent update was performed through March 17, 2014.

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 with 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 (eg, decreased pain, swelling, 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 randomly assigned 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.(1) Both the water in the Polar Care pad and the ice packs were changed every 4 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.(2) The 1 study reviewed compared continuous cryotherapy with intermittent 20-minute ice applications over the first 3 days after carpal tunnel release.(3) Continuous cooling resulted in a decrease in pain and wrist circumference in comparison with 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.(2) Schroder and Passler compared the CryoCuff device with ice therapy in 44 patients who had undergone repair of the ACL.(4) Those receiving ice therapy received an ice bag 3 times a day postoperatively. While those randomly assigned to the CryoCuff groups reported significant decreases in pain, swelling, and analgesic use, it is not clear whether icing 3 times a day is a typical icing regimen.

### Unknown Cooling Regimens

Whitelaw et al reported results of a trial that randomly assigned 102 patients undergoing knee arthroscopy in the outpatient setting to receive either a CryoCuff device or traditional ice therapy.(5) Those in the CryoCuff group reported decreased pain medication compared with the control group, but there was no significant difference in average pain assessment. Interpretation of these results is limited because 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 with ice packs in a randomized trial of 76 patients (105 knees) undergoing total knee arthroplasty (TKA).(6) 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 et al studied the outcomes of 71 patients undergoing ACL reconstruction who were randomly assigned to receive either CryoCuff therapy with ice water, CryoCuff therapy with room temperature water, or no cold therapy.(7) Therefore, this trial did not include the relevant control group of patients treated with conventional ice packs. Another randomized trial by Brandsson et al suffers from the same limitation; in this study of 50 patients undergoing ACL repair, no group received standard therapy with ice packs.(8) Levy and Marmar compared the outcomes in a trial that randomly assigned 80 patients (100 knees) undergoing TKA to receive either passive cold therapy with a CryoCuff device or no cold therapy.(9) 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**

### Intermittent Cooling Regimens

A randomized, controlled trial (n=60) compared a temperature-controlled cryotherapy device with a standard icing regimen following outpatient knee arthroscopy.(10) 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 night time, the cooling device group was instructed to use the device throughout the first 4 nights, whereas the control group was advised to use ice packs at their own discretion. No differences in daytime pain were observed between the 2 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.

Another study compared a consecutive series of patients who were instructed to use ice packs with results from a prior group that had used active cooling devices following ACL repair.(11,12) For the first 3 days, patients were instructed to 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 nonconcurrent design.

Several studies have been reported by 1 research group comparing the Hilotherm® device versus cooling compresses. In 1 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.(13) Both cooling methods were intended to be used continuously for 12 hours daily for 3 days after surgery, however no data were 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 1, 2, 3, and 7 for the Hilotherm® group. The visual analog scale (VAS) for pain was lower in the Hilotherm® group on day 1 (2.38 vs 4.10 on a 10-point scale) and day 2 (2.34 vs 4.38), but not on day 7 (1.43 vs 1.90). There were also significant differences between the groups for postoperative neurologic score and eye motility and diplopia on postoperative day 1. Another randomized study with 32 patients assessed postoperative swelling of bilateral mandibular fractures using a cooling mask around the head and jaw.(14) The study design was similar to that reported by Modabber et al. Swelling was reduced for the cooling mask group on day 1, 2, and 3 after surgery. VAS for pain was also reduced for the cooling mask group on day 1 (3.87 vs 5.53) and day 2 (3.63 vs 6.31). There was no significant difference between groups in postoperative neurologic score, trismus, or mandibular dysfunction.

### No Icing Control

Several randomized studies compared active cooling devices with no cold therapy and therefore are not relevant to the documentation of benefit compared with standard therapy with ice packs.(12,15-17)

## **Combination Active Cooling and Compression (Cryopneumatic) Devices**

### Intermittent Cooling Regimens

A multicenter randomized trial with 280 TKA patients compared the GameReady cryopneumatic device versus ice packs with static compression.(18) On discharge from the hospital, the treatments were given at the same application cycle of 1 hour on and 30 minutes off. Compliance rates were similar for the 2 groups. Blinded evaluation of 187 patients (67% of patients had complete evaluations) found no significant difference between the groups in VAS for pain, range of motion, 6-minute walk test, timed up and go test, or knee girth under this more typical icing regimen. Narcotic consumption was decreased from 680 mg to 509 mg morphine equivalents over the first 2 weeks (14 mg less per day), and patient satisfaction was increased with the cryopneumatic device.

Waterman et al reported a randomized controlled trial (RCT) of the GameReady device in 36 patients with ACL reconstruction.(19) Patients were instructed to use ice or the cryopneumatic device for 30 minutes at least 3 times per day and return to the clinic at 1, 2, and 6 weeks postoperatively. Compliance during the first 2 weeks was not significantly different between the 2 groups (100% for GameReady and 83% for icing). The primary outcome measure (VAS) was not comparable at baseline, limiting interpretation of the results. There were no significant differences between the groups for knee circumference, the Lysholm Short Form-36, SF-36, or Single Assessment Numerical Evaluation scores. A greater percentage of patients treated with the GameReady device discontinued narcotic use by 6 weeks (83% vs 28%).

## **Other Devices and Indications**

Use of cooling devices after TKA in the inpatient setting was examined in a 2009 systematic review and meta-analysis.(20) The 11 RCTs 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.

No published articles focusing on the role of cooling devices in nonsurgical settings, ie, for the treatment of sprains or strains or chiropractic treatments have been identified.

### **Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 specialty societies and 3 academic medical centers while the policy was under review in 2008. Input was mixed regarding the medical necessity of continuous cooling devices.

### **Summary**

Most of the published randomized studies of passive cooling devices failed to adequately describe the cooling regimens or include the relevant control group of standard ice pack treatment. When passive 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 devices result in improved health outcomes when compared with usual ice pack exchange in the home environment. Several small studies report that a cooling mask used after facial surgery provides greater pain relief and reduction of swelling compared with cool compresses, but these studies have limitations and results need to be replicated in larger, higher quality studies. Overall, the available scientific literature is insufficient to document that the use of passive or active cooling systems is associated with a benefit beyond convenience; these devices are considered not medically necessary.

For combination active cryotherapy/compression (cryopneumatic) devices, 2 recent studies reported that narcotic use is decreased and that patient satisfaction is higher. However, no other outcome measures were improved, and one of the studies suffered from a low follow-up rate. Based on these new studies with active cryotherapy/compression devices and limited evidence of an improvement in clinical outcomes, active cryotherapy/compression devices are considered investigational. Additional study is needed to permit conclusions regarding the effect of this technology with greater certainty.

### **Medicare National Coverage**

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.”

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### **Billing Coding/Physician Documentation Information**

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<b>97010</b>	Application of a modality to one or more areas; hot or cold packs
<b>97016</b>	Application of a modality to one or more areas; vasopneumatic devices
<b>A9270</b>	Noncovered item or service
<b>E0218</b>	Water circulating cold pad with pump
<b>E0236</b>	Pump for water circulating pad

Active cooling devices may be identified by the following HCPCS codes:  
E0218: Water circulating cold pad with pump  
E0236: Pump for water circulating pad

According to Medicare's DMERC (Durable Medical Equipment Regional Carrier) regional policy, passive cooling devices are not considered durable medical equipment and thus should be coded as:  
A9270: Noncovered device or service

*97016 has been used for the Game Ready devices, but is not the correct code.*

### **Additional Policy Key Words**

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N/A

### **Policy Implementation/Update Information**

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10/1/07	New policy; considered not medically necessary.
10/1/08	No policy statement changes.
10/1/09	No policy statement changes.
10/1/10	No policy statement changes.
10/1/11	No policy statement changes.
10/1/13	Policy statement clarified to distinguish between active cooling devices and cryopneumatic devices (investigational).
10/1/14	No policy statement changes.

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