Cooling Devices Used in the Outpatient Setting

**Description**

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 manually fill with iced water, to motorized units that both cool and circulate chilled water. These devices are typically used when ice packs would normally be applied (eg, after orthopedic surgical procedures).

**Background**

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 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 CryoCuff 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 water drained. 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 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 active cooling device. It consists of 2 rubber pads connected by a rubber hose to the main cooling unit. Fluid is 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 active cooling device combined with a pneumatic component. The system consists of various soft wraps and a computer-control unit to circulate the water through the wraps and to 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). CTM™ 5000 and cTreatment are computer-controlled devices that provide cooling at a specific (11°C) and continuous temperature.

**Regulatory Status**

A large number of active and passive heating and cooling devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process since 1976. FDA product code: ILO.

**Related Policies**

1.01.10 Continuous Passive Motion (CPM) in the Home Setting

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims*

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

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

**Rationale**

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.

This evidence review focused on the following questions to evaluate whether cooling devices provide a benefit (e.g., 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 compared with icing regimens typically used in a home or outpatient environment?

**Manually Operated Passive Cooling Devices**

**Continuous vs 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.¹ The single study reviewed compared continuous cryotherapy with intermittent 20-minute ice applications over the first 3 days after carpal tunnel release.² Continuous cooling resulted in a decrease in pain and wrist circumference compared with intermittent ice packs. Reviewers
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.\(^1\) Schroder and Passler compared the CryoCuff device with ice therapy in 44 patients who had undergone repair of the anterior cruciate ligament (ACL).\(^3\) Those receiving ice therapy administered 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 a CryoCuff device or traditional ice therapy.\(^4\) 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).\(^5\) 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 CryoCuff therapy with ice water, CryoCuff therapy with room temperature water, or no cold therapy.\(^6\) 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.\(^7\) Levy and Marmar compared the outcomes of a trial that randomly assigned 80 patients (100 knees) undergoing TKA to receive passive cold therapy with a CryoCuff device or to no cold therapy.\(^8\) Although the CryoCuff group reported a significant decrease in blood loss and mild decrease in analgesic requirements, this trial did not include the relevant control group.

**Section Summary: Manually Operated Passive Cooling Devices**

Manually operated passive cooling devices circulate water that has been cooled by ice. Evidence on manually operated passive cooling devices is limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications do not provide sufficient evidence of comparative efficacy. Other studies have provided no information on the frequency of ice changes, limiting interpretation of the results. Only 1 RCT identified compared continuous cooling to a standard icing regimen of intermittent 20-minute ice application.

**Active Cooling Devices**

**Intermittent Cooling Regimens**

In the largest study to date, 116 patients who had undergone TKA were assigned in a quasi-randomized order to 8 hours daily of advanced cryotherapy at a fixed temperature (cTreatment) or to application of cold packs for 15 minutes after each of 2 physical therapy sessions.\(^9\) Both groups could apply cryotherapy during the evening and night whenever they wanted for comfort and pain
control. Thirty percent of patients in the treatment group did not use the device at night due to excessive noise. Primary outcomes were visual analog scale (VAS) score at rest and during deep active knee flexion, walking without aid, and analgesic use. Secondary outcomes were knee range of motion, active straight-leg raising, walking without aid, swelling, visual hematoma, and length of stay. There were no significant differences between groups in VAS scores, need for analgesics, or any of the secondary outcomes. There was a significant decrease in flexion at 6 weeks in the advanced cryotherapy group (114° vs 120°).

A randomized controlled trial (RCT; N=60) compared a temperature-controlled cryotherapy device with a standard icing regimen following outpatient knee arthroscopy. Both groups were instructed to apply the treatment for 20 minutes every 2 hours during waking hours for the first 4 days after surgery. All night, 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 as needed. No differences in daytime pain were observed between 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 was significant 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.

Several studies have been reported by 1 research group comparing the Hilotherm device to 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. Both cooling methods were intended to be used continuously for 12 hours daily for 3 days after surgery; 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 days 1, 2, 3, and 7 for the Hilotherm group. The VAS score 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. 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 scores for pain were 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 for postoperative neurologic score, trismus, or mandibular dysfunction.

No Icing Control

Several randomized studies have 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.

Section Summary: Active Cooling Devices

Several randomized trials that compared active cooling devices with standard intermittent icing or cold packs. Two smaller trials suggested a benefit of continuous cooling on pain and swelling of the face. Two larger trials found no significant benefit of the continuous cooling devices compared...
with standard cryotherapy after knee surgery.

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

**Intermittent Cooling Regimens**

Several RCTs have been reported with the Game Ready cryopneumatic device in the outpatient setting.

A multicenter RCT with 280 TKA patients compared the Game Ready cryopneumatic device to ice packs with static compression. On hospital discharge, 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 score 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 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 an RCT of the Game Ready device in 36 patients with ACL reconstruction. Patients were instructed to use ice or the cryopneumatic device for 30 minutes at least 3 times a day and return to the clinic at 1, 2, and 6 weeks postoperatively. Compliance during the first 2 weeks did not differ significantly between groups (100% for Game Ready vs 83% for icing). The primary outcome measure (VAS score) was not comparable at baseline, limiting interpretation of the results. There were no significant differences between the groups for knee circumference, the Lysholm knee score, 36-Item Short-Form Health Survey, or Single Assessment Numerical Evaluation scores. A greater percentage of patients treated with the Game Ready device discontinued narcotic use by 6 weeks (83% vs 28%).

Kraeutler et al compared the Game Ready shoulder wrap to standard icing in an RCT of 46 patients who had undergone rotator cuff repair or subacromial decompression. Patients were instructed to apply the cryotherapy every other hour for the first 3 days and 2 to 3 times a day until the follow-up visit at 7 to 10 days. Analysis of patient diaries showed no significant differences in average pain, worst pain, and morphine equivalent dosage between the 2 groups on any day during the week after surgery. Post hoc power analysis showed that 13 patients per group would provide sufficient power to detect a 25 mm (out of 100) difference in VAS scores between the 2 groups.

**Section Summary: Combination Active Cooling and Compression (Cryopneumatic) Devices**

One large and 2 smaller RCTs were identified that compared cryopneumatic therapy with the Game Ready device to standard icing regimens. In the largest study, which had blinded outcome measures, narcotic consumption was slightly reduced, but there were no significant differences in pain, function, or swelling between cryopneumotherapy and icing. A smaller but adequately powered RCT also found no significant difference between similarly timed applications of the cryopneumatic device and icing. Although these results do not support the intermittent use of the Game Ready, it would be informative to determine whether constant cooling provides greater pain relief than a standard icing regimen or intermittent use of the device.
Other Devices and Indications

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.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Summary of Evidence

For individuals who have pain and/or swelling after surgery who receive a passive cooling device, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. Most published randomized trials of passive cooling devices have failed to adequately describe the cooling regimens or include the relevant control group (standard ice pack treatment). Studies that used either a no-icing control or infrequent ice applications do not provide sufficient evidence of comparative efficacy. Other reports have provided no information on the frequency of ice changes, limiting interpretation of the results. Only 1 RCT was identified that compared continuous cooling to a standard icing regimen of intermittent 20-minute ice application. Currently available evidence is insufficient to determine whether continuous cooling results in a reduction in pain and swelling compared with a standard icing regimen in the home environment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after surgery who receive an active cooling device, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. Several RCTs have compared active cooling devices with standard intermittent icing or cold packs. Some trials have reported that a cooling mask used after facial surgery provides greater pain relief and reduction of swelling than cold compresses, but these studies have limitations and results need to be replicated in larger, higher quality studies. Other trials have found no benefit of active cooling devices compared to a standard icing regimen after knee surgery. There is a potential to decrease awakenings from pain during the night, but sleep disrupting noise from the device has been reported. Overall, use of active cooling systems has not been shown to be associated with a benefit beyond convenience. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after surgery who receive combination cooling and compression devices, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. The available evidence does not indicate that combination cryotherapy and compression (cryopneumatic) devices improve health outcomes when applied at a similar frequency as ices changes. Two studies have reported that narcotic use is decreased and that patient satisfaction is higher. However, no other outcome measures were improved, and 1 study suffered from differences at baseline. A third trial found no significant differences in outcomes between cryopneumatic therapy and icing when both used the same intermittent regimen. No studies were identified that compared continuous cryotherapy plus
intermittent compression to a standard icing regimen. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Medicare National Coverage**

While there is no national coverage decision for Medicare, cooling devices are addressed in Durable Medical Equipment Resource Center (DMERC) policy (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.

A water circulating cold pad with pump will be denied as not medically necessary.”

**References**


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Signature on File
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