Regence

Medical Policy Manual Durable Medical Equipment, Policy No. 07

Cooling Devices Used in the Home Setting

Effective: July 1, 2023

Next Review: May 2024
Last Review: May 2023

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Cooling devices, which may also include compression, are used in lieu of ice packs to decrease pain, swelling, and bleeding after injury or surgery usually of the joint such as the knee.

MEDICAL POLICY CRITERIA

Active circulating and passive noncirculating cooling devices, with or without compression, used in the home setting are considered **not medically necessary** for any indication including the use of compression only.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

COLD AND COMPRESSION THERAPY

Use of ice packs and various bandages and wraps following surgery or musculoskeletal and soft tissue injury are common. A variety of manually operated and mechanical continuous cooling devices are commercially available.

The standard postoperative treatment for musculoskeletal surgeries consists of cryotherapy (cold therapy) and various types of compressive warps. Both ice packs (with or without additives to maintain temperature) and cooling devices can provide cryotherapy. Circulating 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. Noncirculating 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.

NONCIRCULATING COLD THERAPY

The CryoCuff® (DJO Global) and the Polar Care Cub (Berg Inc.) devices are examples of passive, noncirculating 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 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 which circulates the water through the pads at the same time as increasing the compression around the joint.

CIRCULATING COLD THERAPY

In active, circulating cooling devices, a motorized pump both circulates cold water and may also provide pneumatic compression. For example, the AutoChill® (DJO Global) 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, which consists of two 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 (CoolSystems, Inc.) is an example of a circulating cooling device combined with a pneumatic compression component. The system consists of various soft wraps and a computer-controlled unit to circulate the water through the wraps. The ProThermo and the NanoTherm™ Therapy Unit (ThermoTek), OPTI-ICE™ Cold Therapy System, Hilotherm® Clinic facial mask (Hilotherapy), ThermaZone® and the Iceman® Cold Therapy (DonJoy) are other examples of combination active cooling with and without compression devices. 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 circulating and noncirculating cooling devices have received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) since 1976. FDA product code: ILO.

EVIDENCE SUMMARY

The primary difference between ice packs and passive cooling devices is that water recirculation is more convenient with passive cooling devices. Active cooling devices are designed to provide a steady low temperature, which, in addition to convenience, might provide a unique benefit compared to the more variable temperature achieved with ice packs or passive cooling devices. Benefit is typically focused on pain control and swelling.

The focus of this evidence section is on randomized controlled trials (RCTs) of cold therapy in the home setting that evaluate whether cooling devices provide a benefit (e.g., decreased pain, swelling, analgesic use) beyond convenience. Studies should include standard ice packs as treatment in the control groups. RCTs performed in the inpatient setting and those lacking an appropriate control group are excluded from this review. Appropriate trial design for passive cooling devices should include an equal number of exchanges of ice bags and episodes of water recirculation between groups.

PASSIVE COOLING DEVICES

Post-Knee Surgery

Coviello (2022) investigated the use of continuous cold flow device therapy on pain reduction, opioid consumption, recovery time, perioperative bleeding, and patient satisfaction in patients undergoing a total knee arthroplasty.[1] Patients (N=100) were randomized into two groups receiving either postoperative continuous cold flow therapy (5°) or standard ice pack therapy. There were no differences in preoperative visual analog scale pain scores between groups. Reduction of pain per visual analog scale scores was lower in the continuous cold flow therapy group only at day 1 postoperatively (p =0.01). There was an increase in passive range of movement post-surgery in both groups, and a larger difference in the continuous cold flow group at days 1 (111.57° ± 7.04 vs 105.49° ± 11.24; p=0.01) and 3 (110.94° ± 7.52 vs 107.39° ± 7.89; p=0.01). There was no difference in blood loss between groups. Limitations include small sample size, no mention of blinding, short follow-up time, and measurement of opioids defined as tramadol capsules, which differs from practice in the United States.

Edwards (1996) studied the outcomes of 71 patients undergoing ACL reconstruction who were randomized to CryoCuff® therapy with ice water, CryoCuff® therapy with room temperature water, or no cold therapy.[2] Therefore, this trial did not include the relevant control group of patients treated with conventional ice packs. Another randomized trial by Brandsson (1996) suffers from the same limitation; in this study of 50 patients undergoing ACL repair, no group received standard therapy with ice packs.[3]

Whitelaw (1995) reported on the results of a trial that randomized 102 patients undergoing knee arthroscopy in the outpatient setting to receive either the CryoCuff® device or traditional ice therapy.[4] The number of exchanges of ice packs and water recirculation was not reported. There was no significant difference in average pain assessment, although those in the CryoCuff® group reported decreased pain medication use compared to the control group.

Schroder (1994) compared the CryoCuff® device to ice therapy in 44 patients who had undergone ACL repair.[5] Those randomly receiving ice therapy received an ice bag three times a day postoperatively. While those randomly assigned to the CryoCuff® group reported significant decreases in pain, swelling, and analgesic use, it is not clear whether icing three times a day is a typical icing regimen.

Healy (1994) reported that the CryoCuff® device provided no benefit for pain control or

swelling compared to ice packs in a randomized trial of 76 patients (105 knees) undergoing total knee arthroplasty.[6] No data was provided on the number of ice pack exchanges, although the water was recirculated in the CryoCuff® device every one to four hours. The duration of therapy and whether it was applied in the inpatient or outpatient setting is not clear from the published article.

Levy (1993) compared the outcomes of a trial that randomized 80 patients (100 knees) undergoing total knee arthroplasty (TKA) with noncirculating cold therapy with a CryoCuff® device or to no cold therapy.[7] Although the CryoCuff® group reported a significant decrease in blood loss and a mild decrease in analgesic requirements, this trial did not include the relevant control group.

Post-Wrist Surgery

In a randomized trial comparing CryoCuff® (n=25) to ice packs (n=26) following arthroscopic wrist surgery, Meyer-Marcotty (2011) reported no significant between-group differences in swelling, range of motion, use of pain medication, and subjective functional impairment.[8] Pain levels were significantly less in the CryoCuff® group for postoperative day one and two, but not significantly different from the control group during the remainder of the 21 days follow-up. The authors concluded that home-based combined cryotherapy and compression using the Cryo/Cuff wrist bandage provided no additional benefit to pain, swelling, range of motion, or subjective impairment over control over three weeks. Active Cooling Devices

Post-Knee SurgeryRufilli (2017) investigated the use of the continuous-flow cold device in a RCT of 50 patients with end-stage knee osteoarthritis after primary TKA who had the same rehabilitation program and pain-relieving strategy.[9] The intervention group (n=24) received the continuous-flow cold device (10° and 30°C) and the control group (n=26) received crushed ice bags postoperatively. There were no statistically significant differences between groups in terms of subjective pain scores (using a numeric rating scale), medication use, or knee circumference. In addition, there were no statistically significant differences in blood loss, need for transfusion, or range of motion. However, there was a nonsignificant trend at day seven toward a lesser increase in knee circumference in the intervention group. Reported limitations included small sample size, lack of blinding, lack of evaluation of longer term efficacy after hospital discharge, and no skin temperature evaluation. Compared with a traditional icing regimen, the use of a continuous-flow cold device was no better than traditional icing in patients following TKA.

A RCT of 47 participants by Rufilli (2015) compared two homogenous groups of patients with ACL reconstruction to evaluate the efficacy of a continuous cold flow device (10°-30°C) relative to conventional crushed ice bags (intervention group n=23, control group n=24).[10] All patients were discharged the day after surgery. Primary end points included: knee pain (using the numeric rating scale that ranged from 0 [no pain] to 10 [worst pain]); blood loss; measures of knee swelling at three sites (patellar apex, 10 cm proximal to the superior patellar pole, 15 cm distal to the superior patellar pole); knee range of motion; and the use of pain medicine. Relative to the control, the intervention group had a significant reduction in numeric rating scale pain scores ($p<0.001$) and a significant decrease in blood loss ($p<0.001$). Knee volume was also significantly lower in the intervention group at the patellar apex ($p=0.013$) and 10 cm proximal to the superior patellar pole ($p=0.001$). Although there was a significant increase in mean flexion ($p<0.001$) for the intervention group relative to the control, there was no difference between groups in the use of pain medication. No adverse events were reported in

either group postoperatively, or related to the use of the cooling device or the ice bags. Researchers noted several limitations to the trial, including small sample size, lack of blinding, and lack of evaluation of longer term efficacy after hospital discharge.

In the largest study to date, Thienpont (2014) reported on 116 patients who had undergone TKA.[11] Study participants were assigned in a quasi-randomized order to eight hours daily of advanced cryotherapy at a fixed temperature (cTreatment) or to application of cold packs for 15 minutes after each of the two physical therapy sessions. Both groups could apply cryotherapy during the evening and night, whenever they wanted, for comfort and pain control. Thirty percent of patients in the cTreatment group did not use the device at night due to excessive noise. Primary outcomes were visual analogue scale (VAS), at rest and during deep active knee flexion, walking without aid, and analgesic use. Secondary outcomes were knee range of motion (ROM), active straight leg raising, walking without aid, swelling, visual hematoma, and length of stay. There was no significant difference between the groups in VAS, need for analgesics, or for any of the secondary outcomes. There was a significant decrease in flexion at six weeks in the advanced cryotherapy group (114° vs 120°).

In a 2008 randomized controlled trial (n=60), Woolf compared a temperature-controlled cryotherapy device to a standard icing regimen following outpatient knee arthroscopy.[12] 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 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.

Konrath (1996) reported on the results of a trial that randomized 103 patients undergoing ACL reconstruction to one of four different postoperative cold therapy strategies:[13] 1) Active cooling with a Polar Care pad set at a temperature of 40 to 50 degrees Fahrenheit, 2) Active cooling with a Polar Care pad set at a temperature of 70 to 80 degrees Fahrenheit, 3) Ice packs, or 4) No cold therapy. Although the skin temperatures in Groups 1 and 3 were significantly lower than the skin temperatures in Groups 2 and 4 ($p < 0.001$), the length of hospital stay, range of motion at discharge, use of oral and intramuscular pain medicine, and drain output were not significantly different between groups.

Post-Facial Surgery

Several studies have been reported by a single research group comparing the Hilotherm® device versus cooling compresses. In a randomized observer-blinded study by Modabber (2013), 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.[14] Both cooling methods were intended to be used continuously for 12 hours daily for three 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 in the treatment group who used the face mask. Blinded evaluation with a three-dimensional optical scanner showed a significant reduction in swelling on day one, two, three, and seven for the Hilotherm® group; however, no difference in swelling was observed between the groups on postoperative day 28.

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, p=0.00105) and day two (2.34 vs. 4.38, p=0.00003), but not on day seven (1.43 vs. 1.90, p=0.11627). There were also significant differences between the groups for postoperative neurologic score and eye motility and diplopia on postoperative day one.

Another randomized study with 32 patients assessed postoperative swelling of bilateral mandibular fractures using the Hilotherm® cooling mask around the head and jaw.[15] The study design was similar to that reported by Modabber. 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 neurologic score, trismus, or mandibular dysfunction. In addition, it is not clear that the cold compresses used by the control group were applied in a similar frequency as the masks used in the treatment group, limiting conclusions regarding the superiority of the Hilotherm cooling mask compared to standard postoperative therapy regimens.

COMBINATION ACTIVE COOLING AND COMPRESSION (CRYOPNEUMATIC) DEVICES

In studies evaluating combination active cooling and compression, the control group should also receive both active cooling and compression.

Post-Knee Surgery

A multicenter randomized trial with 280 TKA patients compared the GameReady cryopneumatic device versus ice packs with static compression.[16] On discharge from the hospital, the treatments were given at the same application cycle of one hour on and 30 minutes off. Compliance rates were similar for the two 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, six-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 two weeks (14 mg less per day), and patient satisfaction was increased with the cryopneumatic device.

In 2012, Waterman reported a randomized controlled trial (RCT) of the GameReady device in 36 patients with ACL reconstruction.[17] Patients were instructed to use ice or the cryopneumatic device for 30 minutes at least three times per day and return to the clinic at one, two, and six weeks postoperatively. Compliance during the first two weeks was not significantly different between the two 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 (SANE) scores. A greater percentage of patients treated with the GameReady device discontinued narcotic use by six weeks (83% vs 28%).

Post-Shoulder Surgery

Noyes (2018) published a RCT comparing continuous cryotherapy (CC; Polar Care) and standard ice packs (ICE) as a means of improving postoperative pain control for patients undergoing a primary or revision shoulder arthroplasty procedure.[18] Forty patients (20 in each group), from 30 to 90 years old, were randomly assigned to the 2 treatments. VAS pain scores were similar for both the CC and ICE groups preoperatively (5.9 vs 6.8; p=0.121) and

postoperatively at 24 hours (4.2 vs 4.3; p=0.989), 3 days (4.8 vs 4.7; p=0.944), 7 days (2.9 vs 3.3; p=0.593), and 14 days (2.5 vs 2.7; p=0.742). CC and ICE did not differ significantly in the number of morphine equivalents of pain medication postoperatively at 24 hours (43 vs 38 mg; p=0.579), 3 days (149 vs 116 mg; p=0.201), 7 days (308 vs 228 mg; p=0.181), or 14 days (431 vs 348 mg; p=0.213). VAS for quality of sleep was not different between CC and ICE postoperatively at 24 hours (5.1 vs 4.3; p=0.382), 3 days (5.1 vs 5.3; p=0.601), 7 days (6.0 vs 6.7; p=0.319), or 14 days (6.5 vs 7.2; p=0.348). The study was limited by patient compliance not being measured objectively, all patients receiving a single-shot interscalene block, and final outcomes not being evaluated.

Kraeutler (2015) compared the Game Ready shoulder wrap to standard icing in a RCT of 46 patients who had undergone rotator cuff repair or subacromial decompression.[19] Patients were instructed to apply the cryotherapy every other hour for the first three days and two to three times a day until the follow-up visit at seven to 10 days. Analysis of patient diaries showed no significant differences in average pain, worst pain, and morphine equivalent dosage between the two 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 two groups.

PRACTICE GUIDELINE SUMMARY

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

In 2016, the American Academy of Orthopaedic Surgeons released guidelines on the surgical management of osteoarthritis of the knee after knee arthroplasty.[20] They state, “Moderate evidence supports that cryotherapy devices after knee arthroscopy do not improve outcomes.”

No clinical practice guidelines were found that recommend use of active or passive cooling devices or combination cold/compression devices.

SUMMARY

Current research for cooling devices to treat some indications have been shown to have comparable, but not superior, clinical outcomes compared to other standard treatments using traditional ice packs and/or compression. For other indications there is not enough research to show an improvement in health outcomes as a result of using cooling devices. No clinical guidelines based on research recommend these cooling devices for any indication. Therefore, use of these cooling devices for any indication is considered not medically necessary.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	E0218	Fluid circulating cold pad with pump, any type
	E0236	Pump for water circulating pad

Date of Origin: *January 1996*