Healthy Blue

# Medical Policy

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| **Subject:** | Cooling Devices and Combined Cooling/Heating Devices | | |
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## Description/Scope

This document addresses the devices utilized for the treatment of pain and swelling after trauma and surgery and for musculoskeletal and other conditions. Included are both passive cold therapy devices and active cold therapy devices, as well as devices that combine compression or heat therapy in the same device.

**Note:** This document does not address the use of whole body or head cooling devices for adult or pediatric individuals with *acute neurologic injury or after sudden cardiac death*.

**Note:** This document does not address the use of compression pumps for *deep vein thrombosis prophylaxis*.

**Note:** This document does not address the use of cold therapy for *prevention of hair loss* related to chemotherapy.

## Position Statement

**Investigational and Not Medically Necessary:**

Active or passive cooling devices (with or without pneumatic compression) are considered **investigational and not medically necessary** for all uses, including but not limited to recovery after orthopedic surgery or trauma.

Active or passive devices that combine cooling and heating are considered **investigational and not medically necessary** for all uses.

## Rationale

*General Considerations*

Icepacks (cryotherapy) and compressive wraps are standard treatment of musculoskeletal injuries and after orthopedic surgery to control both pain and swelling. To document the effectiveness of various cooling devices in comparison to standard methods of cryotherapy, randomized controlled trials (RCTs) are required. The goal of such studies is to demonstrate a greater likelihood of incremental benefit compared to conventional cryotherapy when used in the outpatient setting. Both conventional cryotherapy and the passive cooling devices are essentially designed to provide cold therapy, with the primary difference being that water recirculation is more convenient with passive cooling devices. To document a medical benefit of passive devices (i.e., beyond user or medical staff convenience), the trial design must control the number of exchanges of ice bags and episodes of water recirculation.

In contrast, active cooling devices are designed to provide a steady low temperature, which 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, and trials investigating these devices need to focus on these aspects of care. The discussion below focuses only on randomized studies.

In 2016 the American Academy of Orthopaedic Surgeons reviewed the literature addressing the use of cryotherapy following knee arthroplasty in their guideline for surgical management of osteoarthritis of the knee. Their conclusion was that "Moderate evidence supports that cryotherapy devices after knee arthroplasty (KA) do not improve outcomes."

*Passive Cooling Devices*

Passive cooling devices involve non-mechanically powered methods to circulate the cold water through a compressive device applied to the treatment area. The Cryo/Cuff® device, for instance, consists of an insulated container filled with iced water that is attached to a compressive cuff. Another example of a passive device is the Polar Care Cub™ unit, which 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.

Schroder and Passler describe a small randomized trial that compared the Cryo/Cuff device to traditional ice therapy in 44 subjects that had undergone repair of the anterior cruciate ligament (ACL) (Schroder, 1994). Those receiving ice therapy received an ice bag 3 times per day postoperatively, while the Cryo/Cuff group used the device. While those randomized to the Cryo/Cuff group reported significant decreases in pain, swelling and analgesic use, it was not reported how frequently the cold water was recirculated in the device as compared to the 3 times daily ice pack changes. Additionally, subjects in this study were hospitalized for 14 days postoperatively, which is significantly longer than is practiced today.

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

Healy and colleagues reported that the Cryo/Cuff device provided no benefit to pain control or swelling compared to ice packs in an RCT of 76 participants (105 knees) undergoing total knee arthroplasty (Healy, 1994). No data was provided on the number of ice pack exchanges, although the water was recirculated in the Cryo/Cuff device every 1 to 4 hours. The duration of therapy and whether or not it was applied in the inpatient or outpatient setting is not clear from the published article.

Edwards and colleagues studied the outcomes of 71 subjects undergoing ACL reconstruction who were randomized to receive either Cryo/Cuff therapy with ice water, Cryo/Cuff therapy with room temperature water or no cold therapy (Edwards, 1996). Therefore, this trial did not include the relevant control group treated with conventional

ice packs. Nevertheless, there were no significant differences in analgesic use or pain assessment among the three groups, including the group that received no cold therapy.

Levy and colleagues also compared the outcomes in a trial randomizing 80 participants (100 knees) undergoing total knee arthroplasty to receive either passive cold therapy with a Cryo/Cuff device or no cold therapy (Levy, 1993). The Cryo/Cuff group reported a significant decrease in blood loss and mild decrease in analgesic requirements. Similar to the Edwards trial, this trial did not include the relevant control group of ice packs.

An RCT by Meyer-Marcotty and others involved 54 subjects who underwent wrist arthroscopy and were randomized evenly to receive treatment with either standard care or with the Cryo/Cuff device (2011). Follow-up was conducted 1, 8, and 21 days postoperatively. The authors noted that there was no significant benefit of the Cryo/Cuff device versus standard care with regard to pain, swelling, ROM, and subjective impairment assessed using the DASH score.

Another RCT by Brandsson suffers from the same limitation; in this study of 50 subjects undergoing ACL repair, there was no group which received standard therapy with ice packs (Brandsson, 1996).

Raynor and colleagues conducted a meta-analysis of studies investigating the use of cryotherapy following anterior cruciate ligament (ACL) reconstruction (2005). The authors identified six studies that met criteria and that were included in the analysis. They concluded that, while some individual studies did find significant impact on pain, drainage, or range of motion (ROM), the pooled analysis did not when controlling for data quality. In addition, the studies included in the analysis involved mostly small study populations and multiple groups, diluting the power of the findings.

The most recent study addressing the use of a passive cooling device was published in 2015 by Yu and colleagues, who described a prospective, single-blind (subject side) study involving 59 subjects who underwent elbow arthrolysis. Randomization assigned 31 subjects to receive postoperative treatment with the Cryo/Cuff device 3 times a day for 60 minutes each session for 1 week. The control group included 28 subjects, who received no postoperative cryotherapy. For postoperative days 1 through 7, visual analog scale scores of pain indicated significantly better pain control in the cryotherapy group ($p<0.05$). This difference was not sustained beyond this point, as no differences were noted at postoperative week 2 or at 3 months ($p>0.05$). This finding was supported by analgesic consumption data, which showed that the cryotherapy group utilized less sufentanil compared to the control group ($p<0.01$). No differences in postoperative blood loss, range of motion, or scores on the Mayo Elbow Performance Score tool were reported. One limitation to the study was the lack of conventional application of cold therapy in the control group.

In summary, the available scientific literature is insufficient to document that the use of passive cooling systems is associated with a greater likelihood of incremental benefit compared to standard ice packs. Many of the published randomized studies failed to include the relevant control group of standard ice packs. Studies that did include a control group of standard ice packs reported inconsistent results (Healy, 1994), and some studies reported no significant benefit of passive cooling devices compared to no cold therapy (Edwards, 1996).

*Active Cooling Devices*

In contrast, a literature search identified only a small number of RCTs that compared the outcomes of an active cooling device with traditional ice therapy. Konrath and colleagues reported on the results of a trial that randomized 103 participants undergoing ACL reconstruction to 1 of 4 different postoperative cold therapy strategies; (1 & 2) active cooling with a Polar Care™ pad set at a temperature of 40 to 50 degrees or 70 to 80 degrees centigrade, respectively; (3) ice packs; and (4) no cold therapy (Konrath, 1996). Both the water in the Polar Care pad and the ice packs were changed every 4 hours. The length of hospital stay, ROM at discharge, use of oral and intramuscular pain medicine and drain output were not significantly different between groups. These results suggest that the active cooling device is similar to ice packs, but there is inadequate evidence to demonstrate that the active cooling device is associated with a greater likelihood of incremental benefit.

Modabber (2013) reported on a study evaluating an active cooling device called the Hilotherm® Clinic (Hilotherm GmbH, Argenbühl-Eisenharz, Germany) for the postoperative treatment of unilateral zygomatic bone fractures. This study involved 42 subjects that were randomly assigned to treatment with either a Hilotherm cooling face mask or conventional cooling compresses (n=21 for each group). Cooling was initiated as soon as possible after surgery until postoperative day 3 and was applied continuously for 12 hours daily. Subjects were followed for 28 days. A statistically significant reduction in swelling was noted in the Hilotherm group vs. controls on postoperative day 1 (p=0.00002), day 2 (p=0.00036), day 3 (p=0.00217), and on day 7 (p=0.01907). Pain, as measured by visual analog scale, was significantly reduced in the device group vs. the control group on postoperative days 1 and 2 (p=0.00105 and p=0.00003 respectively). No statistically significant difference could be seen on postoperative day 7. Neurological function, as measured by cotton, pin prick, and blunt touch test of the upper lip, demonstrated significant improvement only on day 1 (p=0.00775), but not thereafter. Eye motility and diplopia testing was found to be significantly different between groups only on day 1 (p=0.019). Although the results of this study are encouraging, it is limited by its small size.

Thienpoint and others (2014) reported the results of a quasi-randomized controlled study involving 116 subjects who underwent knee arthroscopy. Subjects were assigned to undergo postoperative cryotherapy with either the cTreatment® device (n=58) or standard cold packs (n=58). Complete follow-up data was available for 100 subjects (86.2%). Using a per-protocol analysis, the authors reported no significant differences between groups at the 6 week follow-up point with regard to ROM, straight leg raising, walking without aid, swelling, hematoma, length of stay, blood loss, or inflammatory response. Only active flexion at 66 weeks was noted to be significantly different, with the benefit in favor of the control group (102º vs. 114º; p=0.0235). This is one of the most robust studies available addressing the use of active cryotherapy devices. These negative findings indicate that the use of such devices may not provide any significant benefits for individuals undergoing knee arthroscopy.

Results of a prospective, non-blind RCT were reported by Ruffilli in 2015. This study involved 47 subjects undergoing ACL reconstruction assigned to either active cryotherapy with the Hilotherm device (n=23) vs. treatment with ice bags (n=24). When compared to the control group, the Hilotherm group had lower pain perception as measured by visual analog scale (p<0.0001), less blood loss (p<0.0001), less knee volume increase at the patellar apex and 10 cm proximal to the superior patellar pole (p=0.013 and p=0.001, respectively), and higher range of motion in the first postoperative day (p<0.0001). There were no differences noted in analgesic drug

consumption. The authors concluded that the Hilotherm group showed significantly better results in the first postoperative day, but that additional studies with higher number of subjects and longer follow-up are required to assess the beneficial effects of the Hilotherm device.

Bech and others conducted a non-blind RCT involving 78 subjects undergoing primary total knee arthroplasty (2015). Subjects were assigned to treatment with the Donjoy® Iceman® cooling device (n=37) or standard care with ice bags (n=34). Measurement of pain intensity, passive range of motion, nausea or vomiting, opioid use, blood loss, and lower limb function were assessed at 48 hours, and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) and hospital length of stay were assessed at 6 weeks. There were no statistically significant between-group differences in nausea or vomiting, opioid use, change in hemoglobin at 24-48 hours after surgery, passive range of motion, WOMAC, or LOS.

In 2017 Ruffilli and others published the results of a small RCT involving 50 subjects who underwent knee arthroplasty and were assigned to postoperative care with either the Hilotherm active cooling device (n=24) or with crushed ice pack, (n=26). The authors reported no significant differences between groups on postoperative days 1, 3, and 7 with regard to postoperative pain, analgesic consumption, active knee range of motion, drain output, transfusion requirement, or total blood loss.

Several RCTs compared active cooling devices to no cold therapy, which is not relevant to the documentation of benefit compared to standard therapy with ice packs (Barber, 1998; Cohn, 1989; Dervin, 1998).

*Other Cooling Devices and Indications*

A literature search identified several recent RCTs evaluating the use of devices that combine cooling and compression simultaneously. Su and colleagues reported on the results of an RCT of 280 subjects who underwent total knee arthroplasty (2012). Study participants were randomized to receive post-operative cryotherapy with either the Game Ready™ cryopneumatic device or ice packs with static compression. Upon discharge from the hospital, cryotherapy treatments were given in an application cycle of 1 hour on and 30 minutes off. Compliance rates were similar for the two groups. Blinded evaluations were conducted for 187 (67%) of the original 208 subjects. The investigators reported finding no significant difference between the groups with regard to visual analog score (VAS) for pain, ROM, 6-minute walk test, timed up and go test, or knee girth. The Game Ready group reported a significant decrease in narcotic consumption, from 680 mg to 509 mg morphine equivalents, over the first 2 weeks (14 mg less per day).

Another RCT of the Game Ready device was published by Waterman and others (2012). Their study involved 36 subjects who had undergone ACL reconstruction surgery. The subjects were randomized to undergo cryotherapy with either ice or the Game Ready device for 30 minutes, at least 3 times per day. Evaluations were made at 1, 2, and 6 weeks postoperatively. Compliance during the first 2 weeks was not significantly different between the two groups (100% for Game Ready and 83% for icing). The primary outcome measure, visual analog scale (VAS) of pain, was not comparable at baseline, with the Game Ready having a VAS of 54.9 compared to the ice group with a VAS of 35.6 (p=0.01). This significantly limits 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 subjects treated with the Game Ready device discontinued narcotic use by 6 weeks (83% vs. 28%; p=0.0008).

Two of these studies do demonstrate a significant benefit in decreased narcotic requirement, but not for any other endpoint. The incremental value to this benefit is unclear compared to standard ice cryotherapy. Further studies are warranted to fully understand this issue.

*Combined Cooling/Heating Devices*

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. At this time, only one such device is available, the VitalWrap™ 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.

*Summary*

Overall, the quality of evidence addressing the use of various devices for cooling/heating/compression for postoperative therapy is weak. Adie and colleagues support this conclusion in a 2012 Cochrane review that concluded:

> Potential benefits of cryotherapy on blood loss, postoperative pain, and range of motion may be too small to justify its use, and the quality of the evidence was very low or low for all main outcomes. This needs to be balanced against potential inconveniences and expenses of using cryotherapy. Well designed randomised trials are required to improve the quality of the evidence.

The use of passive or active cooling devices, with or without compression, has been proposed as a method of decreasing pain and improving post-operative function. As noted above, the overall quality of the available evidence is poor, and to-date the evidence addressing these proposed benefits is weak. Another proposed benefit of the use of these types of devices is decreased use of opioid and other pain medications. The available studies that have included changes in opioid use as a study endpoint have reported mixed results. Additionally, the majority of studies look at short-term outcomes in the immediate post-operative period, and there is little data currently available to address how such devices impact pain and pain medication use in the long-term. Larger, well-designed and conducted trials are warranted to address this issue.

## Background/Overview

Cold and 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. Continuous cooling devices can be broadly subdivided into those providing passive cold therapy, and those providing active cold therapy using a mechanical device.

*Passive Devices*

The Cryo/Cuff device (Aircast, Inc., Boca Raton, FL) and the Polar Care Cub devices (Breg, Inc., Vista, CA) are examples of passive cooling devices. These devices use a method other than an electric pump to circulate cooled water from a cooling device to the area targeted for treatment. This may include gravity-fed or hand-pumped mechanisms.

*Active devices*

In active (mechanical) devices, a motorized pump both circulates cold water and may also provide pneumatic compression. For example, the AutoChill® device (Aircast, Inc., Boca Raton, FL), which may be used in conjunction with a Cryo/Cuff, 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™ (Thermo Temp Inc., Tampa, FL) 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 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 Polar Care 300 and 500 devices (Breg, Inc., Vista, CA) are other types of active cooling devices. Unlike the Polar Care Cub, the 300 and 500 devices have an electric pump which circulates water for cooling through the pad.

The Game Ready Accelerated Recovery System (Game Ready Inc., Berkeley, CA) is an example of an active cooling device combined with a pneumatic component. The system consists of various soft wraps and a computer controlled unit to circulate the water through the wraps.

The VitalWrap (VitalWear Inc., South San Francisco, CA) is an active heating/cooling device that allows the user to circulate either hot or cold fluid through the system. The VitalWrap system consists of a bladder filled body wrap/pad, tubing and a reservoir/pump device. Cooled or heated water may be added to the pump reservoir and then circulated through the tubing to the body wrap/pad and then back to the reservoir. The benefits of this type of device above other cooling or heating methods have not been established at this time.

## Definitions

Active cooling or heating device: A device that provides cooling or heating with the use of mechanical circulation of the thermal medium from a reservoir that may cool or heat the medium before returning it to the site of injury.

Passive cooling or heating device: A device that provides cooling or heating without the benefit of mechanical circulation of the thermal medium.

## Coding

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

**When services are Investigational and Not Medically Necessary:**

**HCPCS**

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| E0218 | Fluid circulating cold pad with pump, any type |
| E0236 | Pump for water circulating pad |
| E0217 | Water circulating heat pad with pump [when specified as a cooling/heating combination device] |
| E0676 | Intermittent limb compression device (includes all accessories), not otherwise specified [when specified as a compression cooling device for pain therapy] |
| E1399 | Durable medical equipment, miscellaneous [when specified as an active cooling device with heating or compression for pain therapy]<br>Note: HCPCS code E0675 Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral and bilateral system) is not correct coding for a pain therapy device; if used to describe a device addressed in this document it would be considered investigational and not medically necessary. |

**ICD-10 Diagnosis**

All diagnoses

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## Index

Aircast Cryo/Strap®
AutoChill Device
BioCryo Cold Compression System
Cold Rush® Cold Therapy System
Cooling Devices
Cryo/Cuff
cTreatment
Donjoy Iceman
Game Ready Accelerated Recovery System
Hilotherm®
Hot/Ice Thermal Blanket
IceMan® Cryotherapy Unit
Kinex ThermoComp™ Device
Polar Care Cub
Polar Pack®
Prothermo
NanoTherm™
TEC Thermoelectric Cooling System
Thermacure
VascuTherm2®
VascuTherm3®
VascuTherm4®
VitalWear Cold/Hot Wrap
VitalWrap
VPULSE™

**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

## Document History

| Status | Date | Action |
|---|---|---|
| | 12/27/2018 | Updated Coding section with 01/01/2019 HCPCS changes. |
| Reviewed | 07/26/2018 | Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections. |

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| Reviewed | 08/03/2017 | MPTAC review. Updated Rationale and References sections. |
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| Reviewed | 08/06/2015 | MPTAC review. Updated Rationale, Background, and Reference sections. |
| Reviewed | 08/14/2014 | MPTAC review. Updated Rationale, Coding and Reference sections. |
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