

Subject: Cooling Devices and Combined Cooling/Heating Devices**Document #:** DME.00037**Status:** Reviewed**Publish Date:** 06/28/2023**Last Review Date:** 05/11/2023

Description/Scope

This document addresses 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, vibration 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
- Cold therapy for the prevention of hair loss related to chemotherapy
- Use of compression pumps with or without cooling or heating capabilities for deep vein thrombosis prophylaxis. For more information regarding such devices, please see the following document:
 - [CG-DME-46 Pneumatic Compression Devices for Prevention of Deep Vein Thrombosis of the Extremities in the Home Setting](#)

Position Statement

Investigational and Not Medically Necessary:

Active or passive cooling devices (with or without pneumatic compression or vibration) 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 (for example, 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.

In 2016, the American Academy of Orthopaedic Surgeons (AAOS) 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." In the 2020 AAOS guideline regarding the management of glenohumeral joint osteoarthritis, the workgroup again recommended that either continuous cryotherapy or cold packs could be used in the postoperative period. The workgroup noted that there is an absence of reliable evidence that either modality is more effective.

The Orthopaedic Trauma Association Musculoskeletal Pain Task Force guidelines for pain management in acute musculoskeletal injury recommends adjunctive cryotherapy as a modality to treat pain associated with acute musculoskeletal injury and following orthopaedic surgery (Hsu, 2019). However, the panel did not recommend a specific delivery modality citing a lack of quality evidence which shows superior pain control or a decrease in pain medication consumption with continuous cryotherapy compared to ice packs.

Passive Cooling Devices

A RCT by Meyer-Marcotty and others (2011) involved 54 subjects who underwent wrist arthroscopy and were randomized evenly to receive treatment with either standard care (cool packs or crushed ice wrapped in a towel) or with the Cryo/Cuff device. 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 in terms of pain, swelling, range of motion (ROM), and subjective impairment assessed using the Disabilities of the Arm, Shoulder and Hand (DASH) score.

A study addressing the use of a passive cooling device (Yu, 2015) described a prospective, participant-blinded study involving 59 participants who underwent elbow arthrolysis. Randomization assigned 31 participants 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 participants, 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. This difference was not sustained beyond this point, as no differences were noted at postoperative week 2 or at 3 months. This finding was supported by analgesic consumption data, which showed that the cryotherapy group utilized significantly less sufentanil compared to the control group. No differences in postoperative blood loss, range of motion, or scores on the Mayo Elbow Performance Score tool were reported. The applicability of the results was limited, as the control group did not have access to standard therapy which includes the application of postoperative cryotherapy.

Noyes and Denard (2018) performed a prospective randomized control study comparing the effectiveness of continuous cryotherapy to plain ice following total shoulder arthroplasty. Individuals were randomized to receive a Polar Care device (n=20) or plain ice (n=20). Outcomes measures included pain control, narcotic consumption and quality of sleep for up to 14 days following surgery.

There were no significant differences in pain control, satisfaction, narcotic consumption or sleep quality between the groups at any point in the study.

In a systematic review of RCTs, Dantas and associates (2019) investigated the effectiveness of cryotherapy on pain and physical function in knee osteoarthritis. The systematic review incorporated RCTs and quasi-RCTs that compared different modalities of cryotherapy for treatment of pain in individuals with knee osteoarthritis. Studies which used ice packs, ice cubes, cold compresses, cold sprays, cold tubs, ice massage, and cold chambers were included. A total of five studies (n=202) comprised of individuals with knee osteoarthritis symptoms for greater than 6 months were evaluated. While cryotherapy combined with another therapy showed a high within-group effect size, the effect size was generally moderate when used alone. The authors cited multiple limitations and methodological shortcomings in the available studies and noted there is still a lack of quality in the evidence regarding the use of cryotherapy in individuals with knee osteoarthritis.

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 earlier published randomized studies failed to include the relevant control group of standard ice packs (Brandsson, 1996; Edwards, 1996; Levy, 1993; Raynor, 2005). Studies that did include a control group of standard ice packs reported inconsistent results (Healy, 1994; Whitelaw, 1995), and some studies reported no significant benefit of passive cooling devices compared to no cold therapy (Edwards, 1996).

Active Cooling Devices

Modabber and colleagues (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, day 2, day 3, and on day 7. Pain, as measured by visual analog scale, was significantly reduced in the device group vs. the control group on postoperative days 1 and 2. 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, but not thereafter. Eye motility and diplopia testing was found to be significantly different between groups only on day 19. Although the results of this study are encouraging, it is limited by its small size.

Thienpoint and associates (2014) reported the results of a quasi-RCT involving 116 subjects who underwent knee arthroscopy. Subjects were assigned to undergo postoperative cryotherapy with either the cTreatment[®] (Waegener[®] Health Care Applications) 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 in terms of 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. 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) or treatment with ice bags (n=24). The primary endpoint was pain reduction. The active cryotherapy group reported significantly lower levels of pain. There were no differences noted in analgesic consumption. This small study was limited by several factors, including the short study period, which was limited to the initial surgical day. While the authors described the application and use of the active cryotherapy device, no description was included regarding the ice bag therapy protocol.

Bech and others (2015) conducted a non-blind RCT involving 78 subjects undergoing primary total knee arthroplasty. 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 in terms of postoperative pain, analgesic consumption, active knee range of motion, drain output, transfusion requirement, or total blood loss.

Several earlier 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; Konrath, 1996).

Other Cooling Devices and Indications

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 (Game Ready Inc., Berkeley, CA) 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 in terms of 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).

Waterman and colleagues (2012) compared the effect of cryotherapy to cryotherapy with compression following surgery. Consecutive individuals undergoing ACL reconstruction were randomized to receive ice pack therapy (n=18) or the compressive cooling device (n=18) postoperatively. Participants were instructed to apply their respective therapy at least 3 times a day for 30 minutes duration. Participants were evaluated for 6 weeks following surgery. Compliance during the first 2 weeks was not significantly different between the two groups (100% for Game Ready and 83% for icing). The mean difference in pain scores relative to baseline were significantly improved in the cryotherapy with compression group compared to the ice pack therapy. However, the baseline pain scores were significantly different between the groups, representing a potential source of bias.

VibraCool[®] (PainCareLabs, Atlanta, GA) combines vibration and cooling, in the form of reusable ice packs, in one device. The device combines high-frequency low-amplitude vibration and cryotherapy, which is claimed to activate the gate control mechanism and relieve pain. In addition, the device makers assert that use of ice will reduce inflammation while the vibration will increase blood flow to the affected area to promote healing. There is no available data in the published peer-reviewed literature which addresses the use of, and any benefits related to treatment which combines vibration and cooling therapy. Further studies are needed to assess the

efficacy of this therapy compared to standard therapy modalities.

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. 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 American Academy of Orthopaedic Surgeons (AAOS) guideline regarding pain alleviation following musculoskeletal extremity/pelvis surgery (2021) concludes "Limited evidence suggests no significant difference in patient pain, function and opioid use between cryo-compression and control/ice/circulating water." The society recommendation does not compare active or passive devices to ice packs or wraps.

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. 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

Passive cooling devices involve non-mechanically powered methods, such as gravity or a hand pump, to circulate the cold water through a compressive device applied to the treatment area. The Cryo/Cuff® device (Aircast, Inc., Boca Raton, FL), 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 (Breg, Inc., Vista, CA), 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.

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 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 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.

In 2020, in response to a number of reports of injuries associated with water-circulating hot/cold therapy devices, the FDA issued a safety communication to educate individuals and health care providers about the importance of following the instructions for these devices. Inappropriate use of these devices can result in a range of injuries from temporary minor symptoms (numbness or discoloration) to frostbite and necrosis, which can require skin grafts, muscle/skin flap reconstruction, or amputation.

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:

HPCPS

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, compression, or vibration for pain therapy] Note: HPCPS 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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Aircast Cryo/Strap®
 AutoChill Device
 BioCryo Cold Compression System
 Breg VPULSE®
 Cold Rush® Cold Therapy System
 Cooling Devices
 Cryo/Cuff
 Cryo-compression
 cTreatment®
 Donjoy Iceman
 Game Ready Accelerated Recovery System
 Hilotherm®
 Hot/Ice Thermal Blanket
 IceMan® Cryotherapy Unit
 Icryo
 Kinex ThermoComp™ Device
 NICE1
 Ossur Cold Rush
 Polar Care Cub
 Polar Pack®
 Power Play ice bags
 Prothermo
 NanoTherm™
 TEC Thermoelectric Cooling System
 Thermacure
 VascuTherm2®
 VascuTherm3®
 VascuTherm4®
 VibraCool®
 VitalWear Cold/Hot Wrap
 VitalWrap
 Waegener cTreatment

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
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Reviewed	05/12/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	05/13/2021	MPTAC review. Updated Rationale, Background, and Reference sections.
Reviewed	05/14/2020	MPTAC review. Updated Description, Rationale and References sections.
Revised	06/06/2019	MPTAC review. Added devices which combine cooling and vibration to the Investigational and not medically necessary statement. Updated Coding, Rationale and Index sections.
Reviewed	12/27/2018	Updated Coding section with 01/01/2019 HCPCS changes.
	07/26/2018	MPTAC review. Updated Rationale and References sections.
	05/15/2018	The document header wording updated from "Current Effective Date" to "Publish Date."
Reviewed	12/27/2017	Updated Rationale section.
	08/03/2017	MPTAC review. Updated Rationale and References sections.
	08/04/2016	MPTAC review. Updated Reference and Index sections. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. Updated Rationale, Background, and Reference sections.
Reviewed	08/14/2014	MPTAC review. Updated Rationale, Coding and Reference sections.
New	08/08/2013	MPTAC review. Initial document development.

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