Policy Number	**THE801.004**
Policy Effective Date	**01/01/2026**

Heat and Cold Therapy Devices

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

Scalp cooling devices approved by the United States Food and Drug Administration (FDA) (e.g., DigniCap and Paxman Scalp Cooling System) **may be considered medically necessary** when used during chemotherapy to prevent hair loss.

Circulating and noncirculating cooling devices **are considered not medically necessary**.

Combination circulating cooling and compression (cryopneumatic) devices **are considered not medically necessary**.

A moist heating pad or water circulating heat pad with pump **is considered not medically necessary.**

Therapeutic induction of intra-brain hypothermia using the pro2cool® device **is considered experimental, investigational and/or unproven** for all indications, including but not limited to treating symptoms of concussion or traumatic brain injury.

Policy Guidelines

Heat or cold packs (e.g., ice, gel, chemical, etc.), hot water bottles, ice bags, etc., are supplies purchased over the counter without a prescription. Over the counter supplies are generally contract exclusions. Member contract benefit may vary.

Description

Cold and Compression Therapy
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 (e.g., after orthopedic surgical procedures).

Use of ice packs and various bandages and wraps following surgery or musculoskeletal and soft tissue injury is 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 wraps. 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.

Scalp Cooling Devices
Alopecia is a common side effect of chemotherapy. Chemotherapy agents generally target rapidly proliferating cells such as hair follicles, causing apoptosis. Most hair follicle cells represent keratinocytes (epidermal cells) within the epithelial matrix of the hair follicle, which proliferate rapidly. Because chemotherapy does not discriminate between tumor cells (which also proliferate rapidly) and keratinocytes, these cells are also damaged causing the hair shafts

to fall out. Scalp cooling has been widely used to decrease chemotherapy induced alopecia (CIA). There are several mechanisms that have been postulated as to how scalp cooling prevents CIA. These include cutaneous vasoconstriction leading to a decrease in the concentration of chemotherapy in the scalp, decrease in cellular uptake of chemotherapy by the hair follicle, and reduction in the hair follicle metabolic rate. (1)

Current devices include caps frozen to very low temperatures (e.g., −18°C to −25°C), then placed on the head before, during, and after chemotherapy treatment; the caps must be changed every 30 minutes because they thaw (Penguin Cold Caps). Although this technology has been reported to be effective in preventing alopecia, it requires refrigeration for storage as well as freezing before use, and support with changing the caps every 30 minutes during and after treatment. Newer self-contained technologies use a machine to cool and circulate a glycol-based fluid in channels within a cap, allowing the scalp temperature to be controlled and maintained throughout the treatment course. These systems include the DigniCap Scalp Cooling System (Dignitana) and the Orbis (Paxman). (1)

Noncirculating Cooling Devices

The CryoCuff® and Polar Care Cube 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 water drained. The cooler is then raised above the affected limb, and cold water refills the compressive cuff. The Polar Care Cube 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.

Circulating Cooling Devices

In active, circulating 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 Game Ready™ Accelerated Recovery System is a circulating 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, other cuffs may be attached for uses outside 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.

Heat Therapy

Heating devices may be used for a variety of indications including muscle spasms and joint pain. Application of heat results in the production of hyperemia, induction of reflex vasodilation, and

acceleration of metabolic processes. The application of heat may ease pain by dilating the blood vessels and decreasing painful stiffness of soft tissues surrounding the injured area. General indications for therapeutic heat include pain, muscle spasm, contracture, tension myalgia, hematoma resolution, bursitis, tenosynovitis, fibrositis, fibromyalgia, superficial thrombophlebitis, and collagen vascular diseases.

Moist Heating Pads

A moist heating delivers warm, damp heat, often using ambient moisture captured by a special cover or by applying a damp cloth.

Water Circulating Heating Pad with Pump

Active heating devices work very similar to the cooling devices. A water circulating heat pad with pump is a flexible pad containing a series of channels through which water is circulated by means of an electrical pumping mechanism. The water is heated in an external reservoir. An example includes the Hot/Ice Thermal Blanket. 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.

A similar device is the VitalWrap™ (VitalWear Inc., San Francisco, CA), an active heating/cooling device that allows the user to circulate either hot or cold fluid through the system. This system provides an option for compression as well.

Regulatory Status

A large number of cooling and heating devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Several examples are listed in Table 1 below. See the FDA website for a current listing of all approved devices.

Table 1. Cooling Devices Cleared by the United States (U.S.) Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Xrecovery	Shenzhen Xinrun Electric Appliances Co., LTD	11/14/2024	K242940	To treat post-surgical and acute injuries to reduce swelling and pain
Cold Compression	JKH Health Co., Ltd	05/01/2024	K240986	To treat post-surgical and acute injuries to reduce swelling and pain
Cold/Hot Compression	JKH Health Co., Ltd	10/27/2023	K223541	To treat post-surgical and acute injuries to reduce swelling and pain.
Cryo-Thermo Compression Device	Suzhou MicroPort	03/08/2023	K222136	To treat post-surgical and acute injuries to reduce swelling and pain.

	RehabTech (Group) Co., Ltd.			
Armory Motion	Pain Management Technologies, Inc.	06/10/2022	K213097	To treat post-surgical and acute injuries to reduce swelling and pain.
Ice Compression First, Duo, & Moove Systems	MksParis	01/11/2021	K193079	To treat post-surgical and acute injuries to reduce swelling and pain.
Game Ready GRPro 2.1 System	Cool Systems, Inc (Dba Game Ready)	10/29/2019	K192114	To treat post-surgical and acute injuries to reduce swelling and pain.
Polar Care Wave	Breg Inc	03/01/2019	K183702	To treat post-surgical and acute injuries to reduce swelling and pain.
Therm-X, Therm-X At, Therm-X Pro Ath	Zenith Technical Innovations	05/10/2019 08/03/2018	K190854 K181149	To treat post-surgical and acute injuries to reduce swelling and pain.
Med4 Elite	Cool Systems, Inc (Dba Game Ready)	09/29/2017	K171685	To treat post-surgical and acute injuries to reduce swelling and pain.
Nice1	Nice Recovery Systems, LLC	12/23/2014	K143197	To treat post-surgical and acute injuries to reduce swelling and pain.
Dynatron Peltier Thermostim Probe	Dynatronics Corp.	01/24/2014	K132057	To treat post-surgical and acute injuries to reduce swelling and pain.
Dignicap Scalp Cooling System	Dignitana AB	07/03/2017	K170871	To treat alopecia associated with chemotherapy.
Paxman Scalp Cooler	Paxman Coolers Limited	04/17/2017	K163484	To treat alopecia associated with chemotherapy.

TecTraum Inc. has designed and developed the world's first-ever medical device treatment for concussions, potentially reducing the signs and symptoms of concussion, the pro2cool®. Designated by the U.S. Food and Drug Administration as a Breakthrough Device, pro2cool® delivers precise amounts of cooling therapy for patients who have suffered a mild traumatic brain injury (mTBI, or concussion). Currently, the pro2cool® system is an investigational use only device and has not yet received market authorization from the FDA. (2)

Rationale

Medical polices assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life,

quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Cooling Device Post-Knee Surgery

Clinical Context and Therapy Purpose

The purpose of a cooling device is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as a standard icing regimen, in individuals with pain and/or swelling after knee surgery.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with pain and/or swelling after knee surgery.

Interventions

The therapy being considered is a cooling device.

Comparators

Comparators of interest include a standard icing regimen. Treatments include postoperative exercises, nonsteroidal anti-inflammatory drugs (NSAIDs), and opioids.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, medication use, and resource utilization.

The existing literature evaluating a cooling device as a treatment for pain and/or swelling after knee surgery has varying lengths of follow-up, ranging from 1 to 6 weeks. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to

fully observe outcomes. Therefore, 1 to 6 weeks of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Because studies that include the preferred comparator (standard icing regimen) are available, studies that use other comparators, such as no icing therapy or room temperature devices, were not evaluated in this medical policy.

Noncirculating Cooling Devices

Randomized Controlled Trials

Schroder and Passler (1994) compared the CryoCuff device with ice therapy in 44 patients who had undergone repair of the anterior cruciate ligament (Table 2). (3) Those receiving ice therapy administered an ice bag 3 times a day postoperatively. While those randomized to the CryoCuff group reported significant decreases in pain, swelling, and analgesic use, it is not clear whether icing 3 times a day is a typical icing regimen (Table 3).

Whitelaw et al. (1995) reported on results of a trial that randomized 102 patients undergoing knee arthroscopy in the outpatient setting to a CryoCuff device or traditional ice therapy (Tables 2 and 3). (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. In 1994, 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. (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.

Table 2. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Schroder and Passler (1994) (3)	EU	NR	NR	Patients undergoing anterior cruciate	CC (n=21)	ICE (n=23)

				ligament reconstruction using autologous patellar tendon graft		
Whitelaw et al. (1995) (4)	U.S.	NR	NR	Patients undergoing diagnostic knee arthroscopy	CC (n=56)	ICE with elastic bandages (n=46)

CC: CryoCuff; EU: European Union; ICE: standard ice packs; NR: not reported; RCT: randomized controlled trial; U.S.: United States.

Table 3. Summary of Key RCT Results

Study	Range of Motion between Groups	Pain Score between Groups	Average Pain Assessment, 24 hrs; 72 hrs	Pain Medication Usage over 24 hr Period, Day 1; 2; 3
Schroder and Passler (1994) (3)	p=.0001 to.0177	p=.01		
Whitelaw et al. (1995) (4)				
CC			4.34; 3.15	4.23; 3.21; 2.7
ICE			4.98; 3.58	5.00; 4.22; 3.12

CC: CryoCuff; hr(s): hour(s); ICE: standard ice packs; RCT: randomized controlled trial.

Tables 4 and 5 summarize notable limitations identified in each study.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Schroder and Passler (1994) (3)					
Whitelaw et al. (1995) (4)					1,2 Follow-up was only 72 hrs post-surgery

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as

comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Schroder and Passler (1994) (3)	1. Randomization not described	1,2,3. Not blinded				
Whitelaw et al. (1995) (4)	1. Randomization method did not produce groups of equal numbers (56 vs. 46 patients)	1,2,3. Not blinded				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

<u>Circulating Cooling Devices</u>

Systematic Reviews

Liang et al. (2024) conducted a systematic review and meta-analysis to compare both cryotherapy to no cryotherapy and cryotherapy with circulating cooling devices to standard cold pack therapy. (6) Only the information relevant to the circulating cooling devices comparison to standard cold pack therapy is included here. A total of 13 RCTs were identified. The included studies are summarized in Table 6, and the characteristics and results in Tables 7

and 8, respectively. There were no significant differences between groups for any of the evaluated outcomes including pain, opioid consumption, blood loss, range of motion, and knee swelling. The meta-analysis is limited by the small sample sizes of the trials as well as the significant heterogeneity for most of the analyzed outcomes.

Table 6. Comparison of Trials Included in Meta-analyses

Study	Liang (2024) (6)
Bech et al. (2015)	●
Borgers et al. (2020)	●
Demoulin et al. (2012)	●
Desteli et al. (2015)	●
Healy et al. (1993)	●
Karaduman et al. (2019)	●
Marinova et al. (2023)	●
Quesnot et al. (2024)	●
Ruffilli et al. (2017)	●
Sadoghi et al. (2017)	●
Schinsky et al. (2016)	●
Su et al. (2012)	●
Thienpont et al. (2014)	●

Table 7. Meta-analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Liang (2024) (6)	Through May 2024	13	Patients undergoing TKA in trials comparing circulating cooling devices with standard cold pack	1061 (40-187)	RCT	NR

NR: not reported; RCT: randomized controlled trial; TKA: total knee arthroplasty.

Table 8. Meta-analyses Results

Study	Pain (VAS) within 3 days	Pain (VAS) after 3 days	ROM within 7 days	ROM after 7 days
Liang 2024 (6)				
Total N	678	252	622	252
Pooled effect (95% CI); p-value	MD, -0.16 (-1.40 to 1.09); .80	MD, -0.4 (-1.04 to 0.23); .21	MD, 0.63 (-3.91 to 5.17); .79	MD, 3.78 (-6.54 to 14.10); .47
I^2 (p)	*96%* (<.00001)	*0%* (.43)	*70%* (.00009)	*93%* (<.00001)

CI: confidence interval; MD: mean difference; ROM: range of motion; VAS: visual analogue scale.

Randomized Controlled Trials

Select RCTs are summarized below and in Tables 9 to 12.

In one of the largest studies to date, Thienpont (2014) evaluated 116 patients who had undergone total knee arthroplasty who were assigned in a quasi-randomized order to 8 hours of daily advanced cryotherapy at a fixed temperature or to the application of cold packs for 15 minutes after each of 2 physical therapy sessions. (7) Both groups could apply cryotherapy during the evening and night whenever they wanted for comfort and pain control. Thirty percent of patients in the advanced cryotherapy group did not use the device at night due to excessive noise. Primary outcomes were visual analog scale pain scores 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 visual analog 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°).

Woolf et al. (2008), in a RCT of 60 patients, compared a temperature-controlled cryotherapy device with a standard icing regimen following outpatient knee arthroscopy. (8) 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=.04). Additional study with a larger number of patients is needed to determine whether the use of continuous cooling at night improves health outcomes.

More recently, a RCT of 47 participants by Ruffilli et al. (2015) compared 2 homogenous groups of patients with anterior cruciate ligament reconstruction to evaluate the efficacy of a continuous cold flow device (10° to 30°C) relative to conventional crushed ice bags (intervention group n=23; control group n=24). (9) All patients were discharged the day after surgery. Primary endpoints 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 3 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<.001) and a significant decrease in blood loss (p<.001). Knee volume was also significantly lower in the intervention group at the patellar apex (p=.013) and 10 cm proximal to the superior patellar pole (p=.001). Although there was a significant increase in mean flexion (p<.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.

Ruffilli et al. (2017) investigated the use of the continuous-flow cold device in a RCT of 50 patients with end-stage knee osteoarthritis after primary total knee arthroplasty who had the same rehabilitation program and pain-relieving strategy. (10) 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 7 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 with total knee arthroplasty.

Coviello et al. (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. (11) Patients (N=100) were randomized into 2 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=.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=.01) and 3 (110.94° ± 7.52 vs 107.39° ± 7.89; p=.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.

Quesnot et al. (2024) compared compressive cryotherapy (Game Ready) with standard cryotherapy in 40 patients undergoing total knee arthroplasty in France. (12) There was minimal reporting of baseline characteristics, but the patients had similar median age (76 and 77 years). The median BMI was numerically higher in the intervention group (31 vs 25.9 kg/m^2), but this group also contained a higher percentage of men (35% vs 10%). There were no differences between groups in passive or active range of motion on day 21. On day 21 there were significant improvements in joint effusion, pain during activity, the 6-minute walk test, and the Knee Injury and Osteoarthritis Outcome Score with circulating cryotherapy, but the numerical differences were small. This study is limited by lack of baseline demographic information, the small sample size, as well as the limited number of sites.

Table 9. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Woolf et al. (2008) (8)	U.S.	1	NR	Patients receiving outpatient knee arthroscopy	Continuous temperature-controlled	ICE regimen (n=29)

					cryotherapy system (n=24)	
Thienpont (2014) (7)	EU	1	2012	Patients receiving primary knee arthroplasty for osteoarthritis	Advanced cryotherapy (n=58)	ICE (Cold packs) (n=58)
Ruffilli et al. (2015) (9)	EU	NR	NR	Patients undergoing anterior cruciate ligament reconstruction	Continuous cold flow device (Hilotherm; n=23)	ICE (Ice bags) (n=24)
Ruffilli et al. (2017) (10)	EU	1	2013-2014	Patients affected by end-stage knee osteoarthritis and treated with primary total knee arthroplasty	Continuous cold flow device (Hilotherm; n=24)	ICE (Crushed ice packs) (n=26)
Coviello et al. (2022) (11)	EU	1	2020-2022	Patients affected by end-stage knee osteoarthritis and treated with primary total knee arthroplasty	Continuous cold flow device (n=50)	ICE (Cold packs) (n=50)
Quesnot et al. (2024) (12)	France	1	2019-2022	Patients affected by end-stage knee osteoarthritis and treated with primary total knee arthroplasty	Continuous cold flow device (n=20)	ICE (Ice packs) (n=20)

EU: European Union; ICE: standard ice packs; NR: not reported; RCT: randomized controlled trial; U.S.: United States.

Table 10. Summary of Key RCT Results

Study	Patients with Mild[1] Pain Intensity	Mean visual analog score at Rest 2 Days Post-Surgery	Pain Evaluation Scores[2] 1 Day Post-Surgery	Pain Evaluation Scores[2] 7 Days Post-Surgery	Blood Loss	ROM, days 1; 3; and 4 (°)
Woolf et al. (2008) (8)						
Device	35.7%					
ICE	5.9%					
p-value	.04					

Thienpont (2014) (7)						
Device (mean ± SD)		4 ± 3				
ICE (mean ± SD)		3.5 ± 2.5				
p-value		.1842				
Ruffilli et al. (2015) (9)						
Device (mean ± SD)			0.9 ± 8		26.7 ± 27.3 ml	
ICE (mean ± SD)			2.4 ± 1.7		108.0 ± 91.4 ml	
p-value			<.001		<.001	
Ruffilli et al. (2017) (10)						
Device (mean ± SD)			2.6 ± 1.8	2.0 ± 1.6	242.9 ± 225.1 ml	
ICE (mean ± SD)			3.5 ± 2.3	1.6 ± 1.5	230.3 ± 216.5 ml	
p-value			.2	.3	.8	
Coviello et al. (2022) (11)						
Device (mean ± SD)			5.09 ± 0.94		1.03 ± 0.42	111.57 ± 7.04; 110.94 ± 7.52; 108.84 ± 6.07
ICE (mean ± SD)			5.69 ± 1.08		1.06 ± 0.55	105.49 ± 11.24; 107.39 ± 7.89; 108.22 ± 6.61
p-value			.01		.86	.01;.01;.64
Quesnot et al. (2024) (12)						
Device (median, IQR)			Day 1: 3.0 (0-5.0)	Day 21: 1.0 (0-2.0)		Day 21: flexion, 110 (95.0-115.0); AEL, 0 (0-5.0)

ICE (median, IQR)			Day 1: 3.0 (2.0-4.0)	Day 21: 2.0 (0-3.5)		Day 21: flexion, 100 (92.5-107.5); AEL, 0 (0-7.5)
p-value			.549	.252		Flexion,.186; AEL,.308

AEL: active extension lag; ICE: standard ice packs; IQR: interquartile range; RCT: randomized controlled trial; ROM: range of motion; SD: standard deviation.

[1] Mild defined as "did not awaken" due to pain.

[2] Pain evaluated using a numeric rating scale ranging from 0, no pain, to 10, worst pain imaginable.

Tables 11 and 12 summarize notable limitations identified in each study.

Table 11. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Woolf et al. (2008) (8)					
Thienpont (2014) (7)		2. Version used unclear			
Ruffilli et al. (2015) (9)					1.2, Follow-up was limited to the duration of patients' hospital stay
Ruffilli et al. (2017) (10)					1,2. Follow-up duration was 7 days
Coviello et al. (2022) (11)		2. Brand not available in the U.S., unclear if similar to FDA-approved products			1,2. Follow-up duration was limited to hospital stay (max 4 days post-surgery)
Quesnot et al. (2024) (12)					

FDA: Food and Drug Administration; U.S. United States.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is

unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 12. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Woolf et al. (2008) (8)	2. Allocation not concealed	1,2,3. No blinding				
Thienpont (2014) (7)	1. Randomization not described	1,2. Patients and physicians not blinded		1. 30% lost to follow-up		
Ruffilli et al. (2015) (9)	2. Allocation not concealed	1,2,3. No blinding				
Ruffilli et al. (2017) (10)	2. Allocation not concealed	1,2,3. No blinding				
Coviello et al. (2022) (11)	2. Allocation not concealed	1,2,3. No mention of blinding				
Quesnot et al. (2024) (12)		1. Patients were not blind				3. No between-group comparative effect sizes or confidence intervals

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome

assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Combination Circulating Cooling and Compression (Cryopneumatic) Devices

Randomized Controlled Trials

In a multicenter RCT, Su et al. (2012) compared 280 total knee arthroplasty patients treated with the Game Ready cryopneumatic device or with ice packs plus static compression (Tables 13 and 14). (13) 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 visual analog score for pain, range of motion, 6-minute walk test, Timed Up & Go test, or knee girth under this more typical icing regimen. Narcotic consumption decreased from 680 to 509 mg morphine equivalents over the first 2 weeks (14 mg less per day), and patient satisfaction increased with the cryopneumatic device.

Waterman et al. (2012) reported on a RCT of the Game Ready device in 36 patients who had anterior cruciate ligament reconstruction (Tables 13 and 14). (14) 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 (visual analog pain score) differed 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%).

Table 13. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Su et al. (2012) (13)	U.S., Australia	11	NR	Patients with unilateral osteoarthritis	Cryopneumatic device (n=103)	ICE with static compression (n=84)

Waterman et al. (2012) (14)	U.S.	1	NR	Patients undergoing anterior cruciate ligament reconstruction	Compressive cryotherapy (n=18)	ICE (n=18)

ICE: standard ice packs; NR: not reported; RCT: Randomized controlled trials; U.S.: United States.

Table 14. Summary of Key RCT Results

Study	Decrease[1] in 6-Minute Walk Test at 2 and 6 Weeks Post-Surgery	Flexion at 2 and 6 Weeks Post-Surgery	Extension at 2 and 6 Weeks Post-Surgery	Discontinuation of Pain Medication at 6 weeks
Su et al. (2012) (13)				
Device	-118.2 m	-33.0	1.5	
ICE	-107.7 m	-28.7	1.6	
Waterman et al. (2012) (14)				
Device				15/18 (83.3%) patients
ICE				5/18 (27.8%) patients
p-value				.0008

ICE: standard ice packs; RCT: randomized controlled trial

[1] Decrease from preoperative values.

Tables 15 and 16 summarize notable limitations identified in each study.

Table 15. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Su et al. (2012) (13)	3. Surgical patients had different surgeons using the implants of their choice.				
Waterman et al. (2012) (14)				5. Clinically significant difference not prespecified	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is

unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 16. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Su et al. (2012) (13)	2. Allocation known by operating surgeon and patient					
Waterman et al. (2012) (14)	2. Allocation not concealed	1,2,3. Not blinded				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

Murgier et al. (2017) conducted a prospective case-control study of the Game Ready device, comparing 43 individuals (27 men, 16 women) recovering from revision total knee arthroplasty; the control group (n=19) was treated with a cold pack applied intermittently (4 hours daily), while the Game Ready group was treated with 2, 8-hour cycles in 30-minute off-on increments.

(15) While the main outcome was the reduction of total blood loss, a secondary outcome was postoperative pain, as measured by visual analog score 3 days postsurgery. Patients using the Game Ready device showed decreased blood loss compared with the control group (260 mL vs. 465 mL; p<.05), as well as an improvement in postoperative pain (visual analog score, 1 vs. 3; p<.05). Limitations included the possibility of a type II error due to the specialized surgical unit where the study was performed; additional limitations (e.g., variability of results, concerns about patients' comorbidities) affected the study's secondary outcomes. The authors concluded that, overall, the cryopneumatic device aided patients' recovery from revision total knee arthroplasty but additional prospective randomized trials would be needed to confirm results.

Section Summary: Post-Knee Surgery

For individuals who have pain and/or swelling after knee surgery, the evidence includes a systematic review, several RCTs and a case-control study. Studies on manually operated passive noncirculating cooling devices were limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications did not provide sufficient evidence of comparative efficacy. Other studies provided no information on the frequency of ice changes, limiting interpretation of the results. Randomized trials comparing active circulating cooling devices with standard intermittent icing or cold packs have had mixed results, with several studies reporting a significant reduction in medication use or other outcomes (e.g., pain, blood loss, swelling, range of motion) and others finding no significant improvements in outcomes. The results also differ across patient populations. A case-control study of the Game Ready device, which provides cooling and compression, found that the device decreased postoperative blood loss and reduced postoperative pain, compared with intermittent application of a cold pack. However, it is unclear whether constant cooling provides greater pain relief than standard icing or intermittent use of the device.

Cooling Device Post-Shoulder Surgery

Clinical Context and Therapy Purpose

The purpose of a cooling device is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as a standard icing regimen, in individuals with pain and/or swelling after shoulder surgery.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with pain and/or swelling after shoulder surgery.

Interventions

The therapy being considered is a cooling device.

Comparators

Comparators of interest include a standard icing regimen. Treatments include postoperative exercises, NSAIDs, and opioids.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, medication use, and resource utilization.

The existing literature evaluating a cooling device as a treatment for pain and/or swelling after shoulder surgery has varying lengths of follow-up, ranging from 7 to 10 days. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 7 to 10 days of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Because studies that include the preferred comparator (standard icing regimen) are available, studies that use other comparators, such as no icing therapy or room temperature devices, were not evaluated in this medical policy.

Combination Circulating Cooling and Compression (Cryopneumatic) Devices
Randomized Controlled Trials
Kraeutler et al. (2015) compared the Game Ready shoulder wrap with standard icing in a RCT of 46 patients who had undergone rotator cuff repair or subacromial decompression. (16) The average age at the time of surgery was 55.4 years in the compressive cryotherapy intervention group (n=25) and 55.8 years in the control group (n=21). 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. In the immediate postoperative week (days 0 to 7), participants used diaries to document pain level using a visual analog score (no pain to extreme pain) twice per day. They also reported use of pain medication (converted to morphine equivalent dosage). 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 mm) difference in visual analog scores between the 2 groups. Trial limitations included a small sample size (noting that 11 [19%] enrolled patients were excluded due to noncompliance), lack of blinding, potential recall bias due to the use of patient-reported diaries, and uncertainty whether the correct usage of cryotherapy was followed.

Noyes et al. (2018) published a RCT comparing continuous cryotherapy (CC) (Polar Care) and standard ice packs (plain ice, ICE) as a means of improving postoperative pain control for patients undergoing a primary or revision shoulder arthroplasty procedure. (17) Forty patients (20 in each group), 30 to 90 years of age, were randomly assigned to the 2 treatments. Visual analog pain scores were similar for both the CC and ICE groups preoperatively (5.9 vs. 6.8; p=.121) and postoperatively at 24 hours (4.2 vs. 4.3; p=.989), 3 days (4.8 vs. 4.7; p=.944), 7 days (2.9 vs. 3.3; p=.593), and 14 days (2.5 vs. 2.7; p=.742). Continuous cryotherapy and ICE did not differ significantly in the number of morphine equivalents of pain medication postoperatively at 24 hours (43 vs. 38 mg; p=.579), 3 days (149 vs. 116 mg; p=.201), 7 days (308 vs. 228 mg; p=.181), or 14 days (431 vs. 348 mg; p=.213). The visual analog score for quality of sleep was not different between CC and ICE postoperatively at 24 hours (5.1 vs. 4.3; p=.382), 3 days (5.1 vs. 5.3; p=.601), 7 days (6.0 vs. 6.7; p=.319), or 14 days (6.5 vs. 7.2; p=.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.

Khan et al. (2024) published an open-label RCT in 200 patients undergoing unilateral shoulder surgery. (18) Patients were randomized to a cyropneumatic device (Game Ready GRPro 2.1) or standard of care. The primary outcomes was numeric rating scale pain score at 12 weeks. The majority of patients were undergoing rotator cuff repair (about 50%), the majority of patients were male (60% to 70%), and the average age was about 54 to 55 years. Standard care included CryoCuff (43%), ice packs (30%), no cryotherapy (6%), and no patient reporting (21%). There was no difference in pain between groups at baseline, week 2, week 6, or week 12 (NRS score of 2 in each group at week 12; p=.748) Opioid consumption was lower in the cryopneumatic group (56.1 oral morphine mg equivalents) vs the standard of care group (112 oral morphine mg equivalents; p=.02468), but the interquartile range was large (66.1 mg and 99.4 mg, respectively). The study is limited by the open-label design, the heterogeneity in the standard of care (including missing information for 21% of patients), and an error at one site that required a restart of recruitment.

Section Summary: Post-Shoulder Surgery

Two RCTs found that, for patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression, the use of compressive cryotherapy produced no significant reductions in pain or medication use compared with the standard ice wrap. One RCT found no improvements in pain, but a significant reduction in opioid use with cryopneumatic therapy compared with standard of care, but major limitations to the trial prohibit definitive conclusions.

Cooling Devices Post-Facial Surgery

Clinical Context and Therapy Purpose

The purpose of a cooling device is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as a standard icing regimen, in individuals with pain and/or swelling after facial surgery.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with pain and/or swelling after facial surgery.

Interventions
The therapy being considered is a cooling device.

Comparators
Comparators of interest include a standard icing regimen. Treatments include postoperative exercises, NSAIDs, and opioids.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, medication use, and resource utilization.

The existing literature evaluating a cooling device as a treatment for pain and/or swelling after facial surgery has varying lengths of follow-up, ranging from 1 to 6 weeks. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1 to 6 weeks of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Because studies that include the preferred comparator (standard icing regimen) are available, studies that use other comparators, such as no icing therapy or room temperature devices, were not evaluated in this medical policy.

Circulating Cooling Devices
Randomized Controlled Trials
Several studies have been reported by a research group that compared the Hilotherm cooling mask device with cooling compresses. In a 2013 randomized trial, Rana et al. assessed 32 patients with postoperative swelling of bilateral mandibular fractures using a cooling mask around the head and jaw. (19) Swelling was reduced for the cooling mask group on days 1, 2, and 3 after surgery. Visual analog scores for pain were also reduced for the cooling mask group compared with compresses on day 1 (3.87 vs. 5.53) and day 2 (3.63 vs. 6.31). There were no significant differences between groups for a postoperative neurologic score, trismus, or

mandibular dysfunction. Earlier research by Rana et al. (2011) randomized 30 patients scheduled for third molar surgery to a water circulating cooling face mask (Hilotherm; n=15) or cool compresses (control, n=15). (20) The intervention group had significantly less facial swelling (72.2 mL) relative to the control group (96.6 mL) on postoperative day 2 (p=.005). This trend was maintained at day 10 (intervention, 23.3 mL; control, 46.7 mL, p<.001). There was also a significantly lower pain score in the intervention group relative to the control group on both postoperative days 2 (intervention, 3.4; control, 4.8; p<.05) and 3 (intervention, 2.9; control, 3.7; p<.05). Both the intervention and the control groups had a significant decrease in the neurologic score on day 10 compared with day 2, but there were no significant differences between groups in the neurologic score. Compared with immediately after surgery, both groups had a significant increase in mouth opening on postoperative day 2. At postoperative day 28, there were no differences between the groups with regard to facial swelling, pain score, or neurologic score. The authors did not report study limitations. However, it should be noted the study had a small sample size and used observer-blinding only. In a 2011 pilot study, Rana et al. found that the use of the cooling device in patients scheduled for treatment of bilateral mandibular fractures also reduced postoperative swelling and pain relative to the traditional cooling regimen. (21) But there were no significant benefits with regard to mandible functioning, mouth opening, or neurologic scores.

A similar study design was reported by Modabber et al. (2013), who treated 42 patients for unilateral zygomatic fractures. (22) Patients were randomized to a water circulating continuous cooling face mask, the Hilotherm device (n=21), or conventional cooling (n=21) postoperatively. Three-dimensional optical scans were recorded postoperatively. On postoperative days 1, 2, and 3, respectively, there were significant decreases in swelling with the intervention relative to control (intervention, 9.45 mL; control, 20.69 mL; p<.001; intervention, 13.20 mL; control, 22.97 mL; p<.001; intervention, 14.44 mL; control, 23.52 mL; p=.002, respectively). This trend was maintained on day 7 (p=.019). After 28 days, there were no significant differences between groups. Pain analysis conducted using a visual analog score, ranging from 0 (no pain) to 10 (maximum pain), was reported before surgery and postoperatively. There were significant increases in pain in the control group relative to the intervention during postoperative day 1 (intervention, 2.38; control, 4.10; p=.001) and day 2 (intervention, 2.34; control, 4.38; p<.001). However, there were no significant differences in pain between groups by day 7. Nerve dysfunction, reported on a 9-point scale (9 being the worst) and assessed pre- and postoperatively, showed a significant reduction in the neurologic score in the intervention group (2.57) relative to the control (3.90) at day 1 (p=.008), with no significant differences between the groups at days 7, 28, and 90 postoperatively. On postoperative day 1, there was a significant (p=.050) reduction in eye motility limitation in the intervention group (n=17 with no limitation; n=4 with limitation) relative to the control (n=11 with no limitation; n=10 with limitation). There were also significantly fewer patients in the intervention group with diplopia (n=18 without diplopia, n=3 with diplopia) compared with the control group (n=11 without diplopia, n=10 with diplopia; p=.019). There were no statistically significant differences in eye motility limitation or diplopia between the groups on days 7 and 28. Overall patient satisfaction was significantly higher in the intervention group (1.43) relative to the control (2.29; p<.001). In

addition to the small sample size, trial limitations included observer-only blinding and 3-dimensional optical scans that only measured localized facial swelling.

Section Summary: Post-Facial Surgery

Several small RCTs and a pilot study of patients receiving cooling therapy found significant decreases in facial swelling and pain. However, there were mixed results in terms of the intervention's efficacy in reducing neurologic problems as well as improving eye motility, diplopia, mandible functioning, and mouth opening compared with conventional cooling regimens. Several of the trials had observer-only blinding.

Summary of Evidence

For individuals who have pain and/or swelling after knee surgery who receive a cooling device, the evidence includes a systematic review, several randomized controlled trials (RCTs), and a case-control study. Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. Studies on manually operated passive noncirculating cooling devices were limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications did not provide sufficient evidence of comparative efficacy. Other studies provided no information on the frequency of ice changes, limiting interpretation of the results. Several randomized trials have compared active circulating cooling devices with standard intermittent icing or cold packs, and results have demonstrated mixed benefits, with 1 trial (N=100) finding acute pain reduction with a cooling device and 2 of the larger trials finding no significant benefit of the continuous cooling devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have pain and/or swelling after shoulder surgery who receive a cooling device, the evidence includes 3 RCTs. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. Evidence from 2 RCTs found that use of compressive cryotherapy produced no significant reduction in pain or medication use compared with the standard ice wrap. One RCT found a reduction in opioid use with cryopneumatic therapy compared with standard of care, but there was no difference in pain scores between groups, and diversity in the icing methods in the control group prohibit conclusions regarding the efficacy of cryopneumatic therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have pain and/or swelling after facial surgery who receive a cooling device, the evidence includes several small RCTs and a pilot study. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. There have been mixed results regarding the intervention's efficacy in reducing neurologic problems as well as improving eye motility, diplopia, mandible functioning, and mouth opening compared with conventional cooling regimens. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons

In 2022, the American Academy of Orthopaedic Surgeons updated the 2016 guidelines on the surgical management of osteoarthritis of the knee after knee arthroplasty. (23) The 2016 guideline statement, “Moderate evidence supports that the use of cryotherapy devices after knee arthroscopy do not improve outcomes" was not modified in the 2022 update. The update did not revisit several prior recommendations including cryotherapy devices. (23, 24)

National Comprehensive Cancer Network (NCCN)

The NCCN guidelines on breast cancer (v.5.2025) state “Consider scalp cooling to reduce incidence of chemotherapy-induced alopecia for patients receiving neoadjuvant/adjuvant chemotherapy. Results may be less effective with anthracycline-containing regimens.” (25)

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

According to Local Coverage Determination (LCD) L33784 on heating pads and heat lamps, it has not been established that a moist electric heating pad or water circulating heat pad with pump is reasonable and necessary compared to a standard electric heating pad. Because a water circulating heating pad system is not medically necessary, a replacement pump or pad is not also considered to be not reasonable and necessary. (26)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 17.

Table 17. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT05095909	Utility of Intermittent Cryo-Compression Versus Traditional Icing Following Arthroscopic Rotator Cuff Repair	100	Jun 2025

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member’s benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	97008, 97009, 0662T, 0663T, 0776T
HCPCS Codes	A9273, C9810, C9817, E0215, E0217, E0218, E0236, E0249

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. Coverage language revised without change to intent. Added references 2, 3, 6, 12, 45, 15, 17-24, and 26; others updated and some removed.
09/15/2024	Document updated with literature review. Coverage unchanged. References 4, 7 and 12 added; others updated.
12/01/2023	Document updated with literature review. Coverage unchanged. Reference 11 added; others updated, some removed.
06/15/2023	Document updated with literature review. The following change was made to Coverage: Added "Therapeutic induction of intra-brain hypothermia using the Pro2cool® device is considered experimental, investigational and/or unproven for all indications, including but not limited to treating symptoms of concussion or traumatic brain injury." References 13 and 14 added.
12/01/2022	Reviewed. No changes.
07/15/2021	Document updated with literature review. The following change was made to Coverage: Added scalp cooling devices as medically necessary when used during chemotherapy to prevent hair loss. References 7, 8 and 12 added.
12/15/2020	Document updated with literature review. The follow change was made to the Coverage statement Added "with or without pneumatic compression". Added references 1-7 and 9-10; others removed.
11/15/2019	Reviewed. No changes.
11/15/2018	Document updated with literature review. Coverage unchanged.
06/01/2017	Document updated with literature review. Coverage unchanged.
09/01/2016	Reviewed. No changes.

09/15/2015	Document updated with literature review. Coverage position is unchanged. The following examples were added: AutoChill™, IceMan™, NanoTherm, Prothermo, and Vascutherm™.
04/15/2014	Literature reviewed. No change.
01/01/2011	The following changes were made: 1) Nonelectric moist heat pads and heat or cold wraps of any type are considered not medically necessary; 2) heat packs, hot water bottles, ice bags, etc., were added to list of examples of supplies purchased over the counter without a prescription; 3) Document title changed from Cold Therapy Devices; 4) CPT/HCPCS code(s) updated.
03/15/2008	Policy reviewed without literature review; new review date only.
11/15/2006	Revised/Updated Entire Document
07/01/2004	Revised/Updated Entire Document
07/05/2004	Codes Revised/Added/Deleted
04/01/1999	Revised/Updated Entire Document
08/01/1998	Revised/Updated Entire Document
05/01/1996	Revised/Updated Entire Document
07/01/1993	Revised/Updated Entire Document
04/01/1993	Revised/Updated Entire Document
07/01/1992	Revised/Updated Entire Document
04/01/1992	Revised/Updated Entire Document
03/01/1991	Revised/Updated Entire Document