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Heat and Cold Therapy Devices

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Related Policies (if applicable)
None

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., Dinocap and Paxman Scalp Cooling System) **may be considered medically necessary** when used during chemotherapy to prevent hair loss.

The following heat and cold therapy devices (with or without pneumatic compression) are considered convenience items and not durable medical equipment and therefore **are considered not medically necessary**:

1. A device in which ice water is put in a reservoir and then circulated through a pad by means of gravity; **OR**
2. Motorized water circulating cold pads (e.g., including but not limited to, Polar Care Therapy Pads™, Auto Chill™, IceMan™, NanoTherm, Prothermo, and Acuter™, etc.); **OR**
3. Cryogenic machines attached to an insulated disposable blanket; **OR**
4. Vaso pneumatic cryotherapy devices (e.g., including but not limited to, Game Ready ™); **OR**
5. Non-electric moist or dry heat pads; **OR**
6. Heat or cold wraps of any type; **OR**
7. Other similar products.

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.

NOTE: 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.

Policy Guidelines

None.

Description

Heat or cold therapy may be used for any of the following:

1. Post-operatively (e.g., after total knee replacement or hip arthroplasty or anterior cruciate ligament repair); or
2. Immediately following injury; or
3. Before or after physical therapy sessions; or
4. To reduce muscle spasm and improve flexibility of tendons and ligaments; or
5. Improve circulation; or
6. Relieve pain; or
7. Typical athletic cold therapy sessions in order to lower skin temperature and reduce swelling thus decrease bleeding and possibly reduce pain medication requirements; or
8. To prevent hair loss during chemotherapy.

Methods of administering heat or cold therapy include:

1. Electric and non-electric dry or moist heat pads; or
2. Heat wraps; or
3. Cryogenic machines attached to insulated blankets; or

4. Cold packs (e.g., ice, gel, chemical, etc.); or
5. Noncirculating Cooling Devices (e.g., Polar Care Cub); or
6. Circulating Cooling/Heating Devices (e.g., Game Ready ™, Nonother™, VitalWrap™, Pro2cool®) or
7. Scalp cooling products (e.g., Dinocap and Paxman Scalp Cooling System).

Noncirculating Cooling and Heating Devices

Passive, noncirculating cooling devices consist of an insulated container filled with iced water that is attached to a compressive cuff. When the container is raised, the water fills and pressurizes the cuff. The pads are held in place with elastic straps and attached to a built-in hand pump that circulates the water through the pads, increasing the compression around the joint.

Available noncirculating or passive cold therapy devices that provide cooling and compression include, but are not limited to:

1. Polar Care Cub (BREG Inc.)
2. Cryo/Cuff™ (Aircast® Inc.)

Passive, noncirculating heating devices can be used for a variety of indications including joint pain and muscle spasms. The application of heat may ease pain by dilating the blood vessels and decreasing painful stiffness of soft tissues surrounding the injured area. Therapeutic heat can be used for multiple indications including but not limited to, muscle spasms, contracture, pain relief, tension myalgia, hematoma resolution, and fibromyalgia. General contraindications and precautions for therapeutic heat include acute inflammation, trauma, or hemorrhage; bleeding disorders; temperature insensitivity and inability to communicate or respond to pain.

Available noncirculating or passive heat therapy devices that provide heat and compression include, but are not limited to:

1. Heat wraps
2. Thermoactive™

Circulating Cooling and Heating 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 Hot/Ice Thermal Blanket is another circulating cooling device. It consists of 2 rubber pads connected by a rubber hose to the main cooling unit. Fluid is circulated via the hose through the thermal blankets. The temperature of the fluid is controlled by the main unit and can be either hot or cold. The Game Ready™ Accelerated Recovery System is 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. 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.

Available active/circulating cold therapy devices that operate by a battery or electric powered pump that provides cooling and compression include, but are not limited to:

1. Game Ready™ Accelerated Recovery System (CoolSystems, Inc.)
2. Iceman Cold Therapy unit (DJO Incorporated Inc.)
3. AutoChill® system (Aircast®)
4. Nanotherm™ (ThermoTek)
5. Vascutherm™ and ProThermo (ThermoTek)
6. Pro2cool® (TecTraum)

Active heating devices work very similar to the cooling devices. The VitalWrap™ (VitalWear Inc., 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 Hot/Ice Thermal Blanket is another circulating device. It consists of 2 rubber pads connected by a rubber hose to the main cooling unit. Fluid is circulated via the hose through the thermal blankets. The temperature of the fluid is controlled by the main unit and can be either hot or cold.

Available active (circulating) heat or cooling therapy devices that operate by a battery or electric powered pump that provides cooling and compression include, but are not limited to: VitalWrap™ (VitalWear Inc.).

Regulatory Status

A large number of circulating and noncirculating cooling devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process since 1976 and are listed in Table 1.

FDA product code: ILO.

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
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 RehabTech (Group) Co., Ltd.	03/08/2023	K222136	To treat post-surgical and acute injuries to reduce swelling and pain.
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	Dynaronics 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.

According to a press release by TecTraum in December 2021, Pro2cool® received the FDA designation of a breakthrough device for the treatment of concussions. A large multi-site clinical trial for pro2cool® was completed in April 2022, with planned submission of data to the FDA for consideration of market authorization in Q4 2023. No further information on this can be found on the FDA website. (1)

Rationale

This medical policy was created in 1991 with searches of the PubMed database. The most recent literature update was performed through January 15, 2024.

Medical policies 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.

Heat and cold therapy, particularly post-operative cold therapy, are standard treatment modalities that can be provided by a variety of methods. None of these methods has been demonstrated in clinical trials to demonstrate health benefit over others, or over simple compress.

Convenience items are items that are primarily used for the convenience of the patient. Water circulating cold pads (e.g., Polar Care Cold Therapy Pads) or a cryogenic machine attached to an insulated disposable blanket or similar products are considered convenience items since the same outcome can be achieved with over-the-counter cold packs.

Heat and cold wraps and packs, ice bags, and hot water bottles are not considered durable medical equipment and can be purchased over the counter without a prescription.

Scalp Cooling Devices

In a meta-analysis of RCTs, Rugo and Voigt studies the effects of scalp cooling on the end point of alopecia. Ten studies were included in the analysis comprised of 654 patients. Most were patients with breast cancer 432 patients [66%] mainly receiving anthracyclines. For the binary outcome of < 50% versus > 50% alopecia, the use of scalp cooling reduced relative risk (RR) of alopecia by 43% (RR, 0.57; 95% CI, 0.45-0.72; I^2 =1%; P < .00001). For ordinal outcomes (alopecia on a scale of 0-3), use of scalp cooling significantly reduced alopecia (MD, 0.80; 95%

CI, 1.19 to 0.41; I^2= 0%; P < .0001). The systematic review and meta-analysis support the use of scalp cooling to prevent alopecia in patients with solid tumors undergoing chemotherapy. (2)

Kinoshita et al. aimed to assess whether a scalp-cooling device improved hair volume recovery over a 12-week period after completing chemotherapy. This multicenter controlled trial included women with breast cancer undergoing chemotherapy between February 2016 and March 2018. A total of 48 patients were enrolled. There were more patients judged to have no alopecia at the end of chemotherapy in the scalp-cooling group than in the control group (26.7% [8/30] vs. 0% [0/13]; *P* = 0.011). The proportion of patients with alopecia who experienced an increase in hair volume of ≥50% within 12 weeks duration after chemotherapy was 85.7% (24/28) in the scalp-cooling group and 50.0% (6/12) in the control group. No patient developed serious adverse events related to the scalp-cooling device. The primary endpoint was the proportion of patients with no alopecia at the end of chemotherapy. The secondary endpoint included hair volume at 12 weeks after completing chemotherapy. (3)

Brunner et al. (2022) conducted a prospective interventional study to look at the effects of scalp cooling on hair preservation and hair regrowth in breast cancer patients receiving chemotherapy. (4) The study population included 128 patients; 88 individuals were assigned to the intervention group (CAP) and underwent scalp cooling (SC), and 40 patients were allocated to the control group (NCAP). The control group consisted of patients who were eligible to participate in the study and consented for data collection but declined to undergo scalp cooling. Cooling was maintained throughout the administration of chemotherapy and was stopped 60–90 min after termination of infusion of cytotoxic agents. Alopecia was evaluated by the patients themselves and by an expert group. Twenty-four percent of patients in the CAP group and 0% in the NCAP group evaluated their hair loss as grade 1 (<50% hair loss) (P = 0.001). However, none of the patients graded their hair loss as grade 0. Experts evaluated the hair loss in CAP group members as grade 0 in 13%, grade 1 in 59% and grade 2 in 28%. This showed hair preservation in 72% of patients using SC, whereas hair preservation was 0% in the NCAP group (P ≤ 0.001). Patients as well as experts agreed on the evaluation in the NCAP group (100% alopecia). Interestingly, a significant difference was noted between evaluation by experts (72%, <50% hair loss) and patients' self- assessment (24%, <50% hair loss) regarding HP in the CAP group. After three months, 50% of patients in the CAP group and 38% in the NCAP group had complete regrowth of their hair. SC is the most promising approach to prevent alopecia in terms of efficacy and safety. Patients can highly benefit from the application of scalp cooling devices. SC should be integrated into clinical practice and targeted towards patients with potentially high success rates of SC selected by chemotherapy regimen.

Noncirculating Cooling Devices

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. (5) Those in the CryoCuff group reported decreased pain medication compared with the control group but there was no significant difference in average pain assessment. Interpretation of these results is limited because the number of exchanges of ice packs and water recirculation was not reported. Healy et al. (1994) reported 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. (6) 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.

Wyatt et al. (2022) conducted a systematic review to further investigate the effect of various methods of cryotherapy on pain, swelling, postoperative opioid use, and range of motion (ROM). (7) This review looked at six randomized controlled trials (RCTs) examining cryotherapy following TKA published between February 1, 2017, and February 24, 2022. Previous reviews were unable to draw any conclusions regarding whether cryotherapy was indeed helpful in TKA at all. One previous study was able to conclude that pain and postoperative opioid consumption likely benefited from cryotherapy but did not reach any conclusions regarding its effect on ROM and swelling. Another previous study was able to conclude that pain and postoperative opioid consumption likely benefit from cryotherapy but did not reach any conclusions regarding its effect on ROM and swelling. The current study results showed that cryotherapy was superior to noncryotherapy during the first postoperative week. No significant difference in pain ratings was observed between cryotherapy and noncryotherapy groups at 2 weeks, 6 weeks, or 3 months. No differences were noted between computer assisted cryotherapy (CAC) and traditional ice packs when measuring 'pain at rest' within the first postoperative week. Range of motion (ROM) was largely unaffected by cryotherapy. Each of the 6 studies used infrapatellar, midpatellar, and suprapatellar circumferential measurements to assess joint swelling/edema. Cryotherapy appeared to have a minimal effect on operative leg swelling. Only one study demonstrated a significant difference in operative leg edema in a cryotherapy group compared to a noncryotherapy group within the first postoperative week. Opioid use was significantly decreased in cryotherapy groups compared to noncryotherapy groups within the first postoperative week only ($P < .05$). The noncryotherapy group consumed 15.6 mg of oxycodone (23.4 morphine milligram equivalents [MME]) per patient over the course of the first postoperative week compared to 7.5 mg (11.2 MME) in the CAC group, demonstrating a 52% reduction in consumption in the CAC group. However, no significant difference was found in opioid consumption between CAC and ice pack groups. In conclusion, cryotherapy's role after TKA appears to be in decreasing opioid consumption primarily in the first postoperative week. Pain ratings also decrease consistently with cryotherapy use, but this decrease may not be clinically relevant. Study heterogeneity requires further research focusing on optimizing cryotherapy modalities within the first postoperative week, and analyzing cost associated with modern outpatient postoperative TKA protocols.

Circulating Cooling Devices

In the largest study 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. (8) 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 score 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 an RCT of 60 patients, compared a temperature-controlled cryotherapy device with a standard icing regimen following outpatient knee arthroscopy. (9) 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%; =0.04). 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, Rufilli 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°-30°C) relative to conventional crushed ice bags (intervention group n=23, control group n=24). (10) All patients were discharged the day after surgery. Primary 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 ($p<0.001$) and a significant decrease in blood loss ($p<0.001$). Knee volume was also significantly lower in the intervention group at the patellar apex ($p=0.013$) and 10 cm proximal to the superior patellar pole ($p=0.001$). Although there was a significant increase in mean flexion ($p<0.001$) for the intervention group relative to the control, there was no difference between groups in the use of pain medication. No adverse events were reported in either group postoperatively or related to the use of the cooling device or the ice bags. Researchers noted several limitations to the trial, including small sample size, lack of blinding, and lack of evaluation of longer-term efficacy after hospital discharge.

Rufilli et al. (2017) investigated the use of the continuous-flow cold device in an RCT of 50 patients with end-stage knee osteoarthritis after primary total knee arthroplasty who had the same rehabilitation program and pain-relieving strategy. (11) 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 (Table 6). (12) 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.

Congeni et al. (2022) published results from a randomized nonblinded pilot trial for adolescent athletes aged 12-17 years diagnosed with a concussion within 2 weeks of injury. (13) The control group (n = 27) received standard treatment (short term brain rest), whereas the treatment group (n = 28) received standard treatment and head and neck cooling. Head and neck cooling treatment was applied to patients at the postinjury assessment visit and at 72 hours post-injury. The SCAT5 (Sport Concussion Assessment Tool) total symptom severity score was collected at the postinjury assessment visit, pre- and post-treatment at 72 hours, and at 10 days, and at 4 weeks post-treatment. Athletes who received head and neck cooling had a faster symptom recovery ($P = 0.003$) and experienced significant reduction in symptom severity scores after treatment ($P < 0.001$). Sport type and gender did not influence the treatment outcome ($P = 0.447$ and 0.940, respectively). This pilot study demonstrates feasibility of head and neck cooling for the management of acute concussion in adolescent athletes. The small sample size renders it too early to draw conclusions around the efficacy and clinical relevancy of head and neck cooling therapy as an effective intervention for enhancing concussion recovery in this population.

Combination Circulating Cooling and Compression (Cryopneumatic) Devices

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. (14) 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.

Kraeutler et al. (2015) compared the Game Ready shoulder wrap with standard icing in an RCT of 46 patients who had undergone rotator cuff repair or subacromial decompression. (15) 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; p=0.91). 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 0-7) 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 score scores between the 2 groups. Trial limitations included small sample size (noting that 11 [19%] of 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.

Heat Devices

No published articles focusing on the role of heating devices or water circulating heat pads compared with heat therapy typically used in a home/outpatient environment have been identified.

Summary of Evidence

For individuals who use a scalp cooling device to prevent hair loss during chemotherapy, the evidence includes randomized controlled trials (RCTs), systematic reviews, a prospective review and meta-analysis. Studies provided evidence of reduced alopecia in patients with solid tumors undergoing chemotherapy when scalp cooling devices were used. Other studies showed improved hair volume recovery, after completing chemotherapy, when scalp cooling devices were used during chemotherapy administration. No published articles showed any serious adverse events relating to the use of scalp cooling devices. The evidence is sufficient to determine the effects of the technology on health outcome.

For individuals with have pain and/or swelling who receive a cooling device, the evidence includes several randomized controlled trials (RCTs), a systematic review 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 2 of the larger trials found no significant benefit of the continuous cooling devices. No published articles focusing on the role of heating devices or water circulating heat pads compared with heat therapy typically used in a home/outpatient environment have been identified. 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 2020 (reaffirmed in 2023), the American Academy of Orthopaedic Surgeons released guidelines on the management of glenohumeral joint osteoarthritis. (16) They state "In the absence of reliable evidence, it is the opinion of the workgroup that either continuous cryotherapy or cold packs can be used following shoulder arthroplasty. "

National Comprehensive Cancer Network (NCCN)

The NCCN guidelines on breast cancer (v.4.2023) 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." (17)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05095909	Utility of Intermittent Cryo-Compression Versus Traditional Icing Following Arthroscopic Rotator Cuff Repair	100	Jun 2025
Unpublished			
NCT02426515	Cryotherapy to Improve Outcomes in Lower Third Molar Surgery (COOL)	63	Jun 2018 (completed)
NCT04185064[a]	Randomized-Controlled Trial and Evaluation Cohort Study of Patients Using a Cryopneumatic Device After Open or Arthroscopic Shoulder Surgeries	250	May 2023 (completed)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored 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	0662T, 0663T, 0776T
HCPCS Codes	A9273, E0217, E0218, E0236, E0249

*Current Procedural Terminology (CPT®) ©2023 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 have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed 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
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