MEDICAL POLICY

Medical Policy Title	**Cryotherapy (Cold Therapy) Devices**
Policy Number	**1.01.21**
Current Effective Date	June 26, 2025
Next Review Date	June 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

The use of active or passive cryotherapy (cold therapy) devices is considered **not medically necessary** for any indication.

RELATED POLICIES

Corporate Medical Policy

1.01.51 Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis

1.01.00 Durable Medical Equipment- Standard and Non-Standard

8.01.12 Physical Therapy (PT)

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Cryotherapy or "cold therapy" refers to the local or general application of therapeutic cold-whether that be through passive durable medical items such as icepacks, cold packs, compresses, and garments (e.g., vests, cuffs, or gel caps) that may or may not use gravity or a hand pump to circulate cold water, or via active cold therapy, which uses separate pumps for circulation in order to maintain temperature. These active devices may or may not include compression or vibration in addition to cooling.

Cold therapy is considered a standard part of treating pain and inflammation following injuries involving musculoskeletal tissue, trauma, or orthopedic surgery. Recent applications aim to reduce or prevent chemotherapy-related side effects such as alopecia, mucositis, and peripheral neuropathy. This policy does not address whole body cooling devices or the use of compression devices for venous thromboembolism prophylaxis. Refer to CMP #1.01.51 Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis.

SUPPORTIVE LITERATURE

Studies supporting the use of various cooling devices for pain and inflammation have not demonstrated health outcome improvements beyond increased convenience for the user, that exceed what is achieved with standard cryotherapy and compression using ice and wraps.

Cold Therapy Following Surgery

Quesnot and colleagues (2024) conducted a single-center randomized controlled trial (NCT06037824) of compressive cryotherapy versus standard cryotherapy after total knee arthroplasty (TKA) and compared knee range of position after 21 days of rehabilitation following surgery. A total of 40 patients were randomized into two groups, patients whose treatment included compressive cryotherapy (n=20) versus those that included cryotherapy alone (n=20). Authors additionally compared other skin, pain and functional outcomes including knee circumference, fluctuation tests, pain at rest and during activity, six-minute walking tests and Knee Injury and Osteoarthritis Score (KOOS) questionnaires. Reported baseline characteristics of the two groups were minimal, aside from the median age. Study participants in the cryotherapy and compression group used the Game Ready Device (Coolsystems, Inc.) which consisted of a control unit, connector hose, and knee wrap. A block of ice was placed inside the Game Ready reservoir, the wrap was placed around the patient's knee, and parameters for the controller were set. Sessions were 30 minutes long. Alternatively, patients in the standard cryotherapy group received standard ice wraps placed in sleeves to protect the skin for 30 minutes, three times per day. On day 21, there were no differences between the groups in passive or active range of motion. Authors reported significant improvements in joint effusion, pain during activity, the 6-minute walk test, and the Knee Injury and Osteoarthritis Score (KOOS) in the cryotherapy and compression group, but numerically, the differences were small, given the limitation of small sample size.

Liang and Colleagues (2024) conducted a systematic review and meta-analysis to investigate whether cryotherapy is able to improve the rehabilitation of patients undergoing TKA and to also determine which device type offered superior results, either continuous cold flow or cold packs. A literature search was conducted in May 2024 for randomized controlled trials comparing cryotherapy with no cryotherapy or continuous cold flow devices with cold packs after TKA. The primary outcome was the visual analogue scale (VAS) for pain. Secondary outcomes included adverse events, range of motion, swelling, blood loss and length of stay. A total of 31 trials were included in the metanalysis (18 cryotherapy versus no cryotherapy, and 13 comparing continuous cold flow device versus cold packs). Results indicated lower VAS scores for the cryotherapy group compared to the no cryotherapy group on post-operative days 1, 2, and 3. Additionally, cryotherapy reduced opioid consumption, improved range of motion, as well as reduced blood loss and drainage. Results of the continuous cold flow device group were comparable to all outcomes in the cold pack group. Authors concluded that the findings support the use of cryotherapy in TKA patients, but that traditional cold packs are still recommended over continuous cold flow devices.

Khan and colleagues (2024) investigated the outcomes for 200 patients post unilateral shoulder surgery in an open- label randomized controlled trial. The patients were randomized to either the Game Ready GRPro 2.1 cooling device or standard care, which consisted of one of the following

treatments: CryoCuff, ice packs or no cryotherapy. There was no difference in pain between groups at baseline, week 2, week 6, or week 12. Opioid consumption was lower in the Game Ready group versus the standard of care group, but the interquartile range was 66.1 mg -99.4mg, which is large. In addition to the open label design, the study is limited by the heterogeneity in the standard of care treatments. Further studies with improved methodologies are warranted.

A Cochrane Review by Aggarwal and colleagues (2023) investigated cryotherapy after surgery compared with other or no treatments following TKR for osteoarthritis. A total of 22 trials (20 randomized trials, two controlled trials) representing 1,839 patients were included. The authors cite several limitations of the studies which included poor design, lack of true randomization, drop outs, small number of participants, and homogeneity. The plain language summary states, "We have little confidence in the evidence showing that cold therapy may slightly improve blood loss, pain and range of motion after surgery. We are uncertain if it lowers the risk of blood transfusion, improves knee function, increases the risk of adverse events or contributed to withdrawals due to adverse events."

Oral Cryotherapy

A 2016 Cochrane Review by Riley and colleagues defined oral cryotherapy as "the cooling of the mouth using ice, ice-cold water, ice cream, or ice lollies/popsicles". An independent search was conducted by two authors and resulted in 14 randomized controlled trials (n=1,280) included in the review. The authors determined that based upon the results from the studies, oral cryotherapy reduces oral mucositis across all severities in adults receiving fluorouracil-based chemotherapy for solid cancers. Further, that it is a low cost, natural treatment without serious side effects.

In 2024, Bragues and colleagues set out to identify therapies for the prevention and treatment of oral mucositis in pediatric patients through a systematic review of the literature. The review included observational and experimental studies of children up to age 18 who had completed or were undergoing oncologic treatment. Studies were required to present outcomes for an oral mucositis therapeutic intervention. A total of 59 articles were included. The treatment that was deemed most effective for oral mucositis was chlorhexidine. The use of oral cryotherapy (i.e. ice chips), although demonstrating a reduction in incidence and severity of mucositis in adults, only showed a reduction when administered with propantheline and demonstrated no effect when administered alone in children. The authors identify that the number of studies in the pediatric population are small, and that scientific evidence for cryotherapy is lacking in this age group.

In 2022, Walladbegi and colleagues conducted a vendor-sponsored randomized, blinded, parallel group, multi-center, phase 3 trial (NCT03203733) comparing the use of conventional ice therapy with an intraoral cooling device for the prevention of chemotherapy induced oral mucositis in 172 patients diagnosed with multiple myeloma (n=146) or lymphoma (n=26), scheduled to receive high-dose chemotherapy prior to autologous hematopoietic stem cell transplantation. The primary outcome was the highest oral mucositis score during the study period. Secondary outcomes included the degree of tolerability and patient-reported oral pain. Tertiary outcomes evaluated were the quality of life upon admission and discharge, number of days with total parenteral nutrition, number of hospital days, total dose of analgesics, weight loss, number of days from transplant to bone marrow engraftment, and maximum temperature increase. Outcomes inclusive of the entire study cohort determined there was no statistically significant difference between the use of ice and the intraoral device in the

prevention of chemotherapy induced oral mucositis. A significant difference was noted in the lymphoma group, however the number of lymphoma patients included was small, with the majority enrolled from a single site which uses BEAC (carmustine, cytarabine, etoposide, cyclophosphamide) regimens as a conditioning for lymphoma, which is already known to cause less severe mucositis when compared with BEAM (carmustine, cytarabine, etoposide and melphalan). For secondary outcomes, discomfort experienced was less for the device group compared to the group randomized to ice (5% vs. 16.1%) which was statistically significant at 4.4% vs. 15.8% in the multiple myeloma group compared with 8.3% vs. 18.2% in the lymphoma group. There were no statistically significant differences identified for the tertiary outcomes. Authors concluded that the use of the device enhances the efficacy of the ice in the prevention of mucositis in lymphoma, as well as improves tolerability, although not statistically significant. Authors suggest that the use of the device would eliminate the risk of contaminated water and subsequent infection in immunodeficient patients, however, this was not included as part of the study.

There is a paucity of literature available regarding the effectiveness of the Cooral device, and therefore, conclusions regarding comparison to standard, less costly treatments with ice cannot be made.

Hypothermia Devices for the Prevention of Chemotherapy-Induced Alopecia (CIA)

Rugo and colleagues (2017), through an investigational device exemption from the FDA, conducted a multicenter, prospective cohort study (NCT01831024) to evaluate whether the use of a scalp cooling system (DigniCap, Dignitana) is associated with a lower amount of hair loss among women receiving specific chemotherapy regimens for early-stage breast cancer as well as assess for changes in quality of life. Women with stage I or II breast cancer who were receiving adjuvant or neoadjuvant chemotherapy regimens were recruited for the study. Eligible treatment regimens included docetaxel and cyclophosphamide, doxorubicin and cyclophosphamide, docetaxel and carboplatin, weekly paclitaxel, dose-dense paclitaxel, paclitaxel and carboplatin, and docetaxel with HER2/ERBB2-targeted therapy. The treatment group consisted of 106 patients. These patients were fitted with a silicone cap, followed by a neoprene cap for insulation 30 minutes prior to each chemotherapy cycle when cooling with the device was initiated. The control group consisted of individuals who did not desire the use of the device (n=16). Authors sought to measure the prevention of hair loss four weeks after the completion of chemotherapy, with success defined through a patient self-assessment using a Dean Score of 2 or less, indicating hair loss less than or equal to 50% (score range: 0, 0% hair loss to 4, hair loss >75%). Photographs of patient's hair were taken for the treatment and control groups before the start of chemotherapy and at regular intervals based on selected regimen. The four-week follow-up photographs were scored by an independent panel using the Dean scale and were blinded to the treatment group. Secondary outcomes included tolerability and patient-reported toxic effects. The European Organization for Research and Treatment of Cancer Breast Cancer-Specific Quality of Life (EORTC-QOL) Questionnaire was administered at baseline, at the time of the last chemotherapy cycle, and one month after completion of chemotherapy. Patients in the scalp cooling group were only included if they answered QOL questions 1 month following the end of chemotherapy treatment, and missing data was replaced with the last observation data for the control group. A total of 101 patients in the scalp cooling group were included in the primary analysis, 67 (66.3%; 95% CI, 56.2%–75.4%) of whom demonstrated hair loss of 50% or less (Dean

score of 0–2) compared with the control group 0 of 16 (0%) with a Dean score greater than 2 (P < .001; Table 3). When photographs were analyzed by the independent panel, 74 of the 88 patients (84.1%) were reported to have hair loss of 50% or less. At interim, 15 patients were classified as a Dean score of 4 and one Dean score was 3, and therefore, as a planned part of the study, recruitment was stopped for the control group. QOL benefits were reported by the treatment group with 27.3% reporting feeling less physically attractive compared to 56.3% in the control group. Adverse events were reported by six patients and included headache, skin pain and head discomfort. None were rated as severe. Pain from the scalp cooling treatment was reported by 71% of treated patients with pain medication used in 101/517 chemotherapy cycles. Authors concluded that for women undergoing non-anthracine-based chemotherapy for stage I or II breast cancer, the use of the scalp cooling system was associated with less hair loss after 4 weeks of chemotherapy. Limitations of the study include the non-randomized cohort design, the small sample size, and the lack of blinding of patients for the primary outcome of hair loss.

The SCALP trial (The Scalp Cooling Alopecia Prevention Trial) was conducted from December 2013 thru September 2016 as a multi-center randomized, nonblinded study of women planning to have adjuvant or neoadjuvant chemotherapy. A total of 182 participants were enrolled and randomized to scalp cooling (n=119) or control (n=63). An interim analysis was planned to allow for efficiency. Nangia and colleagues reported on this interim analysis (2017), with 142 participants being eligible to evaluate. Authors aimed to determine successful hair preservation using the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 scale, with grade 0 equivalent to no hair loss, grade 1 less than 50% hair loss. The treatment was defined successful if the patient was considered a grade 1 or less at the end of four cycles of chemotherapy, evaluated by a blinded clinician. Secondary end points included wig use, and scores obtained by the EORTC-QOL questionnaire, Hospital Anxiety and Depression Scale, and Body Image Scale. Patients in the treatment group wore a scalp cooling device for 30 minutes prior to, during and 90 minutes after each infusion. Of those evaluated at interim, 36% (n=51) received a chemotherapy regimen that was anthracycline-based and 64% (n=91) received a taxane-based regimen. A total of 48/95 women in the scalp cooling group achieved successful hair preservation. None of the 47 women included in the control group had hair preservation. Given that preservation in the cooling group was statistically higher than the control group, the study was stopped early. The authors concluded that for women with stage I to II breast cancer receiving chemotherapy with a taxane, anthracycline, or both, individuals treated with scalp cooling were significantly more likely to have less than 50% hair loss after the fourth chemotherapy cycle compared with those who received no scalp cooling, but that further research is needed to assess the efficacy of scalp cooling over time as well as adverse events.

In 2020, Bajpai and colleagues conducted a randomized controlled trial to assess the ability of scalp cooling (using the Paxman device) to preserve hair after chemotherapy in 51 patients being treated with anthracycline and taxane chemotherapy. Patients were stratified by the chemotherapy regimen (anthracycline or taxane first) and then subsequently randomized to scalp cooling (SC) (n=34) or the control arm, no SC (n=17) in a 2:1 ratio. The treatment group utilized SC beginning 30 minutes prior to chemotherapy, completing 90 minutes post infusion, and were treated during each cycle. Participants were photographed and alopecia grading was conducted by the primary investigator, independent observers, and subjects themselves. Successful hair preservation was defined as grade 0

or 1 alopecia based on the CTCAE version 4.0 scale, with grade 0 equivalent to no hair loss, and grade 1 less than 50% hair loss not requiring a wig. Failure was defined as grade 2, with greater than 50% hair loss, requiring the use of a wig. Outcomes determined that there were significant differences in hair preservation which were dependent on order that drugs were used. 77% of patients (13/17) who received taxane first had successful hair preservation, while only 33% (5/15) of those who received anthracyline first experienced successful preservation. The hair regrowth (HR) rate at six weeks was significantly better in the treatment group (89%) versus the control (12%). 100% of the treatment group had grade 0/1 alopecia versus 59% in the control arm (difference 41%; 95%CI18%-64%, P = 0.0003). Adverse events consisted of grade 1 and 2 events, with headache and feeling of coldness being the most common. Authors report that there was no scalp metastases identified at median follow up. There were several limitations to the study. The trial protocol was amended prior to inception to include other anthracycline or taxane based treatment regimens and schedules. Additionally, the sample size is small, and only 80% of participants completed the study past 4 weeks of treatment. Authors concluded that although the scalp cooling device was well tolerated, with limited side-effects, larger long-term studies are needed in patients with advanced breast cancer to comment on safety.

PROFESSIONAL GUIDELINE(S)

In 2016, the American Academy of Orthopaedic Surgeons (AAOS) published guidelines on the surgical management of osteoarthritis of the knee, stating "Moderate evidence supports that the use of cryotherapy devices after knee arthroscopy do not improve outcomes". The guidelines were updated in 2022 and no longer make any reference to the use of cryotherapy as a recommendation.

In 2021, The American Academy of Orthopaedic Surgeons (AAOS)published clinical practice guidelines for pharmacologic, physical, and cognitive pain alleviation for musculoskeletal extremity and pelvic surgeries. The authors downgraded the strength of the 2015 guideline recommendation of cryotherapy two levels to "limited" and state the following, "limited evidence suggests no significant difference in patient pain, function and opioid use between cryo-compression and control/ice/circulating water."

The European Society for Medical Oncology (ESMO) published clinical practice guidelines for dermatological toxicities related to anticancer agents in 2020. For preventative management of chemotherapy-induced alopecia, the society identifies scalp cooling as the only method that has demonstrated some extent of efficacy, and is therefore, considered a level IIB recommendation.

The National Comprehensive Cancer Network (NCCN) Guidelines V. 4.2025 for Invasive Breast Cancer, under general considerations related to preoperative/adjuvant therapy regimens, and systemic therapy for recurrent unresectable or stage IV disease, recommends the consideration of scalp cooling to reduce incidence of chemotherapy-induced alopecia for patients receiving chemotherapy. NCCN additionally recognizes that the available data applies to the adjuvant setting and has demonstrated that the results of scalp cooling may be less effective with anthracycline regimens of chemotherapy.

NCCN Guidelines V.1.2025 for Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer recommend the consideration of scalp cooling under principles of systemic therapy by stating,

"Consider scalp cooling to reduce incidence of alopecia for patients receiving chemotherapy with high rates of alopecia."

REGULATORY STATUS

A large number of circulating and noncirculating cooling devices have been cleared for marketing by the FDA since 1976. The following list may not be all inclusive. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 May 15]

Device	**Manufacturer**	**Date cleared**	**Indication**
Xrecovery	Shenzhen Xinrun Electric Appliances Co, LTD	11/14/2024	To treat post-surgical and acute injuries to reduce swelling and pain
Cold Compression	JKH Health Co., Ltd	05/01/2024	To treat post-surgical and acute injuries to reduce swelling and pain
Cold/Hot Compression	JKH Health Co., Ltd	10/27/2023	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	To treat post-surgical and acute injuries to reduce swelling and pain
Armory Motion	Pain Management Technologies, Inc.	06/10/2022	To treat post-surgical and acute injuries to reduce swelling and pain
Ice Compression First, Duo, & Moove Systems	MksParis	1/11/2021	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	To treat post-surgical and acute injuries to reduce swelling and pain
Polar Care Wave	Breg Inc	03/01/2019	To treat post-surgical and acute injuries to reduce swelling and pain
Therm-X, Therm-X At, Therm-X Pro Ath	Zenith Technical Innovations	5/10/2019	To treat post-surgical and acute injuries to reduce swelling and pain

Med4 Elite	Cool Systems, Inc (DBA Game Ready)	09/29/2017	To treat post-surgical and acute injuries to reduce swelling and pain
Nice1	Nice Recovery Systems, LLC	12/23/2014	To treat post-surgical and acute injuries to reduce swelling and pain
Dynatron Peltier Thermostim Probe	Dynatronics Corp.	08/20/2012	To treat post-surgical and acute injuries to reduce swelling and pain
DigniCap	Dignitana , Inc.	DeNovo 03/06/2015 07/2017	To reduce the likelihood of chemotherapy-induced alopecia in patients with solid tumors
DigniCap Delta	Dignitana, Inc.	06/26/2019	To reduce the likelihood of chemotherapy-induced alopecia in patients with solid tumors
Paxman	Paxman Coolers Limited	04/17/2017	To reduce the likelihood of chemotherapy-induced alopecia in women with breast cancer
Paxman	Paxman Coolers Limited	06/07/2018	To reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors
Amma	Cooler Heads Care, inc.	10/21/2021	To reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors, for adult patients only
VibraCool	MMJ Labs, LLC	05/15/2023	Temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. Also for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion, and muscle tension.

In 2015, the FDA approved the DigniCap Scalp Cooling system, a scalp hypothermia device for the prevention of chemotherapy-induced alopecia (CIA) for patients with solid tumors and lists the following contraindications:

- The use of Dignicap is contraindicated in pediatric patients
- The use of Dignicap is contraindicated in adult patients with:
    - cold sensitivity
    - cold agglutinin disease
    - cryoglobulinemia
    - cryofibrinogenemia
    - Cold urticaria
    - CNS malignancies (either primary or metastatic),
    - squamous cell carcinoma of the lung,
    - small cell carcinoma of the lung,
    - cancers of the head and neck,
    - skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma.
    - hematological malignancies treated with curative intent by chemotherapy
    - solid tumor malignancies with a high likelihood of metastases in transit.
    - patients who are scheduled for bone marrow ablation chemotherapy
    - patients who are scheduled to undergo skull irradiation
    - patients who have previously received skull irradiation

Additionally, the approval included the following warnings:

- "Long-term effects of scalp-cooling and scalp metastasis have not been fully studied,
- Use of scalp cooling with taxanes plus anthracyclines when used together or in sequence has not been shown to be successful in preventing chemotherapeutic drug induced alopecia
- Clinical studies have produced variable success rates in patient reduction of chemotherapy induced alopecia with scalp cooling since the outcome is dependent on several factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities
- Breast cancer patients treated with taxanes plus anthracyclines, when used together or in sequence, have not been shown to respond to scalp cooling for reducing chemotherapeutic drug induced alopecia. Dignicap Scalp Cooling System should not be used in these patients."

The Paxman Scalp Cooler was cleared by the FDA in April 2017, indicated to reduce the likelihood of chemotherapy-induced alopecia in women with breast cancer. In 2018, the indications were expanded to include patients with cancer being treated for solid tumors and lists the following contraindications:

- Scalp cooling is contraindicated in pediatric patients
- Scalp cooling is contraindicated in patients with:
- An existing history of scalp metastases or the presence of scalp metastasis is suspected.
- Cancers of the head and neck.
- CNS malignancies (either primary or metastatic).
- Cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, cold migraine, cold urticaria, and post-traumatic cold dystrophy.
- Hematological malignancies (leukemia, non-Hodgkin and other generalized lymphomas) or hematological malignancies that are being treated for cure.
- Imminent bone marrow ablation chemotherapy.
- Imminent skull irradiation.
- Previously received or scheduled to undergo skull irradiation.
- Scalp metastases have rarely been reported in the literature, but caution regarding their development has been a limitation for the broad-scale application of scalp cooling during chemotherapy. Theoretically, tumor cells that have seeded in the scalp might not receive adequate chemotherapy during hypothermia, thus allowing them to grow at a later date.
- Severe liver or renal disease from any etiology who may not be able to metabolize or clear the metabolites of the chemotherapeutic agent.
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma.
- Small cell carcinoma of the lung.
- Solid tumors that have a high likelihood for metastasis in transit.
- Squamous cell carcinoma of the lung.

In 2020, the FDA published a consumer update regarding the risk of injury related to devices that circulate water to provide hot or cold therapy, when not used properly, with an emphasis on cold-induced injuries- particularly numbness to frostbite.

In 2022 the FDA initiated a Class 2 device recall regarding the DigniCap Delta Scalp Cooling System and required an update to labeling that recommends use of a headband to prevent direct skin contact with the inner cooling cap, that staff should be retrained to ensure the headband is used correctly, and that condensation on the device should be wiped down before, during, and after use.

In December of 2024, New York State amended the insurance law to require any policy delivered or issued for delivery within the state that provides medical, major medical, or similar comprehensive-type coverage and provides cancer chemotherapy treatment, to cover scalp cooling systems for the preservation of hair during cancer chemotherapy treatment, effective January 1, 2026. The device must be designed and intended for repeated use and primarily and customarily used to serve a medical purpose.

In 2022, the U.S. Food and Drug Administration (FDA) awarded breakthrough device designation to the Cooral intraoral cooling system (for oral mucositis prevention). The system consists of closed conduit that continuously circulates sterile, cold water via a portable thermostat unit to a mouthpiece that is fitted to the patient. The duration of treatment is dependent on chemotherapy type, with treatment typically beginning 30 minutes prior to the start of an infusion and continuing until 30 minutes after the infusion is stopped. Treatment can be administered as often as required.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0662T (NMN)	Scalp cooling, mechanical; initial measurement and calibration of cap
0663T (NMN)	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)
0881T (NMN)	Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device

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HCPCS Codes

Code	Description
A9273 (NMN)	Cold or hot fluid bottle, ice cap or collar, heat and/or cold wrap, any type (Effective 01/01/2019)
E0218 (NMN)	Fluid circulating cold pad with pump, any type
E0236 (NMN)	Pump for water circulating pad
E1399 (*NMN)	Durable medical equipment, miscellaneous. *NMN when specified as an active cooling device with heating, compression, or vibration for pain therapy (Effective 01/01/2000)

ICD10 Codes

Code	Description
C00-C96.9	Malignant neoplasm (code range)
G62.0	Drug-induced polyneuropathy
K12.31	Oral mucositis (ulcerative) due to antineoplastic therapy
L65.9	Nonscarring hair loss, unspecified
M17.0-M17.9	Osteoarthritis of knee (code range)
M23.50	Chronic instability of knee, unspecified knee
Z51.11	Encounter for antineoplastic chemotherapy

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Woolf SK., et al. Comparison of a continuous temperature-controlled cryotherapy device to a simple icing regimen following outpatient knee arthroscopy. J Knee Surg 2008;21(1):15-19.

SEARCH TERMS

Cold therapy, Cryotherapy, Game Ready, Ice therapy

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Cold Therapy (L33735) [accessed 2025 Apr 11]

LCA - Cold Therapy (A52460) [accessed 2025 May 8]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

10/18/01, 06/27/02, 06/26/03, 05/27/04, 04/27/06, 04/26/07, 04/24/08, 04/23/09, 04/29/10, 06/24/11, 06/28/12, 06/27/13, 06/26/14, 06/25/15, 06/23/16, 06/22/17, 06/28/18, 06/27/19, 06/25/20, 06/24/21, 06/16/22, 07/20/23, 06/20/24, 06/26/25

Date	Summary of Changes
06/26/25	• Annual review. Policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.

10/18/01	• Original effective date