MEDICAL POLICY

Medical Policy Title	**Cryotherapy (Cold Therapy) Devices**
Policy Number	**1.01.21**
Current Effective Date	**January 1, 2027**
Next Review Date	**June 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(Link to Product Disclaimer)

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.

POLICY STATEMENT(S)

I. 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 (DME) and Devices: Standard and Non-Standard

8.01.24 Therapies (Speech, Physical & Occupational)

Administrative Policy

AP-53 Chemotherapy Treatment

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.

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, dropouts, 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.

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."

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates [device] as medical devices. All [device] including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Apr 02]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 April 02]

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.

Device	Manufacturer	Clearance Date	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	Dynatronics Corp.	08/20/2012	To treat post-surgical and acute injuries to reduce swelling and pain

Probe			
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 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 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 conduits 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
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

Code	Description
C9817 (NMN)	Electronic cryo-pneumatic compression, pain management system (e.g., Game Ready GRPro 2.1 system), including control unit, anatomically correct wrap(s), and other system component(s), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023) (Effective 01/01/26)
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)

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
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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U.S. Food & Drug Administration [FDA] [Internet]. Consumer Updates: cold facts to help avoid injury from water-circulating hot/cold devices. 2020 Sep 09 [accessed 2026 Apr 02]. Available from: https://www.fda.gov/consumers/consumer-updates/cold-facts-help-avoid-injury-water-circulating-hotcold-therapy-devices

Walladbegi J, et al. Efficacy of a novel device for cryoprevention of oral mucositis: a randomized, blinded, multicenter, parallel group, phase 3 trial. BMT. 2022.57:191-197.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Cold Therapy (L33735) [accessed 2026 March 31]

LCA - Cold Therapy (A52460) [accessed 2026 March 31]

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 covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date