


MEDICAL POLICY	Cold Therapy and Cooling Devices in the Home Setting	
Effective Date: 1/1/2021  1/1/2021	Section: DME	Policy No.: 303
	Technology Assessment Committee Approved Date: 1/14; 1/15; 1/16 Medical Policy Committee approved Date: 8/04; 8/05; 9/07; 3/10; 3/12; 7/13; 3/17; 3/18; 8/19; 12/19; 12/2020	
Medical Officer	Date	

See Policy HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Note: this medical policy does not address in-facility use of passive or active cooling devices or cold therapy. Use of passive or active cooling devices or cold therapy in a facility, such as a hospital or ambulatory care center, is not separately reimbursable.

Passive or active cooling devices or cold therapy are considered convenience items and are therefore **not medically necessary and are not covered** for any condition including, but not limited to, control of pain and swelling following surgery. Non-covered passive or active cooling therapies may include, but are not limited to, any of the following:

- A. Gravity controlled cold therapy devices:
 - 1. ArcticFlow Cold therapy system
 - 2. Cryo/Cuff™
 - 3. EBI® Gravity Cold Therapy System
 - 4. Polar Care Cub

- B. Active cold therapy devices:
 - 1. AutoChill® system
 - 2. BioCryo Cold Compression System
 - 3. Cryotherapy Cold Water Therapy System by Artic® Ice
 - 4. DeRoyal® Cold Therapy Unit
 - 5. EBIce® Cold Therapy System
 - 6. Game Ready™ Accelerated Recovery System
 - 7. Iceman Cold Therapy unit
 - 8. Nanotherm™
 - 9. OPTI-ICE™ Cold Therapy System
 - 10. Polar Care 500, Polar Care 300
 - 11. TEC Iceless Cold Therapy/Compression/DVT Prophylaxis
 - 12. VitalWrap System®
 - 13. Vascutherm™

- C. Active and passive cooling garments:
 - 1. Chill-Its® cooling vests, hats, headbands
 - 2. Cooltemp Vest
 - 3. FAST® Personal Medical Cooling Suit System
 - 4. HeatShield™
 - 5. Polar Active Cooling Vest
 - 6. Silver Eagle Cooling Vest and headwear
 - 7. SteeleVest® Body Cooling Comfort System™

BILLING GUIDELINES

Code E0218 describes a device which has an electric pump that circulates cold water through a pad.

Note: Use of passive or active cooling devices or cold therapy in a facility, such as a hospital or ambulatory care center, is not separately reimbursable.

HCPCS CODES

All Lines of Business	
Not Covered	
E0218	Water circulating cold pad with pump
E0236	Pump for water circulating pad
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered .	
E1399	Durable medical equipment, miscellaneous

DESCRIPTION

The application of cold (e.g., ice packs) and compression (e.g., compressive bandages) to treat musculoskeletal injuries and post-operative orthopedic trauma is well established and accepted for the treatment of strains/sprains, and to reduce pain and swelling before and after surgery in both inpatient and outpatient settings. To facilitate the delivery of cold/compression therapy, a number of device systems have been developed. Both passive, gravity-powered systems and active, pump-controlled mechanical systems are on the market. Some devices may also provide pneumatic compression.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of cooling compression and devices as a treatment of swelling. Below is a summary of the available evidence identified through September 2020.

- A 2019 (Reviewed in 2020) Hayes review was conducted on the comparative effectiveness of cold compression (CC) therapy for patients undergoing total knee arthroplasty.¹ Eleven randomized trials comparing CC therapy with an active comparator were included in the analysis. Across studies and comparators, outcomes were similar between CC therapy and standard treatments. There was no difference in length of hospital stay in 4 of 5 studies, no difference in pain measures in 8 of 11 studies, no difference in medication consumption (5 of 7), function and range of motion (8 of 10), swelling (5 of 6), and blood loss (3 of 4). Patient-reported satisfaction was higher in the CC therapy group in 2 of 3 studies, compared to active control.

Two studies compared CC therapy with compression alone and found no difference in hospital length of stay, swelling, or function, with one study favoring CC for medication consumption in early postsurgical period, and another study favoring CC for blood loss. Three studies compared CC with cryotherapy only, with 2 of the studies favoring CC for pain and swelling in early postoperative periods, although only one study found significant improvement. The last study favored cryotherapy alone for pain and range of motion. Two studies compared CC therapy with epidural analgesia and three studies compared CC therapy to cryotherapy plus static compression and the results were largely similar.

Hayes found that the quality of evidence from the available trials was moderate. Limitations included variations in treatment protocols and variations in active control therapies. Hayes gave CC therapy a D1 rating, concluding that, “The available evidence suggests that CC therapy is not associated with any additional overall benefits for reducing pain and inflammation compared with alternative postsurgical therapies in patients who have undergone TKA; instead, benefits were generally similar between CC therapy and alternative therapies. CC therapy was found to be reasonably safe and caused minor or no complications. Additional studies are needed to elucidate optimal treatment protocols and provide longer term outcomes.”¹

- In 2019, Hayes published a comparative effectiveness review on cold compression (CC) therapy for patients undergoing orthopedic procedures to major joints (other than knee). Hayes reviewed 6 trials, with sample sizes from 40 to 125 patients. CC therapy offered no consistent additional benefits when compared with standard postoperative care or cryotherapy. Hospital length of stay, pain, medication consumption, swelling, function and range of motion, and patient satisfaction were largely the same in every study between CC therapy and alternative care. No major complications were reported from CC therapy. Hayes noted that quality of evidence among these trials was low, due to limited studies, wide heterogeneity in treatment protocols, and individual study limitations.

Hayes gave a D2 rating for CC therapy for orthopedic procedures to major joint beside knees. They conclude, “A very-low-quality body of evidence suggests that CC therapy is not associated with any additional overall benefits for reducing pain and inflammation compared with alternative postsurgical therapies in patients who have undergone orthopedic procedures to major joints other than the knee; instead, benefits were generally similar between CC therapy and alternative therapies. However, substantial uncertainty remains with respect to the comparative efficacy of CC therapy because of limitations within the individual studies and across the body of evidence. Therefore, the evidence is insufficient to conclude that CC therapy does not offer additional benefit compared with alternative interventions. CC therapy was found to be reasonably safe and caused minor or no complications. Additional studies are needed to determine whether CC therapy does provide clinical benefit beyond standard interventions, elucidate optimal treatment protocols, establish which patients may benefit from CC therapy, and provide longer-term outcomes.”²

- In 2018 (archived 2019), Hayes conducted a review on continuous cold therapy versus ice packs after total knee arthroplasty. Hayes reviewed 7 abstracts consisting of 6 randomized trials and one systematic review. Devices used for continuous cold therapy varied among trials. While patient compliance and satisfaction were higher in the continuous cold therapy groups, there was no significant differences between cold therapy devices and ice/ice packs in the majority of outcomes measured. All authors concluded that continuous cold therapy devices were not superior to

traditional ice pack therapy. This review was greatly limited due to the fact that Hayes only reviewed abstracts. Hayes concluded, “Based on an abstract review of the available evidence, the data suggested that traditional icing therapy is non-inferior to continuous cold therapy in relation to pain relief, swelling, range of motion, blood loss, and adverse events. The data regarding patient compliance and patient satisfaction suggested better results with the use of continuous cold therapy. Nevertheless, the ability to inform definitive conclusions was limited by the lack of specificity in identifying which continuous cold therapy devices were used in the comparisons.”³

- An ECRI Custom Rapid Response – Guidance was published in 2015 (last updated in 2018) regarding continuous cold therapy devices for treating orthopedic trauma.⁴ ECRI noted that although cold therapy devices conferred higher rates of patient satisfaction, “(a) comprehensive systematic review directly comparing the use of standard cold pack/ice to continuous cold therapy devices would be useful to determine the utility of these devices in a clinical setting.”

CLINICAL PRACTICE GUIDELINES

National Comprehensive Cancer Network (NCCN)

In NCCN Clinical Practice Guidelines on Breast Cancer, Version 6.2020, the NCCN panel recommends considering scalp cooling to reduce incidence of chemotherapy-induced alopecia for patients receiving chemotherapy. The data on efficacy of scalp cooling is mainly from the adjuvant setting and also show that results may be less effective with anthracycline-containing regimens.⁵

CENTERS FOR MEDICARE & MEDICAID

As of September 2020, the Centers for Medicare & Medicaid Local Coverage Determination (LCD): Cold Therapy ([L33735](#)) and Local Coverage Article (LCA): Cold Therapy ([A52460](#)) were identified.^{6,7} The CMS coverage guideline is in-line with this policy; therefore, the coverage criteria above may be applied to Medicare members.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food & Drug Administration (FDA) Device Approval

Active and passive cooling devices with or without compression have been receiving 510(k) marketing clearance by the FDA since 1976. There are more than 30 devices with approval under the 510(k) process (Product Code: ILO).

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

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