Cold Therapy and Cooling Devices in the Home Setting

MEDICAL POLICY NUMBER: 51

Effective Date: 2/1/2023

Last Review Date: 12/2023

Next Annual Review: 12/2023

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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

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

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: This medical policy does not address in-facility use of passive or active cooling devices or cold therapy. The includes, but is not limited to, the use of cooling caps for the prevention of hair loss during chemotherapy. 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.

I. 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.-C.):

   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™

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

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.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

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).

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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 October 2022.

- A 2019 (Reviewed in 2022) 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 (updated 2021), 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]

- An ECRI Custom Rapid Response – Guidance was published in 2015 (last updated in 2018) regarding continuous cold therapy devices for treating orthopedic trauma.[3] 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

American Academy of Orthopaedic Surgeons (AAOS)

In 2015, the AAOS published clinical practice guidelines on Surgical Management of Osteoarthritis of the Knee.[4] The guideline reviewed the use of cryotherapy devices (continuous cooling/cold devices) and found: "Moderate evidence supports that cryotherapy devices after knee arthroplasty (KA) do not improve outcomes."

EVIDENCE SUMMARY

There is insufficient evidence to support the medical necessity of cold therapy, active or passive, in the home setting. Systematic reviews show no additional benefit of this therapy, although it may improve patient satisfaction. Furthermore, the use of cold therapy devices is not supported by the American Academy of Orthopaedic Surgeon's clinical practice guidelines.

BILLING GUIDELINES AND CODING

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.

CODES*		
HCPCS	A9273	Cold or hot fluid bottle, ice cap or collar, heat and/or cold wrap, any type
	E0218	Water circulating cold pad with pump
	E0236	Pump for water circulating pad
	E1399	Durable medical equipment, miscellaneous

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Hayes Inc. Comparative Effectiveness Review Of Cold Compression Therapy For Patients Undergoing Total Knee Arthroplasty. https://evidence.hayesinc.com/report/dir.cold2278. Published 2019 (updated 2022). Accessed 11/2/2022.
2. Hayes Inc. Cold Compression Therapy for Patients Undergoing Orthopedic Procedures to Major Joints (Other than Knee). https://evidence.hayesinc.com/report/dir.coldcompress4674. Published 2019 (updated 2022). Accessed 11/2/2022.
3. ECRI Institute. Continuous Cold Therapy Devices for Orthopedic Trauma. Plymouth Meeting (PA): ECRI Institute; Updated: 2018 Jun 30. (Custom Rapid Review). https://www.ecri.org/components/Hotline/Pages/24100.aspx?tab=1. Accessed 10/26/2020.
4. American Academy of Orthopaedic Surgeons (AAOS). Surgical Management of Osteoarthritis of the Knee. https://www.aaos.org/globalassets/quality-and-practice-resources/surgical-management-knee/smoak-cpg_4.22.2016.pdf. Published 2015. Accessed 11/2/2022.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.