MEDICAL POLICY

Cold Therapy and Cooling Devices in the Home Setting

Effective Date: 1/1/2020

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

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 Ayin 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
MEDICAL POLICY

Cold Therapy and Cooling Devices in the Home Setting

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

<table>
<thead>
<tr>
<th>All Lines of Business</th>
<th>Not Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0218</td>
<td>Water circulating cold pad with pump</td>
</tr>
<tr>
<td>E0236</td>
<td>Pump for water circulating pad</td>
</tr>
</tbody>
</table>
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 December of 2019.

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

Ideally, studies would include standard ice packs as the comparison treatment for active/passive cooling devices with or without compressive therapy in a randomized controlled design, specifically for home use. No large, well-designed RCTs or systematic reviews were identified to treat any condition since the ECRI review of evidence noted above.

CLINICAL PRACTICE GUIDELINES

No evidence-based clinical practice guidelines were identified regarding the use of active or passive cooling devices or cold compression.

CENTERS FOR MEDICARE & MEDICAID

As of December 2019, the Centers for Medicare & Medicaid Local Coverage Determination (LCD): Cold Therapy (L33735) and Local Coverage Article (LCA): Cold Therapy (A52460) were identified. 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.

REFERENCES