MEDICAL POLICY – 1.01.26
Cooling Devices Used in the Outpatient Setting

BCBSA Ref. Policy: 1.01.26
Effective Date: June 1, 2016
Last Revised: April 11, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
1.01.525  Postsurgical Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Applying ice is known as cold therapy and helps reduce pain and swelling. Using a bandage or wrap to apply light pressure is known as compression therapy. Cold and compression therapy after surgery or injury is very effective in reducing inflammation, pain, and swelling. Using ice packs and bandages is the usual way of applying cold and compression therapy. A number of cooling devices have been developed. Some are manual while others use a small motor to cool and move the water. Sometimes cooling devices are used in place of an ice pack and bandage. Cooling devices, including the types that add compression, are not medically necessary. Published medical studies do not show cooling devices provide better health results than ice packs and bandages.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
<table>
<thead>
<tr>
<th>Cooling Devices</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td>Active and passive cooling devices, with or without compression, used in the outpatient setting are considered <strong>not</strong> medically necessary.</td>
</tr>
<tr>
<td>Passive</td>
<td></td>
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</tbody>
</table>

**Coding**

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
<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>
<tr>
<td>E0650</td>
<td>Pneumatic Compressor, nonsegmental home model</td>
</tr>
<tr>
<td>E0651</td>
<td>Pneumatic compressor, segmental home model without calibrated gradient pressure</td>
</tr>
<tr>
<td>E0652</td>
<td>Pneumatic compressor, segmental home model with calibrated gradient pressure</td>
</tr>
</tbody>
</table>

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**Related Information**

**Benefit Application**

Refer to benefit or contract language when assessing whether passive cooling devices would be considered durable medical equipment.

**Evidence Review**
Description

Cooling devices use chilled water to decrease the local temperature of tissue. There are a variety of cooling devices available, ranging from gravity-fed devices that are manually filled with iced water, to motorized units that both cool and circulate the chilled water. These devices are typically used when ice packs would normally be applied, e.g., after orthopedic surgical procedures.

Background

Cold and/or compression therapy following surgery or musculoskeletal and soft tissue injury has long been accepted in the medical field as an effective tool for reducing inflammation, pain, and swelling. Ice packs and various bandages and wraps are commonly used. In addition, a variety of continuous cooling devices are commercially available and can be broadly subdivided into those providing manually operated passive cold therapy and those providing active cold therapy using a mechanical device.

Passive Cooling Devices

The CryoCuff® and Polar Care Cub devices are examples of passive cooling devices.

- CryoCuff® device consists of an insulated container filled with iced water that is attached to a compressive cuff. When the CryoCuff® container is raised, the water fills and pressurizes the cuff. The amount of pressure is proportional to the height of the container. When body heat warms the water, the cooler is lowered and the water drains out. The cooler is then raised above the affected limb, and cold water refills the compressive cuff.

- Polar Care Cub unit consists of pads held in place with elastic straps, which may also provide compression. The pads are attached to a built-in hand pump that circulates the water through the pads at the same time as increasing the compression around the joint.

Active Cooling Devices

In active cooling devices, a motorized pump circulates chilled water and may also provide pneumatic compression.
• AutoChill® device, which may be used in conjunction with a CryoCuff®, consists of a pump that automatically exchanges water from the cuff to the cooler, eliminating the need for manual water recycling.

• CTM™ 5000 and cTreatment are computer-controlled devices that provide cooling at a specific (11°C) and continuous temperature.

• Game Ready™ Accelerated Recovery System is an example of an active cooling device combined with a pneumatic component. The system consists of various soft wraps and a computer-control unit to circulate the water through the wraps and provide intermittent pneumatic compression.

• HiloTherm® Clinic circulates cooled water through preshaped thermoplastic polyurethane facial masks for use after different types of facial surgery.

• Hot/Ice Thermal Blanket is another example of an active cooling device. It consists of 2 rubber pads connected by a rubber hose to the main cooling unit. Fluid is circulated via the hose through the thermal blankets. The temperature of the fluid is controlled by the main unit and can be either hot or cold.

• IceMan Cryotherapy unit uses a semi-closed loop system with a mechanical pump that allows warm water to circulate, at a constant flow rate, with cooler water providing consistent cold distribution throughout the pad.

• Kinex ThermoComp Device and NanoTherm systems combine cold therapy with intermittent pneumatic compression.

• ThermaZone® provides thermal therapy with pads specific to various joints, as well as different areas of the head (front, sides, back, eyes).

Summary of Evidence

Most of the published randomized studies of passive cooling devices failed to adequately describe the cooling regimens or include the relevant control group of standard ice pack treatment. When passive cooling devices and ice packs were used with the same regimen, no differences in health outcomes were observed. Currently available evidence is insufficient to determine whether continuous cooling devices result in improved health outcomes when compared with usual ice pack exchange in the home environment. Several small studies report that a cooling mask used after facial surgery provides greater pain relief and reduction of swelling compared with cool compresses, but these studies have limitations and results need to
be replicated in larger, higher quality studies. Overall, the available scientific literature is insufficient to document that the use of passive or active cooling systems is associated with a benefit beyond convenience; these devices are considered not medically necessary.

**Combination Active/Compression (Cryopneumatic)**

For combination active cryotherapy/compression (cryopneumatic) devices, 2 studies in 2012 reported that narcotic use was decreased and that patient satisfaction was higher. However, no other outcome measures were improved, and one of the studies suffered from a low follow-up rate.

A 2015 RCT comparing compressive therapy to a standard ice wrap reported no significant difference in postoperative pain or narcotic use on any day.

A 2015 Health Technology Brief published by Hayes, Inc. concluded that, while cold compression therapy appears to be safe, there is insufficient evidence of a clinical benefit of cold compression therapy.

Based on these new studies with active cryotherapy/compression devices and limited evidence of an improvement in clinical outcomes, active cryotherapy/compression devices are considered not medically necessary.

**Practice Guidelines and Position Statements**

In December 2015, the American Academy of Orthopedic Surgeons released a clinical practice guideline on surgical management of osteoarthritis of the knee. Regarding cryotherapy devices, they stated: “Moderate evidence supports that cryotherapy devices after knee arthroplasty (KA) do not improve outcomes.” Cryotherapy was also included in a list of interventions that “were considered but not recommended.”

**Medicare National Coverage**

While there is no national coverage decision for Medicare, cooling devices are addressed in Durable Medical Equipment Resource Center (DMERC) policy. Last reviewed in July 2004, the DMERC policy reads as follows:
A device in which ice water is put in a reservoir and then circulated through a pad by means of gravity is not considered durable medical equipment (DME). Other devices (not all-inclusive which are also not considered to be DME are: single use packs which generate cold temperature by a chemical reaction; packs which contain gel or other material which can be repeatedly frozen; simple containers into which ice water can be placed. All of these types of devices must be coded A9270 if claims are submitted to the DMERC... Code E0218 describes a device which has an electric pump that circulates cold water through a pad.... A water circulating cold pad with pump (E0218) will be denied as not medically necessary.

Regulatory Status

A large number of active and passive heating and cooling devices have received U.S Food and Drug Administration (FDA) 510(k) clearance since 1976. FDA product code: ILO.

References


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**History**

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<th>Date</th>
<th>Comments</th>
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<tr>
<td>08/09/11</td>
<td>New policy created with literature review through 2010 with not medically necessary</td>
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<tr>
<td>Date</td>
<td>Comments</td>
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<td>policy statement. ICD-10 codes included. Policy approved with 90-day hold for provider notification; the policy effective date is February 8, 2012.</td>
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<tr>
<td>02/23/12</td>
<td>Typo corrected; code A9273 corrected within Policy Guidelines section.</td>
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<tr>
<td>04/25/12</td>
<td>Replace policy. Policy updated with literature review through November 2011; need for policy affirmed; policy statement unchanged.</td>
</tr>
<tr>
<td>04/08/13</td>
<td>Replace policy. Policy updated with literature review through January 7 2013; references 10 and 12 added; active cryopneumatic/compression devices now considered investigational; passive cooling devices remain not medically necessary. HCPCS code E1399 added to policy.</td>
</tr>
<tr>
<td>06/10/13</td>
<td>Replace policy. Policy statements clarified to distinguish between active cooling devices (not medically necessary) and combination active cryopneumatic devices (investigational). Passive cooling devices remain not medically necessary. VascuTherm added as an example of combination active cooling/compression device. HCPCS code A9270 removed from the policy; A codes are not utilized for billing.</td>
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<td>02/13/14</td>
<td>Update Related Policies. Change title to 1.01.525.</td>
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<tr>
<td>06/19/14</td>
<td>Annual Review. Policy updated with literature review through March 17, 2014; references 13-14 added; policy statement unchanged. CPT code 97010 removed; it does not suspend for review.</td>
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<td>06/17/15</td>
<td>Annual Review. Policy updated with literature review through March 2, 2015; reference 10 added; policy statement unchanged.</td>
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<td>02/01/16</td>
<td>Coding update. Added E0650 and E0651.</td>
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<tr>
<td>05/10/16</td>
<td>Annual Review. Policy updated with literature review. Policy statement on combination active cooling and compression changed from investigational to not medically necessary. References added. Trade names for active cooling devices added to Description section. Added code E0650.</td>
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<tr>
<td>04/11/17</td>
<td>Policy moved into new format; no change to policy statements. Evidence Review section reformatted.</td>
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