MEDICAL POLICY – 1.01.26
Cooling Devices Used in the Outpatient Setting

BCBSA Ref. Policy: 1.01.26*

Effective Date: May 1, 2018
Last Revised: April 18, 2018
Replaces: N/A

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

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 water and move it within the wrap. 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.
**Cooling Devices**

<table>
<thead>
<tr>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circulating and noncirculating cooling devices, with or without compression, used in the outpatient setting are considered not medically necessary.</td>
</tr>
</tbody>
</table>

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</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>
<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>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</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 chilled water. These devices are typically used when ice packs would normally be applied, (eg, after orthopedic surgical procedures).

Background

Cold and Compression Therapy

Use of ice packs and various bandages and wraps following surgery or musculoskeletal and soft tissue injury is common. The standard postoperative treatment for musculoskeletal surgeries consists of cryotherapy (cold therapy) and various types of compressive wraps. Both ice packs (with or without additives to maintain temperature) and cooling devices can provide cryotherapy. A variety of manually operated and mechanical continuous cooling devices are commercially available.

Noncirculating Cooling Devices

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

- The 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 is drained and replaced with fresh iced water. 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 cold water through the pads at the same time as increasing the compression around the joint.
Circulating Cooling Devices

In active, circulating cooling devices, a motorized pump circulates chilled water and may also provide pneumatic compression.

- The AutoChill® device, which may be used 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, or 52ºF) and continuous temperature.
- Game Ready™ Accelerated Recovery System is an active circulating 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 circulating 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.
- 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

For individuals who have pain and/or swelling after knee surgery who receive a cooling device, the evidence includes systematic reviews, several randomized controlled trials, and a case-control study. Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. Evidence on manually operated passive noncirculating cooling devices is limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications do not provide sufficient evidence of comparative efficacy. Other studies have provided no information on the frequency of ice changes, limiting interpretation of the results. Several randomized trials have compared active circulating cooling devices with standard intermittent icing or cold packs, and two of the larger trials found no significant benefit.
of the continuous cooling devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after shoulder surgery who receive a cooling device, the evidence includes a randomized controlled trial. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. Evidence found that use of compressive cryotherapy produced no significant reduction in pain or medication use compared with the standard ice wrap. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after facial surgery who receive a cooling device, the evidence includes several small randomized controlled trials and a pilot study. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. There have been mixed results regarding the intervention’s efficacy in reducing neurologic problems as well as improving eye motility, diplopia, mandible functioning, and mouth opening compared with conventional cooling regimens. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A currently ongoing trial that might influence this review is listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02426515</td>
<td>Cryotherapy to Improve Outcomes in Lower Third Molar Surgery (COOL)</td>
<td>60</td>
<td>Dec 2017 (ongoing)</td>
</tr>
</tbody>
</table>

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process,
input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 specialty societies and 3 academic medical centers while the policy was under review in 2008. Input was mixed regarding the medical necessity of continuous cooling devices.

Practice Guidelines and Position Statements

American Academy of Orthopedic Surgeons

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.
Regulatory Status

A large number of circulating and noncirculating cooling devices have been cleared for marketing by the U.S Food and Drug Administration (FDA) through the 510(k) process since 1976.

FDA product code: ILO.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/09/11</td>
<td>New policy created with literature review through 2010 with not medically necessary policy statement. ICD-10 codes included. Policy approved with 90-day hold for provider notification; the policy effective date is February 8, 2012.</td>
</tr>
<tr>
<td>02/23/12</td>
<td>Typo corrected; code A9273 corrected within Policy Guidelines section.</td>
</tr>
<tr>
<td>04/25/12</td>
<td>Replace policy. Policy updated with literature review through November 2011; need for</td>
</tr>
</tbody>
</table>
Date | Comments
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policy affirmed; policy statement unchanged.

04/08/13 | 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.

06/10/13 | 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.

02/13/14 | Update Related Policies. Change title to 1.01.525.

06/19/14 | 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.

06/17/15 | Annual Review. Policy updated with literature review through March 2, 2015; reference 10 added; policy statement unchanged.

02/01/16 | Coding update. Added E0650 and E0651.

06/01/16 | Annual Review, approved May 10, 2016. 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.

04/11/17 | Policy moved into new format; no change to policy statements. Evidence Review section reformatted.

12/01/17 | Annual Review, approved November 9, 2017. Policy updated with literature review through August 24, 2017; references 18 and 23 added. Policy section edited; policy statements otherwise unchanged.

05/01/18 | Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; reference s24 and 25 added. Policy statements unchanged.

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**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to
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