MEDICAL POLICY – 1.01.26

Cooling Devices Used in the Outpatient Setting

BCBSA Ref. Policy: 1.01.26*

Effective Date: Dec. 1, 2017
Last Revised: Nov. 9, 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

∞ Clicking this icon returns you to the hyperlinks menu above.

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>Cooling Devices</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circulating and noncirculating</td>
<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>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>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

### 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**

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.

**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 52°F) 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, 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, the evidence includes a randomized controlled trial. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. Evidence found that using compressive cryotherapy produced no significant reduction in pain or medication 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, 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 search of ClinicalTrials.gov in August 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

**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.... A water circulating cold pad with pump (E0218) will be denied as not medically necessary.

Regulatory Status

A large number of circulating and noncircling 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.


### History

<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 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>
</tr>
<tr>
<td>02/13/14</td>
<td>Update Related Policies. Change title to 1.01.525.</td>
</tr>
<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>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>06/17/15</td>
<td>Annual Review. Policy updated with literature review through March 2, 2015; reference 10 added; policy statement unchanged.</td>
</tr>
<tr>
<td>02/01/16</td>
<td>Coding update. Added E0650 and E0651.</td>
</tr>
<tr>
<td>06/01/16</td>
<td>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.</td>
</tr>
<tr>
<td>04/11/17</td>
<td>Policy moved into new format; no change to policy statements. Evidence Review section reformatted.</td>
</tr>
<tr>
<td>12/01/17</td>
<td>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 other unde unchanged.</td>
</tr>
</tbody>
</table>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

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 the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/office/file/index.html. Complaint forms are available at:

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
لا يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّасِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَнْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِيّةُ بِمَعَالَةً أَنْثئٍ أو عَلَى مَعَالَةٍ أَنْثئٍ يُحَرِّمُ مُجْلِسُ الرِّيَاثِ النَّاسِي**
Premera Blue Cross.

For more information, contact Premera Blue Cross at 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Pagawa na ito ay naglalaman ng mahalagang impormasyon. Ang pagawa na ito ay nagmamahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring maga affecting sa iyong pagsakop sa kalusugan o tulong na may potensyal na disenyo na maaaring umuusbay sa iyong aplicasyon.

ไทย (Thai):
ประกาศนี้มีข้อมูลสําคัญ ประกาศนี้มีข้อมูลสําคัญเกี่ยวกับการอุทิศหรือการรับประกันสุขภาพของคุณ Premera Blue Cross และคุณมีสิทธิในการร้องเรียนคุณคําที่จะมีค่าใน cazamiento ขอสิทธิในการทราบและร้องเรียนเรื่องการประกอบธุรกิจที่มีผลต่อชีวิตถึงการรับประกันสุขภาพของคุณ Premera Blue Cross.

Română (Romanian):

Polski (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):