MEDICAL POLICY – 1.01.26
Cooling Devices Used in the Outpatient Setting

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

Circulating and noncirculating

Medical Necessity

Circulating and noncirculating cooling devices, with or without compression, used in the outpatient setting are considered not medically necessary.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>E0218</td>
<td>Fluid circulating cold pad with pump, any type</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>

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 manually fill 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. A variety of manually operated and mechanical continuous cooling devices are commercially available.

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. Circulating cooling devices are designed to provide a constant low temperature, which might provide additional benefit compared with the more variable temperature achieved with the intermittent replacement of ice packs. Noncirculating cooling devices might also allow less variable cooling due to the larger volume of ice stored in the insulated tank and the use of circulated ice water.

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 water drained. The cooler is then raised above the affected limb, and cold water refills the compressive cuff. The 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.
Circulating Cooling Devices

In active, circulating cooling devices, a motorized pump circulates chilled water and may also provide pneumatic compression. For example, 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. The Hot/Ice Thermal Blanket is another circulating cooling device. It consists of two 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. The Game Ready™ Accelerated Recovery System is a 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 to provide intermittent pneumatic compression. The Hilotherm® Clinic circulates cooled water through preshaped thermoplastic polyurethane facial masks for use after different types of facial surgery. ThermaZone® provides thermal therapy with pads specific to various joints as well as different areas of the head (front, sides, back, eyes). CTM™ 5000 and cTreatment are computer-controlled devices that provide cooling at a specific (11°C) and continuous temperature.

Summary of Evidence

For individuals with pain and/or swelling after knee surgery who receive a cooling device, the evidence includes systematic reviews, several randomized controlled trials (RCTs), and a case-control study. The 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 an RCT. The 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 RCTs and a pilot study. The 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><strong>Ongoing</strong></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>
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</table>

**Clinical Input from Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, 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

No guidelines or statements were identified.

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 2004, the 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.

Code E0218 describes a device which has an electric pump that circulates cold water through a pad.25

Regulatory Status

A large number of circulating and noncirculating cooling devices (Table 2) have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process since 1976. U.S. Food and Drug Administration product code: ILO.

Table 2. Cooling Devices Cleared by the US Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therma-X, Term-X At, Therm-X Pro Ath</td>
<td>Zenith Technical Innovations</td>
<td>08/03/2018</td>
<td>K181149</td>
<td>To treat post-surgical and acute injuries to reduce swelling and pain</td>
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<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Date Cleared</td>
<td>510(k) No.</td>
<td>Indication</td>
</tr>
<tr>
<td>--------------------------------</td>
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</tr>
<tr>
<td>Med4 Elite</td>
<td>Cool Systems, Inc (DBA Game Ready)</td>
<td>09/29/2017</td>
<td>K171685</td>
<td>To treat post-surgical and acute injuries to reduce swelling and pain</td>
</tr>
<tr>
<td>Nice1</td>
<td>Nice Recovery Systems, LLC</td>
<td>12/23/2014</td>
<td>K143197</td>
<td>To treat post-surgical and acute injuries to reduce swelling and pain</td>
</tr>
<tr>
<td>Dynatron Peltier Thermostim Probe</td>
<td>Dynatronics Corp.</td>
<td>01/24/2014</td>
<td>K132057</td>
<td>To treat post-surgical and acute injuries to reduce swelling and pain</td>
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</tbody>
</table>

References


### 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>Date</td>
<td>Comments</td>
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<tr>
<td>------------</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>
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<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 A9273 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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<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>
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<tr>
<td>02/01/16</td>
<td>Coding update. Added E0650 and E0651.</td>
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<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>
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<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 otherwise unchanged.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; references 24 and 25 added. Policy statements 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.
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.
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  • Qualified interpreters
  • Information written in other languages

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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/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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):
اللغة العربية

يحوي هذا الإشعار معلومات هامة. عند إجراء هذه الإشارات، قد يحتوي هذا الإشعار على معلومات هامة يعودون إلى سوء فهم أو خطأ. الوحدات التي تدير الخدمات على مدار الساعة

دوامًا، تنظر إشعارًا وإخطارًا في نتائج المقابلة على تطبيق المعايير الصحية والسلامة

في هذه الإشارة. قد تحتاج إلى إجراء توضيحات للإجابة على مسألتك الصحية أو المساعدة

في إشعار الكشف. يتحمل المسؤولية على هذه المعلومات والمساعدة بكل تكلفة دون تذكرة إشارة. أصل

800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能含有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromoo (Cushite):
Lakkoofsa billila 800-722-1471 (TTY: 800-842-5357) ti billila.

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Efemasony Enpòtan ladann. Avi sila a kapab genyen efemasony enpòtan konsénas aplikasyon w lan oswa konvèn kouvètli asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kentbe kouvètli asirans sante w la oswa pou yo ka ede w avèk depans yo.
Se dwa w pou resewwa efemasony sa a ak asistans nan lang ou pale a, san ou pa gen pou puye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):
Tsab ntawv tshaj xo no muaj cov ntsiab lus tseem ceeb. Tjez taum tsab ntawv tshaj xo no muaj cov ntsiab lus tseem ceeb borg koj daim ntawv thov kev pab los yoj koj qhev kev pab cuam los ntawm Premera Blue Cross. Tjez taum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawm no. Tjez taum koj kju yuav tau uu qee yam uu peb kem koj uas tis pub dhaav cov caj nyoy uas teev tsag rau hauv daim ntawv no mas koj thaj yuav tau baas kev pab cuam kho mob los yoj kev pab tem tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntsiab lus no uas tau muab sau uu koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Illoko (Ilocano):
Daytuyo a Pakdaar ket naglao iti Napateg nga Impomarsa. Daytuyo a pakdaar mabalay nga adda ket naglao iti Napagete nga imomarsa maiapanggan ngi aplisyaronyo wenno coverage babaen iti Premera Blue Cross. Daytuyo ket mabalay dagiti importante a peta iiti daytuyo a pakdaar. Mabalay nga adda rumbeg nga aramidenyo nga addang sakyay dagiti partikular a naiturence nga adda aldaw tapo mapagtagalneyong ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbengayo a mangala iti daytuyo nga impomarsa ken tulong ti bukodyo a pageasagao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Talvez seja necessário que você tome providências dentro de um determinado período.

나는 (Korean): 이 통보에는 중요한 내용이 포함되어 있습니다. 이 통보는 Premera Blue Cross를 통한 커버지에 관한 정보를 포함하고 있습니다. 본 통보에는 변경이 되는 날짜들이 있을 수 있습니다. 귀하의 귀하의 건강 커버지로 평가 또는 비용을 점검하기 위해 일정한 미리 알림 시기를 취해야 할 필요가 있을 수 있습니다.

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