FEP Medical Policy Manual

FEP 1.01.26 Cooling Devices Used in the Outpatient Setting

Effective Policy Date: July 1, 2019

Original Policy Date: September 2011

Related Policies:

None

Cooling Devices Used in the Outpatient Setting

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).

OBJECTIVE

The objective of this evidence review is to determine whether use of cooling devices improves the net health outcome in postsurgical patients compared with standard icing regimens.

POLICY STATEMENT

Circulating and noncirculating cooling devices are considered not medically necessary.

Combination circulating cooling and compression (cryopneumatic) devices are considered investigational.

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BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A large number of circulating and noncirculating cooling devices 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 1. 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>ThermoX, Term-X At, Them-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>
</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>
</tr>
</tbody>
</table>

RATIONALE

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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

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U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

While there is no national coverage decision for Medicare, cooling devices are addressed in durable medical equipment regional carrier 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 DME [durable medical equipment]. 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.”

REFERENCES


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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>September 2011</td>
<td>New policy</td>
<td>Policy updated with literature review, references 10 and 12 added, others removed and reordered; Policy statement changed to: active cryopneumatic devices considered not medically necessary.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Policy statement unchanged.</td>
</tr>
<tr>
<td>March 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Policy statement unchanged.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 8, 2018; reference 24 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Policy statement unchanged.</td>
</tr>
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<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 6, 2019; reference added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

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