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.

POLICY GUIDELINES

None

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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 (FDA) through the 510(k) process since 1976. FDA product code: ILO.

Table 1. Cooling Devices Cleared by the U.S. 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>Game Ready GRPro 2.1 System</td>
<td>Cool Systems, Inc (Dbare Game Ready)</td>
<td>10/29/2019</td>
<td>K192114</td>
<td>To treat post-surgical and acute injuries to reduce swelling and pain</td>
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<tr>
<td>Polar Care Wave</td>
<td>Breg Inc</td>
<td>03/01/2019</td>
<td>K183702</td>
<td>To treat post-surgical and acute injuries to reduce swelling and pain</td>
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<tr>
<td>Therm-X, Therm-X At, Therm-X Pro Ath</td>
<td>Zenith Technical Innovations</td>
<td>5/10/2019</td>
<td>K190854 K181149</td>
<td>To treat post-surgical and acute injuries to reduce swelling and pain</td>
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<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>
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<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>
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<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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</table>

RATIONALE

Summary of Evidence

For individuals who have pain and/or swelling after knee surgery who receive a cooling device, the evidence includes several randomized controlled trials (RCTs) 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 on manually operated passive noncirculating cooling devices were limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications did not provide sufficient evidence of comparative efficacy. Other studies 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 2 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 2 RCTs. 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.

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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. 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

American Academy of Orthopaedic Surgeons

In 2016, the American Academy of Orthopaedic Surgeons released guidelines on the surgical management of osteoarthritis of the knee after knee arthroplasty. They state, “Moderate evidence supports that cryotherapy devices after knee arthroscopy (KA) do not improve outcomes.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

While there is no national coverage decision for Medicare, cooling devices were addressed in a 2004 durable medical equipment regional carrier policy.

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>
</tr>
</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. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 8, 2018; reference 24 added. Policy statements unchanged.</td>
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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>
<tr>
<td>June 2020</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 13, 2020; reference added; Policy statements unchanged.</td>
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