FEP 1.01.26 Cooling Devices Used in the Outpatient Setting

Effective Date: April 15, 2018
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).

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. Food and Drug Administration product code: ILO.

POLICY STATEMENT
Circulating and noncirculating cooling devices are considered not medically necessary.
Combination circulating cooling and compression (cryopneumatic) devices are considered investigational.

POLICY GUIDELINES
According to Medicare’s durable medical equipment regional carrier policy, noncirculating cooling devices are not considered durable medical equipment and thus should be billed as: Noncovered device or service

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

RATIONALE
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
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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 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, 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
No guidelines or statements were identified.

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

REFERENCES

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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**POLICY HISTORY**

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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<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 stmt changed to: active cryopneumatic devices considered not medically necessary.</td>
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<tr>
<td>June 2013</td>
<td>Policy Updated</td>
<td>Policy stmt changed to: active cryopneumatic devices considered not medically necessary.</td>
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<tr>
<td>December 2017</td>
<td>Policy Updated</td>
<td>Policy updated with literature review. Policy statement unchanged.</td>
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<tr>
<td>March 2018</td>
<td>Administrative Update</td>
<td>Removed non-FEP policy which was listed under related policies: 1.01.10 Continuous Passive motion in the Home Setting.</td>
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