

FEP 1.01.26 Cooling Devices Used in the Outpatient Setting

Effective Date: July 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. US 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**.

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 who receive a cooling device, the evidence includes systematic reviews, several 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 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.

Original Policy Date: September 2011

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For individuals who have pain and/or swelling after shoulder surgery who receive a cooling device, the evidence includes an RCT. 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. 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 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."²⁴

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POLICY HISTORY

Date	Action	Description
September 2011	New Policy	
June 2013	Updated Policy	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.
March 2017	Updated Policy	Policy updated with literature review. Policy statement unchanged.

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December 2017	Updated Policy	Policy updated with literature review. Policy statement unchanged.
June 2018	Updated Policy	Policy updated with literature review through January 8, 2018; reference 24 added. Policy statements unchanged.

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