BlueCross BlueShield Federal Employee Program.

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

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."

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POLICY HISTORY

Date	Action	Description
September 2011	New Policy	
June 2013	Policy Updated	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.

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March 2017	Policy Updated	Policy updated with literature review. Policy statement unchanged.
December 2017	Policy Updated	Policy updated with literature review. Policy statement unchanged.
March 2018	Administrative Update	Removed non-FEP policy which was listed under related policies: 1.01.10 Continuous Passive motion in the Home Setting.