

EFFECTIVE DATE: 06/19/2012
POLICY LAST UPDATED: 08/05/2014

OVERVIEW

This policy documents the coverage determination for Cooling Devices Used in the Home and Outpatient Setting. 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 are manually filled with iced water, to motorized units that both cool and circulate the chilled water. These devices are typically used when ice packs would normally be applied, eg, after orthopedic surgical procedures.

PRIOR AUTHORIZATION

Not Applicable

POLICY STATEMENT

BlueCHiP for Medicare: Cooling devices will be considered not covered as the device is not reasonable and necessary.

Please Note: The device will be a provider liability unless the member has signed an advanced beneficiary notice in advance of delivery of the device.

Commercial products: Cooling devices, with or without pumping action, are considered convenience items and are not covered and contract exclusions.

MEDICAL CRITERIA

None

BACKGROUND

Cold and/or compression therapy following surgery or musculoskeletal and soft tissue injury has long been accepted in the medical field as an effective tool for reducing inflammation, pain, and swelling. Ice packs and various bandages and wraps are commonly used. In addition, a variety of continuous cooling devices are commercially available and can be broadly subdivided into those providing manually operated passive cold therapy and those providing active cold therapy using a mechanical device.

The CryoCuff® and Polar Care Cub devices are examples of passive cooling devices. The CryoCuff device consists of an insulated container filled with iced water that is attached to a compressive cuff. When the CryoCuff container is raised, the water fills and pressurizes the cuff. The amount of pressure is proportional to the height of the container. When body heat warms the water, the cooler is lowered and the water drains out. The cooler is then raised above the affected limb, and cold water refills the compressive cuff. The Polar Care Cub unit consists of pads held in place with elastic straps, which may also provide compression. The pads are attached to a built-in hand pump that circulates the water through the pads at the same time as increasing the compression around the joint.

In active cooling devices, a motorized pump circulates chilled water and may also provide pneumatic compression. For example, the AutoChill® device, which may be used in conjunction with a CryoCuff, consists of a pump that automatically exchanges water from the cuff to the cooler, eliminating the need for

manual water recycling. The Hot/Ice Thermal Blanket is another example of an active cooling device. It consists of 2 rubber pads connected by a rubber hose to the main cooling unit. Fluid is circulated via the hose through the thermal blankets. The temperature of the fluid is controlled by the main unit and can be either hot or cold. The Game Ready™ Accelerated Recovery System is an example of an active cooling device combined with a pneumatic component. The system consists of various soft wraps and a computer-controlled control unit to circulate the water through the wraps and provide intermittent pneumatic compression. The Hilotherm® Clinic circulates cooled water through preshaped thermoplastic polyurethane facial masks for use after different types of facial surgery. ThermaZone® provides thermal therapy with pads specific to various joints, as well as different areas of the head (front, sides, back, eyes).

Most of the published randomized studies of passive cooling devices failed to adequately describe the cooling regimens or include the relevant control group of standard ice pack treatment. When passive cooling devices and ice packs were used with the same regimen, no differences in health outcomes were observed. Currently available evidence is insufficient to determine whether continuous cooling devices result in improved health outcomes when compared with usual ice pack exchange in the home environment. Several small studies report that a cooling mask used after facial surgery provides greater pain relief and reduction of swelling compared with cool compresses, but these studies have limitations and results need to be replicated in larger, higher quality studies. Overall, the available scientific literature is insufficient to document that the use of passive or active cooling systems is associated with a benefit beyond convenience; these devices are considered not medically necessary.

For combination active cryotherapy/compression (cryopneumatic) devices, 2 recent studies reported that narcotic use is decreased and that patient satisfaction is higher. However, no other outcome measures were improved, and one of the studies suffered from a low follow-up rate. Based on these new studies with active cryotherapy/compression devices and limited evidence of an improvement in clinical outcomes, active cryotherapy/compression devices are considered investigational. Additional study is needed to permit conclusions regarding the effect of this technology with greater certainty.

While there is no national coverage decision for Medicare, cooling devices are addressed in Durable Medical Equipment Resource Center (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. All of these types of devices must be coded A9270 if claims are submitted to the DMERC.”

“Code E0218 describes a device which has an electric pump that circulates cold water through a pad.... A water circulating cold pad with pump (E0218) will be denied as not medically necessary.”

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable Services Not Medically Necessary coverage.

CODING

BlueCHiP for Medicare and Commercial

The following HCPCS codes are not covered:

E0218 E0236 A9270

RELATED POLICIES

None

PUBLISHED

Provider Update Oct 2014

Provider Update Jul 2013

Provider Update Sep 2012

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