**Payment Policy |** Cooling Devices Used in the Home and Outpatient Setting

**EFFECTIVE DATE:** 06|19|2012
**POLICY LAST UPDATED:** 04|04|2017

## 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, e.g., after orthopedic surgical procedures.

## MEDICAL CRITERIA
Not applicable

## PRIOR AUTHORIZATION
Not applicable

## POLICY STATEMENT
**BlueCHiP for Medicare**
Cooling devices will be considered not covered as the device is not reasonable and necessary.

**Commercial Products**
Cooling devices, with or without pumping action, are considered convenience items and are not covered and contract exclusions apply.

## COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable contract exclusions and limitations of benefits/coverage when services are not medically necessary.

## 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). CTM™ 5000 and cTreatment are computer-controlled devices that provide cooling at a specific (11 degrees C) and continuous temperature.

For individuals who have pain and/or swelling after surgery who receive a passive cooling device, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. Most published randomized trials of passive cooling devices have failed to adequately describe the cooling regimens or include the relevant control group (standard ice pack treatment). Studies that used either a no-icing control or infrequent ice applications do not provide sufficient evidence of comparative efficacy. Other reports have provided no information on the frequency of ice changes, limiting interpretation of the results. Only 1 RCT was identified that compared continuous cooling to a standard icing regimen of intermittent 20-minute ice application. Currently available evidence is insufficient to determine whether continuous cooling results in a reduction in pain and swelling compared with a standard icing regimen in the home environment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after surgery who receive an active cooling device, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. Several RCTs have compared active cooling devices with standard intermittent icing or cold packs. Some trials have reported that a cooling mask used after facial surgery provides greater pain relief and reduction of swelling than cold compresses, but these studies have limitations and results need to be replicated in larger, higher quality studies. Other trials have found no benefit of active cooling devices compared to a standard icing regimen after knee surgery. There is a potential to decrease awakenings from pain during the night, but sleep disrupting noise from the device has been reported. Overall, use of active cooling systems has not been shown to be associated with a benefit beyond convenience. The evidence is insufficient to determine the effects of the technology on health outcomes

For individuals who have pain and/or swelling after surgery who receive combination cooling and compression devices, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. The available evidence does not indicate that combination cryotherapy and compression (cryopneumatic) devices improve health outcomes when applied at a similar frequency as ices changes. Two studies have reported that narcotic use is decreased and that patient satisfaction is higher. However, no other outcome measures were improved, and 1 study suffered from differences at baseline. A third trial found no significant differences in outcomes between cryopneumatic therapy and icing when both used the same intermittent regimen. No studies were identified that compared continuous cryotherapy plus intermittent compression to a standard icing regimen. The evidence is insufficient to determine the effects of the technology on health outcomes.

While there is no national coverage decision for Medicare, cooling devices are addressed in the policy Durable Medical Equipment Resource Center (DMERC). 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."

## CODING

**BlueCHiP for Medicare and Commercial Products**
The following HCPCS codes are not covered:
**E0218** Water circulating cold pad with pump
**E0236** Pump for water circulating pad
**A9270** Noncovered device or service

## RELATED POLICIES

None

## PUBLISHED

Provider Update, June 2017
Provider Update, August 2016
Provider Update, November 2015
Provider Update, October 2014
Provider Update, July 2013
Provider Update, September 2012

## REFERENCES


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3. Modabber A, Rana M, Ghassemi A et al. Three-dimensional evaluation of postoperative swelling in treatment of zygomatic bone fractures using two different cooling therapy methods: a randomized, observer-blind, prospective study. Trials 2013; 14:238.
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