

# **Medical Coverage Policy**

# **Cooling Devices used in the Home and Outpatient Setting**

□ Device/Equipment □ Drug □ Medical □ Surgery □ Test □ Other			
Effective Date:	6/19/2013	Policy Last Updated:	5/7/2013
☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.			
□ Prospective review is not required.			

# **Description:**

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.

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.

## Passive cooling devices:

The CryoCuff® and the 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 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.

#### **Active cooling devices:**

In active cooling devices, a motorized pump circulates chilled water and may also provide pneumatic compression. For example, the AutoChill® device 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.

#### **Clinical Evidence:**

The majority 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 with these devices results in improved health outcomes when compared to usual ice pack exchange in the home environment. Thus, the available scientific literature is insufficient to document that the use of passive cooling systems is associated with a benefit beyond convenience; these devices are considered not medically necessary.

For active cryotherapy/compression 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.

#### Medicare "not reasonable and necessary:"

Medicare indicates cooling therapy items do not fit the definition of reasonable and necessary and are therefore not be covered. Medicare defines services/items "not reasonable and necessary" as items not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Services denied as not reasonable and medically necessary, under section 1862(a)(1) of the Social Security Act, are subject to the Limitation of Liability (Advance Beneficiary Notice) provision. Thus, to be held liable for denied charge(s), the beneficiary must be given appropriate written advance notice of the likelihood of non-coverage and agree to pay for services.

#### **Medical Criteria:**

None

#### Policy:

# **BlueCHiP for Medicare:**

Cooling devices will be considered not covered as the device is not reasonable and necessary. The device will be 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.

#### Coverage:

Benefits may vary by groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable "Medical Equipment, Medical Supplies and Prosthetic Devices" or "Related Exclusions" benefit coverage.

# **Coding:**

The following HCPCS codes are considered not covered for all BCBSRI products:

E0218 Water circulating cold pad with pump

**E0236** Pump for water circulating pad

A9270 Noncovered device or service

# **Related Topics:**

Durable Medical Equipment (DME) Notes Link

#### Also known as:

Ice packs
Cooling devices
CryoCuff®
Polar Care Cub
AutoChill®
Compression therapy

#### **Published:**

Provider Update, July 2013 Provider Update, September 2012

#### References:

Blue Cross and Blue Shield Association. Medical Policy Reference Manual-Policy #1.01.26 Cooling Devices Used in the Outpatient Setting (2:2013)

Centers for Medicare and Medicaid Services: Local Coverage Determination (LCD): COLD THERAPY (L5038).

Centers for Medicare and Medicaid Services: Local Coverage Article for COLD THERAPY – Policy Article – Effective January 2011 (A19799).

## **Review History:**

**5/7/2013:** Annual review of the policy with no changes.

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