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<b>Medical Benefit</b>		<b>Effective Date:</b> 07/01/13	<b>Next Review Date:</b> 05/18
<b>Preauthorization</b>	No	<b>Review Dates:</b> 05/13, 05/14, 05/15, 05/16, 05/17	

***This protocol considers these technologies not medically necessary or investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With pain and/or swelling after surgery	Interventions of interest are: • Passive cooling device	Comparators of interest are: • Standard icing regimen	Relevant outcomes include: • Symptoms • Functional outcomes • Medication use • Resource utilization
Individuals: • With pain and/or swelling after surgery	Interventions of interest are: • Active cooling device	Comparators of interest are: • Standard icing regimen	Relevant outcomes include: • Symptoms • Functional outcomes • Medication use • Resource utilization
Individuals: • With pain and/or swelling after surgery	Interventions of interest are: • Combination cooling and compression device	Comparators of interest are: • Standard icing regimen	Relevant outcomes include: • Symptoms • Functional outcomes • Medication use • Resource utilization

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

### Summary of Evidence

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 one 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 ice changes. Two studies have reported that narcotic use is decreased and that patient satisfaction is higher. However, no other outcome measures were improved, and one 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.

### Policy

Active and passive cooling devices are considered **not medically necessary**.

Combination active cooling and compression (cryopneumatic) devices are considered **investigational**.

### Policy Guidelines

The term active cooling devices in the policy statement refers to devices which involve motorized parts, for example, electrical pumps.

The term passive cooling equipment in the policy statement refers to, for example, ice packs or gravity-fed devices which are manually filled with ice water.

Passive cooling equipment is not considered to fit the definition of durable medical equipment.

### 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 com-

mercially 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 water drained. 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 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 active cooling device. It consists of two 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 active cooling device combined with a pneumatic component. The system consists of various soft wraps and a computer-control unit to circulate the water through the wraps and to 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° C) and continuous temperature.

### Regulatory Status

A large number of active and passive heating and cooling devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process since 1976. FDA product code: ILO.

### Related Protocol

Continuous Passive Motion in the Home Setting

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

### References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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