

## MEDICAL POLICY

POLICY TITLE	COOLING DEVICES USED IN THE OUTPATIENT SETTING
POLICY NUMBER	MP 6.040

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	12/1/2024

[POLICY](#)
[PRODUCT VARIATIONS](#)
[DESCRIPTION/BACKGROUND](#)
[RATIONALE](#)
[DEFINITIONS](#)
[BENEFIT VARIATIONS](#)
[DISCLAIMER](#)
[CODING INFORMATION](#)
[REFERENCES](#)
[POLICY HISTORY](#)

### I. POLICY

The following cooling devices are considered **not medically necessary**:

- Circulating and noncirculating cooling devices
- Combination circulating cooling and compression (cryopneumatic) devices

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

### Policy Guidelines

This policy does not apply to standard reuseable ice packs/wraps/caps (see **MP 6.026 DME**).

### Societal Recommendations

American Academy of Orthopaedic Surgeons

- Moderate evidence supports that the use of cryotherapy devices after knee arthroscopy do not improve outcomes (2016; statement was not revisited in the 2022 update)
- In the absence of reliable evidence, it is the opinion of the workgroup that either continuous cryotherapy or cold packs can be used following shoulder arthroplasty (2020)
- Limited evidence suggests no significant difference in patient pain, function and opioid use between cryo-compression and control/ice/circulating water (2021)

The Orthopaedic Trauma Association Musculoskeletal Pain Task Force 2019

- The panel recommends the use of cryotherapy for acute musculoskeletal injury and the postsurgical orthopaedic patient as an adjunct to other postoperative pain treatments (conditional recommendation, low-quality evidence).
- The panel cannot recommend a specific cryotherapy delivery modality or protocol (no recommendation, limited evidence).

## MEDICAL POLICY

POLICY TITLE	COOLING DEVICES USED IN THE OUTPATIENT SETTING
POLICY NUMBER	MP 6.040

### ***Cross-references:***

**MP 6.026 Durable Medical Equipment**

## II. PRODUCT VARIATIONS

[Top](#)

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

**FEP PPO:** Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

## III. DESCRIPTION/BACKGROUND

[Top](#)

### **Cold and Compression Therapy**

Use of ice packs and various bandages and wraps following surgery or musculoskeletal and soft tissue injury is common. A variety of manually operated and mechanical continuous cooling devices are commercially available.

The standard postoperative treatment for musculoskeletal surgeries consists of cryotherapy (cold therapy) and various types of compressive wraps. Both ice packs (with or without additives to maintain temperature) and cooling devices can provide cryotherapy. Circulating cooling devices are designed to provide a constant low temperature, which might provide additional benefit compared with the more variable temperature achieved with the intermittent replacement of ice packs. Noncirculating cooling devices might also allow less variable cooling due to the larger volume of ice stored in the insulated tank and the use of circulated ice water.

### **Noncirculating Cooling Devices**

The CryoCuff® and Polar Care Cub devices are examples of passive, noncirculating 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.

### **Circulating Cooling Devices**

In active, circulating cooling devices, a motorized pump circulates chilled water and may 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

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>COOLING DEVICES USED IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP 6.040</b>

circulating cooling device. It consists of two (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 a circulating 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 circulating and noncirculating cooling devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process since 1976 and are listed in Table 1.

FDA product code: ILO.

**Table 1. Cooling Devices Cleared by the FDA**

<b>Device</b>	<b>Manufacturer</b>	<b>Date Cleared</b>	<b>510(k) No.</b>	<b>Indication</b>
<b>Cold/Hot Compression</b>	JKH Health Co., Ltd	10/27/2023	K223541	To treat post-surgical and acute injuries to reduce swelling and pain
<b>Cryo-Thermo Compression Device</b>	Suzhou MicroPort RehabTech (Group) Co., Ltd.	3/8/2023	K222136	To treat post-surgical and acute injuries to reduce swelling and pain
<b>Armory Motion</b>	Pain Management Technologies, Inc.	6/10/2022	K213097	To treat post-surgical and acute injuries to reduce swelling and pain
<b>Ice Compression First, Duo, &amp; Moove Systems</b>	MksParis	1/11/2021	K193079	To treat post-surgical and acute injuries to reduce swelling and pain
<b>Game Ready GRPro 2.1 System</b>	Cool Systems, Inc. (Db a Game	10/29/2019	K192114	To treat post-surgical and acute injuries to

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>COOLING DEVICES USED IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP 6.040</b>

	Ready)			reduce swelling and pain
<b>Polar Care Wave</b>	Breg Inc.	03/01/2019	K183702	To treat post-surgical and acute injuries to reduce swelling and pain
<b>Therm-X, Therm-X At, Therm-X Pro Ath</b>	Zenith Technical Innovations	5/10/2019 08/03/2018	K190854 K181149	To treat post-surgical and acute injuries to reduce swelling and pain
<b>Med4 Elite</b>	Cool Systems, Inc. (Dba Game Ready)	09/29/2017	K171685	To treat post-surgical and acute injuries to reduce swelling and pain
<b>Nice1</b>	Nice Recovery Systems, LLC	12/23/2014	K143197	To treat post-surgical and acute injuries to reduce swelling and pain
<b>Dynatron Peltier Thermostim Probe</b>	Dynatronics Corp.	01/24/2014	K132057	To treat post-surgical and acute injuries to reduce swelling and pain

## IV. RATIONALE

[TOP](#)

### Summary of Evidence

For individuals who have pain and/or swelling after knee surgery who receive a cooling device, the evidence includes several randomized controlled trials (RCTs) 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 on manually operated passive noncirculating cooling devices were limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications did not provide sufficient evidence of comparative efficacy. Other studies 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 results have demonstrated mixed benefits, with 1 trial (N=100) finding acute pain reduction with a cooling device and 2 of the larger trials finding no significant benefit of the continuous cooling devices. The evidence is

## MEDICAL POLICY

POLICY TITLE	COOLING DEVICES USED IN THE OUTPATIENT SETTING
POLICY NUMBER	MP 6.040

insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have pain and/or swelling after shoulder surgery who receive a cooling device, the evidence includes 2 RCTs. 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 that the technology results in an improvement in the net health outcome.

For individuals who have pain and/or swelling after facial surgery who receive a cooling device, the evidence includes several small RCTs 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.

### V. DEFINITIONS

[Top](#)

**DURABLE MEDICAL EQUIPMENT** consists of items which are primarily and customarily used to serve a medical purpose; are not useful to a person in the absence of illness or injury; are ordered by a physician; are appropriate for use in the home; are reusable; and can stand repeated use.

### VI. BENEFIT VARIATIONS

[Top](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

### VII. DISCLAIMER

[Top](#)

*Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member*

## MEDICAL POLICY

POLICY TITLE	COOLING DEVICES USED IN THE OUTPATIENT SETTING
POLICY NUMBER	MP 6.040

Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

### VIII. CODING INFORMATION

[Top](#)

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

#### Not Medically Necessary; therefore, not covered:

HCPCS Code								
E0218	E0236	E1399*						

\*E1399 [when used to bill for a combination active cooling and compression (cryopneumatic) device or when used to bill for a noncirculating cooling device]

### IX. REFERENCES

[Top](#)

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# MEDICAL POLICY

POLICY TITLE	COOLING DEVICES USED IN THE OUTPATIENT SETTING
POLICY NUMBER	MP 6.040

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## MEDICAL POLICY

POLICY TITLE	COOLING DEVICES USED IN THE OUTPATIENT SETTING
POLICY NUMBER	MP 6.040

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## X. POLICY HISTORY

[Top](#)

MP 6.040	<b>04/10/2020 Consensus Review.</b> No change to Policy Statement. Coding checked, no change. References reviewed and updated. Variation FEP reviewed, no change.
	<b>03/29/2021 Consensus Review.</b> No change to Policy Statement. Coding checked, no change. References reviewed. FEP reviewed, no change.
	<b>04/19/2022 Consensus Review.</b> Policy statement unchanged. Product variation and FEP language updated. Background and Rationale revised.
	<b>05/19/2023 Consensus Review.</b> Updated background and references. No changes to coding.
	<b>06/26/2024 Minor Review.</b> Cryopneumatic devices went from INV to NMN. Updated background, rationale, and references. Created policy guidelines. Updated asterisks note in coding section.

[Top](#)

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