MEDICAL POLICY

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

Effective Date:	**9/1/2023**

I. Policy

Circulating and noncirculating cooling devices are considered **not medically necessary**.

Combination circulating cooling and compression (cryopneumatic) devices are considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

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 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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Armory Motion	Pain Management Technologies, Inc.	6/10/2022	K213097	To treat post-surgical and acute injuries to reduce swelling and pain
Ice Compression First, Duo, &	MksParis	1/11/2021	K193079	To treat post-surgical and acute injuries to reduce

Moove Systems				swelling and pain
Game Ready GRPro 2.1 System	Cool Systems, Inc. (Dba Game Ready)	10/29/2019	K192114	To treat post-surgical and acute injuries to reduce swelling and pain
Polar Care Wave	Breg Inc.	03/01/2019	K183702	To treat post-surgical and acute injuries to reduce swelling and pain
Therm-X, Therm-X At, Therm-X Pro Ath	Zenith Technical Innovations	5/10/2019 08/03/2018	K190854 K181149	To treat post-surgical and acute injuries to reduce swelling and pain
Med4 Elite	Cool Systems, Inc. (Dba Game Ready)	09/29/2017	K171685	To treat post-surgical and acute injuries to reduce swelling and pain
Nice1	Nice Recovery Systems, LLC	12/23/2014	K143197	To treat post-surgical and acute injuries to reduce swelling and pain
Dynatron Peltier Thermostim Probe	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 2 of the larger trials found no significant benefit of the continuous cooling devices. 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 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's 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 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]

IX. References

Top

1. *Schroder D, Passler HH. Combination of cold and compression after knee surgery. A prospective randomized study. Knee Surg Sports Traumatol Arthrosc. Jan 1994; 2(3):158-165. PMID 7584198*
2. *Whitelaw GP, DeMuth KA, Demos HA, et al. The use of the Cryo/Cuff versus ice and elastic wrap in the postoperative care of knee arthroscopy patients. Am J Knee Surg. Winter 1995; 8(1):28-30; discussion 30-21. PMID 7866800*
3. *Healy WL, Seidman J, Pfeifer BA, et al. Cold compressive dressing after total knee arthroplasty. Clin Orthop Relat Res. Feb 1994(299):143-146. PMID 7907012*
4. *Thienpont E. Does advanced cryotherapy reduce pain and narcotic consumption after knee arthroplasty? Clin Orthop Relat Res. Nov 2014; 472(11):3417-3423. PMID 25059851*
5. *Woolf SK, Barfield WR, Merrill KD, et al. Comparison of a continuous temperature-controlled cryotherapy device to a simple icing regimen following outpatient knee arthroscopy. J Knee Surg. Jan 2008; 21(1):15-19. PMID 18300666*
6. *Ruffilli A, Buda R, Castagnini F, et al. Temperature-controlled continuous cold flow device versus traditional icing regimen following anterior cruciate ligament reconstruction: a prospective randomized comparative trial. Arch Orthop Trauma Surg. Oct 2015; 135(10):1405-1410. PMID 26141535*
7. *Ruffilli A, Castagnini F, Traina F, et al. Temperature-controlled continuous cold flow device after total knee arthroplasty: a randomized controlled trial study. J Knee Surg. Sep 2017; 30(7):675-681. PMID 27903009*
8. *Coviello M, Abate A, Ippolito F, et al. Continuous Cold Flow Device Following Total Knee Arthroplasty: Myths and Reality. Medicina (Kaunas). Oct 27 2022; 58(11). PMID 36363493*
9. *Su EP, Perna M, Boettner F, et al. A prospective, multi-center, randomised trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery. J Bone Joint Surg Br. Nov 2012; 94(11 Suppl A):153- 156. PMID 23118406*
10. *Waterman B, Walker JJ, Swaims C, et al. The efficacy of combined cryotherapy and compression compared with cryotherapy alone following anterior cruciate ligament reconstruction. J Knee Surg. May 2012; 25(2):155-160. PMID 22928433*
11. *Murgier J, Cailliez J, Wargny M, et al. Cryotherapy with dynamic intermittent compression improves recovery from revision total knee arthroplasty. J Arthroplasty. Sep 2017; 32(9):2788-2791. PMID 28465126*
12. *Kraeutler MJ, Reynolds KA, Long C, et al. Compressive cryotherapy versus ice-a prospective, randomized study on postoperative pain in patients undergoing arthroscopic*

rotator cuff repair or subacromial decompression. J Shoulder Elbow Surg. Jun 2015; 24(6):854-859. PMID 25825138

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15. *Rana M, Gellrich NC, Ghassemi A, et al. Three-dimensional evaluation of postoperative swelling after third molar surgery using 2 different cooling therapy methods: a randomized observer-blind prospective study. J Oral Maxillofac Surg. Aug 2011; 69(8):2092-2098. PMID 21496998*
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19. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 1.01.26, Cooling Devices Used in the Outpatient Setting. April 2023*

X. POLICY HISTORY

TOP

MP 6.040	**CAC 2/22/05**
	CAC 3/28/06
	CAC 3/27/07
	CAC 3/25/08
	CAC 1/27/09
	CAC 1/26/10 Consensus review. No change in policy statement. References updated.
	CAC 4/26/11 Minor review. Adopt BCBSA criteria. No change to policy statements but the information on the heating pad and lamp was removed and placed in the MP-6.026 Durable Medical Equipment policy.
	1/1/12 Administrative update. FEP variation added for Cooling Devices used in the Outpatient Setting.

	CAC 10/30/12 Consensus review. References updated but no changes to policy statement.
	04/22/13 Admin update. Code review.
	CAC 11/26/13 Minor review. Added statement indicating combination active cooling and compression (cryopneumatic) devices are investigational**.** Rationale section added.
	CAC 11/25/14 Consensus review. References and rationale updated. No changes to the policy statements. Codes reviewed.
	CAC 11/24/15 Consensus review. No change to policy statements. References and rationale updated. Coding updated
	CAC 11/29/16 Consensus review. No change to policy statements. Variation reformatting completed. Reference and Rationale sections updated. Coding reviewed.
	CAC 12/19/17 Consensus review. Changed "active and passive cooling devices" to "circulating and noncirculating" cooling devices. Intent of policy unchanged. References and rationale updated.
	9/11/18 Consensus review. No changes to the policy statements. References updated. Rationale revised.
	2/1/19 Admin Update: Updated revised CPT description for E0218. Coding reviewed. No other coding changes.
	5/29/19 Consensus review. No changes to the policy statements. References updated.
	4/10/2020 Consensus Review. No change to Policy Statement. Coding checked, no change. References reviewed and updated. Variation FEP reviewed, no change.
	3/29/2021 Consensus Review. No change to Policy Statement. Coding checked, no change. References reviewed. FEP reviewed, no change.
	04/19/2022 Consensus review. Policy statement unchanged. Product variation and FEP language updated. Background and Rationale revised.
	5/19/2023 Consensus review. Updated background and references. No changes to coding.

Top