MEDICAL POLICY

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

Original Issue Date:	**5/23/2005**
Most Recent Review Date:	**9/11/2018**
Effective Date:	**2/1/2019**

I. POLICY

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

Combination circulating cooling and compression (cryopneumatic) devices (cryopneumatic) devices are considered **investigational**. There is insufficient evidence to support a 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 applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: Refer to FEP Medical Policy Manual MP-1.01.26, Cooling Devices Used in the Outpatient Setting**.** 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
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.

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 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 circulating 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 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 through the 510(k) process since 1976. Food and Drug Administration product code: ILO.

IV. RATIONALE

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SUMMARY OF EVIDENCE
For individuals who have pain and/or swelling after knee surgery who receive a cooling device, the evidence includes systematic reviews, several 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 that used either a no-icing control or infrequent ice applications do not provide sufficient evidence of comparative efficacy. Other studies have 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 two of the larger trials found no significant benefit of the continuous cooling devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after shoulder surgery who receive a cooling device, the evidence includes an RCT. 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 the effects of the technology on health outcomes.

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

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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

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

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VII. DISCLAIMER

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

VIII. CODING INFORMATION

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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	Description
E0218	Fluid circulating cold pad with pump, any type
E0236	Pump for water circulating pad
E1399	Durable medical equipment, miscellaneous **[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. *Edwards DJ, Rimmer M, Keene GC. The use of cold therapy in the postoperative management of patients undergoing arthroscopic anterior cruciate ligament reconstruction. Am J Sports Med. Mar-Apr 1996;24(2):193-195. PMID 8775119*

5. *Brandsson S, Rydgren B, Hedner T, et al. Postoperative analgesic effects of an external cooling system and intra-articular bupivacaine/morphine after arthroscopic cruciate ligament surgery. Knee Surg Sports Traumatol Arthrosc. Jan 1996;4(4):200-205. PMID 9046503*
6. *Levy AS, Marmar E. The role of cold compression dressings in the postoperative treatment of total knee arthroplasty. Clin Orthop Relat Res. Dec 1993(297):174-178. PMID 7902225*
7. *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*
8. *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*
9. *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*
10. *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*
11. *Barber FA, McGuire DA, Click S. Continuous-flow cold therapy for outpatient anterior cruciate ligament reconstruction. Arthroscopy. Mar 1998;14(2):130-135. PMID 9531122*
12. *Cohn BT, Draeger RI, Jackson DW. The effects of cold therapy in the postoperative management of pain in patients undergoing anterior cruciate ligament reconstruction. Am J Sports Med. May-Jun 1989;17(3):344-349. PMID 2729484*
13. *Dervin GF, Taylor DE, Keene GC. Effects of cold and compression dressings on early postoperative outcomes for the arthroscopic anterior cruciate ligament reconstruction patient. J Orthop Sports Phys Ther. Jun 1998;27(6):403-406. PMID 9617725*
14. *Saito N, Horiuchi H, Kobayashi S, et al. Continuous local cooling for pain relief following total hip arthroplasty. J Arthroplasty. Apr 2004;19(3):334-337. PMID 15067647*
15. *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*
16. *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*

17. *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*
18. *Gatewood CT, Tran AA, Dragoo JL. The efficacy of post-operative devices following knee arthroscopic surgery: a systematic review. Knee Surg Sports Traumatol Arthrosc. Feb 2017;25(2):501-516. PMID 27695905*
19. *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*
20. *Rana M, Gellrich NC, von See C, et al. 3D evaluation of postoperative swelling in treatment of bilateral mandibular fractures using 2 different cooling therapy methods: a randomized observer blind prospective study. J Craniomaxillofac Surg. Jan 2013;41(1):e17-23. PMID 22626630*
21. *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*
22. *Rana M, Gellrich NC, Joos U, et al. 3D evaluation of postoperative swelling using two different cooling methods following orthognathic surgery: a randomised observer blind prospective pilot study. Int J Oral Maxillofac Surg. Jul 2011;40(7):690-696. PMID 21411291*
23. *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. Jul 29 2013;14:238. PMID 23895539*
24. *The Health Plan. Durable Medical Equipment (DME) Medical Policies. 2016; https://www.healthplan.org/sites/default/files/documents/resources/DME/DME_fullmanual_121316.pdf. Accessed March 13, 2018.*
25. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 1.01.26, Cooling Devices Used in the Outpatient Setting March 2018.*

X. POLICY HISTORY

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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 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.
	Administrative posting 1/1/12 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 code review.
	CAC 11/26/13 Minor –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. 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.

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