

MEDICAL POLICY – 1.01.538

Cooling Devices Used in the Outpatient Setting

BCBSA Ref. Policy: 1.01.26

Effective Date: June 1, 2023

Last Revised: May 9, 2023


Replaces: 1.01.26

RELATED MEDICAL POLICIES:

1.01.540 Continuous Passive Motion in the Home Setting

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Introduction

Applying ice is known as cold therapy and helps reduce pain and swelling. Using a bandage or wrap to apply light pressure is known as compression therapy. Cold and compression therapy after surgery or injury is very effective in reducing inflammation, pain, and swelling. Using ice packs and bandages is the usual way of applying cold and compression therapy. A number of cooling devices have been developed. Some are manual while others use a small motor to cool water and move it within the wrap. Sometimes cooling devices are used in place of an ice pack and bandage. Cooling devices, including the types that add compression, are not medically necessary. Published medical studies do not show cooling devices provide better health results than ice packs and bandages.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Cooling Devices	Medical Necessity
Circulating and noncirculating	Circulating and noncirculating cooling devices, with or without compression (cryopneumatic), used in the outpatient setting are considered not medically necessary.

Coding

Code	Description
CPT	
E0218	Fluid circulating cold pad with pump, any type
E0236	Pump for water circulating pad
E0650	Pneumatic Compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E1399	Durable medical equipment, miscellaneous

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Related Information

Benefit Application

Refer to benefit or contract language when assessing whether passive cooling devices would be considered durable medical equipment.

Evidence Review



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).

Background

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 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 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 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.

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. The relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. 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 two 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 two RCTs. The 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. The 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 that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trial that might influence this review are listed in [Table 1](#).

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04185064^a	Randomized-Controlled Trial and Evaluation Cohort Study of Patients Using a Cryopneumatic Device After Open or Arthroscopic Shoulder Surgeries	250	Dec 2021 (recruiting)
NCT05095909	Utility of Intermittent Cryo-Compression Versus Traditional Icing Following Arthroscopic Rotator Cuff Repair	100	June 2024
Unpublished			
NCT02426515	Cryotherapy to Improve Outcomes in Lower Third Molar Surgery (COOL)	63	June 2018 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.



Clinical Input from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2008 Input

In response to requests, input was received from three specialty societies and three academic medical centers while the policy was under review in 2008. Input was mixed regarding the medical necessity of continuous cooling devices.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons

In 2016, the American Academy of Orthopaedic Surgeons released guidelines on the surgical management of osteoarthritis of the knee after knee arthroplasty.¹⁸ They state, "Moderate evidence supports that the use of cryotherapy devices after knee arthroscopy (KA) do not improve outcomes."



Medicare National Coverage

There is no national coverage determination.

Regulatory Status

A large number of circulating and noncirculating cooling devices ([Table 2](#)) 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 2..

FDA product code: ILO.

Table 2. Cooling Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Armory Motion	Pain Management Technologies, Inc.	06/10/2022	K213097	To treat post-surgical and acute injuries to reduce swelling and pain
Ice Compression First, Duo, & Moove Systems	MksParis	1/11/2021	K193079	To treat post-surgical and acute injuries to reduce 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



Device	Manufacturer	Date Cleared	510(k) No.	Indication
Dynatron Peltier Thermostim Probe	Dynatronics Corp.	01/24/2014	K132057	To treat post-surgical and acute injuries to reduce swelling and pain

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History

Date	Comments
08/09/11	New policy created with literature review through 2010 with not medically necessary policy statement. ICD-10 codes included. Policy approved with 90-day hold for provider notification; the policy effective date is February 8, 2012.
02/23/12	Typo corrected; code A9273 corrected within Policy Guidelines section.
04/25/12	Replace policy. Policy updated with literature review through November 2011; need for policy affirmed; policy statement unchanged.
04/08/13	Replace policy. Policy updated with literature review through January 7 2013; references 10 and 12 added; active cryopneumatic/compression devices now considered investigational; passive cooling devices remain not medically necessary. HCPCS code E1399 added to policy.
06/10/13	Replace policy. Policy statements clarified to distinguish between active cooling devices (not medically necessary) and combination active cryopneumatic devices (investigational). Passive cooling devices remain not medically necessary. VascuTherm added as an example of combination active cooling/compression device. HCPCS code A9273 removed from the policy; A codes are not utilized for billing.
02/13/14	Update Related Policies. Change title to 1.01.525.
06/19/14	Annual Review. Policy updated with literature review through March 17, 2014; references 13-14 added; policy statement unchanged. CPT code 97010 removed; it does not suspend for review.
06/17/15	Annual Review. Policy updated with literature review through March 2, 2015; reference 10 added; policy statement unchanged.
02/01/16	Coding update. Added E0650 and E0651.



Date	Comments
06/01/16	Annual Review, approved May 10, 2016. Policy updated with literature review. Policy statement on combination active cooling and compression changed from investigational to not medically necessary. References added. Trade names for active cooling devices added to Description section. Added code E0650.
04/11/17	Policy moved into new format; no change to policy statements. Evidence Review section reformatted.
12/01/17	Annual Review, approved November 9, 2017. Policy updated with literature review through August 24, 2017; references 18 and 23 added. Policy section edited; policy statements otherwise unchanged.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; references 24 and 25 added. Policy statements unchanged.
06/01/19	Annual Review, approved May 7, 2019. Policy updated with literature review through January 2019; reference added. Policy statements unchanged.
06/01/20	Annual Review, approved May 5, 2020. Policy updated with literature review through January 2020; reference updated; Policy statements unchanged.
06/01/21	Annual Review, approved May 4, 2021. Policy updated with literature review through December 13, 2020; no references added. Policy statements unchanged.
06/01/22	Annual Review, approved May 9, 2022. Policy updated with literature review through January 14, 2022; no references added. Policy statements unchanged.
06/01/23	Policy renumbered, approved May 9, 2023, from 1.01.26 to 1.01.538 Cooling Devices Used in the Outpatient Setting. Policy updated with literature review through January 17, 2023; reference added. Minor editorial refinement to policy statement; intent unchanged.

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