PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 1.01.538

Cooling Devices Used in the Outpatient Setting

BCBSA Ref. Policy:	1.01.26	
Effective Date:	Jun. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	May 12, 2025	1.01.540 Continuous Passive Motion in the Home Setting
Replaces:	1.01.26	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

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 Cube 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 a systematic review, 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 finding 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 three RCTs. The relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. Evidence from 2 RCTs found that use of compressive cryotherapy produced no significant reduction in pain or medication use compared with the standard ice wrap. One RCT found a reduction in opioid use with cryopneumatic

therapy compared with standard of care, but there was no difference in pain scores between groups, and diversity in the icing methods in the control group prohibit conclusions regarding the efficacy of cryopneumatic therapy. 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 trials 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			
NCT05095909	Utility of Intermittent Cryo-Compression Versus Traditional Icing Following Arthroscopic Rotator Cuff Repair	100	June 2025

NCT: national clinical trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

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

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US 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 2022, the American Academy of Orthopaedic Surgeons updated the 2016 guidelines on the surgical management of osteoarthritis of the knee after knee arthroplasty.[21] The 2016 guideline statement, "Moderate evidence supports that the use of cryotherapy devices after knee arthroscopy (KA) do not improve outcomes", was not modified in the 2022 update. The update did not revisit several prior recommendations including cryotherapy devices.[21,22]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

A large number of circulating and noncirculating cooling devices have been cleared for marketing by the US 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 US Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Xrecovery	Shenzhen Xinrun Electric Appliances Co, LTD	11/14/2024	K242940	To treat post-surgical and acute injuries to reduce swelling and pain
Cold Compression	JKH Health Co., Ltd	05/01/2024	K240986	To treat post-surgical and acute injuries to reduce swelling and pain
Cold/Hot Compression	JKH Health Co., Ltd	10/27/2023	K223541	To treat post-surgical and acute injuries to reduce swelling and pain
Cryo-Thermo Compression Device	Suzhou MicroPort RehabTech (Group) Co., Ltd.	03/08/2023	K222136	To treat post-surgical and acute injuries to reduce swelling and pain
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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
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

References

1. Schröder D, Pässler HH. Combination of cold and compression after knee surgery. A prospective randomized study. Knee Surg Sports Traumatol Arthrosc. 1994; 2(3): 158-65. 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. 1995; 8(1): 28-30; discussion 30-1. 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): 143-6. PMID 7907012
4. Liang Z, Ding Z, Wang D, et al. Cryotherapy for Rehabilitation After Total Knee Arthroplasty: A Comprehensive Systematic Review and Meta-Analysis. Orthop Surg. Dec 2024; 16(12): 2897-2915. PMID 39402654
5. Thienpont E. Does advanced cryotherapy reduce pain and narcotic consumption after knee arthroplasty?. Clin Orthop Relat Res. Nov 2014; 472(11): 3417-23. PMID 25059851
6. 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): 15-9. PMID 18300666
7. 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): 1405-10. PMID 26141535
8. 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

9. 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

10. Quesnot A, Mouchel S, Salah SB, et al. Randomized controlled trial of compressive cryotherapy versus standard cryotherapy after total knee arthroplasty: pain, swelling, range of motion and functional recovery. BMC Musculoskelet Disord. Feb 28 2024; 25(1): 182. PMID 38419032

11. 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): 153-6. PMID 23118406

12. 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): 155-60. PMID 22928433

13. 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

14. 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): 854-9. PMID 25825138

15. Noyes MP, Denard PJ. Continuous Cryotherapy vs Ice Following Total Shoulder Arthroplasty: A Randomized Control Trial. Am J Orthop (Belle Mead NJ). Jun 2018; 47(6). PMID 29979799

16. Khan M, Phillips SA, Mathew P, et al. Cryo-Pneumatic Compression Results in a Significant Decrease in Opioid Consumption After Shoulder Surgery: A Multicenter Randomized Controlled Trial. Am J Sports Med. Sep 2024; 52(11): 2860-2865. PMID 39165152

17. 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

18. 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): 2092-8. PMID 21496998

19. 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): 690-6. PMID 21411291

20. 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

21. Srivastava AK, Godin J, Srivastava A, et al. American Academy of Orthopaedic Surgeons Clinical Practice Guideline Summary of Surgical Management of Osteoarthritis of the Knee. J Am Acad Orthop Surg. Dec 15 2023; 31(24): 1211-1220. PMID 37883429

22. McGrory BJ, Weber KL, Jevsevar DS, et al. Surgical Management of Osteoarthritis of the Knee: Evidence-based Guideline. J Am Acad Orthop Surg. Aug 2016; 24(8): e87-93. PMID 27355286

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.
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.

Date	Comments
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.
06/01/24	Annual Review, approved May 13, 2024. Policy updated with literature review through January 15, 2024; reference added. Policy statements unchanged.
06/01/25	Annual Review, approved May 12, 2025. Policy updated with literature review through January 17, 2025; references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.