Protocol

Cooling Devices Used in the Outpatient Setting

(10126)

Medical Benefit		**Effective Date**: 07/01/13	**Next Review Date**: 05/21
Preauthorization	No	**Review Dates**: 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 05/20	

This protocol considers these technologies not medically necessary or investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With pain and/or swelling after knee surgery	Interventions of interest are: • Cooling device	Comparators of interest are: • Standard icing regimen	Relevant outcomes include: • Symptoms • Functional outcomes • Medication use • Resource utilization
Individuals: • With pain and/or swelling after shoulder surgery	Interventions of interest are: • Cooling device	Comparators of interest are: • Standard icing regimen	Relevant outcomes include: • Symptoms • Functional outcomes • Medication use • Resource utilization
Individuals: • With pain and/or swelling after facial surgery	Interventions of interest are: • Cooling devices	Comparators of interest are: • Standard icing regimen	Relevant outcomes include: • Symptoms • Functional outcomes • Medication use • Resource utilization

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).

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 randomized controlled trials, and a case-control study. The 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 a randomized controlled trial. 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 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 randomized controlled trials 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 the effects of the technology on health outcomes.

POLICY

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

Combination circulating cooling and compression (cryo pneumatic) devices are considered **investigational**.

POLICY GUIDELINES

The term circulating cooling devices in the policy statement refers to devices which involve motorized parts, for example, electrical pumps.

The term noncirculating cooling equipment in the policy statement refers to, for example, ice packs or gravity-fed devices which are manually filled with ice water.

Noncirculating cooling equipment is not considered to fit the definition of durable medical equipment.

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.

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. U.S. Food and Drug Administration product code: ILO.

Table 1. Cooling Devices Cleared by the US Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Therma-X, Term-X At, Therm-X Pro Ath	Zenith Technical Innovations	08/03/2018	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

RELATED PROTOCOL

Continuous Passive Motion in the Home Setting

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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 post-operative 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. 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.

16. 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.
17. 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.
18. 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.
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. Noyes MP, Denard PJ. Continuous Cryotherapy vs. Ice Following Total Shoulder Arthroplasty: A Randomized Control Trial. Am J Orthop (Belle Mead NJ). 2018 Jun;47(6). doi: 10.12788/ajo.2018.0045. PubMed PMID: 29979799.
21. 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.
22. 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.
23. 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.
24. 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.
25. 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.