FEP Medical Policy Manual

FEP 1.01.26 Cooling Devices Used in the Outpatient Setting

Effective Policy Date: July 1, 2022

Original Policy Date: September 2011

Related Policies:

None

Cooling Devices Used in the Outpatient Setting

Description

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 (eg, after orthopedic surgical procedures).

OBJECTIVE

The objective of this evidence review is to determine whether the use of cooling devices improves the net health outcome in postsurgical patients compared with standard icing regimens.

POLICY STATEMENT

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

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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.

FDA product code: ILO.

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

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

RATIONALE

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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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 2016, the American Academy of Orthopaedic Surgeons released guidelines on the surgical management of osteoarthritis of the knee after knee arthroplasty.[17,] They state, "Moderate evidence supports that cryotherapy devices after knee arthroscopy (KA) do not improve outcomes."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. Schroder D, Passler 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. 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
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): 15-9. 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): 1405-10. 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. 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

9. 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
10. 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
11. 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
12. 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
13. 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
14. 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
15. 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
16. 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
17. Weber KL, Jevsevar DS, McGrory BJ. AAOS Clinical Practice Guideline: Surgical Management of Osteoarthritis of the Knee: Evidence-based Guideline. J Am Acad Orthop Surg. Aug 2016; 24(8): e94-6. PMID 27355287

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2011	New policy	
June 2013	Replace policy	Policy updated with literature review, references 10 and 12 added, others removed and reordered; Policy statement changed to: active cryopneumatic devices considered not medically necessary.
March 2017	Replace policy	Policy updated with literature review. Policy statement unchanged.
December 2017	Replace policy	Policy updated with literature review. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; reference 24 added. Policy statements unchanged.
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; reference added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; reference added; Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through December 13, 2020; no references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through January 14, 2022; no references added. Policy statements unchanged.