FEP Medical Policy Manual

FEP 1.01.26 Cooling Devices Used in the Outpatient Setting

Annual Effective Policy Date: July 1, 2026

Original Policy Date: September 2011

Related Policies:

None

Cooling Devices Used in the Outpatient Setting

Description

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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 individuals 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**.

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POLICY GUIDELINES

None

BENEFIT APPLICATION

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

Screening (other than the preventive services listed in the brochure) is not covered. Please see Section 6 General exclusions.

Benefits are available for specialized diagnostic genetic testing when it is medically necessary to diagnose and/or manage a patient's existing medical condition. Benefits are not provided for genetic panels when some or all of the tests included in the panel are not covered, are experimental or investigational, or are not medically necessary.

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, and are listed in Table 1.

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
Cryon-X Cold Compression	JKH Health	10/04/2025	K253150	To treat post-surgical and acute injuries to reduce swelling and pain
Z-ONE/ZTCube	ZAMAR Medical	05/05/2025	K242754	To treat post-surgical and acute injuries to reduce swelling and pain
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

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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
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 a systematic review, several randomized controlled trials (RCTs), and a case-control study. 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 2 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 3 RCTs. 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. 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

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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 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 do not improve outcomes" was not modified in the 2022 update. The update did not revisit several prior recommendations including cryotherapy devices.[21,22,]

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.

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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.
June 2023	Replace policy	Policy updated with literature review through January 17, 2023; reference added. Minor editorial refinements to policy statements; intent unchanged.
June 2024	Replace policy	Policy updated with literature review through January 15, 2024; reference added. Policy statements unchanged.
June 2025	Replace policy	Policy updated with literature review through January 17, 2025; references added. Policy statements unchanged. Plans affirmed the need for an active policy.
June 2026	Replace policy	Policy updated with literature review through January 12, 2026; no references added. Policy statements unchanged.

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