

Cooling Devices Used in the Outpatient Setting

Policy # 00139

Original Effective Date: 06/28/2004

Current Effective Date: 02/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Continuous Passive Motion (CPM) is addressed separately in medical policy 00020.

Services Are Not Covered

Based on review of available data, the Company considers the use of active and passive cooling devices or combination cooling and compression (cryopneumatic) devices (e.g., the Game Ready system) in the outpatient setting mainly for the comfort or convenience of the member is **not covered.****

Note: Cooling Devices Used in the Outpatient Setting are considered an exclusion in most member contracts.

Background/Overview

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

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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 2 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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
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/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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



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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).

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. 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 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

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.



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2008 Input

In response to requests, input was received from 3 specialty societies and 3 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 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. 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. did not revisit several prior recommendations including cryotherapy devices.

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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05095909	Utility of Intermittent Cryo-Compression Versus Traditional Icing Following Arthroscopic Rotator Cuff Repair	100	June 2025



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<i>Unpublished</i>			
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.

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| 06/01/2004 | Medical Director review |
| 06/15/2004 | Medical Policy Committee review |
| 06/28/2004 | Managed Care Advisory Council approval |
| 12/07/2004 | Medical Director review |
| 12/14/2004 | Medical Policy Committee review. Format revision. Name changed from Cryo Therapy to Cooling Devices Used in the Outpatient Setting. Policy/Guideline section revised to reflect member contract non-coverage of convenience items. |
| 01/31/2005 | Managed Care Advisory Council approval |
| 07/07/2006 | Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. |
| 01/10/2007 | Medical Director review |
| 01/17/2007 | Medical Policy Committee approval |
| 01/09/2008 | Medical Director review |



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01/23/2008 Medical Policy Committee approval
01/07/2009 Medical Director review
01/14/2009 Medical Policy Committee approval. No change to coverage.
01/07/2010 Medical Director approval
01/20/2010 Medical Policy Implementation Committee approval. No change to coverage.
Coding review.
010/6/2011 Medical Director approval
01/19/2011 Medical Policy Implementation Committee approval. No change to coverage
02/02/2012 Medical Policy Committee review
02/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2013 Medical Policy Committee review
01/09/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/09/2014 Medical Policy Committee review
01/15/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/08/2015 Medical Policy Committee review
01/21/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/07/2016 Medical Policy Committee review
01/22/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017 Medical Policy Committee review
01/18/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged
01/04/2018 Medical Policy Committee review
01/17/2018 Medical Policy Implementation Committee approval. Added combination cooling and compression (cryopneumatic) devices (e.g., the Game Ready system) to the services are not covered statement.
08/09/2018 Coding update
01/10/2019 Medical Policy Committee review
01/23/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2020 Medical Policy Committee review
01/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2021 Medical Policy Committee review



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01/13/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/21/2021 Coding update

01/06/2022 Medical Policy Committee review

01/12/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/05/2023 Medical Policy Committee review

01/11/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/23/2023 Coding update

01/04/2024 Medical Policy Committee review

01/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/02/2025 Medical Policy Committee review

01/08/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	E0218, E0236
ICD-10 Diagnosis	All related diagnoses

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

