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| **MEDICAL COVERAGE POLICY** | |
| **SERVICE:** | **Cold Therapy Devices** |
| **Policy Number:** | **035** |
| **Effective Date:** | **02/01/2025** |
| **Last Review:** | **01/13/2025** |
| **Next Review:** | **01/13/2026** |

***Important note:*** *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

**SERVICE:** Cold Therapy Devices

**PRIOR AUTHORIZATION:** Not applicable.

**POLICY:** Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

**Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.**

**For Medicare plans**, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination) L33735 - Cold Therapy. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

**For Medicaid plans**, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

**BSWHP considers the use of cryogenic machines NOT medically necessary.** These devices which can range from insulated blankets to water circulating cold pads (i.e., Polar Care Cold Therapy), or cold packs (ice, gel, chemical, etc.), or vaso-pneumatic cryotherapy devices (e.g., Game Ready™ which delivers active compression and cold therapy and runs on AC power or optional battery pack) are alternative methods of delivery of cold therapy. Therapy administered with these devices has not been proven to be any more efficacious than traditional delivery of cold therapy and are considered items of convenience and therefore are not medically necessary.

**BACKGROUND:**

Cryotherapy, or cold therapy, is the therapeutic application of cold temperatures. Its purpose is to promote vasoconstriction and to relieve edema, inflammation, and reduce pain.

Cold therapy can be applied in a number of settings, including:
- Post-operative (e.g., after total knee replacement or hip arthroplasty or anterior cruciate ligament repair), or
- At home, immediately following injury, or exercise
- In the rehab setting - following physical therapy sessions, or

- In athletic facilities for post exercise recovery (cold immersion)

Cold therapy can be delivered in a number of ways, including, ice packs, cold compresses, coolant sprays, ice baths, or specialized cold therapy devices. Cold therapy devices generally include a cooler or reservoir that is filled with iced water and a cuff or wrap. Non-circulating devices use gravity or a hand pump to move this water to the cooling pad; while circulating devices, a motorized pump circulates the cold water.

**Cooling Devices Cleared by the US Food and Drug Administration**

| Device | Manufacturer | Date Cleared |
|---|---|---|
| Armory Motion | Pain Management Technologies, Inc. | 06/10/2022 |
| Ice Compression First, Duo, & Moove Systems | MksParis | 1/11/2021 |
| Game Ready GRPro 2.1 System | Cool Systems, Inc (Dba Game Ready) | 10/29/2019 |
| Polar Care Wave | Breg Inc | 03/01/2019 |
| Therm-X, Therm-X At, Therm-X Pro Ath | Zenith Technical Innovations | 5/10/2019<br>08/03/2018 |
| Med4 Elite | Cool Systems, Inc (DBA Game Ready) | 09/29/2017 |
| Nice1 | Nice Recovery Systems, LLC | 12/23/2014 |
| Dynatron Peltier Thermostim Probe | Dynatronics Corp. | 01/24/2014 |

Cold therapy, particularly post-operative cold therapy, is a standard treatment modality which can be provided by a variety of methods. Clinical trials have not demonstrated superior health benefits of any methods compared to simple cold compresses.

Water circulating cold pads or a cryogenic machine attached to an insulated disposable blanket or similar products are primarily used for patient convenience, since the same outcome can be achieved with over-the-counter cold packs.

Cold packs are not considered DME and can be purchased over the counter without a prescription.

**MANDATES:** None

**CODES:**

***Important note:***

*CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

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| CPT Codes | |
| CPT Not Covered | |
| ICD-10 codes | |
| ICD-10 Not covered | |
| HCPCS Codes Not covered | E0218 |

**POLICY HISTORY:**

| Status | Date | Action |
|---|---|---|
| New | 12/6/2010 | New policy |
| Reviewed | 12/6/2011 | Reviewed. |
| Reviewed | 10/5/2012 | Reviewed with minor revisions. |
| Reviewed | 10/3/2013 | No changes |
| Reviewed | 07/24/2014 | No changes |
| Reviewed | 08/11/2015 | No changes |
| Reviewed | 08/18/2016 | No changes |
| Reviewed | 08/08/2017 | Updated HCPCS codes and references |
| Reviewed | 05/29/2018 | No changes |
| Reviewed | 08/22/2019 | No changes |
| Reviewed | 09/24/2020 | Re-formatted for SWHP/FirstCare |
| Reviewed | 09/23/2021 | No changes |
| Reviewed | 09/22/2022 | No changes |
| Reviewed | 11/29/2023 | Formatting changes and added hyperlinks to NCD and TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity changes |
| Reviewed | 03/11/2024 | Corrected the “For Medicaid Plans” section to utilize this Medical Policy if TMPPM does not have medical necessity guidance. |
| Reviewed | 01/13/2025 | Added table of FDA cleared devices. Updated and revised language and references. Ending note section updated to align with business entity changes. |
| Updated | 08/11/2025 | Removed, “Medicare NCD or LCD specific InterQual criteria may be used when available.” |

**REFERENCES:**

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Daniel, D.M., Stone, M.L., et al. The effect of cold therapy on pain, swelling, and range of motion after anterior cruciate ligament reconstructive surgery. Arthroscopy (1994 October) 10(5): 530-3.
2. Leutz, D.W., H. Harris. Continuous cold therapy in total knee arthroplasty. American Journal of Knee Surgery (1995 Fall) 8(4): 121-3.
3. American Journal of Orthopedics (1995 November) 24(11): 847-52.
4. Konrath, G.A., T. Lock.: The use of cold therapy after anterior cruciate ligament reconstruction. The American Journal of Sports Medicine (1996 September-October) 24(5): 629-33.
5. Konrath, G.A.,T. Lock. The use of cold therapy in the post-operative management of patients undergoing arthroscopic anterior cruciate ligament reconstruction The American Journal of Sports Medicine (1996 March-April) 24(2): 193-5.
6. Barber, F.A., McGuire, D.A., et al. Continuous flow cold therapy for outpatient anterior cruciate ligament reconstruction. Arthroscopy (1998 March) 14(2): 130-5.
7. Palmetto GBA, DMERC, Medical Policy: Cold Therapy. (2003 Spring) Revision, 1-6.
8. Airaksinen, O.V., Kyeklund, N., et al. Efficacy of cold gel for soft tissue injuries: a prospective randomized double-blinded trial. American Journal of Sports Medicine (2003 September-October) 31(5): 680-4.
9. Block, Jon E.: Cold and compression in the management of musculoskeletal injuries and orthopedic operative procedures: a narrative review. Open Access J Sports Med. 2010: 1: 105-113. Published online 2010 Jul 7.
10. Kuyucu, Ersin et al. “Is Cold Therapy Really Efficient after Knee Arthroplasty?” Annals of Medicine and Surgery 4.4 (2015): 475–478. PMC. Web. 21 July 2017.
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. 2012;94(11 Suppl A):153-156.
12. Bech M, Moorhen J, Cho M, Lavergne MR, Stothers K, Hoens AM. Device or ice: the effect of consistent cooling using a device compared with intermittent cooling using an ice bag after total knee arthroplasty. Physiother Can. 2015;67(1):48-55.

***Note**:*
*Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.*

*RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.*