09-E0000-53

Original Effective Date: 10/15/05

Reviewed: 07/25/24

Revised: 01/01/26

Subject: Cooling and Heating Devices Used in the Outpatient Setting

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement | Billing/Coding | Reimbursement | Program Exceptions | Definitions | Related Guidelines | Other | References | Update

DESCRIPTION:

Heat, cold and/or compression therapy following surgery or musculoskeletal and soft tissue injury has long been accepted in the medical field as an effective tool for reducing inflammation, pain, and swelling. Ice packs and various bandages and wraps are commonly used. In addition, a variety of continuous cooling and heating devices are commercially available and can be broadly subdivided into those providing passive cold or heat therapy and those providing active cold or heat therapy using a mechanical device.

Passive devices generally operate using gravity or a hand pump, and do not use a battery or electricity. Passive devices usually consist of a cuff or wrap and a cooler. Examples of passive devices include, but are not limited to, the AirCast Cryo/Cuff System and the Polar Care (PC) Cub Unit.

In active devices, a motorized pump both circulates water and may also provide pneumatic compression. Examples of active devices include, but are not limited to, the Auto Chill Device, Bio-Cryo System, Cothera VPulse, Kinex ThermoComp Device, Game Ready Accelerated Recovery System, Hot/Ice Thermal Blanket, JetStream Hot/Cold Therapy Unit, IceMan Cryotherapy Unit, VascuTherm, and the VitalWrap System.

Hybrid active/passive devices include, but are not limited to, the VibraCool Massaging Ice Therapy system, which uses a high frequency vibration unit and specially designed ice packs secured with a neoprene strap.

Scalp hypothermia using a cooling cap has been proposed for preventing alopecia (hair loss) for individuals undergoing chemotherapy. The rationale is that scalp hypothermia causes cutaneous vasoconstriction which thereby reduces the amount of chemotherapeutic agent delivered to the hair follicles. Cellular uptake by the hair follicle would also be reduced since this occurs more readily at

warmer temperatures. It is thought that scalp hypothermia lowers the metabolic rate of the hair follicles and thereby further reduce chemotherapy-induced hair loss.

Scalp hypothermia may be accomplished manually, or using a machine-based device. Manual caps include, but are not limited to, the Arctic Cold Cap, Chemo Cold Cap, Penguin Cold Cap Therapy System, Warrior Caps and Wishcaps. Machine-based devices include, but are not limited to the DigniCap® Cooling System and Paxman® Scalp Cooling System.

Cryotherapy of the oral cavity has been proposed for use in the prevention of chemotherapy-induced oral mucositis. One oral cryotherapy device, the Cooral Oral Cooling System, consists of a single-use mouthpiece connected to a portable cryotherapy system that circulates sterile cold water through the oral mucosal surfaces.

POSITION STATEMENT:

Active or passive heating or cooling devices, with or without pneumatic compression, **do not meet the definition of medical necessity**, as there is insufficient scientific evidence published to conclude that these therapy devices provide any additional therapeutic effect over conventional ice or heat application.

Combination active heating, cooling and compression (cryopneumatic) devices are considered **experimental or investigational**, as there is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on clinical outcomes.

The use of a DigniCap® or Paxman® scalp cooling system **meets the definition of medical necessity** when **ALL** of the following are met:

- The purpose is to reduce or prevent alopecia during chemotherapy, **AND**
- The member has a solid tumor cancer, **AND**
- The scalp cooling system will be used in the chemotherapy infusion suite (not in the home setting), **AND**
- None of the following contraindications are present:
    - Use in a pediatric member
    - Member receiving continuous-infusion chemotherapy regimens over one day or longer that result in alopecia
    - Undergoing whole-brain or targeted brain irradiation
    - The presence of cold agglutinin disease, cryoglobulinemia, or post-traumatic cold dystrophy
    - Member has small cell or squamous lung cancer
    - Member has skin cancer, including melanoma, squamous cell carcinoma, or Merkel cell carcinoma
    - Memer has a hematologic malignancy, including leukemia and lymphoma
    - Member is undergoing bone marrow or stem cell transplantation with myeloablative doses of chemotherapy and/or radiation therapy

A cap to be used with the DigniCap® or Paxman® scalp cooling system in the infusion suite **meets the definition of medical necessity.**

The following are considered **experimental or investigational**:

- The use of a scalp cooling device for any indication other than chemotherapy-induced alopecia
- The use of a non-FDA approved or cleared scalp cooling device (e.g., Penguin Cold Caps, Artic Caps, Polar Caps, Chemo Cold Caps, Wishcaps, Warrior Caps, non-automated/manual frozen elastogel, ice-filled bags or bandages, etc.)
- The use of a scalp cooling device in the home setting

Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

BILLING/CODING INFORMATION:

The following codes may be used to describe passive or active cooling devices, or scalp cooling systems:

CPT Coding:

97007	Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education
97008	Mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and precooling period
97009	Mechanical scalp cooling; provided after discontinuation of chemotherapy, each 30 minutes (List separately in addition to code for primary procedure)
0881T	Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device (eg, Cooral Oral Cooling System) **(Investigational)**

HCPCS Coding:

E0217	Water circulating heat pad with pump (**non-covered**)
E0218	Fluid circulating cold pad with pump, any type (**non-covered**)
E0236	Pump for water circulating pad (**non-covered**)

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline review date: National Coverage Determination (NCD) for SCALP HYPOTHERMIA During Chemotherapy to Prevent Hair Loss (110.6); Durable Medical Equipment Reference List (280.1), located at cms.gov.

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determinations (LCDs) were reviewed on the last guideline reviewed date: Cold Therapy (L33735); Heating Pads and Heat Lamps (L33784); Infrared HEATING PAD Systems L33825, located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Durable Medical Equipment (DME), 09-E0000-01

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/25/24.

GUIDELINE UPDATE INFORMATION:

10/15/05	New Medical Coverage Guideline.
08/15/07	Scheduled review; reformatted guideline; updated references.
10/15/09	Scheduled review; no change in position statement; updated references.
06/15/13	Revision: Position Statement revised regarding combination active cooling and compression (cryopneumatic) devices; Program Exceptions section updated; references updated.
11/15/15	Revision. Added coverage statement for active/passive heating devices. Revised HCPCS coding section. Updated references.
01/01/19	Annual CPT/HCPCS coding update. Revised descriptor E0218.
04/15/19	Scheduled review. Revised description, index terms, and program exceptions. Added coverage statement for scalp cooling devices. Updated references.
03/15/20	Scheduled review. Maintained position statement and updated references.
05/15/21	Scheduled review. Maintained position statement and updated references.

07/01/21	Quarterly CPT/HCPCS coding update. Added 0662T and 0663T.
09/15/22	Scheduled review. Added coverage statement for the use of scalp cooling caps. Updated references.
07/01/24	Quarterly CPT/HCPCS coding update. Added 0881T.
08/15/24	Scheduled review. Revised description, maintained position statement and updated references.
01/01/26	Annual CPT/HCPCS coding update. Added 97007, 97008, 97009. Deleted 0662T, 0663T.