

MEDICAL POLICY



SUBJECT: HYPERTHERMIA AS A CANCER TREATMENT	EFFECTIVE DATE: 05/18/00 REVISED DATE: 11/15/01, 09/19/02, 11/20/03, 09/16/04, 07/21/05, 05/18/06, 03/15/07, 07/17/14, 06/18/15, 05/25/16, 05/18/17, 05/17/18 (ARCHIVED DATE: 03/20/08, EDITED DATE: 03/19/09, 03/18/10, 03/17/11, 03/15/12, 03/21/13, 03/20/14)
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer reviewed literature, *superficial* hyperthermia has been medically proven to be effective and therefore, **medically appropriate** when used in combination with radiation therapy for the treatment of patients with the following:
 - A. Superficially recurrent melanoma;
 - B. Chest wall recurrence of breast cancer; or
 - C. Recurrent cervical lymph nodes from head and neck cancer.
- II. Based upon our criteria and assessment of peer-reviewed literature, the following forms of hyperthermia have not been medically proven to be effective and are considered **investigational**:
 - A. Interstitial hyperthermia;
 - B. Regional hyperthermia;
 - C. Regional perfusion hyperthermia (*Please see guidelines below related to requests for intraperitoneal hyperthermic chemotherapy combined with cytoreductive surgery*); and
 - D. Whole body hyperthermia.

Refer to Corporate Medical Policy #7.01.52 regarding Isolated Limb Perfusion/Infusion.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Refer to Corporate Medical Policy # 11.01.10 regarding Clinical Trials.

POLICY GUIDELINES:

- I. Requests for intraperitoneal hyperthermic chemotherapy combined with cytoreductive surgery should be reviewed for medical necessity as an inpatient surgical procedure using nationally recognized InterQual standards.
- II. The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Hyperthermia, a procedure in which body tissue is exposed to high temperatures (106-113 degrees F), is under investigation to assess its effectiveness in the treatment of cancer. Cancer cells differ from normal cells in their biochemical and biophysical response to heat. Hyperthermia damages the vascular structure of tumors, causes changes in cell membranes and affects the protein synthesis within the cell.

Hyperthermia can be administered using internal or external devices and is thought to be most effective when used in conjunction with other forms of cancer therapy such as chemotherapy, biological therapy or radiation therapy. When used in combination with chemotherapy or radiation therapy, hyperthermia inhibits the ability of cancer cells to repair radiation-induced damage. It also sensitizes certain types of cells that are normally resistant to radiation and

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chemotherapy. “Triple Therapy” is the combination of hyperthermia with both chemotherapy and radiation therapy. Hyperthermia does not cause any marked increase in chemotherapy or radiation side effects or complications.

- I. **Local Hyperthermia** refers to heat that is applied to a very small area, such as a tumor (site- specific). Local hyperthermia is limited to solid tumor cancers. The treatment area may be heated externally with high frequency waves aimed at a tumor from a device outside the body; or to achieve internal heating, one of several sterile probes may be used, including thin, heated wires or hollow tubes filled with warm water, implanted microwave antennae, and radiofrequency electrodes. Methods of heat application used in local hyperthermia include microwaves, interstitial radiofrequency, laser and ultrasound. Examples of the types of local hyperthermia (based on the location of heat application and method of heat application used) include:
 - A. **Surface or Superficial Hyperthermia** - specifically treats superficial tumors such a skin cancers and skin metastases; and
 - B. **Interstitial Hyperthermia** -Interstitial microwave hyperthermia and Interstitial nd:YAG laser hyperthermia involves the delivery of heat specifically to the tumor tissue (e.g., prostate, rectal tumor).

- II. **Regional Hyperthermia (RHT)** is used for treating specific areas of the patient’s body, such the pelvis, abdominal cavity or limbs. RHT utilizes multiple microwaves or ultrasound devices or applicators that deliver deep heat treatment that are used to create an increase in temperature of up to 42 degrees C in a reasonably large area around a tumor. Radiation therapy or chemotherapy is then administered. Regional Hyperthermia can be further delineated into Regional Perfusion Hyperthermia when the clinical application of heat is through a perfusion method. Examples of Regional Perfusion Hyperthermia include:
 - A. **Hyperthermic Antineoplastic Perfusion** - simultaneous delivery of an antineoplastic agent by perfusion with the application of hyperthermia; and
 - B. **Hyperthermic Isolated Limb Perfusion**- See Corporate Medical Policy #7.01.52 that separately addresses Isolated Limb Perfusion/Infusion.

- III. **Whole-body/Systemic Hyperthermia (WBH)** in which radiant heat is used to induce systemic temperatures of 41 degrees Centigrade. WBH is used to treat metastatic cancer that has spread throughout the body. It can be accomplished using warm-water blankets, hot wax, inductive coils (like those in electric blankets), thermal suits or thermal chambers, which are similar to large incubators or by heating blood delivered through a high-flow arteriovenous shunt (extracorporeal whole body hyperthermia). WBH is a complex, labor-intensive technique. The patient may require anesthesia and intubation and always requires careful monitoring. Thus, multiple sessions of WBH may be difficult to accomplish.

RATIONALE:

The Food and Drug Administration (FDA) has approved hyperthermia for use in the treatment of cancer when combined with radiation therapy for the palliative management of certain sold surface and subsurface malignant tumors that are progressive or recurrent despite conventional therapy. The BSD-500 device (BSD Medical Corporation) has FDA clearance for superficial heating (less than a 4 cm depth). Substantial clinical data exist demonstrating the efficacy of combined radiation and hyperthermia in the treatment of superficial tumors. The complete response rate of combined therapy has been reported at approximately 70%, compared to a response rate of 35% for radiotherapy alone. Toxicity (principally, thermal burns and blisters) is generally low (approximately 10%) and not treatment-limiting.

Studies investigating the clinical application of whole body, interstitial and regional hyperthermia combined with conventional treatment modalities (radiation, chemotherapy) in the treatment of multiple malignant diseases are numerous, but the studies have a small number of patients, lack standardized technique, are not randomized or controlled and lack long-term outcomes.

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CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	77600	Hyperthermia, externally generated, superficial (i.e., heating to a depth of 4 cm or less)
	77605 (E/I)	Hyperthermia, externally generated, deep (heating to depths greater than 4 cm)
	77610 (E/I)	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators
	77615 (E/I)	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators
	77620 (E/I)	Hyperthermia, generated by intracavity probe(s)

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HCPCS: No code(s)

ICD10:	C44.00-C44.99	Other and unspecified neoplasm of the skin (code range)
	C47.0-C47.9	Malignant neoplasm peripheral nerves (code range)
	C49.0-C49.9	Malignant neoplasm of connective and soft tissue (code range)
	C79.2	Secondary neoplasm of skin
	Other multiple diagnosis codes considered investigational	

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*key articles

KEY WORDS:

Extracorporeal whole body hyperthermia, Hyperthermia, Intraperitoneal hyperthermic perfusion, Local hyperthermia, Regional hyperthermia, Regional perfusion hyperthermia, Whole body hyperthermia.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for hyperthermia for treatment of cancer. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=66&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>