I. Policy: Hyperthermia in Cancer Therapy (e.g., HIPEC)

II. Purpose/Objective:
To provide a policy of coverage regarding Hyperthermia in Cancer Therapy (e.g., HIPEC)

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
According to the National Cancer Institute, research has shown that high temperature can damage and kill cancer cells usually with minimal injury to normal tissues. The treatment may also cause shrinkage of the tumor since the treatment kills cancer cells and damages protein within the cells. Hyperthermia is almost always used with other forms of cancer therapy, such as radiation therapy and chemotherapy. The goal of hyperthermia in cancer therapy is to produce tumor tissue temperatures above 41 degrees centigrade.

INDICATIONS:
1. Local or regional external hyperthermia when used in combination with radiation therapy may be considered medically necessary for the treatment of any of the following:
   a) primary or metastatic cutaneous or subcutaneous superficial tumors (lesions less than 3 cm from the surface); or
   b) Superficial recurrent melanoma (lesions less than 3 cm from the surface); or,
   c) locally advanced/recurrent breast cancer; or
   d) cervical lymph node metastases from head and neck cancer.
2. Regional hyperthermic melphalan isolated limb perfusion is considered to be medically necessary in individuals with Stage II and IIIA extremity melanoma.
3. HIPEC: Hyperthermic intraperitoneal chemotherapy (HIPEC) following cytoreductive surgery is considered medically necessary for the following indications in individuals meeting the following criteria:
   a) A diagnosis of:
      • pseudomyxoma peritonei (PMP), or
      • peritoneal carcinomatosis from colorectal cancer; or
      • diffuse malignant peritoneal mesothelioma
   b) no extraperitoneal disease spread, and
   c) a good performance status, and
   d) who can be predicted to achieve complete surgical cytoreduction,
4. Microwave, or radiofrequency ablation is considered medically necessary for members with primary and/or metastatic liver malignancies who are not candidates for open surgical resection when the following criteria are met:
   a. Diagnosis of hepatic metastases from a colorectal primary cancer or a hepatocellular cancer; and
   b. Isolated liver disease. and
   c. Medical documentation based on pre-operative imaging to support a reasonable expectation that all tumors in the liver would be potentially destroyed; and
   d. Medical documentation that the members is an unacceptable open surgical candidate because of:
      i. the location or extent of the liver disease; or
      ii. co-morbid conditions such that the member is unable to tolerate an open surgical resection; and
   e. Medical documentation showing that liver lesions are 4 cm or less in diameter and occupy less than 50 % of the liver parenchyma.

LIMITATIONS:
Members with nodal or extra-hepatic systemic metastases are not considered candidates for microwave or radiofrequency ablation.

EXCLUSIONS:
Local or regional external hyperthermia when used in combination with radiation therapy in lesions greater than 3 cm from the surface is considered experimental, investigational or unproven.

Local hyperthermia is considered experimental, investigational or unproven when used alone or in combination with chemotherapy.

Whole body hyperthermia therapy is considered experimental, investigational or unproven for all indications.

Hyperthermia in combination with radiation therapy for the treatment of chest wall recurrence of breast cancer is considered experimental, investigational or unproven due of insufficient evidence regarding its effectiveness in this condition.
Hyperthermia in combination with radiation therapy for the treatment of locally advanced prostate cancer is considered experimental, investigational or unproven due of insufficient evidence regarding its effectiveness in this condition.

Hyperthermic intrapleural chemotherapy for the treatment of intrapleural mesothelioma is considered to be experimental, investigational or unproven due of insufficient evidence regarding its effectiveness in this condition.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Hyperthermia in Cancer Therapy
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

77600 Hyperthermia, externally generated, superficial
77605 Hyperthermia, externally generated, deep
77610 Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators
77615 Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators
77620 Hyperthermia generated by intracavitary probe(s)


LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supercede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


National Coverage Determination (NCD) for Hyperthermia for Treatment of Cancer (110.1)


This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/20/2013

Reviewed: 10/14; 9/15, 10/16; 9/17, 9/18, 9/19