Local or Whole Body Hyperthermia
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00071
Original Effective Date: 06/24/2002
Archived Date: 08/15/2007

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.

When Services are Eligible for Coverage
Note: Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company considers local hyperthermia therapy when used in combination with radiation therapy for the treatment of patients with primary or metastatic cutaneous or subcutaneous superficial tumors to be eligible for coverage.

When Services are Considered Investigational
Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers local hyperthermia when used alone or in combination with chemotherapy to be investigational.*

Based on review of available data, the Company considers whole body hyperthermia therapy to be investigational.*

Background/Overview
Hyperthermia can be administered using local and whole body techniques. Local hyperthermia entails elevating the temperature of superficial or subcutaneous tumors while sparing surrounding normal tissue, using either external or interstitial modalities. Whole body hyperthermia requires the patient to be placed under either general anesthesia or deep sedation. The patient’s body temperature is increased to 108°F by packing the patient in heated (hot water) blankets. The elevated body temperature is maintained for a period of four hours, while the essential body functions are closely monitored. Approximately one hour is required for a “cooling off” period, after which the patient is constantly observed for a minimum of 12 hours. This modality has been variously termed “systemic thermotherapy” or “whole body hyperthermia.”

Rationale/Source
The use of hyperthermia as an adjunct to radiation or chemotherapy of superficial tumors has been an area of active investigation for the past 20 years, in part due to improvements in instrumentation and temperature monitoring technique, as well as an increasing understanding of the biology of hyperthermia. One of the first randomized trials of hyperthermia was reported by Overgaard, who randomized 71 patients with superficial melanoma to receive either radiation therapy or combined radiation and hyperthermia. The combined
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treatment group reported a 46% complete response rate compared to 28% in the radiation only group. In 1991, Perez and colleagues reported on the results of a study that randomized 236 patients with superficial tumors measuring less than 5 cm in thickness to receive either radiation alone, or radiation in conjunction with hyperthermia. The major endpoints for the study were the initial tumor response, its continuous control, and treatment delivery. The overall complete response rate was not different between the two groups (30%–32%). However, when the treatment comparisons were made by the size of the lesion in the patients with lesions <3 cm in diameter, the difference in local control was significantly better for patients assigned to the combined treatment group (52% vs. 39%). In 1996, the International Collaborative Hyperthermia Group reported on the outcomes of a trial that focused on hyperthermia treatment of superficial breast cancer. A total of 306 patients with advanced primary or recurrent breast cancer were randomized to receive either radiation therapy alone or combined radiation and hyperthermia therapy. The primary endpoint of the trial was complete local control; 59% of those in the combined treatment group achieved complete local response compared to 41% in the radiation therapy alone group. Similar to the findings of Perez, results were improved in patients with smaller lesions, as indicated by diameter or depth.

Other studies have reported conflicting results. For example, Emami and colleagues reported negative results in a study that randomized 173 patients with persistent or recurrent superficial tumors to receive either interstitial radiation therapy alone, or radiation combined with hyperthermia. In this study, the hyperthermia was administered interstitially, primarily as a technique to provide more uniform heat to the target lesion. There was no difference between the complete response rates in the two groups. The Radiation Trials Oncology Group (RTOG) has published guidelines outlining quality control criteria for adequate hyperthermia treatment. When the investigators compared these criteria to their data, they found that only one patient met the criteria for adequate hyperthermia sessions. The issue of quality assurance and reproducible parameters for delivering hyperthermia has been identified as an obstacle by other authors as well. Identification of the optimal parameters for hyperthermia have also been researched. The majority of the clinical trials describe eight to 12 hyperthermia regimens delivered twice weekly, or every 72 hours. These schedules recognize the phenomenon of thermotolerance, a transient resistance to subsequent heat treatment.

There are inadequate data to permit scientific conclusions regarding the use of whole body hyperthermia as an adjunct to either radiation or chemotherapy, and inadequate data regarding the use of local hyperthermia in conjunction with chemotherapy alone. A literature search of the MEDLINE database targeted at clinical articles published between 1995 and 2001 found citations describing technical feasibility studies and a few phase I and II studies, but there were no controlled studies reporting on patient outcomes. There were no studies identified that focused on the use of local hyperthermia with chemotherapy alone.

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Policy History
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06/11/2002 Medical Director review
06/20/2002 Medical Policy Committee review
06/24/2002 Managed Care Advisory Council approval. Format revision. No substance change to policy.
07/06/2004 Medical Director review
07/20/2004 Medical Policy Committee review. Format revision. No substance change to policy.
07/26/2004 Managed Care Advisory Council approval
08/03/2005 Medical Director review
08/16/2005 Medical Policy Committee review. Coverage eligibility unchanged
08/24/2005 Managed Care Advisory Committee review
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
09/06/2006 Medical Director review
09/20/2006 Medical Policy Committee approval. Coverage eligibility unchanged.
08/01/2007 Medical Director review
08/15/2007 Medical Policy Committee approval. Decision was made to archive this policy.

Next Scheduled Review Date: Archived Medical Policy

*Investigational – A medical treatment, procedure, drug, device, or biological product is investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination We make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:
A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other non-affiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

**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.

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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.

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.