

Whole Body Hyperthermia

Effective: October 1, 2023

Next Review: August 2024

Last Review: August 2023

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Hyperthermia can be administered using local and whole body techniques. The patient's body temperature is increased by packing the patient in heated blankets or by placing the patient in a cylinder constructed of copper tubing with circulating hot water. The elevated body temperature is maintained for a period of several hours and can be used for the treatment of malignancies.

MEDICAL POLICY CRITERIA

Notes: This policy only applies to whole body hyperthermia. This policy does not apply to local or regional hyperthermia which may be considered medically necessary.

Whole body hyperthermia therapy is considered **investigational** for all indications, including but not limited to the treatment of malignancies.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

Hyperthermia can be administered using local and whole body techniques. Whole body hyperthermia requires the patient to be placed under either general anesthesia or deep sedation. The patient's body temperature is increased to 41.8 degrees C by packing the patient in heated (hot water) blankets or by placing the patient in a cylinder constructed of copper tubing with circulating hot water. The elevated body temperature is maintained for a period of four hours while the essential body functions are closely monitored by an anesthesiologist. Approximately one hour is required for a "cooling off" period, after which the patient is constantly observed for a minimum of twelve hours. This modality has been variously termed "systemic thermotherapy" or "whole body hyperthermia."

EVIDENCE SUMMARY

WHOLE BODY HYPERTHERMIA

The initial body of evidence for whole body hyperthermia consisted of phase I and II clinical studies describing the technical feasibility of the procedure.^[1-5] More recent phase II studies describe use of the Aquatherm device, which produces radiant heat through circulating hot water in a cylinder constructed of copper tubing.^[6-9] The device includes a humidification system to eliminate evaporative heat losses during the treatment period. Patients are sedated for whole body hyperthermia, typically with intravenous thiopental and lidocaine. In addition, patients receive boluses of sedatives and antiemetics as needed.

Systematic Reviews

A systematic review (SR) by Liebl (2022) included 53 publications concerning 53 studies with 2006 patients.^[10] The authors concluded that there is no evidence of improvement in survival or quality of life in cancer patients receiving whole body hyperthermia and electro hyperthermia. Similar results were reported by another SR by Peeters (2022) that searched clinicaltrials.gov for all trials including hyperthermia and cancer registered between 2000 and 2020.^[11]

Van der Horst (2018) included 14 studies with 395 patients in his SR to evaluate the clinical benefit of regional, intraoperative, or whole body hyperthermia in pancreatic cancer patients.^[12] Only two studies utilized whole body hyperthermia in a total of 20 patients. The authors did not show separate results for the patients who received whole body hyperthermia. Additionally, the included studies are of low quality and future randomized trials with follow up are needed to determine efficacy.

Randomized Controlled Trials

Langhorst (2023) published an RCT comparing mild water-filtered infrared-A whole body hyperthermia to a sham hyperthermia treatment in patients with fibromyalgia.^[13] Of the 41 participants enrolled, 21 received whole body hyperthermia at 38.7 celsius for approximately 15 minutes and 20 received the sham treatment. The primary outcome was Brief Pain Inventory score at 4 weeks for which the authors reported a significant difference favoring the treatment group. A significant reduction in pain was also identified at 30 weeks follow-up. The study is limited by a small sample size and the lack of long-term follow-up.

Non-Randomized Trials

Westermann (2003) treated 108 patients with advanced progressive soft tissue sarcomas with whole body hyperthermia to a body temperature of 41.8 degrees centigrade followed by ifosfamide, carboplatin and etoposide (ICE).^[6] Of 95 patients available for evaluation, there were four complete responders and 23 partial responders for an overall response rate of 29%. The median overall survival based on Kaplan-Meier estimates was 393 days. The median time to treatment failure was 123 days. Eighty percent of patients developed grade III-IV neutropenia and 61% developed thrombocytopenia. Bakhshandeh (2003) treated 27 patients with stage III pleural mesothelioma with whole body hyperthermia followed by ICE.^[7] The two-year overall survival was 20%. Among those responding, the overall progression free survival was 29.6 weeks. Other preliminary phase I/II case series investigated treatment of a variety of malignancies with whole body hyperthermia combined with chemotherapy regimens appropriate to the malignancy; none of these studies reported long-term outcomes or survival data.^[8, 9, 14]

In summary, the published studies of whole body hyperthermia are primarily non-randomized case series in which patients were highly selected, and data on long term outcomes and survival were not available. Additional high-quality studies with long-term follow up are necessary to make conclusions about the safety and efficacy of whole body hyperthermia. Therefore, it is not possible to reach scientific conclusions concerning the effects of whole body hyperthermia on health outcomes, either alone or as an adjunct to radiation or chemotherapy.

PRACTICE GUIDELINE SUMMARY

None

SUMMARY

There is not enough research to show that whole body hyperthermia improves health outcomes when used for the treatment of malignancies. No clinical guidelines based on research recommend whole body hyperthermia for the treatment of patients with malignancies. Therefore, whole body hyperthermia is considered investigational for all indications, including but not limited to the treatment of malignancies.

REFERENCES

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CODES

| Codes | Number | Description |
|-------|--------|--|
| CPT | 77600 | Hyperthermia, externally generated; superficial (ie, heating to a depth of 4 cm or less) |
| | 77605 | Hyperthermia, externally generated; deep (ie, heating to depths greater than 4 cm) |
| | 77610 | Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators |

| Codes | Number | Description |
|--------------|---------------|---|
| | 77615 | Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators |
| | 77620 | Hyperthermia generated by intracavitary probe(s) |
| HCPCS | None | |

Date of Origin: August 2020