National Imaging Associates, Inc. *	
Clinical guideline: HYPERTHERMIA	**Original Date: November 2013**
CPT Codes: 77600, 77605, 77610, 77615, 77620	**Last Revised Date: January 2022**
Guideline Number: NIA_CG_227	**Implementation Date: January 2023**

INDICATIONS FOR HYPERTHERMIA WITH RADIATION THERAPY

- Superficially recurrent melanoma[1]
- Chest wall recurrence of breast cancer[2]
- Recurrent cervical lymph nodes from head and neck cancer[3]

FREQUENCY OF PROCEDURE

A maximum of ten (10) hyperthermia treatments may be delivered two times per week at 72 hour intervals.

CONTRAINDICATIONS FOR HYPERTHERMIA

- The use of intraluminal, endocavitary, interstitial, regional deep tissue hyperthermia exceeding 4 cm. in depth and whole body hyperthermia are considered *investigational*.
- There can not be any evidence of depth of tumor recurrence greater than 4 cm.
- There can be no evidence of metastatic disease for which systemic chemotherapy or hormonal therapy is planned or being given.

NOTE: Hyperthermia is not approvable when used alone or in conjunction with chemotherapy.

BACKGROUND

Hyperthermia in combination with radiation therapy has FDA approval[4] for the "palliative management of certain solid surface and subservice malignant tumors (i.e. melanoma, squamous or basal cell tumors, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional radiation therapy."[5] The National Cancer Center Network recommends the use of hyperthermia be limited to treatment centers with appropriate training, expertise, and equipment.[6]

OVERVIEW

(Adapted from the National Cancer Institute[7])

* National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.

Hyperthermia is a treatment for cancer in which body tissue is exposed to high temperatures. Research has shown that hyperthermia can damage and kill cancer cells in some circumstances when it is used with radiation therapy.

Local Hyperthermia - Heat is applied to a small area only. Local hyperthermia is typically administered every 72 hours (i.e., twice a week) for a total of 10 to 12 treatments using applicators that are placed close to, or in, the tumor. Local hyperthermia can be administered using various techniques: external, intraluminal or endocavitary, and interstitial.

- **External Hyperthermia** - This technique is used for cancers that are on, or just below, the skin. The tumor is heated externally using applicators that are placed on, or near to, the affected area. Heat is then applied using high-frequency energy waves generated from a device outside the body (such as a microwave or ultrasound).
- **Intraluminal or Endocavitary Hyperthermia** - This technique may be used to treat cancers that are within or near to body cavities. A sterile probe that can be heated is placed inside the cavity where the tumor is. This heats the affected area.
- **Interstitial Hyperthermia -** This is used to treat tumors that are deep within the body. Under anesthetic, probes or wires are placed within the tumor tissue and then heated. This method allows tumors to be heated to a higher temperature than external techniques.

Regional Hyperthermia - Various approaches may be used to heat large areas of tissue, such as a body cavity, organ, or limb. This includes **all** of the following:

- **Deep Tissue** - This may be used to treat cancers within the body, such as cervical or bladder cancer. External applicators are positioned around the body cavity or organ to be treated, and microwave or radiofrequency energy is focused on the area to raise its temperature.
- **Regional perfusion** - In this procedure, some of the patient's blood is removed, heated, and then perfused back into the limb or organ.
- **Continuous hyperthermic peritoneal perfusion (CHPP)** - This is a technique used to treat cancers within the peritoneal cavity. During surgery, heated chemotherapy drugs flow from a warming device through the peritoneal cavity. The peritoneal cavity temperature reaches 106–108°F.

Whole-body hyperthermia - used to treat metastatic cancer. This can be accomplished by several techniques that raise the body temperature to 107–108°F, including the use of thermal chambers or hot water blankets.

Additional Terminology:
Hyperthermia is also called thermal therapy or thermotherapy.

POLICY HISTORY

Date	Summary
January 2022	No significant changes
February 2021	No Changes
February 2020	No Changes
February 2019	Added and updated references

REFERENCES

1. Overgaard J, Gonzalez Gonzalez D, Hulshof MC, et al. Randomised trial of hyperthermia as adjuvant to radiotherapy for recurrent or metastatic malignant melanoma. European Society for Hyperthermic Oncology. *Lancet*. Mar 4 1995;345(8949):540-3. doi:10.1016/s0140-6736(95)90463-8
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Breast Cancer Version 1.2022. National Comprehensive Cancer Network (NCCN). Updated November 24, 2021. Accessed December 10, 2021. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
3. Huilgol NG, Gupta S, Sridhar CR. Hyperthermia with radiation in the treatment of locally advanced head and neck cancer: a report of randomized trial. *J Cancer Res Ther*. Oct-Dec 2010;6(4):492-6. doi:10.4103/0973-1482.77101
4. H090002: Conditions of Approval For An HDE. HUD and HDE for BSD-2000. . Food and Drug Administration; Department of Health and Human Services (HHS). Updated November 18, 2011. Accessed December 10, 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf9/H090002a.pdf
5. Eldridge L, Paul D. What is Hyperthermia for Cancer Treatment? Verywell Health. Updated May 12, 2021. Accessed December 10, 2021. https://www.verywellhealth.com/hyperthermia-and-cancer-5076038
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Breast Cancer Version 1.2018. National Comprehensive Cancer Network (NCCN). Accessed May 1, 2018. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
7. National Cancer Institute. Hyperthermia in Cancer Treatment. National Institutes of Health. Updated June 17, 2021. Accessed December 13, 2021. https://www.cancer.gov/about-cancer/treatment/types/hyperthermia

ADDITIONAL RESOURCES

1. American Cancer Society. Hyperthermia to Treat Cancer. Updated May 3, 2016. Accessed October 13, 2021. https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/hyperthermia.html
2. American College of Radiology, American Society for Radiation Oncology. ACR-ASTRO practice parameter for radiation oncology. American College of Radiology. Updated 2018. Accessed December 13, 2021. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/radonc.pdf
3. Bath C. Using Hyperthermia for Cancer Treatment: Proofs, Promises, and Uncertainties. HSP News Service, LLC. Updated January 15, 2014. Accessed December 13, 2021. https://ascopost.com/issues/january-15-2014/using-hyperthermia-for-cancer-treatment-proofs-promises-and-uncertainties/
4. Centers for Medicare & Medicaid Services. NCD 110.1: Hyperthermia for Treatment of Cancer. Accessed December 13, 2021. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=66&ncdver=1&bc=AAAAEAAAAAAA&
5. Dooley WC, Vargas HI, Fenn AJ, Tomaselli MB, Harness JK. Focused microwave thermotherapy for preoperative treatment of invasive breast cancer: a review of clinical studies. *Ann Surg Oncol*. Apr 2010;17(4):1076-93. doi:10.1245/s10434-009-0872-z

6. Feldman AL, Libutti SK, Pingpank JF, et al. Analysis of factors associated with outcome in patients with malignant peritoneal mesothelioma undergoing surgical debulking and intraperitoneal chemotherapy. *J Clin Oncol*. Dec 15 2003;21(24):4560-7. doi:10.1200/jco.2003.04.150
7. Gardner RA, Vargas HI, Block JB, et al. Focused microwave phased array thermotherapy for primary breast cancer. *Ann Surg Oncol*. May 2002;9(4):326-32. doi:10.1007/bf02573866
8. Hildebrandt B, Wust P, Ahlers O, et al. The cellular and molecular basis of hyperthermia. *Crit Rev Oncol Hematol*. Jul 2002;43(1):33-56. doi:10.1016/s1040-8428(01)00179-2
9. Jones EL, Oleson JR, Prosnitz LR, et al. Randomized trial of hyperthermia and radiation for superficial tumors. *J Clin Oncol*. May 1 2005;23(13):3079-85. doi:10.1200/jco.2005.05.520
10. Linthorst M, van Rhoon GC, van Geel AN, et al. The tolerance of reirradiation and hyperthermia in breast cancer patients with reconstructions. *Int J Hyperthermia*. 2012;28(3):267-77. doi:10.3109/02656736.2012.663951
11. Müller AC, Eckert F, Heinrich V, Bamberg M, Brucker S, Hehr T. Re-surgery and chest wall re-irradiation for recurrent breast cancer: a second curative approach. *BMC Cancer*. May 25 2011;11:197. doi:10.1186/1471-2407-11-197
12. Oldenborg S, Van Os RM, Van rij CM, et al. Elective re-irradiation and hyperthermia following resection of persistent locoregional recurrent breast cancer: A retrospective study. *Int J Hyperthermia*. 2010;26(2):136-44. doi:10.3109/02656730903341340
13. BSD-2000 Deep Regional Hyperthermia. Pyrexar Medical. Updated 2021. Accessed December 13, 2021. https://www.pyrexar.com/hyperthermia/bsd-2000
14. BSD-500 Superficial Hyperthermia. Pyrexar Medical. Updated 2021. Accessed December 13, 2021. https://www.pyrexar.com/hyperthermia/bsd-500
15. Singletary SE. Minimally invasive ablation techniques in breast cancer treatment. *Ann Surg Oncol*. May 2002;9(4):319-20. doi:10.1007/bf02573863
16. van der Zee J. Heating the patient: a promising approach? *Ann Oncol*. Aug 2002;13(8):1173-84. doi:10.1093/annonc/mdf280
17. Vargas HI, Dooley WC, Gardner RA, et al. Focused microwave phased array thermotherapy for ablation of early-stage breast cancer: results of thermal dose escalation. *Ann Surg Oncol*. Feb 2004;11(2):139-46. doi:10.1245/aso.2004.03.059
18. Vernon CC, Hand JW, Field SB, et al. Radiotherapy with or without hyperthermia in the treatment of superficial localized breast cancer: results from five randomized controlled trials. International Collaborative Hyperthermia Group. *Int J Radiat Oncol Biol Phys*. Jul 1 1996;35(4):731-44. doi:10.1016/0360-3016(96)00154-x
19. Vlastos G, Verkooijen HM. Minimally invasive approaches for diagnosis and treatment of early-stage breast cancer. *Oncologist*. Jan 2007;12(1):1-10. doi:10.1634/theoncologist.12-1-1
20. Wust P, Hildebrandt B, Sreenivasa G, et al. Hyperthermia in combined treatment of cancer. *Lancet Oncol*. Aug 2002;3(8):487-97. doi:10.1016/s1470-2045(02)00818-5
21. Zagar TM, Higgins KA, Miles EF, et al. Durable palliation of breast cancer chest wall recurrence with radiation therapy, hyperthermia, and chemotherapy. *Radiother Oncol*. Dec 2010;97(3):535-40. doi:10.1016/j.radonc.2010.10.020
22. Zhao Z, Wu F. Minimally-invasive thermal ablation of early-stage breast cancer: a systemic review. *Eur J Surg Oncol*. Dec 2010;36(12):1149-55. doi:10.1016/j.ejso.2010.09.012

Reviewed / Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.