Hyperthermia for Treatment of Cancer



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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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Hyperthermia for Treatment of Cancer

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NCD Hyperthermia for Treatment of Cancer	110.1		
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Description

Hyperthermia treatment involves exposing body tissues to high temperatures of up to 113°F using various heating methods. Hyperthermia may be used with other treatments (eg, chemotherapy, radiation) in order to kill cancer cells and shrink tumors with little or no harm to normal tissue.

Local hyperthermia confines the treatment to a small area, such as a tumor. Various methods to deliver local hyperthermia may be used, which include heated probes, lasers, needles, or ultrasound. High-energy water vapor thermotherapy is also being investigated for the treatment of malignancies of the prostate; however, at this time it appears to only be utilized for benign prostatic hyperplasia (BPH).

Approaches to local hyperthermia include:

- **External** Used to treat tumors that are near the body surface in which external applicators are placed around or near the appropriate region and energy is focused on the tumor to raise the temperature.
- Interstitial Used to treat tumors deep within the body (eg, brain tumors) where probes or needles are inserted into the tumor under anesthesia and heated to higher temperatures than external techniques.
- Intracavity (also called intraluminal) Used to treat tumors within body cavities (eg, esophagus, prostate) by placing probes inside the cavity to deliver energy and heat to the tumor.
- Laser Used to treat tumors by utilizing laser light to raise the temperature of the tumor cells to damage or destroy them. Examples of this procedure include, but may not be limited to, magnetic resonance imaging (MRI) guided laser ablation and MRI guided laser interstitial thermal therapy (LITT).
- Magnetic nanoparticle hyperthermia —Used to purportedly cause cell death within a tumor.
 Nanoparticles injected into the tumor or delivered to the tumor via an intravenous solution are exposed to heat either by changing the magnetic polarity of the nanoparticles (eg, MagForceAG) or by utilizing near-infrared light that is targeted to the lesion (AuroLase). At this time, there are no US Food & Drug Administration (FDA) approved devices for this treatment.
- Ultrasound Used to destroy tumor tissue by utilizing sound energy to generate heat. Typically, high intensity focused ultrasound (HIFU) is used and is being investigated for various cancers (eg, hepatocellular, palliative treatment of pain associated with bone metastases, prostate). In regard to use for prostate cancer, ultrasound therapy purportedly may be delivered by either using a transrectal or a transurethral approach (eg, transurethral ultrasound ablation [TULSA]). Either approach may utilize magnetic resonance (MR) and/or real-time imaging to guide treatment. FDA-approved HIFU devices (eg, Sonablate) have been indicated for the destruction of prostate tissue; however, they have not been approved specifically for the treatment of prostate cancer. An example of a HIFU device that is under study for treatment of prostate cancer is the Exablate prostate system. Histotripsy, which may also be

known as robotically assisted sonic therapy (RAST) (eg, **HistoSonics**), is being investigated to provide nonthermal ablation via ultrasound. The technology utilizes short microsecond bursts of ultrasound energy to mechanically create microbubbles in the gas of the extracellular matrix of tissues (also known as acoustic cavitation). Reportedly, the expansion and collapse of the microbubbles mechanically destroys targeted tissues. There are no FDA approved devices to deliver histotripsy at this time.

Regional hyperthermia treats large areas of tissue, such as a body cavity or organ. It is usually combined with chemotherapy or radiation therapy.

Approaches to regional hyperthermia include:

- **Deep tissue** May be utilized to treat cancers within the body. External applicators are placed around the body cavity or organ to be treated and energy is focused on the area to raise the temperature.
- **Hyperthermic intraperitoneal chemotherapy (HIPEC)** Used in treatment along with surgery for cancers in the peritoneum (space that contains the intestines and other digestive organs). During surgery, heated chemotherapy drugs are circulated through the peritoneal cavity.
- Isolated limb infusion (ILI)/perfusion (ILP) Used to treat in-transit metastases that occur in the upper and lower limbs of the body. ILI is less invasive and uses smaller catheters to infuse the chemotherapy into the main artery and vein, while a tourniquet blocks blood flow between the affected limb and the rest of the body. ILP involves the placement of catheters in the limb's main artery and vein to create an arterio-venous loop, followed by circulation in the limb of high-dose chemotherapy, which is often heated.

Whole-body hyperthermia is reportedly used to treat metastatic cancer that has spread throughout the body. It can be performed using warm water blankets, inductive coils (like those in electric blankets) or thermal chambers (similar to large incubators).

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for **hyperthermia treatment for cancer**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Hyperthermia for Treatment of Cancer

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically

necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
36823	Insertion of arterial and venous cannula(s) for isolated extracorporeal circulation including regional chemotherapy perfusion to an extremity, with or without hyperthermia, with removal of cannula(s) and repair of arteriotomy and venotomy sites	
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	
55899	Unlisted procedure, male genital system	
64999	Unlisted procedure, nervous system	
76999	Unlisted ultrasound procedure (eg, diagnostic, interventional)	
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	
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators	
77620	Hyperthermia generated by intracavitary probe(s)	
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter	
96547	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when	

	performed; first 60 minutes (List separately in addition to code for primary procedure)	
96548	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes (List separately in addition to code for primary procedure)	
96549	Unlisted chemotherapy procedure	
CPT® Category III Code(s)	Description	Comments
0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance	
0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	
0738T	Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination	
0739Т	Ablation of malignant prostate tissue by magnetic field induction, including all intraprocedural, transperineal needle/catheter placement for nanoparticle installation and intraprocedural temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation	
HCPCS Code(s)	Description	Comments
C9790	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	

References

1. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Hyperthermia for treatment of cancer (110.0). https://www.cms.gov. Published December 31, 1984. Accessed October 31, 2023.

Change Summary

- 01/01/2024 New Policy.