

Heating Pads – Response to Comments

1. Topical heat therapy is beneficial for a variety of medical conditions.

Response: We agree that topical heat provides symptomatic improvement for various conditions. The medical policy does provide coverage for heating pads.

2. Water circulating heat pads should not be categorically downcoded.

Response: We disagree. The medical directors did not find published clinical studies that identified significantly improved outcomes with the use of water circulating heat pads compared to standard heat pads.

CMS has instructed contractors that effective for claims with dates of service on or after February 4, “downcoding” – i.e., payment based on the least costly medically appropriate alternative (LCA) – is no longer permissible. Therefore, the determination for water circulating heat pads has been changed from partial payment based on LCA to a complete denial.

3. Water circulating heat pads are safer than electric heating pads because they have better temperature controls.
 - There are multiple reports of electric heating pads causing skin burns. Risk for burns is a function of surface temperature and duration of use. Risk is particularly high in older adults.
 - Temperature limits of water circulating heat pads allows them to be used for prolonged periods of time – i.e., many hours.
 - Temperature limits of water circulating heat pads allows the patient to lie on the pad.
 - Water circulating heat pads have better temperature controls (e.g., multiple thermostats, alarms) than electric heating pads.
 - Water circulating heat pads can be used by patients with diabetes because of the lower temperatures.

Response: Complications are possible if any medical device is not used correctly. In order to be covered by Medicare, heating pads must be ordered by a physician. As part of the order, physicians must provide instructions to beneficiaries concerning appropriate use of the device.

4. There are no electric heating pads currently on the market that have a maximum temperature limit of 105.8° as specified in the draft Policy Article.

Response: That requirement has been removed from the Policy Article.

5. Water circulating heat pads are safer than electric heating pads because their electrical systems meet various standards established by ASTM International, Underwriters Laboratories, or the International Electrotechnical Commission (IEC).
- There are multiple reports of electric shocks or fires caused by electric heating pads.
 - Meeting established products standards decreases the risk of fires.
 - Many electric heating pads are not certified by at least one of these organizations.
 - Folding electric heating pads can cause problems with wires in the pads. This is not an issue with water circulating heat pads.

Response: We have added a requirement that in order to be covered, a heating pad must be certified by Underwriters Laboratories.

6. An FDA Public Health Advisory states that heating pads should not be used near oxygen equipment.

Response: Any electrical device has a potential risk when used in an oxygen-enriched environment. That would also apply to water circulating heating pads.

7. FDA 510(k) clearance helps to assure that products are safe and effective.
- Most water circulating heat pads have 510(k) clearance.
 - Electric heating pads are not required to have FDA 510(k) clearance.

Response: The process of obtaining 510(k) clearance does not address the safety and effectiveness of individual devices. Our requirement for compliance with safety standards established by Underwriters Laboratories does address this issue.

8. Low level prolonged heat is more beneficial than short duration high heat for many chronic conditions. This can be accomplished with water circulating heat pads, but not with electric heating pads.

Response: No medical literature was provided to support this statement.

9. Providing compression in wraps used on extremities adds to the benefit of heat therapy.

Response: No medical literature was provided to support this statement.