

1 **Clinical Practice Guideline:** **Superficial Heat and Cold**

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3 **Date of Implementation:** **June 16, 2016**

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5 **Product:** **Specialty**

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Related Policies:
 CPG 121: Passive Physiotherapy Modalities
 CPG 135: Physical Therapy Medical Policy/Guideline
 CPG 155: Occupational Therapy Medical Policy/Guideline

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11 **GUIDELINES**

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I. A. ASH considers the proper application of hot or cold packs performed with other therapeutic procedures to be clinically appropriate for many patients with musculoskeletal disorders who have reported pain, edema, inflammation or documented loss of mobility. The use of hot or cold packs as stand-alone treatments is rarely therapeutic, and thus not required or indicated as the sole treatment approach to a patient’s condition.

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B. Circulating and noncirculating cooling devices, with or without compression, used in the outpatient setting are considered not medically necessary.

22 **Notes Related to Guidelines**

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- The stand-alone application of hot or cold packs does not typically require the skills of a licensed health care professional and can be safely self-administered in accordance with provider instructions.
 - Services which do not require the skills of a licensed health care professional are considered not medically necessary.
- Cold and heat are believed to have therapeutic benefits to modify the disease processes (e.g., cold to reduce acute inflammation and swelling, and heat to speed healing through increased blood supply).
- Typical use involves application of cold for the first few days after onset of symptoms and thereafter application of heat.
- Use of ice packs and various bandages and wraps following surgery or musculoskeletal and soft tissue injury is common. It is medically reasonable to use hot/cold therapy for any musculoskeletal disorder, in which there may be inflammation (e.g., strains, sprains, tendinitis, tenosynovitis, contusions, fractures, epicondylitis, carpal tunnel syndrome, and osteoarthritis), or post-surgery.
 - The standard postoperative treatment for musculoskeletal surgeries consists of cryotherapy (cold therapy) and various types of compressive wraps. Both ice packs (with or without additives to maintain temperature) and cooling devices

1 can provide cryotherapy. Circulating cooling devices are designed to provide a
 2 constant low temperature, which might provide additional benefit compared
 3 with the more variable temperature achieved with the intermittent replacement
 4 of ice packs. Noncirculating cooling devices might also allow less variable
 5 cooling due to the larger volume of ice stored in the insulated tank and the use
 6 of circulated ice water.

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 8 II. ASH considers use of paraffin baths as medically necessary when ALL of the
 9 following criteria are met:

- 10 • Treatment of pain and/or limited mobility of the distal extremities (hands and feet)
 11 (e.g., non-acute, chronic, or post-traumatic inflammatory conditions such as
 12 arthritis); and
- 13 • Applied prior to performance of a primary therapeutic procedure designed to
 14 increase mobility which enhances the ability to perform usual activities of daily
 15 living (e.g., combined with therapeutic exercise or manual therapy for a patient who
 16 has reported pain and/or documented limited mobility); and
- 17 • Patient is free of contraindications; and
- 18 • Documentation of a reduction in the patient's pain and/or an improved mobility and
 19 ability to perform age-appropriate usual activities of daily living within the initial
 20 stages of treatment (i.e., 3 weeks).

21
 22 **Notes Related to Guidelines**

23 Modalities chosen to treat the patient's symptoms/conditions should be selected based on
 24 the most effective and efficient means of achieving the patient's functional goals. Seldom
 25 should a patient require more than one (1) or two (2) modalities to the same body part
 26 during the therapy session. Use of more than two (2) modalities on each visit date is unusual
 27 and should be justified in the documentation.

28
 29 The use of modalities as stand-alone treatments is rarely therapeutic, and thus not required
 30 or indicated as the sole treatment approach to a patient's condition. The use of exercise and
 31 activities has proven to be an essential part of a therapeutic program. Therefore, a treatment
 32 plan should not consist solely of modalities, but should also include therapeutic procedures.
 33 (There are exceptions, including wound care or when patient care is focused on modalities
 34 because the acute patient is unable to endure therapeutic procedures.) Use of only passive
 35 modalities that exceeds 4 visits should be very well supported in the documentation.

36
 37 Multiple heating modalities should not be used on the same day. Exceptions are rare and
 38 usually involve musculoskeletal pathology/injuries in which both superficial and deep
 39 structures are impaired. Documentation must support the use of multiple modalities as
 40 contributing to the patient's progress and restoration of function.

1 When the symptoms that required the use of certain modalities begin to subside and
 2 function improves, the medical record should reflect the discontinuation of those
 3 modalities, so as to determine the patient's ability to self-manage any residual symptoms.
 4 As the patient improves, the medical record should reflect a progression of the other
 5 procedures of the treatment program (therapeutic exercise, therapeutic activities, etc.). In
 6 all cases, the patient and/or caregiver should be taught aspects of self-management of
 7 his/her condition from the start of therapy.

8
 9 The use of superficial heat and cold modalities with pediatric patients is contraindicated if
 10 the patient cannot provide the proper feedback necessary for safe application.

11 CPT CODES AND DESCRIPTIONS

12 (HCPCS codes for DME are not relevant to this CPG)*

CPT Code	Description
97010	Application of a modality to 1 or more areas; hot or cold packs
97018	Application of a modality to 1 or more areas; paraffin bath

14 *Fluidized Therapy does not have a specific CPT code

15 NOTE: It is not appropriate to bill for vasopneumatic device CPT code 97016 for use of
 16 any circulating and noncirculating cooling devices with compression for purposes of
 17 superficial cold application.

18 BACKGROUND AND DESCRIPTION

19 Cryotherapy is the therapeutic use of cold in a superficial manner. In rehabilitation settings,
 20 it is used to control pain and inflammation, edema, reduce spasticity and to facilitate
 21 movement (Cameron, 2022). Cryotherapy influences hemodynamic, neuromuscular and
 22 metabolic systems. Initially vasoconstriction occurs (first 15-20 minutes) followed by
 23 vasodilation if the cold is applied for longer periods of time or when the tissue temperature
 24 reaches less than 10 degrees Celsius. Cold application also decreases nerve conduction
 25 velocity, increases pain threshold and may also alter muscle strength. Cryotherapy has also
 26 been shown to reduce spasticity temporarily (Cameron, 2022). Both conventional
 27 cryotherapy and the passive cooling devices are essentially designed to provide cold
 28 therapy, with the primary difference being that water recirculation is more convenient with
 29 passive cooling devices. Examples of passive cold therapy units are those devices in which
 30 fluid flows through a blanket or cuff, providing immediate cooling to an affected area. The
 31 CryoCuff® uses an insulated jug filled with cold water attached to a cuff. Elevating the jug
 32 fills and pressurizes the cuff. Compression is controlled by gravity and is proportional to
 33 the elevation of the cooler. When body heat warms the water, it is re-chilled simply by
 34 lowering the cooler. Another passive cold compression therapy unit is the Polar Care Cub
 35

1 unit. In contrast, active cooling devices are designed to provide a steady low temperature,
 2 which might provide a unique benefit compared to the more variable temperature achieved
 3 with ice packs or passive cooling devices. These more complicated cold therapy units may
 4 employ mechanical pumps and refrigerators that are powered by battery or electricity. The
 5 Game Ready™ Accelerated Recovery System is an example of an active cooling device
 6 that combines cold and intermittent pneumatic compression therapies. The system consists
 7 of a wrap, a connector hose, and a control unit. The wrap contains two internal chambers,
 8 one for air and the other for cooling water. The microprocessor control unit features various
 9 adjustable compression cycles and temperature controls. Another active system is the
 10 AutoChill® device, which may be used with a CryoCuff®, consists of a pump that
 11 automatically exchanges water from the cuff to the cooler, eliminating the need for manual
 12 water recycling. The Hot/Ice Thermal Blanket is another circulating cooling device. It
 13 consists of 2 rubber pads connected by a rubber hose to the main cooling unit. Fluid is
 14 circulated via the hose through the thermal blankets. The temperature of the fluid is
 15 controlled by the main unit and can be either hot or cold. The Hilotherm® Clinic circulates
 16 cooled water through preshaped thermoplastic polyurethane facial masks for use after
 17 different types of facial surgery. ThermaZone® provides thermal therapy with pads
 18 specific to various joints as well as different areas of the head (front, sides, back, eyes).
 19 CTM™ 5000 and cTreatment are computer-controlled devices that provide cooling at a
 20 specific (11°C, or 52°F) and continuous temperature. However, there is no evidence that
 21 these more complicated cold therapy units provide any additional benefit over the
 22 CryoCuff or conventional ice bags or packs.

23 24 **Contraindications and Precautions**

25 The use of cryotherapy is contraindicated for the following:

- 26 • Cold hypersensitivity
- 27 • Cold intolerance
- 28 • Cryoglobulinemia
- 29 • Paroxysmal cold hemoglobinuria
- 30 • Raynaud disease or phenomenon
- 31 • Over regenerating peripheral nerves
- 32 • Over an area with circulatory compromise or peripheral vascular disease

33
34 Precautions for cryotherapy include:

- 35 • Over the superficial branch of a nerve
- 36 • Over an open wound
- 37 • Hypertension
- 38 • Impaired or insufficient sensation or mentation

1 Thermotherapy is the application of superficial heat. Within the rehabilitation environment,
2 superficial heat is used to control pain, increase soft tissue extensibility and circulation,
3 and accelerate healing. It also has hemodynamic, neuromuscular and metabolic effects.
4 Heat causes vasodilation with resultant increases in blood flow. Superficial heat agents do
5 not heat to the level of most muscle tissue. Deep heating modalities such as ultrasound or
6 diathermy are used for that purpose. Increased tissue temperature increases nerve
7 conduction velocity and firing rates. Some studies have also found that heat will increase
8 pain thresholds and reduce muscle strength (initial 30 minutes following heat application).
9 Heat will also increase the metabolic rate, thus any heating agents should be avoided or
10 used with caution in patients with acute inflammation (Cameron, 2022).

11
12 Hot packs, also known as hydrocollator packs, warm tissue by conduction. They typically
13 consist of canvas bags filled with silicon dioxide that absorbs many times its own weight
14 in water. Hot packs are immersed in a hot water bath, and are removed from the bath when
15 needed, wrapped in 6 to 8 layers of toweling or an insulating cover, and applied to the
16 patient. They are often used to heat the body part prior to rehabilitation/therapy. To avoid
17 scalding, excess water should be drained from the pack and the covering towels or pad
18 should be checked for excessive dampness. The packs cool slowly and can remain warm
19 for 30 or more minutes. Medicare considers hydrocollator units as non-covered
20 institutional equipment. Air-activated wearable heat wraps are another form of superficial
21 heat that are commercially available and can be worn for up to 8 hours. They are made of
22 cloth embedded with multiple discs made of iron powder, activated charcoal, sodium
23 chloride and water. When the wrap is removed from the plastic and exposed to oxygen, the
24 discs oxidize producing an exothermic reaction and thus heat. General indications for
25 therapeutic heat include pain, muscle spasm, contracture, tension myalgia, hematoma
26 resolution, bursitis, tenosynovitis, fibrositis, fibromyalgia, superficial thrombophlebitis,
27 and collagen vascular diseases.

28
29 A paraffin bath is a modality designed to apply heat to the hands or feet through the use of
30 paraffin wax. Paraffin baths are a device that delivers heat to a distal extremity by the use
31 of melted paraffin and mineral oil, for the purpose of treating the extremity by creating a
32 transient tissue temperature rise through heat conduction. Paraffin baths are primarily used
33 to treat contractures or loss of mobility, particularly for patients with osteoarthritis,
34 rheumatoid arthritis, hand contractures, or scleroderma. It can be used post surgically as
35 well once surgical incisions are healed. It is applied prior to performing other therapeutic
36 procedures designed to increase mobility which enhances the ability to perform usual
37 activities of daily living. The typical paraffin bath consists of a container filled with
38 approximately a 1:7 mixture of mineral oil and paraffin maintained at 52°C to 54°C. The
39 patient may either continuously immerse the treated part for 20 to 30 mins or may
40 repetitively dip and remove the treated area from the paraffin.

1 Fluidized therapy (fluidotherapy) is a high intensity heat modality consisting of a dry
 2 whirlpool of finely divided solid particles suspended in a heated air stream, the mixture
 3 having the properties of a liquid. It heats via convection. Warm air is circulated through
 4 the bottom of a bed of finely divided cellulose particles in a container. The combination of
 5 air flowing around the high surface area of the finely divided particles and the bulk
 6 movements of solids produces high heat fluxes and uniform temperatures throughout thus
 7 providing a strong massaging action, sensory stimulation and levitation. Both temperature
 8 and amount of agitation can be adjusted. Temperatures for intervention typically range
 9 from 102° F to 118° F. The lower ranges are recommended for patients with edema
 10 formation and are used in the initial treatments. Patients can also do exercises while they
 11 are using fluidized therapy. The indications for fluidized therapy are similar to paraffin
 12 baths and whirlpool. Use of fluidized therapy dry heat is an acceptable alternative to other
 13 heat therapy modalities in reducing pain, edema, and muscle spasm from acute or subacute
 14 traumatic or non-traumatic musculoskeletal disorders of the extremities.

15
 16 **Contraindications and Precautions**The use of thermotherapy is contraindicated for the
 17 following:

- 18 • Recent or potential hemorrhage
- 19 • Thrombophlebitis
- 20 • Impaired sensation
- 21 • Impaired mentation
- 22 • Malignant tumor
- 23 • IR irradiation of the eyes

24
 25 Precautions for use of thermotherapy include:

- 26 • Acute injury or inflammation
- 27 • Pregnancy
- 28 • Impaired circulation
- 29 • Poor thermal regulation
- 30 • Edema
- 31 • Cardiac insufficiency
- 32 • Metal in the area
- 33 • Over an open wound
- 34 • Over areas where topical counterirritants have recently been applied
- 35 • Demyelinated nerve

36 37 **EVIDENCE AND RESEARCH**

38 **Cryotherapy and Hydrocollator Packs**

39 The Philadelphia Panel Practice Guidelines did not support the use of thermotherapy for
 40 knee pain (Philadelphia Panel Practice Guidelines, 2001). Brosseau et al. reviewed the

1 literature on thermal modalities for the treatment of knee osteoarthritis (Brosseau et al.,
2 2003). Three RCTs met their inclusion criteria. A study by Yurtkuran and Kocagil found
3 that ice massage administered for 20 minutes, five days a week for two weeks led to
4 significant improvements in quadriceps strength, gait speed, and knee flexion compared to
5 a placebo control (Yurtkuran and Kocagil, 1999). Only quad strength changes (29%
6 improvement) met the Cochrane reviews threshold of 20% difference for clinical
7 significance. A study by Hecht for patients post total knee arthroplasty showed that cold
8 packs administered over the course of 10 visits significantly reduced swelling compared to
9 hot packs or a control group (Hecht et al., 1983).

10
11 A Cochrane review by Robinson et al. (2002) for patients with rheumatoid arthritis
12 identified seven RCTs that examined the effectiveness of thermal modalities. They found
13 no significant effects on pain or secondary outcomes in any of the seven studies. Modalities
14 covered in the review included various forms of cryotherapy (four studies), heat application
15 (three studies), and paraffin bath (two studies). Methodological problems included the lack
16 of standardized outcomes, lack of blinding, and confounding influence of concurrent
17 treatments. The Ottawa Panel Evidence-Based Clinical Practice Guidelines reviewed the
18 available literature for the effectiveness of thermotherapy for rheumatoid arthritis and
19 concluded that hot wax plus exercise was more effective than a control treatment for
20 increasing finger mobility (Ottawa Panel Evidence-Based Clinical Practice Guidelines,
21 2004). There were also “clinically important” improvements in pain and stiffness that did
22 not reach statistical significance, suggesting the study was underpowered (n=13 per group).

23
24 In a review of the evidence for the treatment of LBP, Chou and Huffman (2007) found that
25 superficial heat was effective in the treatment of acute LBP (good evidence with moderate
26 benefit). No evidence supported its use for chronic LBP. In another Cochrane
27 Collaboration systematic review (French et al., 2006), superficial heat or cold was assessed
28 for its effectiveness in treating LBP. Nine trials were included in this review. Authors
29 concluded that the available evidence is limited to support the use of ice or heat for LBP.
30 Some studies did report that over-the-counter heat wraps significantly reduced pain over
31 the short-term. In a review by Poitras and Brosseau (2008), no studies were found eligible
32 to support or refute the use of hot, cold, or ice packs for chronic LBP.

33 Graham et al. (2013) completed a systematic review on physical modalities for acute to
34 chronic neck pain. Of 103 reviews eligible, 20 were included and 83 were excluded. No
35 benefit was noted for infrared light over placebo for whiplash associated disorder (WAD),
36 Moderate evidence of no benefit: infrared light was no better than placebo for acute
37 whiplash associated disorder, chronic myofascial neck pain or subacute to chronic neck
38 pain. No added benefit was noted when hot packs were combined with mobilization,
39 manipulation or electrical muscle stimulation for chronic neck pain. Improved design and
40 long term follow up were suggested for future research.

1 Raynor et al. (2005) conducted a meta-analysis of studies investigating the use of
2 cryotherapy following anterior cruciate ligament (ACL) reconstruction. The authors
3 identified six studies that met criteria and that were included in the analysis. They
4 concluded that, while some individual studies did find significant impact on pain, drainage,
5 or range of motion (ROM), the pooled analysis did not when controlling for data quality.
6 In addition, the studies included in the analysis involved mostly small study populations
7 and multiple groups, diluting the power of the findings. A study addressing the use of a
8 passive cooling device was published in 2015 by Yu and colleagues investigated the effect
9 of cryotherapy after elbow arthrolysis on elbow pain, blood loss, analgesic consumption,
10 range of motion, and long-term elbow function. Patients were randomly assigned into a
11 cryotherapy group (n=31, cryotherapy plus standard care) or a control group (n=28,
12 standard care). For postoperative days 1 through 7, visual analog scale scores of pain both
13 at rest and in motion indicated significantly better pain control in the cryotherapy group
14 ($p < 0.05$). There were no significant differences between the 2 groups in VAS scores at 2
15 weeks and 3 months after surgery. Less medication was consumed by the cryotherapy
16 group than the control group for pain relief ($P < .01$). Authors concluded that cryotherapy
17 was effective in relieving pain and reducing analgesic consumption for patients received
18 elbow arthrolysis and that the application of cryotherapy will not affect blood loss, ROM,
19 or elbow function.

20
21 Ruffilli et al. (2015) compared two homogeneous groups of patients, one receiving
22 traditional icing regimen and the other a temperature-controlled continuous cold flow
23 device, in post-operative setting after ACL reconstruction. The Hilotherm group resulted
24 in lower pain perception (NRS), blood loss, knee volume increase at the patellar apex and
25 10 cm proximal to the superior patellar pole, and higher range of motion ($p < 0.05$) in the
26 first post-operative day. No difference in pain killers' consumption was noted. Authors
27 concluded that the Hilotherm group showed significant better results in first post-operative
28 day. Further studies with higher number of patients and longer follow-up are required to
29 assess the beneficial effects on rehabilitation and the cost-effectiveness of the routinely use
30 of this device. Kraeutler et al. (2015) compared the effect of compressive cryotherapy (CC)
31 vs. ice on postoperative pain in patients undergoing shoulder arthroscopy for rotator cuff
32 repair or subacromial decompression. A commercial device was used for postoperative CC.
33 A standard ice wrap (IW) was used for postoperative cryotherapy alone. Forty-six patients
34 completed the study and were available for analysis; 25 patients were randomized to CC
35 and 21 patients were randomized to standard IW. No significant differences were found in
36 average pain, worst pain, or morphine equivalent dosage on any day. Authors concluded
37 that there does not appear to be a significant benefit to use of CC over standard IW in
38 patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial
39 decompression. Further study is needed to determine if CC devices are a cost-effective
40 option for postoperative pain management in this population of patients. Ruffilli et al.
41 (2017) completed a similar study on patients with total knee arthroplasty (TKA). The study
42 was a prospective randomized controlled study, involving 50 patients after primary TKA.

1 The two groups were homogenous for preoperative and intraoperative features. The groups
2 showed no statistically significant differences in all the evaluated parameters. Results
3 demonstrated that continuous cold flow device in the acute postoperative setting after TKA
4 did not show superiority in reducing edema, pain, and blood loss, compared with traditional
5 icing regimen. Thus, due to the costs, it should be reserved to selected cases. Gatewood et
6 al. (2017) investigated the efficacy of device modalities used following arthroscopic knee
7 surgery. Twenty-five studies were included in this systematic review, nineteen of which
8 found a significant difference in outcomes. For alleviating pain and decreasing narcotic
9 consumption following arthroscopic knee surgery, cryocompression devices are more
10 effective than traditional icing alone, though not more than compression alone. CPM does
11 not affect post-operative outcomes. Authors concluded that cryotherapy is recommended
12 for inclusion into rehabilitation protocols following arthroscopic knee surgery to assist with
13 pain relief, recovery of muscle strength and knee function, which are all essential to
14 accelerate recovery.

15
16 Despite limited understanding of the response to heat, cold, or contrast modalities in the
17 management of knee OA, the application of superficial heat or cold is very common, often
18 self-initiated, and is considered a component of a “first-line” intervention in the
19 management of knee pain in older adults. Porcheret et al. (2007) reported that of 201 older
20 patients with knee pain surveyed, 84% reported applying superficial heat or cold, and most
21 reported this treatment as a self-initiated intervention. Additionally, Cetin et al. (2008)
22 reported that the use of superficial heat or cold in conjunction with diathermy, TENS or
23 ultrasound led to varying levels of symptom relief and functional improvements in patients
24 with knee OA. Denegar et al. (2010) assessed preferences for, and effects of, 5 days of
25 twice daily superficial heat, cold, or contrast therapy applied with a commercially available
26 system permitting the circulation of water through a wrap-around garment, use of an
27 electric heating pad, or rest for patients with level II-IV osteoarthritis (OA) of the knee.
28 Treatment with the device set to warm was preferred by 48% of subjects. Near equal
29 preferences were observed for cold (24%) and contrast (24%). Pain reduction and
30 improvements in KOOS subscale measures were demonstrated for each treatment but
31 responses were ($P < 0.05$) greater with preferred treatments. Most patients preferred
32 treatment with the water circulating garment system over a heating pad. Authors
33 recommend that when superficial heat or cold is considered in the management of knee
34 OA that patients experiment to identify the intervention that offers them the greatest relief
35 and that contrast is a treatment option. In summary, the available scientific literature is
36 insufficient to document that the use of passive cooling systems is associated with a greater
37 likelihood of incremental benefit compared to standard ice packs. Many of the published
38 randomized studies failed to include the relevant control group of standard ice packs.
39 Studies that did include a control group of standard ice packs reported inconsistent results
40 (Healy, 1994), and some studies reported no significant benefit of passive cooling devices
41 compared to no cold therapy (Edwards, 1996). Several studies support the use of heat wraps
42 for improvement of mobility and pain (Bellew et al., 2016).

1 Essentially, the evidence does not support the isolated use of hot packs, infrared light, for
 2 non-specific neck pain. There is moderate evidence to support the use of superficial heat
 3 for temporary reduction of pain and disability in the treatment of acute and sub-acute LBP.
 4 Although there were some adverse events reported, the literature precludes reliable and
 5 valid estimates of the risk of major and minor harm associated with these modalities.
 6 According to the AHRQ Comparative Effectiveness publication on Non-Invasive
 7 Treatments for Low Back Pain (2016), the following key points were reported for
 8 superficial heat and cold:

- 9 • For acute or subacute low back pain, a systematic review found a heat wrap more
 10 effective than placebo for pain relief at 5 days. Two subsequent trials also found a
 11 heat wrap associated with decreased pain intensity at 3 to 4 days or increased pain
 12 relief at 8 hours. Another trial found a heat wrap during emergency transport
 13 associated with substantially lower pain intensity versus an unheated blanket upon
 14 arrival to the hospital.
- 15 • For acute low back pain, one higher-quality trial found heat plus exercise associated
 16 with greater pain relief at day seven and on the RDQ versus exercise without heat.
- 17 • One fair-quality trial found heat plus an NSAID associated with better pain scores
 18 versus an NSAID without heat at day 15, based on the McGill Pain Questionnaire.
- 19 • For acute or subacute low back pain, a systematic review included one trial that
 20 found heat more effective for pain relief than acetaminophen or ibuprofen after 1
 21 to 2 days of treatment; the heat wrap was also associated with greater improvement
 22 on the RDQ respectively.
- 23 • For acute low back pain, a systematic review included one trial that found no clear
 24 differences between heat versus exercise in pain relief or function.
- 25 • No study compared superficial cold versus placebo or no cold treatment.
- 26 • For acute low back pain, one small trial with methodological shortcomings found
 27 cold plus naproxen associated with better pain scores versus naproxen alone, based
 28 on the McGill Pain Questionnaire.
- 29 • There was insufficient evidence from three trials to determine effects of heat versus
 30 cold, due to methodological limitations and imprecision.
- 31 • Heat was not associated with increased risk of skin flushing versus no heat or
 32 placebo in two trials; no serious adverse events were reported with use of heat.

33
 34 According to the 2017 American College of Physicians (ACP) clinical practice guideline
 35 on noninvasive treatments for acute, subacute, and chronic low back pain, Moderate-
 36 quality evidence showed that a heat wrap moderately improved pain relief (at 5 days) and
 37 disability (at 4 days) compared with placebo. Low quality evidence showed that a
 38 combination of heat plus exercise provided greater pain relief and improved Roland Morris
 39 Disability Questionnaire (RDQ) scores at 7 days compared with exercise alone in patients
 40 with acute pain. Low-quality evidence showed that a heat wrap provided more effective
 41 pain relief and improved RDQ scores compared with acetaminophen or ibuprofen after 1
 42 to 2 days. Low-quality evidence showed no clear differences between a heat wrap and

1 exercise in pain relief or function. Superficial heat is supported as a second-line or
2 adjunctive treatment option for acute low back pain of less than 6 weeks in duration (Foster
3 et al., 2018).

4
5 Szekeres et al. (2018) investigated the immediate effects of using a moist hot pack (MHP)
6 vs therapeutic whirlpool bath (WB) for improving wrist ROM during a therapy session for
7 patients with distal radius fracture. About 60 adult patients, with a mean age of 54 years in
8 the MHP group and 53 years in the WB group, with healed distal radius fracture were
9 randomized into 2 groups of 30. Patients in group 1 were placed in an MHP for 15 minutes
10 during therapy. Patients in group 2 had their arm placed in a WB and were asked to perform
11 active wrist ROM exercises for the same period. This occurred for 3 consecutive therapy
12 visits, with wrist and forearm ROM being measured before and after heat during each visit.
13 Both WB and MHP improved wrist ROM during therapy sessions in this study, making
14 both these acceptable options for clinical use when the goal is to precondition a patient for
15 other treatments. Authors concluded that individuals who received WB showed a
16 statistically greater increase in wrist ROM than those receiving MHP during a therapy
17 session, although the difference between groups may or may not be clinically important
18 considering the small changes in ROM observed in this study.

19
20 Kwiecien and McHugh (2021) authored a paper on cryotherapy. Traditionally, ice is used
21 in the treatment of musculoskeletal injury while cold water immersion or whole-body
22 cryotherapy is used for recovery from exercise. In humans, the primary benefit of
23 traditional cryotherapy is reduced pain following injury or soreness following exercise.
24 Cryotherapy-induced reductions in metabolism, inflammation, and tissue damage have
25 been demonstrated in animal models of muscle injury; however, comparable evidence in
26 humans is lacking. This absence is likely due to the inadequate duration of application of
27 traditional cryotherapy modalities. Traditional cryotherapy application must be repeated to
28 overcome this limitation. Recently, the novel application of cooling with 15 °C phase
29 change material (PCM), has been administered for 3-6 h with success following exercise.
30 Although evidence suggests that chronic use of cryotherapy during resistance training
31 blunts the anabolic training effect, recovery using PCM does not compromise acute
32 adaptation. Therefore, following exercise, cryotherapy is indicated when rapid recovery is
33 required between exercise bouts, as opposed to after routine training. Ultimately, the
34 effectiveness of cryotherapy as a recovery modality is dependent upon its ability to
35 maintain a reduction in muscle temperature and on the timing of treatment with respect to
36 when the injury occurred, or the exercise ceased. Therefore, according to authors, to limit
37 the proliferation of secondary tissue damage that occurs in the hours after an injury or a
38 strenuous exercise bout, it is imperative that cryotherapy be applied in abundance within
39 the first few hours of structural damage.

40
41 Miranda et al. (2021) investigated the effectiveness of cryotherapy on pain intensity,
42 swelling, range of motion, function and recurrence in acute ankle sprain. Only two RCTs

1 with high risk of bias were included. Both evaluated the additional effects of cryotherapy,
2 comparing cryotherapy combined with other intervention versus other intervention stand-
3 alone. Uncertain evidence shows that cryotherapy does not enhance effects of other
4 intervention on swelling, pain intensity and range of motion. Authors concluded that
5 current literature lacks evidence supporting the use of cryotherapy on management of acute
6 ankle sprain. There is an urgent call for larger high-quality randomized controlled trials.

7
8 Klintberg and Larsson (2021) evaluated the certainty of evidence for the use of cryotherapy
9 in patients with musculoskeletal disorders. Eight SRs and 50 RCTs from a total of 6027
10 (+839) were included. In total 34 studies evaluated cryotherapy in surgical procedures,
11 twelve evaluated cryotherapy use in acute pain or injury and twelve studies evaluated
12 cryotherapy in long-term pain and dysfunction. The certainty of evidence is moderate
13 (GRADE III) after surgical procedures to reduce pain, improve ROM, for patient
14 satisfaction and few adverse events are reported. Cryotherapy in acute pain and injury or
15 long-term pain and dysfunction show positive effects but have a higher number of
16 outcomes with low certainty of evidence (GRADE II). Authors concluded that cryotherapy
17 may safely be used in musculoskeletal injuries and dysfunctions. It is well tolerated by
18 patients. More advanced forms of cryotherapy may accentuate the effect. Future research
19 is needed where timing, temperature for cooling, dose (time) and frequency are evaluated.

20
21 Mendes et al. (2022) analyzed the effect of cryotherapy on pain intensity in the immediate
22 post-operative period of ACL reconstruction. 15 studies were included in this review.
23 Authors concluded that cryotherapy is effective in reducing pain intensity because there
24 were reductions in the scores of subjective pain scales in the immediate post-operative
25 period of ACL reconstruction. Cryo-compression was shown to be superior to conventional
26 cryotherapy. Glatke et al. (2022) evaluated the efficacy of various rehabilitative modalities
27 for ACL reconstruction. A total of 824 articles from 2012 to 2020 were identified using
28 multiple search engines. Fifty Level-I or II studies met inclusion criteria and were
29 evaluated. Authors note that cryotherapy is an effective analgesic when used
30 perioperatively. Ruiz-Sánchez et al. (2022) reviewed the current clinical practice
31 guidelines on management and treatment of ankle sprains, assess their quality, analyze the
32 levels of evidence and summarize the grades of recommendation. Seven clinical practice
33 guides were included in this review. Seventeen recommendations were extracted and
34 summarized. Six of the recommendations analyzed present enough evidence to be applied
35 in clinical practice and are highly recommended for ankle sprain management: Ottawa
36 rules, manual therapy, cryotherapy, functional supports, early ambulation, short term
37 NSAIDs and rehabilitation.

38 39 **Paraffin Bath**

40 Chang et al. (2014) compared the efficacy of combining a wrist orthosis with either US
41 therapy or paraffin bath therapy in treating CTS patients. Twice per week, one group
42 underwent paraffin therapy, and the other group underwent ultrasound therapy. Statistical

1 analysis revealed significant improvements in symptom severity scores in both groups.
2 After adjusting for age, gender and baseline data, the analysis of covariance revealed a
3 significant difference in the functional status score between two groups. Authors concluded
4 that the combination of ultrasound therapy with a wrist orthosis may be more effective than
5 paraffin therapy with a wrist orthosis. Rashid et al. (2013) explored differences in the
6 efficacy of mobilization techniques in post-traumatic stiff ankle with and without paraffin
7 wax bath. The inclusion criteria were age range from 20-60 years, pain, loss of ROM, with
8 history of trauma and fracture of ankle. The patients with similar complaints but with
9 surgical treatment were excluded. Group A was given mobilization techniques with
10 paraffin wax bath while group B was treated without paraffin wax bath. Authors concluded
11 that joint mobilization and wax bath therapy is an effective and beneficial tool to improve
12 the symptoms and quality of life in post-traumatic stiff ankle patients. They also noted that
13 joint mobilization techniques combined with wax bath were more effective in the
14 management of post-traumatic stiff ankle as compared to wax therapy alone. Sibtain sought
15 to determine the efficacy of paraffin wax bath with mobilization techniques compared with
16 joint mobilization alone. Authors concluded paraffin wax bath with joint mobilization
17 techniques were more effective than mobilization techniques without paraffin wax bath in
18 the rehabilitation of post traumatic stiff hand. Ordahan and Karahan (2017) investigated
19 the effectiveness of paraffin therapy in patients with CTS. Seventy patients diagnosed with
20 mild or moderate CTS were randomly divided into two groups as splint treatment (during
21 the night and day time as much as possible for 3 weeks) alone and splint (during the night
22 and day time as much as possible for 3 weeks) + paraffin treatment (five consecutive days
23 a week for 3 weeks). Clinical and electrophysiological assessments were performed before
24 and 3 weeks after treatment. The patients were assessed by using visual analog scale (VAS)
25 for pain, electroneuromyography (ENMG), and Boston Carpal Tunnel Syndrome
26 Questionnaire (BCTSQ). The significant improvement was found in VAS scores in both
27 groups when compared with pretreatment values ($p < 0.05$). There was no significant
28 improvement in functional capacity score ($p > 0.05$), whereas a significant improvement
29 was noted in the BCTQ symptom severity scale score in the splint group ($p < 0.05$).
30 Significant improvements were demonstrated in both scorers in the combined treatment
31 group. Similarly, significant improvements were found in the combined treatment group in
32 terms of motor and sensory distal latency, sensory amplitude, and median sensory nerve
33 velocity ($p < 0.05$). There was no significant change in electrophysiologic parameters in
34 the splint group ($p > 0.05$), and the difference in these parameters between the groups was
35 statistically significant ($p < 0.05$). In conclusion, using splinting alone in patients with CTS
36 is an effective treatment for reducing symptoms in the early stages. Paraffin treatment with
37 splint increases the recovery in functional and electrophysiological parameters.

38
39 Dellhag et al. (1992) evaluated the effects of active hand exercise and paraffin bath
40 treatment in 52 subjects with RA. Authors reported that paraffin bath treatment followed
41 by active hand exercise resulted in significant improvements of range of motion (ROM)
42 and grip function. Active hand exercise alone reduced stiffness and pain with non-resisted

1 motion and increased ROM. Paraffin bath alone had no significant effect. Robinson et al.
2 (2002) evaluated the effectiveness of different thermotherapy applications on objective and
3 subjective measures of disease activity in patients with RA. Seven studies (n=328 subjects)
4 met the inclusion criteria. The results of this systematic review of thermotherapy for RA
5 found that there was no significant effect of hot and ice packs applications and cryotherapy
6 on objective measures of disease activity including joint swelling, pain, medication intake,
7 range of motion (ROM), grip strength, hand function compared to a control (no treatment)
8 or active therapy. There is no significant difference between wax and therapeutic
9 ultrasound for all the outcomes measured after 1, 2 or 3 week(s) of treatment No harmful
10 effects of thermotherapy were reported. Authors conclude that superficial moist heat and
11 cryotherapy can be used as a palliative therapy. Paraffin wax baths combined with
12 exercises can be recommended for beneficial short-term effects for arthritic hands. They
13 noted that these conclusions were limited by methodological considerations such as the
14 poor quality of trials.

15
16 Dilek et al. (2013) evaluated the efficacy of paraffin bath therapy on pain, function, and
17 muscle strength in patients with hand osteoarthritis. At baseline, there were no significant
18 differences between groups in any of the parameters ($P>.05$). After treatment, the paraffin
19 group exhibited significant improvement in pain at rest and during ADL, ROM of the right
20 hand, and pain and stiffness dimensions of the outcome measures used. The control group
21 showed a significant deterioration in right hand grip and bilateral lateral pinch and right
22 chuck pinch strength, but there was no significant change in the other outcome measures.
23 When the 2 groups were compared, pain at rest, both at 3 and 12 weeks, and the number of
24 painful and tender joints at 12 weeks significantly decreased in the paraffin group. Bilateral
25 hand-grip strength and the left lateral and chuck pinch strength of the paraffin group were
26 significantly higher than the control group at 12 weeks. Authors conclude that paraffin bath
27 therapy seemed to be effective both in reducing pain and tenderness and maintaining
28 muscle strength in hand osteoarthritis and may be regarded as a beneficial short-term
29 therapy option, which is effective for a 12-week period.

30
31 Sandqvist et al. (2004) investigated the effects of treatment with paraffin bath in patients
32 with systemic sclerosis (scleroderma). In 17 patients with scleroderma one hand was
33 treated daily with paraffin bath in combination with hand exercise. The other hand was
34 treated with exercise only and was considered a control. Hand function was estimated
35 before treatment and after 1 month of treatment, concerning hand mobility and grip force,
36 and perceived pain, stiffness and skin elasticity. At the follow-up, finger flexion and
37 extension, thumb abduction, volar flexion in the wrist, and perceived stiffness and skin
38 elasticity had improved significantly in the paraffin-treated hand compared with the
39 baseline values. In this pilot study, hand exercise in combination with paraffin bath seemed
40 to improve mobility, perceived stiffness and skin elasticity. Mancuso and Poole (2009)
41 investigated whether the use of paraffin and active hand exercises would improve activity
42 and participation in persons with scleroderma. In this series of three single case studies,

1 participants used paraffin and performed active hand exercises daily for eight weeks. All
2 participants experienced clinically significant improvements in both body
3 function/structure measurements of hand function and in their ability to participate in
4 activities. Significant improvements were found more frequently on body
5 function/structure measures than activity/participation measures. Authors reported that this
6 preliminary study lends support in favor of using paraffin and hand exercises as a treatment
7 to improve hand function related to participation in daily activities in persons with
8 scleroderma. Further research with a larger sample and increased variable control should
9 be performed.

10 **Fluidized Therapy (Fluidotherapy)**

11 Kelly et al. (2005) examined the effects of the superficial heating modality, fluidotherapy,
12 on skin temperature and on sensory nerve action potential (SNAP) conduction latency and
13 amplitude of the superficial radial nerve in healthy individuals. Results demonstrated a
14 significantly elevated superficial skin temperature, while tactile stimulation alone and no
15 treatment (control group) did not bring about a temperature change. As the superficial skin
16 temperature increased, there was an associated decrease in the distal sensory latency of the
17 superficial radial sensory nerve action potential. Authors concluded that these results
18 should be an important consideration for the clinician using superficial heating modalities.
19 Studies comparing its effective heating with that of a paraffin bath and whirlpool have
20 found them to be similar (Borrell et al., 1980). Han and Lee (2017) investigated the effect
21 of fluidotherapy on hand's dexterity and activities of daily living for stroke patients with
22 upper limb edema. The objective of the present study was to treat 30 stroke patients with a
23 three-week course of fluidotherapy to investigate the efficacy of such therapy for reduction
24 of edema. Authors conclude that findings suggest that using fluidotherapy can reduce
25 edema, and such a reduction can have a positive effect on activities of daily living.
26

27
28 Sezgin Ozcan et al. (2019) evaluated whether combining fluidotherapy to conventional
29 rehabilitation program provides additional improvements on pain severity, upper extremity
30 functions, and edema volume in patients with poststroke complex regional pain syndrome
31 (CRPS). Thirty hemiplegic patients with subacute stage CRPS type-1 of the upper
32 extremity were randomly divided into 2 groups. Both groups received a 3-week
33 conventional rehabilitation program (5 days/week, 2-4 hours/day). The experimental group
34 received 15 sessions additional fluidotherapy application to the affected upper extremity
35 (40 °C, 20 minutes in continuous mode, 5 sessions/week). At the post-treatment evaluation,
36 significant improvements were revealed regarding to the edema volume, pain visual analog
37 scale, painDETECT and functional independence measure scores, and the Brunnstrom
38 stages of upper extremity and hand in both groups ($P < .05$). But among the parameters
39 mentioned above, only the decrease in edema volume and the painDETECT scores were
40 greater in fluidotherapy group than the control group ($P < .05$). Authors concluded that the
41 addition of the fluidotherapy to the conventional rehabilitation program provides better

1 improvements on neuropathic pain and edema volume in subacute stage poststroke CRPS.
2 Erdinc Gündüz et al. (2019) evaluated the efficacy of dry heat treatment (fluidotherapy) in
3 improving hand function in patients with rheumatoid arthritis. All patients were randomly
4 divided into two groups. Group 1 underwent dry heat treatment (fluidotherapy) and Group
5 2 was a control group. Patients in both groups participated in a joint protection and exercise
6 program. A total of 93 participants were allocated to Group 1 (n = 47) and Group 2 (n = 46).
7 At baseline, there were no significant differences between the groups in any parameter
8 except significantly poorer Health Assessment Questionnaire score in Group 1 (P = 0.007).
9 At week 3, there were no significant differences between the groups in any of the
10 parameters (P > 0.005). At week 12, Duruoz Hand Index scores were significantly better
11 in Group 2 (P = 0.039). Authors concluded that dry heat treatment (fluidotherapy) was not
12 effective in improving hand function in patients with rheumatoid arthritis. Moreover, no
13 positive effect on any other clinical parameters was observed.

14 **PRACTITIONER SCOPE AND TRAINING**

15 Practitioners should practice only in the areas in which they are competent based on their
16 education, training and experience. Levels of education, experience, and proficiency may
17 vary among individual practitioners. It is ethically and legally incumbent on a practitioner
18 to determine where they have the knowledge and skills necessary to perform such services
19 and whether the services are within their scope of practice.
20

21
22 It is best practice for the practitioner to appropriately render services to a member only if
23 they are trained, equally skilled, and adequately competent to deliver a service compared
24 to others trained to perform the same procedure. If the service would be most competently
25 delivered by another health care practitioner who has more skill and training, it would be
26 best practice to refer the member to the more expert practitioner.

27
28 Best practice can be defined as a clinical, scientific, or professional technique, method, or
29 process that is typically evidence-based and consensus driven and is recognized by a
30 majority of professionals in a particular field as more effective at delivering a particular
31 outcome than any other practice (Joint Commission International Accreditation Standards
32 for Hospitals, 2017).
33

34 Depending on the practitioner's scope of practice, training, and experience, a member's
35 condition and/or symptoms during examination or the course of treatment may indicate the
36 need for referral to another practitioner or even emergency care. In such cases it is prudent
37 for the practitioner to refer the member for appropriate co-management (e.g., to their
38 primary care physician) or if immediate emergency care is warranted, to contact 911 as
39 appropriate. See policy *Managing Medical Emergencies (CPG 159 – S)* for information.

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