



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Cooling Devices Used in the Outpatient Setting

Policy Number: 1.01.26

Last Review: 10/2018

Origination: 10/2007

Next Review: 10/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for cooling devices used in the outpatient setting. This is considered not medically necessary.

Heating pads and cooling pads (circulating or non-circulating) are benefit exclusions on most policies.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Active (circulating) and passive (noncirculating) cooling devices are considered **not medically necessary**.

Combination active cooling and compression (cryopneumatic) devices are considered **investigational**.

Considerations

According to Medicare's durable medical equipment regional carrier (DMERC) policy, passive (noncirculating) cooling devices are not considered durable medical equipment and thus should be coded as:

- A9270: Noncovered device or service

Circulating cooling devices may be identified by the following HCPCS codes:
 E0218 Water circulating cold pad with pump
 E0236 Pump for water circulating pad.

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With pain and/or swelling after 	Interventions of interest are: <ul style="list-style-type: none"> • Cooling device 	Comparators of interest are: <ul style="list-style-type: none"> • Standard icing 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes

knee surgery		regimen	<ul style="list-style-type: none"> • Medication use • Resource utilization
Individuals: <ul style="list-style-type: none"> • With pain and/or swelling after shoulder surgery 	Interventions of interest are: <ul style="list-style-type: none"> • Cooling device 	Comparators of interest are: <ul style="list-style-type: none"> • Standard icing regimen 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Medication use • Resource utilization
Individuals: <ul style="list-style-type: none"> • With pain and/or swelling after facial surgery 	Interventions of interest are: <ul style="list-style-type: none"> • Cooling device 	Comparators of interest are: <ul style="list-style-type: none"> • Standard icing regimen 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Medication use • Resource utilization

Cooling devices use chilled water to decrease the local temperature of tissue. There are a variety of cooling devices available, ranging from gravity-fed devices that are manually filled with iced water to motorized units that both cool and circulate the chilled water. These devices are typically used when ice packs would normally be applied, e.g., after orthopedic surgical procedures.

For individuals who have pain and/or swelling after knee surgery who receive a cooling device, the evidence includes systematic reviews, several randomized controlled trials, and a case-control study. Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. Evidence on manually operated passive noncirculating cooling devices is limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications do not provide sufficient evidence of comparative efficacy. Other studies have provided no information on the frequency of ice changes, limiting interpretation of the results. Several randomized trials have compared active circulating cooling devices with standard intermittent icing or cold packs, and two of the larger trials found no significant benefit of the continuous cooling devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after shoulder surgery who receive a cooling device, the evidence includes a randomized controlled trial. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. Evidence found that use of compressive cryotherapy produced no significant reduction in pain or medication use compared with the standard ice wrap. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after facial surgery who receive a cooling device, the evidence includes several small randomized controlled trials and a pilot study. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. There have been mixed results regarding the intervention's efficacy in reducing neurologic problems as well as improving eye motility, diplopia, mandible functioning, and mouth opening compared with conventional cooling regimens. The evidence is insufficient to determine the effects of the technology on health outcomes.

Background

COLD AND COMPRESSION THERAPY

Use of ice packs and various bandages and wraps following surgery or musculoskeletal and soft tissue injury is common. A variety of manually operated and mechanical continuous cooling devices are commercially available.

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

Noncirculating Cooling Devices

The CryoCuff® and Polar Care Cub devices are examples of passive, noncirculating cooling devices. The CryoCuff device consists of an insulated container filled with iced water that is attached to a compressive cuff. When the CryoCuff container is raised, the water fills and pressurizes the cuff. The amount of pressure is proportional to the height of the container. When body heat warms the water, the cooler is lowered and water drained. The cooler is then raised above the affected limb, and cold water refills the compressive cuff. The Polar Care Cub unit consists of pads held in place with elastic straps, which may also provide compression. The pads are attached to a built-in hand pump that circulates the water through the pads at the same time as increasing the compression around the joint.

Circulating Cooling Devices

In active, circulating cooling devices, a motorized pump circulates chilled water and may also provide pneumatic compression. For example, the AutoChill® device, which may be used with a CryoCuff, consists of a pump that automatically exchanges water from the cuff to the cooler, eliminating the need for manual water recycling. The Hot/Ice Thermal Blanket is another circulating cooling device. It consists of 2 rubber pads connected by a rubber hose to the main cooling unit. Fluid is circulated via the hose through the thermal blankets. The temperature of the fluid is controlled by the main unit and can be either hot or cold. The Game Ready™ Accelerated Recovery System is a circulating cooling device combined with a pneumatic component. The system consists of various soft wraps and a computer-control unit to circulate the water through the wraps and to provide intermittent pneumatic compression. The HiloTherm® Clinic circulates cooled water through preshaped thermoplastic polyurethane facial masks for use after different types of facial surgery. ThermaZone® provides thermal therapy with pads specific to various joints as well as different areas of the head (front, sides, back, eyes). CTM™ 5000 and cTreatment are computer-controlled devices that provide cooling at a specific (11°C) and continuous temperature.

Regulatory Status

A large number of circulating and noncirculating cooling devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process since 1976. US Food and Drug Administration product code: ILO.

Rationale

This evidence review was created in November 2004 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 8, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

POST-KNEE SURGERY

Noncirculating Cooling Devices

Schroder and Passler (1994) compared the CryoCuff device with ice therapy in 44 patients who had undergone repair of the anterior cruciate ligament (ACL).¹ Those receiving ice therapy administered an ice bag 3 times a day postoperatively. While those randomized to the CryoCuff groups reported significant decreases in pain, swelling, and analgesic use, it is not clear whether icing 3 times a day is a typical icing regimen.

Whitelaw et al (1995) reported on results of a trial that randomized 102 patients undergoing knee arthroscopy in the outpatient setting to a CryoCuff device or traditional ice therapy.² Those in the CryoCuff group reported decreased pain medication compared with the control group, but there was no significant

difference in average pain assessment. Interpretation of these results is limited because the number of exchanges of ice packs and water recirculation was not reported. Healy et al (1994) reported that the CryoCuff device provided no benefit to pain control or swelling compared with ice packs in a randomized trial of 76 patients (105 knees) undergoing total knee arthroplasty (TKA).³ No data were provided on the number of ice pack exchanges, although the water was recirculated in the CryoCuff device every 1 to 4 hours.

Edwards et al (1996) studied the outcomes of 71 patients undergoing ACL reconstruction who were randomized to CryoCuff therapy with ice water, CryoCuff therapy with room temperature water, or no cold therapy.⁴ Therefore, this trial did not include the relevant control group of patients treated with conventional ice packs. Another randomized trial by Brandsson et al (1996) suffers from the same limitation; in this study of 50 patients undergoing ACL repair, no group received standard therapy with ice packs.⁵ Levy and Marmar (1993) compared the outcomes of a trial that randomized 80 patients (100 knees) undergoing TKA with noncirculating cold therapy with a CryoCuff device or to no cold therapy.⁶ Although the CryoCuff group reported a significant decrease in blood loss and a mild decrease in analgesic requirements, this trial did not include the relevant control group.

Circulating Cooling Devices

In the largest study to date, Thienpont (2014) evaluated 116 patients who had undergone TKA who were assigned in a quasi-randomized order to 8 hours daily of advanced cryotherapy at a fixed temperature or to the application of cold packs for 15 minutes after each of 2 physical therapy sessions.⁷ Both groups could apply cryotherapy during the evening and night whenever they wanted for comfort and pain control. Thirty percent of patients in the advanced cryotherapy group did not use the device at night due to excessive noise. Primary outcomes were visual analog scale (VAS) pain scores at rest and during deep active knee flexion, walking without aid, and analgesic use. Secondary outcomes were knee range of motion, active straight-leg raising, walking without aid, swelling, visual hematoma, and length of stay. There were no significant differences between groups in VAS scores, need for analgesics, or any of the secondary outcomes. There was a significant decrease in flexion at 6 weeks in the advanced cryotherapy group (114° vs 120°).

Woolf et al (2008), in an RCT of 60 patients, compared a temperature-controlled cryotherapy device with a standard icing regimen following outpatient knee arthroscopy.⁸ Both groups were instructed to apply the treatment for 20 minutes every 2 hours during waking hours for the first 4 days after surgery. All night, the cooling device group was instructed to use the device throughout the first 4 nights, whereas the control group was advised to use ice packs as needed. No differences in daytime pain were observed between groups. There was a tendency for more patients in the cryotherapy group to report that they did not awaken from pain during the night; this difference was significant only for postoperative day 2 (36% vs 6%; $p=0.04$). Additional study with a larger number of patients is

needed to determine whether the use of continuous cooling at night improves health outcomes.

More recently, an RCT of 47 participants by Rufilli et al (2015) compared 2 homogenous groups of patients with ACL reconstruction to evaluate the efficacy of a continuous cold flow device (10°-30°C) relative to conventional crushed ice bags (intervention group n=23, control group n=24).⁹ All patients were discharged the day after surgery. Primary end points included: knee pain (using the numeric rating scale that ranged from 0 [no pain] to 10 [worst pain]); blood loss; measures of knee swelling at 3 sites (patellar apex, 10 cm proximal to the superior patellar pole, 15 cm distal to the superior patellar pole); knee range of motion; and the use of pain medicine. Relative to the control, the intervention group had a significant reduction in numeric rating scale pain scores ($p<0.001$) and a significant decrease in blood loss ($p<0.001$). Knee volume was also significantly lower in the intervention group at the patellar apex ($p=0.013$) and 10 cm proximal to the superior patellar pole ($p=0.001$). Although there was a significant increase in mean flexion ($p<0.001$) for the intervention group relative to the control, there was no difference between groups in the use of pain medication. No adverse events were reported in either group postoperatively, or related to the use of the cooling device or the ice bags. Researchers noted several limitations to the trial, including small sample size, lack of blinding, and lack of evaluation of longer term efficacy after hospital discharge.

Rufilli et al (2017) investigated the use of the continuous-flow cold device in an RCT of 50 patients with end-stage knee osteoarthritis after primary TKA who had the same rehabilitation program and pain-relieving strategy.¹⁰ The intervention group (n=24) received the continuous-flow cold device (10° and 30°C) and the control group (n=26) received crushed ice bags postoperatively. There were no statistically significant differences between groups in terms of subjective pain scores (using a numeric rating scale), medication use, or knee circumference. In addition, there were no statistically significant differences in blood loss, need for transfusion, or range of motion. However, there was a nonsignificant trend at day 7 toward a lesser increase in knee circumference in the intervention group. Reported limitations included small sample size, lack of blinding, lack of evaluation of longer term efficacy after hospital discharge, and no skin temperature evaluation. Compared with a traditional icing regimen, the use of a continuous-flow cold device was no better than traditional icing in patients with TKA.

Several randomized studies have compared circulating cooling devices with no cold therapy and therefore are not relevant to this evidence review.¹¹⁻¹⁴

Combination Circulating Cooling and Compression (Cryopneumatic) Devices

Several RCTs and a case-control study have assessed the cryopneumatic devices in the outpatient setting.

In a multicenter RCT, Su et al (2012) compared 280 TKA patients treated with the Game Ready cryopneumatic device or with ice packs plus static compression.¹⁵ On

hospital discharge, the treatments were given at the same application cycle of 1 hour on and 30 minutes off. Compliance rates were similar for the 2 groups. Blinded evaluation of 187 patients (67% of patients had complete evaluations) found no significant difference between the groups in VAS score for pain, range of motion, 6-minute walk test, Timed Up & Go test, or knee girth under this more typical icing regimen. Narcotic consumption decreased from 680 to 509 mg morphine equivalents over the first 2 weeks (14 mg less per day), and patient satisfaction increased with the cryopneumatic device.

Waterman et al (2012) reported on an RCT of the Game Ready device in 36 patients who had ACL reconstruction.¹⁶ Patients were instructed to use ice or the cryopneumatic device for 30 minutes at least 3 times a day and return to the clinic at 1, 2, and 6 weeks postoperatively. Compliance during the first 2 weeks did not differ significantly between groups (100% for Game Ready vs 83% for icing). The primary outcome measure (VAS pain score) differed at baseline, limiting interpretation of the results. There were no significant differences between the groups for knee circumference, the Lysholm Knee Score, 36-Item Short-Form Health Survey, or Single Assessment Numerical Evaluation scores. A greater percentage of patients treated with the Game Ready device discontinued narcotic use by 6 weeks (83% vs 28%).

Murgier et al (2017) conducted a prospective case-control study of the Game Ready device, comparing 43 individuals (27 men, 16 women) recovering from revision TKA; the control group (n=19) was treated with a cold pack applied intermittently (4 hours daily), while the Game Ready group was treated with two 8-hour cycles in 30 minute off-on increments.¹⁷ While the main outcome was the reduction of total blood loss, a secondary outcome was postoperative pain, as measured by VAS 3 days postsurgery. Patients using the Game Ready device showed decreased blood loss compared with the control group (260 mL vs 465 mL; $p < 0.05$), as well as an improvement in postoperative pain (VAS score, 1 vs 3; $p < 0.05$). Limitations included the possibility of a type II error due to the specialized surgical unit where the study was performed; additional limitations (eg, variability of results, concerns about patients' comorbidities) affected the study's secondary outcomes. The authors concluded that, overall, the cryopneumatic device aided patients' recovery from revision TKA, but additional prospective randomized trials would be needed to confirm results.

A systematic review by Gatewood et al (2017) identified 25 studies evaluating various devices used after arthroscopic knee surgery; of these studies, eight assessed cryotherapy as a potential treatment to relieve postoperative pain, reduce blood loss, and decrease the use of narcotics, among other outcomes.¹⁸ Several studies compared the efficacy of a cold compression device with that of icing alone, while other studies compared a cold compression device with a control of no cold or compression. Findings were mixed across the studies, with four reporting a significant improvement in pain relief in the cold compression group over the control ($p < 0.05$ and $p < 0.02$), and four reporting no significant difference between the groups. This review was limited by its inclusion of small studies and some variability in its methodology; also most studies had a relatively short

follow-up period (<6 weeks), indicating a gap in long-term observation. Reviewers concluded that, compared with a traditional icing regimen, cold compression devices seemed to be superior at relieving postoperative pain; however, the same comparison was inconclusive between cold compression devices and compression alone.

Section Summary: Post-Knee Surgery

For individuals who have pain and/or swelling after knee surgery, the evidence includes a systematic review, several RCTs, and a case-control study. Evidence on manually operated passive noncirculating cooling devices is limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications did not provide sufficient evidence of comparative efficacy. Other studies provided no information on the frequency of ice changes, limiting interpretation of the results. Randomized trials comparing active circulating cooling devices with standard intermittent icing or cold packs have had mixed results, with several studies reporting a significant reduction in medication use or other outcomes (eg, pain, blood loss, swelling, range of motion) and others finding no significant improvements in outcomes. The results also differ across patient populations. A case-control study of the Game Ready device found that the device decreased postoperative blood loss and reduced postoperative pain, compared with intermittent application of a cold pack. However, it is unclear whether constant cooling provides greater pain relief than standard icing or intermittent use of the device. The systematic review included studies with a control of icing, as well as studies with a control of no cold or compression alone, concluding that combined cooling and compression is superior to traditional icing in relieving pain; however, the review did not report on the efficacy of specific devices.

POST-SHOULDER SURGERY

Combination Circulating Cooling and Compression (Cryopneumatic) Devices

Kraeutler et al (2015) compared the Game Ready shoulder wrap with standard icing in an RCT of 46 patients who had undergone rotator cuff repair or subacromial decompression.¹⁹ The average age at the time of surgery was 55.4 years in the compressive cryotherapy intervention group (n=25) and 55.8 years in the control group (n=21; p=0.91). Patients were instructed to apply the cryotherapy every other hour for the first 3 days and 2 to 3 times a day until the follow-up visit at 7 to 10 days. In the immediate postoperative week (days 0-7) participants used diaries to document pain level using a VAS score (no pain to extreme pain) twice per day. They also reported use of pain medication (converted to morphine equivalent dosage). Analysis of patient diaries showed no significant differences in average pain, worst pain, and morphine equivalent dosage between the 2 groups on any day during the week after surgery. Post hoc power analysis showed that 13 patients per group would provide sufficient power to detect a 25 mm (out of 100 mm) difference in VAS scores between the 2 groups. Trial limitations included small sample size (noting that 11 [19%] of enrolled patients were excluded due to noncompliance), lack of blinding, potential recall bias due to

the use of patient-reported diaries, and uncertainty whether the correct usage of cryotherapy was followed.

Section Summary: Post-Shoulder Surgery

One RCT found that, for patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression, the use of compressive cryotherapy produced no significant reductions in pain or medication use compared with the standard ice wrap.

POST-FACIAL SURGERY

Circulating Cooling Devices

Several studies have been reported by a research group that compared the Hilotherm device with cooling compresses. In a randomized trial, Rana et al (2013) assessed 32 patients with postoperative swelling of bilateral mandibular fractures using a cooling mask around the head and jaw.²⁰ Swelling was reduced for the cooling mask group on day 1, 2, and 3 after surgery. VAS scores for pain were also reduced for the cooling mask group, compared with day 1 (3.87 vs 5.53) and day 2 (3.63 vs 6.31). There were no significant differences between groups for a postoperative neurologic score, trismus, or mandibular dysfunction. Earlier research by Rana et al (2011) randomized 30 patients scheduled for third molar surgery to a water circulating cooling face mask (Hilotherm; n=15) or cool compresses (control, n=15).²¹ The intervention group had significantly less facial swelling (72.2 mL) relative to the control group (96.6 mL) on postoperative day 2 (p=0.005). This trend was maintained at day 10 (intervention, 23.3 mL; control, 46.7 mL, p<0.001). There was also a significantly lower pain score in the intervention group relative to the control group on both postoperative day 2 (intervention, 3.4; control, 4.8; p<0.05) and day 3 (intervention, 2.9; control, 3.7; p<0.05). Both the intervention and the control groups had a significant decrease in the neurologic score on day 10 compared with day 2, but there were no significant differences between groups in the neurologic score. Compared with immediately after surgery, both groups had a significant increase in mouth opening on postoperative day 2. At postoperative day 28, there were no differences between the groups with regard to facial swelling, pain score, or neurologic score. The authors did not report study limitations. However, it should be noted that the study had a small sample size and used observer-blinding only. In a pilot study, Rana et al (2011) found that the use of the cooling device in patients scheduled for treatment of bilateral mandibular fractures also reduced postoperative swelling and pain relative to the traditional cooling regimen.²² But there were no significant benefits with regard to mandible functioning, mouth opening, or neurologic scores.

A similar study design was reported by Modabber et al (2013), who treated 42 patients for unilateral zygomatic fractures.²³ Patients were randomized to a water circulating continuous cooling face mask, the Hilotherm device, (n=21), or conventional cooling (n=21) postoperatively. Three-dimensional optical scans were recorded postoperatively. On postoperative days 1, 2, and 3, respectively, there were significant decreases in swelling with the intervention relative to control

(intervention, 9.45 mL; control, 20.69 mL; $p < 0.001$; intervention, 13.20 mL; control, 22.97 mL; $p < 0.001$; intervention, 14.44 mL; control, 23.52 mL; $p = 0.002$). This trend was maintained on day 7 ($p = 0.019$). After 28 days, there were no significant differences between groups. Pain analysis conducted using a VAS, ranging from 0 (no pain) to 10 (maximum pain), was reported before surgery and postoperatively. There were significant increases in pain in the control group relative to the intervention during postoperative day 1 (intervention, 2.38; control, 4.10; $p = 0.001$) and day 2 (intervention, 2.34; control, 4.38; $p < 0.001$). However, there were no significant differences in pain between groups by day 7. Nerve dysfunction, reported on a 9-point scale (9 being the worst) and assessed pre- and postoperatively, showed a significant reduction in the neurologic score in the intervention group (2.57) relative to the control (3.90) at day 1 ($p = 0.008$), with no significant differences between the groups at days 7, 28, and 90 postoperatively. On postoperative day 1, there was a significant ($p = 0.050$) reduction in eye motility limitation in the intervention group ($n = 17$ with no limitation; $n = 4$ with limitation) relative to the control ($n = 11$ with no limitation; $n = 10$ with limitation). There were also significantly fewer patients in the intervention group with diplopia ($n = 18$ without diplopia, $n = 3$ with diplopia) compared with the control group ($n = 11$ without diplopia, $n = 10$ with diplopia; $p = 0.019$). There were no statistically significant differences in eye motility limitation or diplopia between the groups on days 7 and 28. Overall patient satisfaction was significantly higher in the intervention group (1.43) relative to the control (2.29; $p < .001$). In addition to the small sample size, trial limitations included observer-only blinding and that the 3-dimensional optical scans used only measured localized facial swelling.

Section Summary: Post-Facial Surgery

Several small RCTs and a pilot study of patients receiving cooling therapy found significant decreases in facial swelling and pain. However, there were mixed results in terms of the intervention's efficacy in reducing neurologic problems as well as improving eye motility, diplopia, mandible functioning, and mouth opening compared with conventional cooling regimens. Several of the trials had observer-only blinding.

Summary of Evidence

For individuals who have pain and/or swelling after knee surgery who receive a cooling device, the evidence includes systematic reviews, several RCTs, and a case-control study. Relevant outcomes are symptoms, functional outcomes, medication use, and resource utilization. Evidence on manually operated passive noncirculating cooling devices is limited by the control condition used in the trials. Studies that used either a no-icing control or infrequent ice applications do not provide sufficient evidence of comparative efficacy. Other studies have provided no information on the frequency of ice changes, limiting interpretation of the results. Several randomized trials have compared active circulating cooling devices with standard intermittent icing or cold packs, and two of the larger trials found no significant benefit of the continuous cooling devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after shoulder surgery who receive a cooling device, the evidence includes an RCT. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. Evidence found that use of compressive cryotherapy produced no significant reduction in pain or medication use compared with the standard ice wrap. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pain and/or swelling after facial surgery who receive a cooling device, the evidence includes several small RCTs and a pilot study. Relevant outcomes include symptoms, functional outcomes, medication use, and resource utilization. There have been mixed results regarding the intervention's efficacy in reducing neurologic problems as well as improving eye motility, diplopia, mandible functioning, and mouth opening compared with conventional cooling regimens. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 specialty societies and 3 academic medical centers while the policy was under review in 2008. Input was mixed regarding the medical necessity of continuous cooling devices.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

While there is no national coverage decision for Medicare, cooling devices are addressed in durable medical equipment regional carrier policy. Last reviewed in 2004, the policy reads as follows:

"A device in which ice water is put in a reservoir and then circulated through a pad by means of gravity is not considered DME [durable medical equipment]. Other devices (not all-inclusive) which are also not considered to be DME are: single-use packs which generate cold temperature by a chemical reaction; packs which contain gel or other material which can be

repeatedly frozen; simple containers into which ice water can be placed. All of these types of devices must be coded **A9270** if claims are submitted.

Code **E0218** describes a device which has an electric pump that circulates cold water through a pad."²⁴

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02426515	Cryotherapy to Improve Outcomes in Lower Third Molar Surgery (COOL)	60	Dec 2017 (ongoing)

NCT: national clinical trial.

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Billing Coding/Physician Documentation Information

97010 Application of a modality to 1 or more areas; hot or cold packs

E0218 Water circulating cold pad with pump

E0236 Pump for water circulating pad

Active cooling devices may be identified by the following HCPCS codes:

E0218: Water circulating cold pad with pump

E0236: Pump for water circulating pad

According to Medicare's DMERC (Durable Medical Equipment Regional Carrier) regional policy, passive cooling devices are not considered durable medical equipment and thus should be coded as:

A9270: Noncovered device or service

97016 has been used for the Game Ready devices, but is not the correct code.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

- 10/1/07 New policy; considered not medically necessary.
- 10/1/08 No policy statement changes.
- 10/1/09 No policy statement changes.
- 10/1/10 No policy statement changes.
- 10/1/11 No policy statement changes.
- 10/1/13 Policy statement clarified to distinguish between active cooling devices and cryopneumatic devices (investigational).
- 10/1/14 No policy statement changes.
- 10/1/15 No policy statement changes.
- 10/1/16 No policy statement changes.
- 10/1/17 No policy statement changes.
- 10/1/18 No policy statement changes.

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