Cooling Devices Used in the Outpatient Setting

Policy # 00139
Original Effective Date: 06/28/2004
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Continuous Passive Motion (CPM) is addressed separately in medical policy 00020.

Services Are Not Covered
The use of active and passive cooling devices or combination cooling and compression (cryopneumatic) devices (e.g., the Game Ready system) in the outpatient setting mainly for the comfort or convenience of the member is **not a covered benefit.**

Background/Overview

COLD AND COMPRESSION THERAPY
Cold and/or compression therapy following surgery or musculoskeletal and soft tissue injury has long been accepted in the medical field as an effective tool for reducing inflammation, pain, and swelling. Ice packs and various bandages and wraps are commonly used. In addition, a variety of continuous cooling devices are commercially available and can be broadly subdivided into those providing manually operated passive cold therapy and those providing active cold therapy using a mechanical device.

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

Centers for Medicare and Medicaid Services (CMS)

While there is no national coverage decision for Medicare, cooling devices are addressed in durable medical equipment regional carrier (DMERC) policy. Last reviewed in July 2004, the DMERC 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 durable medical equipment (DME). 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 to the DMERC.
>
> Code E0218 describes a device which has an electric pump that circulates cold water through a pad…. A water circulating cold pad with pump (E0218) will be denied as not medically necessary."

Rationale/Source

Assessment of efficacy for therapeutic intervention involves a determination of whether an intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

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.

This evidence review focused on the following questions to evaluate whether cooling devices provide a benefit (e.g., decreased pain, swelling, analgesic use) beyond convenience.

- Is there a health benefit from intermittent noncirculating or circulating cooling devices when the number of exchanges of ice bags and episodes of water recirculation are the same?
- Do continuous cooling regimens provide more health benefits than intermittent cooling?
- Does the use of cooling devices in the outpatient setting provide health benefits compared with icing regimens typically used in a home or outpatient environment?

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). 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 results of a trial that randomized 102 patients undergoing knee arthroscopy in the outpatient setting to a CryoCuff device or traditional ice therapy. 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). 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. 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. Levy and Marmar (1993) compared the outcomes of a trial that randomized 80 patients (100 knees) undergoing TKA to noncirculating cold therapy with a CryoCuff device or to no cold therapy. 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 (2014), 116 patients who had undergone TKA were assigned in a quasi-randomized order to 8 hours daily of advanced cryotherapy at a fixed temperature (cTreatment) or to the application of cold packs for 15 minutes after each of 2 physical therapy sessions. Both groups could apply cryotherapy during the evening and night whenever they wanted for comfort and pain control. Thirty percent

of patients in the cTreatment group did not use the device at night due to excessive noise. Primary outcomes were visual analog scale (VAS) score 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°).

A 2008 RCT (N=60) compared a temperature-controlled cryotherapy device with a standard icing regimen following outpatient knee arthroscopy. 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). 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 three 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 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.

In 2017, Rufilli et al 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. 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. Several 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.

Combination Circulating Cooling and Compression (Cryopneumatic) Devices
Several RCTs and a case-control study have been reported with the cryopneumatic devices in the outpatient setting.

A 2012 multicenter RCT of 280 TKA patients compared the Game Ready cryopneumatic device with ice packs with static compression. 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 an RCT of the Game Ready device in 36 patients with ACL reconstruction. 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 score) was not comparable at baseline, limiting interpretation of the results. There were no significant differences between the groups for knee circumference, the Lysholm Knee Scoring Scale, 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%).

In 2017, Murgier et al 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. While the main outcome was the reduction of total blood loss, a secondary outcome was postoperative pain, as measured by VAS three 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; $p<0.05$); both findings were statistically significant. Limitations included the possibility of a type II error due to the specialized surgical unit where the study was performed; additional limitations (e.g., variability of results or 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 that additional prospective randomized trials would be needed.

A 2017 systematic review 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. 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 (e.g., 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. 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) difference in VAS scores between the 2 groups. Limitations of the study 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 comparing the Hilotherm device with cooling compresses. In a 2013 randomized study, Rana et al (2013) assessed 32 patients with postoperative swelling of bilateral mandibular fractures using a cooling mask around the head and jaw. 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 to on day 1 (3.87 vs 5.53) and day 2 (3.63 vs 6.31). There was no significant difference 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). The intervention group had significantly less facial swelling (72.2 mL) relative to the control (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 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 was no difference between the groups with regards 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. A pilot study by 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. But there were no significant benefits with regard to mandible functioning, mouth opening, or neurologic scores.

The study design was similar to that reported by Modabber et al (2013) in which 42 patients treated for unilateral zygomatic fractures 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 was a significant decrease 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<.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 the 2 groups. Pain analysis conducted with 10-point VAS, ranging from 0 (no pain) to 10 (maximum pain), was reported before surgery and postoperatively. There was a significant increase 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 the two groups by day 7. Nerve dysfunction, reported on a 9-point scale (9 being the worst) and assessed before surgery 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, limitations to the study 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, 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, 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, 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.

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Policy History

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06/01/2004	Medical Director review
06/15/2004	Medical Policy Committee review
06/28/2004	Managed Care Advisory Council approval
12/07/2004	Medical Director review
12/14/2004	Medical Policy Committee review. Format revision. Name changed from Cryo Therapy to Cooling Devices Used in the Outpatient Setting. Policy/Guideline section revised to reflect member contract non-coverage of convenience items.
01/31/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
01/10/2007	Medical Director review
01/17/2007	Medical Policy Committee approval
01/09/2008	Medical Director review
01/23/2008	Medical Policy Committee approval
01/07/2009	Medical Director review
01/14/2009	Medical Policy Committee approval. No change to coverage.
01/07/2010	Medical Director approval
01/20/2010	Medical Policy Implementation Committee approval. No change to coverage. Coding review.
010/6/2011	Medical Director approval
01/19/2011	Medical Policy Implementation Committee approval. No change to coverage
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/08/2015	Medical Policy Committee review
01/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/07/2016	Medical Policy Committee review
01/22/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. Added combination cooling and compression (cryopneumatic) devices (e.g., the Game Ready system) to the services are not covered statement.
08/09/2018	Coding update

Next Scheduled Review Date: 01/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	E0218, E0236
ICD-10 Diagnosis	All related diagnoses

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

Cooling Devices Used in the Outpatient Setting

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.